

**Automotive
Quality Systems
Handbook**

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David Hoyle

BUTTERWORTH
HEINEMANN

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Preface

The quest for quality has seen many initiatives and of these the pursuit of compliance with national and international standards is not abating, despite opinions that they have not brought about their intended results. It is a fact of life that unless something is mandated by government or customers, suppliers won't do it. We might learn by listening to others or reading books but we don't necessarily do anything with the knowledge until we have to. The biggest motivator is that if we don't act now we will lose our existing customers and may lose a market to competitors who have acted more promptly.

Since 1994, the automotive industry in the USA and Europe has been operating quality system certification schemes that extended the requirements of ISO 9001, ISO 10011, and EN 45012. One of these schemes was addressed by my *QS-9000 Quality Systems Handbook*, published in 1996. In the same year the automakers of the USA and Europe formed the International Automotive Task Force (IATF) which, in cooperation with the technical committee of the International Organization of Standardization (TC 176), produced ISO/TS 16949. Use of and registration to this new standard is currently voluntary. It is intended that following the first revision to incorporate ISO 9000:2000, the ISO/TS 16949 certification scheme will be mandated by all major vehicle manufacturers on their Tier 1 suppliers. As a result, the standard will be cascaded along the supply chain, ultimately reaching all suppliers to the global automotive industry.

Although the second revision of the ISO 9000 series of standards is promised for the fourth quarter of the year 2000, there is no reason to wait until that standard hits the streets. Many of the requirements in ISO/TS 16949 are likely to be found in the year 2000 edition of ISO 9001. By acting now your organization can create a competitive advantage. Although in the automotive industry the sector quality system requirements do address many of the weaknesses of ISO 9001, there has been distrust with the certification schemes, as the effectiveness of these schemes is only as good as the auditors employed by the certification bodies. By harmonizing the certification schemes and having binding agreements with all vehicle manufacturers, auditor competency will be

enhanced, a higher level of confidence should begin to develop within the global automotive industry, and product quality will improve – not that quality has been a significant problem in the automotive industry in the last 10 years!

I bought my first car in the mid 1960s, at a time when rust started to appear before cars were three years old. Major repair became necessary before engines had done 40,000 miles. On the other hand, I recently sold my 10-year-old car and although it had done 70,000 miles, there was not a sign of any rust and it had never left me stranded away from home. There are countless cars that have traveled more than 100,000 miles and remain in good working order. Durability, however, is not the characteristic challenging the automakers. Safety is number one, followed by reliability and production cost, but it is cost that drives the quest for better methods, better processes, and better ways of preventing defects.

The book is in two parts, with the first part devoted to the origins of the standard and the differences between ISO/TS 16949 and other automotive quality system requirements, with some guidance on implementation. I have included a chapter on basic concepts from my *ISO 9000 Quality Systems Handbook*, with some slight modification. The second part is divided into chapters that reflect the order of subsections in section 4 of the standard. Each chapter dissects the requirements of ISO/TS 16949, taking each “shall” statement and sometimes part of a “shall” statement and explaining the meaning and the applicability, and offering a range of solutions. At the end of each chapter is a task list, questionnaire, and list of “do’s and don’ts”.

Although the book addresses all the requirements of ISO/TS 16946, readers are strongly advised to have access to this technical specification, the ISO 9000 family of standards, and the various supporting publications referenced within them.

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Other books by the same author:

ISO 9000 Quality Systems Handbook 3rd Edition 1998 (ISBN 0-7506-4024-3)

QS-9000 Quality Systems Handbook 1996 (ISBN 0-7506-9861-6)

ISO 9000 Quality System Assessment Handbook 1996 (ISBN 0-7506-2563-5)

ISO 9000 Quality System Development Handbook 1998 (ISBN 0-7506-2562-7)

ISO 9000 Pocket Guide 1998 (ISBN 0-7506-4025-1)

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I acknowledge members of the IATF Training Council, including Robert Frank of the VDA, who assisted with interpretations, Markus Stang of the VDA, who provided VDA 6.1 and other documents, Antonio Ciancio of ANFIA, who provided AVSQ '94, Jacques Letheicq of Euro-Symbiose, who provided EAQF '94, and Al Peterson and Jodi Shorma of Plexus-Training, who with the other members of the Training Council created an environment rich in ideas, knowledge, and experience.

Extracts from BS EN ISO 9001:1994 are reproduced with permission of BSI under license PD\1999 0881. Complete copies of the standard can be obtained by post from BSI Customer Services, 389 Chiswick High Road, London W4 4AL.

Extracts from ISO/TS 16949 and the *Rules for Achieving IATF Recognition* are produced with permission of the IATF. Complete copies of these documents can be obtained from SMMT, Forbes House, Halkin Street, London SW1X 7DS.

I am also indebted to Manfred Martelock of VDA and Robin Lock of SMMT for their critique and help during the final stages.

Part 1

Understanding ISO/TS 16949

Chapter 1

The origins

ISO 9000 is now a familiar label to many organizations. Since 1987 it has dominated the field of quality management and sometimes even to the exclusion of all other quality issues. To some it conjures up mountains of paperwork, bureaucratic procedures, form filling, and non-value added activities, a kind of demon let loose in the workplace! To others it is just common sense, merely codifying principles that have been applied by successful businesses for generations. Both are right because the ISO 9000 family of standards is what people perceive it to be. For a document to become an international standard it must be acknowledged by many nations as defining good practice. This does not mean the standard defines all practices that one should adopt. Standards are “minimums” not “maximums”. Like hygiene standards, there is a minimum standard below which disease becomes virtually inevitable. Such standards do not and should not prohibit anyone in the group exceeding the standards. Within the business community, ISO 9000 represents the minimum system requirements for achieving quality in products and services. In other words, if you do all the things in ISO 9000 there is no reason why you should not *consistently* satisfy your customers.

Most ISO 9000 registered organizations claim to provide quality products and services, so why should there be so many dissatisfied customers when there are over 270,000 organizations in the world certified to ISO 9001, 9002, or 9003?¹ One of the principal requirements in the standard is for the supplier to establish a quality system as a means of ensuring that product or service meet specified requirements. If an organization's products or services do not meet specified requirements then clearly the system has failed, but the failure is no fault of the standard – it is a fault of the way the standard has been applied and interpreted both by the organizations themselves and by the auditors who determine conformity. If the specified requirements are less than those of the customers, it is inevitable that products will bring dissatisfaction. This realization has, in the case of the automotive industry, led to two distinct needs:

¹ The ISO Survey of ISO 9000 and ISO 14000 certificates – eighth cycle, December 1998

- 1 A need to harmonize fundamental supplier quality system requirements and eliminate multiple interpretations.
- 2 A need for a common certification scheme to ensure the integrity of the certification process world-wide.

Emergence of sector requirements

As a set of minimum standards, ISO 9000 addresses the business community. It was intended for purchasers as a means for them to obtain products and services of *consistent* quality from their suppliers. In place of purchaser-specified general quality management requirements, ISO 9000 became the common requirement and hence eliminated the need for such requirements. As a consequence, it provides suppliers that meet its requirements with a demonstrable capability that others may not possess and hence such capability becomes a persuasive marketing tool that will increase market share. ISO 9000 was also intended for application to all types of industry and therefore did not contain requirements for any specific industry sector or type of products or services. Partially due to the scope of misinterpretation and the degree to which particular industries have common supplier requirements, certain industry sectors perceived the need for harmonizing such requirements in a form that added to those requirements in ISO 9000.

The drive for these additional requirements has come not from the suppliers but from users, such as the automotive, utilities, telecommunications, software, and aerospace industries which purchase millions of products and services used to produce the goods and services they provide to the consumer. Rather than invoke customer-specific conditions in each contract, the larger purchasers perceive real benefits from agreeing common quality system requirements for their industry sector. Quite often a supplier will be supplying more than one customer in a particular sector and hence costs increase for both the supplier and the customer if the supplier has to meet different requirements that serve the same objective. All customers desire products and services that *consistently* meet their requirements. While the physical and functional requirements for the product or service will differ, the requirements governing the manner in which their quality is to be achieved, controlled, and assured need not differ. Differences in quality system requirements may arise between industry sectors where the technology, complexity, and risks are different.

There are those who see the emergence of sector standards as a retrograde step, having reached the stage where we have condensed all the world's national quality system standards into one group of 20 standards. Those following the development of ISO 9000 will already be aware that the 20 standards in the ISO 9000 family are soon to be reduced to four (ISO 9000, ISO 9001, ISO 9004, and a replacement for ISO 10011). It

may seem to be a retrograde step if these standards were regarded as the Mount Everest among standards. Unfortunately, ISO 9000 remains a “minimum” and hence does not and was not intended to meet the needs of all users. The alternative to suppressing sector standards at the international level is to see them emerge at the national level or continue with the practice of purchasers invoking their own quality system requirements within contracts, perpetuating fragmentation and duplication, and driving up costs.

Until ISO 9000 emerged in 1987, the automotive industry used a variety of customer-specific standards to govern a supplier’s quality management practices.

The British contribution

Prior to the publication of ISO 9000, several nations had developed national quality system standards, with many used only in the procurement of military equipment. With the emergence of the NATO Quality Control System standards in 1973, the Quality Panel of the UK Society of Motor Manufacturers set out to develop an equivalent standard for non-military applications. The result was BS 4891, which was published in 1972. In 1974 this was followed by BS 5179 with the title *Operation and Evaluation of Quality Assurance Systems*. However, BS 5179 was intended only as a guide and it was not until 1979, with the publication of BS 5750, that major purchasers in the UK had a standard that could be invoked in contracts. A certification scheme was eventually established in 1983, following the UK government’s white paper on competitiveness².

In 1983, BSI approached the International Organization of Standardization in Geneva with a view to developing an international quality system standard and eventually a committee was formed. Using BS 5750 as its basis, the ISO 9000 series of standards was born.

Although the UK, and in particular the UK automotive industry, had been at the forefront of the development of non-military quality system standards, harmonization within the automotive sector beyond BS 5750 was believed too difficult to achieve. Using BS 5750 as a baseline only, the UK motor manufacturers continued to develop their own supplementary standards, many of which are still in use today. BS 5750, and its successor ISO 9000, was enforced by the UK automotive industry and no further harmonization took place.

The American contribution

In 1988, the Purchasing and Supply Vice Presidents of Chrysler, Ford, and General Motors chartered a Task Force to standardize reference manuals, reporting formats, and technical nomenclature, resulting in five standardized reference manuals.

² *Standards, Quality and International Competitiveness* (HMSO, July 1982)

In 1992, the Chrysler, Ford, and General Motors Task Force set out to harmonize the fundamental supplier quality system manuals and assessment tools and produced QS-9000. This new standard embodied the requirements of ISO 9001 and added generic requirements, sector-specific requirements, and customer-specific requirements. QS-9000 was first published in August 1994 and is a harmonization of Chrysler's *Supplier Quality Assurance Manual*, Ford's *Q101*, and General Motor's *Targets for Excellence*, with some input from the Truck Manufacturers. It is pertinent that it was the Purchasing Vice Presidents of Chrysler, Ford, and General Motors that set up the task force and that the initiative was driven by purchasing to improve the quality of supplies. Hence QS-9000 was not intended to apply to the design and assembly plants of Chrysler, Ford, and General Motors.

In 1995, the first edition of QS-9000 was revised and by March 1998 the third edition was published.

The German contribution

In 1991, the Verband der Automobilindustrie e. V. (VDA) published VDA 6.1, *Quality System Audit*, a questionnaire on quality system evaluation based on DIN EN ISO 9004. VDA 6 is a series of guides covering the basics for quality audits, auditing, and certification. They were therefore not intended as supplementary requirements to ISO 9000 but as guides for auditors performing audits of automotive suppliers. Their intention was to improve auditor competency in the industry by providing a uniform interpretation of ISO 9000 requirements and a common approach to automotive audits. VDA 6.1 has been revised several times and is currently in its fourth edition. There are nine volumes in the series (see Appendix A).

Unlike QS-9000, VDA 6.1 does not incorporate the requirements of ISO 9001 section 4. You won't find the words from ISO 9001 in VDA 6.1. Each section carries a statement of intent followed by a series of questions, cross-referenced to ISO 9001 and ISO 9004. Each question is expanded further by a definition and explanation of requirements. There are 23 elements, not 20 as in section 4 of ISO 9001, and the order is different to that in ISO 9001; for example, section 03 addresses Internal Quality Audits, not Contract Review. Although the numbering of sections goes from 01 to 22, there is a section Z1 on Corporate Strategy that covers business planning. While on first encountering VDA 6.1, you may be forgiven for thinking "This is not a standard", in fact it is more useful than ISO 9001 as it provides definitions and explanations more so than ISO 9004. It is, however, a guide to auditors and was not intended for suppliers.

The Italian contribution

In 1994, ANFIA published AVSQ '94 with the title *ANFIA Evaluation of Quality Systems – Guidelines for Use*. This consisted of both a checklist and a user guide. For each question in the checklist there are guidelines on interpretation that are specific to the automotive industry. The checklist of questions is placed on the left-hand page and the guidance on the right-hand page. The guidance actually reads more like requirements, as in many statements the word “must” is used – although this could be translation error and not intent. The questions are derived from ISO 9001. ANFIA published a second document that lists the same questions and includes evaluation forms for completion. By 1995, AVSQ '94 was in the third edition, in which VDA 6 second edition, EAQF '94, and ISO 9004-1:1994 have been used. Thus reciprocal recognition at the European level was achieved whereby certification to AVSQ '94 was recognized as equivalent to VDA 6.1 and EAQF '94 certification.

Like VDA 6.1, AVSQ '94 does not include the requirements of ISO 9001. In this way issues of copyright are overcome, a practice shared by VDA and EAQF but not QS-9000. However, unlike VDA 6.1, AVSQ '94 follows the 20 elements of ISO 9001 with two additional elements, covering financial considerations and product safety. Those questions that go beyond ISO 9001 are marked and as every question is numbered it simplifies the evaluation process. A scoring method is employed to classify organizations in terms of a conformity index. Each question is awarded a point (0, 2.5, 5, 7.5, or 10), where 10 points means full compliance, 7.5 points means minor inadequacies, 5 points means inadequacies in application requiring improvement, 2.5 points means serious inadequacies in application, and 0 points is used for criteria not applied. Unfortunately all questions carry the same weight as no account of the impact of omission on product quality or customer satisfaction is included.

The French contribution

In 1990, PSA Peugeot-Citroen and Renault released a supplier quality assurance publication with the title *Référentiel d'Évaluation d'Aptitude Qualité Fournisseurs* (EAQF). The publication summarizes the requirements of ISO 9001 section 4 but, as with VDA 6.1 and AVSQ, the requirements of ISO 9001 are not incorporated. The layout is very similar to AVSQ but the left-hand page contains statements of fact and the right-hand page questions for guidance. There are many additional requirements to those in ISO 9001 and guidance on the application in the automotive industry. In 1994, the second edition was published and integrated requirements of the German publication VDA 6.1 not previously contained in EAQF '90. Two additional chapters were included covering financial considerations relative to the quality system and safety controls relative to the product. The 1994 edition contains guidance for suppliers of prototypes, production product spares, and accessories. A scoring system similar to AVSQ is used to assess the

degree of compliance. As with AVSQ, each statement is numbered but the numbering below section level does not mirror that in ISO 9001 or AVSQ.

The motivation

In the last few years the motor industry has witnessed many mergers and joint ventures, not just within national boundaries but across nations. The pride of British motor car manufacturers, Rolls Royce, passed into German ownership in 1998 although the sale is somewhat unusual. The Rolls Royce marque will pass to BMW in 2003 with VW retaining the Bentley marque and the Rolls Royce factory at Crewe in England. However, the Rover Group which passed into German ownership in 1994 returned into British ownership in March 2000 when it was sold to the venture capital company Alchemy. As we go to press, the scene changes as GM acquires a 30% stake in Fiat and Ford a 33% stake in Mitsubishi. Table 1-1 illustrates “Who owns who” and shows that Britain is not alone among the countries that has sold its motor industry to foreign buyers. This does not mean that Britain and other countries do not have a motor industry – what it does signify is that the motor industry is now a global industry.

Buying the competition has been a way of entering foreign markets and is not a recent phenomenon. Ford chose another way, by building manufacturing plants overseas and designing and producing cars for the local market. In Europe that market has grown beyond a single country and although the cars may have different names they have the same body parts and engines. GM bought the British company Vauxhall in 1925 and the German company Adam Opel in 1929, then in 1931 GM bought the Australian company Holden. The Big Three (Ford, GM, and Chrysler) have been global players for many years. In Europe acquisitions have been rather slower. In 1969, VW bought Audi and then, after a long gap, acquired Seat in 1986.

There are several joint ventures, such as the Multi Purpose Vehicles (MPV) that Ford, Nissan, and VW produce: exactly the same vehicle with slight modifications. Ford, Seat, and VW also produce a common MPV and there are several partnerships, such as Rover engines being supplied to Proton, Ford, and Honda. Lada get their chassis from Fiat and their engines from GM. Mitsubishi build the Carisma in Holland in the same plant that Volvo build the S40. The Porche Boxster is assembled in Finland by the same company that assembles the Saab 9-3 cabriolet, and so on. One cannot be sure who owns the company that makes your car, where the components come from, and where it is assembled. What matters is that it meets your needs and expectations and this can only be achieved if there are some common systems in use in each of the countries, so that who owns who and who builds what becomes irrelevant to customer confidence. It is reported that within 20 years there may only be six vehicle manufacturers left in the world³.

³ *Auto Express*, January 1999

Marque	Origin	Est.	Owner or Partner	Origin	Acquired
Nissan	Japan	1933	Renault	France	1999 - 36.6%
Skoda	Czechoslovakia	1936	VW	Germany	1990
Audi	Germany	1899	VW	Germany	1969
Bugatti	Italy	1881	VW	Germany	1998
Rolls Royce	UK	1904	VW	Germany	1998
Alfa Romeo	Italy	1906	Fiat	Italy	1986
Ferrari	Italy	1940	Fiat	Italy	1969 - 50% 1988 - 100%
Lancia	Italy	1906	Fiat	Italy	1979
Kia	Korea	1944	Hyundai	Korea	1998 - 51%
Lotus	UK	1948	Proton	Malaysia	1996
Simca	France	1930	Chrysler	USA	1967
Lamborghini	Italy	1921	Chrysler	USA	1987
Daimler-Benz	Germany	1924	Daimler-Chrysler	USA	1998 - 50%
Daimler	UK	1893	Ford	USA	1989
Mazda	Japan	1920	Ford	USA	1979 - 25% 1996 - 33%
Volvo	Sweden	1927	Ford	USA	1999
Aston Martin	UK	1914	Ford	USA	
Jaguar	UK	1936	Ford	USA	1989
Holden	Australia	1931	GM	USA	1931
Adam Opel AG	Germany	1898	GM	USA	1929
Isuzu	Japan	1937	GM	USA	1971
Seat	Spain		VW	USA	1986 - 51%
Saab	Sweden	1947	GM	USA	50%
Vauxhall	UK	1903	GM	USA	1925

Table 1-1 *Who owns who?*

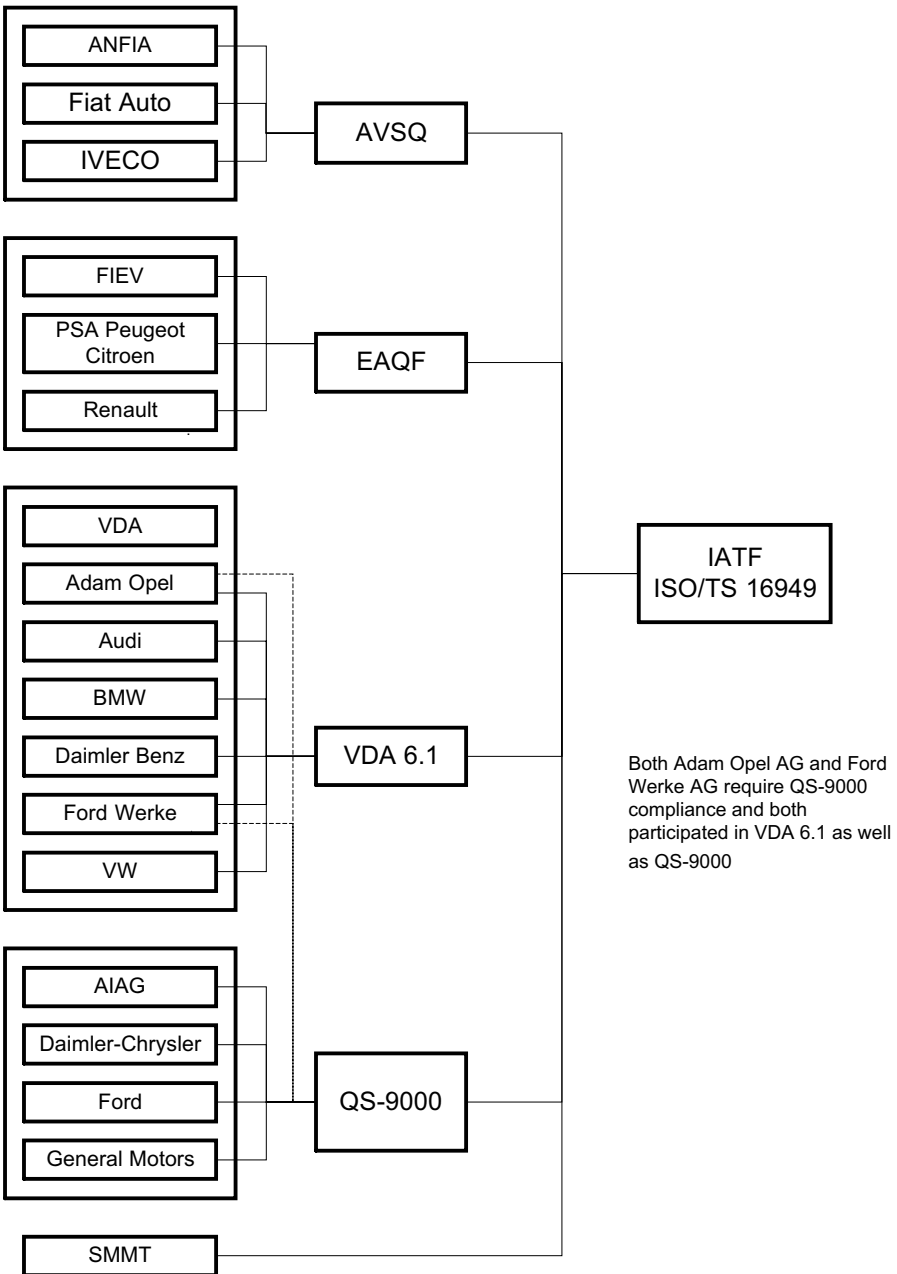


Figure 1.1 Contributors to ISO/TS 16949

Harmonization

The automotive industry has comprised multinational corporations for many decades but there has been little harmonization in quality system requirements across all plants. QS-9000 harmonized these requirements not only in the USA but in every country where GM, Ford, and Chrysler had suppliers. With the emergence of VDA 6, AVSQ '94, and EAQF '94, European suppliers were now being faced with up to four different quality system standards. Hence a UK supplier might have customers such as Ford UK demanding QS-9000, Peugeot in France demanding EAQF '94, and VW in Germany demanding VDA 6. Consequently, the purchasing executives of the large European automakers approached GM, Ford, and Chrysler with a view to harmonizing the USA, Italian, French, and German automotive quality system standards.

In 1996, an International Automotive Task Force was established, comprising representatives of the vehicle manufactures and trade associations from the Americas and Europe (see Figure 1.1).

The nations represented at the launch of the resulting standard were France, Germany, Italy, UK, and USA who together with representatives from ISO/TC 176 developed a sector standard which became ISO/TS 16949. This technical specification incorporates section 4 of ISO 9001:1994 and includes requirements taken from QS-9000, VDA 6, AVSQ '94, and EAQF '94 and some new requirements, all of which have been agreed by the international members. The evolution of ISO/TS 16949 is illustrated in Figure 1.2.

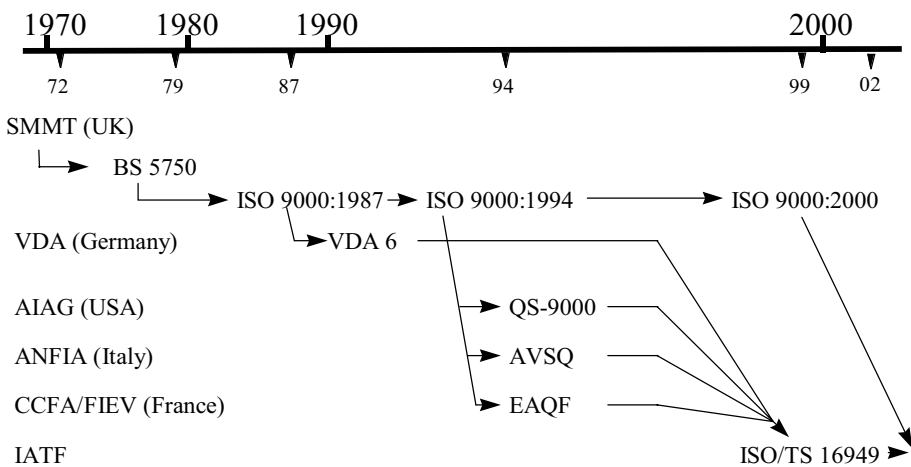


Figure 1.2 Evolution of ISO/TS 16949

The interface between IATF and ISO/TC 176 was in the form of a pilot study to consider the implication of sector standards. The output was in the form of a new ISO document: a *Technical Specification*. The requirements for such a document are for a revision within three years and a limit of only one revision, after which it must either cease or become a full standard. The document when submitted for ballot to ISO/TC 176 significantly exceeded the 66% favorable majority required for its adoption.

With the publication of ISO/TS 16949 occurring during the period that ISO 9000 is undergoing revision, many requirements or enhancements that may appear in ISO 9000:2000 have been incorporated into ISO/TS 16949. Some of these are already contained in QS-9000 but the most significant of these are requirements for:

- Goals and objectives to be defined
- Determination of customer satisfaction
- Continual improvement
- Analysis of data
- Ensuring compliance with regulations
- The management review to monitor strategic quality objectives and the performance of the system
- Process verification
- Defining and maintaining plant, tooling, facilities
- Reviewing the effectiveness of training

By adopting ISO/TS 16949 now, suppliers to the automotive industry will be in a good position to meet ISO 9000:2000 when it is released. Following publication of ISO 9000:2000 towards the end of 2000, work will commence on upgrading ISO/TS 16949. It is anticipated that if ISO/TS 16949:2000 is accepted by the international automotive community, QS-9000, VDA 6, AVSQ '94, and EAQF '94 will be withdrawn.

Emergence of a common certification scheme

The requirements governing certification to ISO 9000 are contained in a number of standards:

ISO Guide 61:1996	<i>General requirements for assessment and accreditation of certification/registration bodies</i>
ISO Guide 62:1996	<i>General requirements for bodies operating assessment and certification/registration of quality systems</i>
ISO 10011	<i>Guidelines for auditing quality systems</i>
EN 45012	<i>General criteria for certification bodies operating quality system certification</i>
EN 45013	<i>General criteria for certification bodies operating certification of personnel</i>

ISO 9000 is not a statutory requirement and neither is certification, hence certification is voluntary. However, suppliers may be under pressure to obtain registration to ISO 9001, ISO 9002, or ISO 9003 in order to tender for contracts. Within the ISO 9000 certification scheme, the certification industry is regulated by *accreditation bodies*. An International Accreditation Forum (IAF) attempts to harmonize accreditation practices world-wide through ISO Guide 61. The accreditation bodies authorize *certification bodies* to conduct certification to prescribed standards – a process that is called *accreditation*. The accreditation body performs witness audits and desk audits of the certification body to ensure compliance with the conditions of accreditation.

To receive ISO 9000 accreditation, a certification body must meet the requirements of ISO Guide 62 and EN 45012, which invokes ISO 10011. There is normally a mark of accreditation (a Crown and Tick in the case of UKAS accreditation) that certification bodies use to signify their credibility. Once accredited, a certification body may perform audits on suppliers offering products and services within the scope of accreditation. In theory, accreditation is granted only if the certification body has expertise (i.e. competent auditors) for the particular industry sectors (EAC codes) requested.

Auditors working for certification bodies should meet the requirements of ISO 10011 and in many countries there is an auditor registration scheme, which is designed so as to ensure that auditors failing to meet prescribed standards are removed from the register.

There are, however, many weaknesses:

- In many countries, there is no law prohibiting an organization setting up as either an accreditation body or a certification body.
- In many countries, both accreditation and certification bodies are commercial organizations that operate without government funding and therefore they are governed by supply and demand.
- In many countries, there is no law requiring all certification bodies to be accredited by registered accreditation bodies.
- Certifications bodies are not compelled to deploy only those auditors qualified as meeting ISO 10011.
- There are gross differences in interpretation of requirements between certification bodies.
- There are differences in interpretation of requirements between different offices of the same certification body, especially those operating in different countries.
- Auditor registration bodies are not compelled to be accredited to EN 45013.
- Auditors are not compelled to register with an accredited auditor registration body.
- The supplier may choose the certification and the scope of registration.
- The supplier is deemed to be the client of the certification body, not the International Organization of Standardization (ISO).
- The customer does not have any power of veto over the issuing or withdrawal of either accreditation or certification.
- The customers have little influence in the training, qualification, and selection of auditors.

Set up with the aim of improving confidence in the quality of supplies, with so many loopholes, the integrity of the whole scheme is therefore questionable. There are a few measures customers can take to improve confidence:

- Demand that the suppliers be registered by an accredited certification body.
- Demand that the accreditation body is recognized by the national government.

- Recognize certain certification bodies as providing services that meet industry requirements.
- Complain to the certification body whenever the auditor performance does not meet expectations.

These measures, however, were insufficient for the automotive industry. Hence a global certification scheme has been developed that addresses each of these weaknesses and as a result creates a very robust system that will yield tremendous benefits for the industry (see also Part 1 Chapter 5).

Benefits

Until the ISO/TS 16949 is updated to align with ISO 9000:2000, its use is voluntary. It is likely that Ford, Daimler-Chrysler, General Motors, Fiat, Peugeot, VW, BMW, etc. will continue to use their existing quality system requirements until the updated ISO/TS 16949 is published. However, for suppliers there are distinct advantages in adopting ISO/TS 16949 now. The members of IATF will recognize ISO/TS 16949 certification as equivalent to QS-9000, VDA 6, etc. and therefore rather than continue to run separate systems or juggle with difficulties in responding to different requirements, suppliers can operate a system that will be accepted as satisfying all generic requirements of their customers.

Improved product and process quality

Product and process quality will be improved as a result of implementing several new requirements, including:

- Goal setting, measurement, and review
- Customer satisfaction measurement
- Product safety
- Compliance with regulations
- Process design management
- Application of common tools and techniques

- Regular measurement of quality system performance
- Accreditation of inspection, test, and calibration laboratories
- Making staff aware of the impact of nonconformities on customers

Additional confidence in global procurement

With one global scheme, disparities between the various schemes employed at a national level should be eliminated. This will give a vehicle manufacturer in one country procuring product from another country the same level of confidence as would be obtained had the product been procured from the home country. This will be achieved by:

- Employing a common standard to evaluate the capability of organizations supplying product or service
- Applying defined criteria to the selection of certification bodies that can award ISO/TS 16949 certificates
- Permitting only IATF qualified third party auditors who are sponsored by certification bodies contracted to perform ISO/TS 16949 audits
- Employing witness auditors sponsored by the vehicle manufacturers and first tier suppliers to verify that the scheme is working effectively

Common quality system approach for subcontractor development

Many subcontractors supply product or services to several vehicle manufacturers. Therefore by harmonizing the standards by which subcontractor development will be conducted, variations in the approach to subcontractors will be minimal.

Reduction of variation and increased efficiency

Variation in quality and delivery performance will reduce through common application of requirements for:

- Continuous improvement in quality and delivery performance
- Mistake-proofing

- Failure modes analysis
- Statistical process control
- Measurement systems analysis
- Employee motivation
- On-the-job training

Efficiency will increase through common application of requirements for:

- Continuous improvement in cost
- Continuous improvement in productivity
- Employee motivation
- On-the-job training
- Measurement and review of product realization stages
- Use of common tools for FMEA, SPC, MSA

Reduction in second party system audits

Currently a supplier supplying customers in the USA, France, Italy, and Germany may be subject to audit by one or more of their customers because of the customer's lack of confidence in quality assurance schemes other than its own. Hence a QS-9000 registered supplier that supplies both Ford USA and BMW Germany could be subject to a VDA 6.1 audit, as the two standards are different. By the USA, Germany, France, UK, and Italy agreeing a common standard and the associated registration scheme, registration to ISO/TS 16949 is recognized by all the manufactures that are members of IATF. These organizations will therefore not find it necessary to perform any further quality system audits of ISO/TS 16949 registered suppliers.

Reduction in multiple third party registrations

Currently a supplier supplying customers in the USA and Europe needs to seek certification to QS-9000 and either VDA 6.1, AVSQ '94, or EAQF '94. Within Europe, certification to any one of the three European quality system requirements is, at least in theory, recognized by customers in the other countries.

Common language to improve understanding of quality system requirements

A common language in quality system requirements is achieved through a common standard. The baseline language of the standard is English and all translations should be made from English to the other language, thereby minimizing scope for error. However, it is common to find that terms in one language do not have the same meaning in another language. Hopefully, through the deliberations of the IATF, any differences will be identified and resolved.

Chapter 2

Basic concepts

Quality

We all have needs, requirements, wants, and expectations. Needs are essential for life, to maintain certain standards, or essential for products and services, to fulfill the purpose for which they have been acquired. Requirements are what we request of others and may encompass our needs but often we don't fully realize what we need until after we have made our request. For example, now that we own a mobile phone we discover we really need hands-free operation when using the phone while driving a vehicle. Hence our requirements at the moment of sale may or may not express all our needs. Our requirements may include wants – what we would like to have but do not need: nice to have but not essential. Expectations are *implied needs* or *requirements*. They have not been requested because we take them for granted – we regard them to be understood within our particular society as the accepted norm. They may be things to which we are accustomed, based on fashion, style, trends, or previous experience. Hence one expects sales staff to be polite and courteous, electronic products to be safe and reliable, policemen to be honest, etc.

In supplying products or services there are three fundamental parameters which determine their saleability. They are price, quality, and delivery. Customers require products and services of a given quality to be delivered by or be available by a given time and to be of a price that reflects value for money. These are the requirements of customers. An organization will survive only if it creates and retains satisfied customers and this will only be achieved if it offers for sale products or services which respond to customer needs and expectations as well as requirements. While price is a function of cost, profit margin, and market forces, and delivery is a function of the organization's efficiency and effectiveness, quality is determined by the extent to which a product or service successfully serves the purposes of the user during usage (not just at the point of sale). Price and delivery are both transient features, whereas the impact of quality is sustained long after the attraction or the pain of price and delivery have subsided.

The word *quality* has many meanings: a degree of excellence; conformance with requirements; the totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs; fitness for use; freedom from defects, imperfections, or contamination; and (a phrase which is gaining popularity) delighting customers. These are just a few meanings; however, the meaning used in the context of ISO/TS 16949 is the one concerned with the totality of characteristics that satisfy needs. The “fitness for use” definition is shorter, more easily remembered and can be used when making decisions about quality. The specification is often an imperfect definition of what a customer needs; because some needs can be difficult to express clearly, it doesn’t mean that by not conforming, the product or service is unfit for use. However, a product that conforms to requirements may be totally useless. It all depends on whose requirements are being met. For example, if a company sets its own standards and these do not meet customer needs, its claim to producing quality products is bogus. On the other hand, if the standards are well in excess of what the customer requires, the price tag may well be too high for what customers are prepared to pay – there probably isn’t a market for a gold-plated mousetrap, for instance, except as an ornament perhaps!

A product which possesses features that satisfy customer needs is a quality product. Likewise, one that possesses features which dissatisfy customers is not a quality product. So the final arbiter on quality is the customer. The customer is the only one who can decide whether the quality of the products and services you supply is satisfactory and you will be conscious of this either by direct feedback or by loss of sales, reduction in market share, and, ultimately, loss of business.

There are other considerations in understanding the word *quality*, such as *grade* and *class*. These are treated in ISO 8402:1994 but will be addressed briefly here so as to give a complete picture.

Classification of products and services

If we group products and services (entities) by type, category, class, and grade we can use the subdivision to make comparisons on an equitable basis. But when we compare entities we must be careful not to claim one is of better quality than the other unless they are of the same grade. Entities of the same type have at least one attribute in common. Entities of the same grade have been designed for the same functional use and therefore comparisons are valid. Comparisons on quality between entities of different grades, classes, categories, or types are invalid as they have been designed for a different use or purpose.

Let us look at some examples to illustrate the point. Food is a type of entity. Transport is another entity. Putting aside the fact that in the food industry the terms *class* and *grade*

are used to denote the condition of post-production product (see bottom of this page), comparisons between *types* is like comparing fruit and trucks – there are no common attributes. Comparisons between *categories* is like comparing fruit and vegetables. Comparisons between *classes* is like comparing apples and oranges. Comparisons between *grades* is like comparing eating apples and cooking apples.

Now let us take another example. Transport is a type of entity. There are different categories of transport such as airliners, ships, automobiles, and trains; they are all modes of transport but each has many different attributes. Differences between categories of transport are therefore differences in *modes* of transport. Within each category there are differences in class. For manufactured products, differences between classes implies differences in *purpose*. Luxury cars, large family cars, small family cars, vans, trucks, four-wheel drive vehicles, etc. fall within the same category of transport but each was designed for a different purpose. Family cars are in a different class to luxury cars; they were not designed for the same purpose. It is therefore inappropriate to compare a Cadillac with a Chevrolet or a Rolls Royce Silver Shadow with a Ford Mondeo. Entities designed for the same purpose but having different specifications are of different grades. A Ford Mondeo GTX is a different grade to a Mondeo LX. They were both designed for the same purpose but differ in their performance and features.

Now take another example from the service industry: accommodation. There are various categories, such as rented, leased, and purchased. In the rented category there are hotels, inns, guest houses, apartments, etc. It would be inappropriate to compare hotels with guest houses or apartments with inns. They are each in a different class. Hotels are a class of accommodation within which are grades such as 5 star, 4 star, 3 star, etc., indicating the facilities offered.

You can legitimately compare the quality of entities if comparing entities of the same grade. If a low-grade service meets the needs for which it was designed, it is of the requisite quality. If a high-grade product or service fails to meet the requirements for which it was designed, it is of poor quality, regardless of it still meeting the requirements for the lower grade. There is a market for such differences in products and services but should customer expectations change then what was acceptable as a particular grade becomes no longer acceptable and regrading has to occur.

Where manufacturing processes are prone to uncontrollable variation it is not uncommon to grade products as a method of selection. The product that is free of imperfections would be the highest grade and would therefore command the highest price. Any product with imperfections would be downgraded and sold at a correspondingly lower price. Examples of such practice arise in the fruit and vegetables trade and the ceramics, glass, and textile industries. In the electronic component industry, grading is a common practice to select devices that operate between certain temperature ranges. In ideal conditions all devices would meet the higher specification but due to manufac-

turing variation only a few may actually reach full performance. The remainder of the devices have a degraded performance but still offer all the functions of the top-grade component at lower temperatures. To say that these differences are not differences in quality would be misleading, since the products were all designed to fulfill the higher specification. As there is a market for such products it is expedient to exploit it. There is a range over which product quality can vary and still create satisfied customers. Outside the lower end of this range the product is considered to be of poor quality.

Quality and price

Most of us are attracted to certain products and services by their price. If the price is outside our reach we don't even consider the product or service, whatever its quality, except perhaps to form an opinion about it. We also rely on price as a comparison, hoping that we can obtain the same characteristics at a lower price. In the luxury goods market, a high price is often a mark of quality but it is occasionally a confidence trick aimed at making more profit for the supplier. When certain products and services are rare, the price tends to be high and when plentiful the price is low, regardless of their quality. One can purchase the same item in different stores at different prices, some as much as 50% less, many at 10% less than the highest price. You can also receive a discount for buying in bulk, buying on customer credit card, and being a trade customer rather than a retail customer. Travelers know that goods are more expensive at the airport than from the country craft shop. However, in the country craft shop, defective goods or "seconds" may well be on sale, whereas at the airport the supplier will want to display only the best examples as a rule. Often an increase in the price of a product may indicate a better service, such as free on-site maintenance, free delivery, free telephone support line. The discount shops may not offer such attractions.

The price label on any product or service should be for a product or service free of defects. If there are defects the label should say as much, otherwise the supplier may well be in breach of national laws and statutes. Price is therefore not a feature or characteristic of the product but is a feature of the service associated with it. Price is negotiable for the same quality of product. Some may argue that quality is expensive but in reality, the saving you make on buying low-priced goods could well be eroded by inferior service or differences in the cost of ownership.

Quality and cost

Philip Crosby published his book *Quality Is Free* in 1979 and caused a lot of raised eyebrows among executives because they always believed the removal of defects was an

in-built cost in running any business. To get quality you had to pay for inspectors to detect the errors! What Crosby told us was that if we could eliminate all the errors and reach zero defects, we would not only reduce our costs but increase the level of customer satisfaction by several orders of magnitude. In fact there is the cost of doing the right things right first time and the cost of *not* doing the right things right first time. The latter are quality costs or the cost incurred because failure is possible. If failure of a product, a process, or a service is not possible, there are no quality costs. We could classify the costs as avoidable costs and unavoidable costs. We have to pay for labor, materials, facilities, machines, transport, etc. These costs are unavoidable but we are also paying in addition some cost to cover the prevention, detection, and removal of errors. Should customers have to pay for the errors made by others? There is a basic cost if failure is not possible and an additional cost in preventing and detecting failures and correcting errors because our prevention and detection programs are ineffective. If you reduce complexity and install failure-prevention measures you will be spending less on failure detection and correction. There is an initial investment to be paid, but in the long term you can meet your customer requirements at a cost far less than you were spending previously. Some customers are now forcing their suppliers to reduce internal costs so that they can offer the same products at lower prices.

High quality and low quality; poor quality and good quality

When a product or service satisfies our needs we are likely to say it is of good quality and likewise when we are dissatisfied we say the product or service is of poor quality. When the product or service exceeds our needs we will probably say it is of high quality and likewise if it falls well below our expectations we say it is of low quality.

These measures of quality are all subjective. What is good to one may be poor to another. In the undeveloped countries, any product, no matter what the quality, is welcomed. When you have nothing, even the poorest of goods is better than none. A product may not need to possess defects for it to be regarded as poor quality – it may not possess the features that we would expect, such as access for maintenance. These are design features which give a product its saleability. Products and services that conform to customer requirements are considered to be products of acceptable quality. However, we need to express our relative satisfaction with products and services and hence use subjective terms such as high, low, good, or poor quality. If a product that meets customer requirements is of acceptable quality, what do we call one that does not quite meet the requirements, or perhaps exceeds the requirements? An otherwise acceptable product has a blemish – is it now unacceptable? Perhaps not. It may still be far superior to other competing products in its acceptable features and characteristics.

While not measurable, these subjective terms enable customers to rate products and services on the extent to which they satisfy their requirements and are therefore suitable for their purpose. However, to the company supplying products and services, a more precise means of measuring quality is needed. To the supplier, a quality product is one that meets in full the perceived customer requirements.

Quality characteristics

Any feature or characteristic of a product or service which is needed to satisfy customer needs or achieve fitness for use is a *quality characteristic*. When dealing with products the characteristics are almost always technical characteristics, whereas service quality characteristics have a human dimension. Some typical quality characteristics are given in the table below.

Product Quality Characteristics		
Accessibility	Functionality	Size
Availability	Interchangeability	Susceptibility
Appearance	Maintainability	Storability
Adaptability	Odor	Taste
Cleanliness	Operability	Testability
Consumption	Portability	Traceability
Durability	Producibility	Toxicity
Disposability	Reliability	Transportability
Emittance	Reparability	Vulnerability
Flammability	Safety	Weight
Flexibility	Security	
Service Quality Characteristics		
Accessibility	Credibility	Honesty
Accuracy	Dependability	Promptness
Courtesy	Efficiency	Responsiveness
Comfort	Effectiveness	Reliability
Competence	Flexibility	Security

These are the characteristics which need to be specified and their achievement controlled, assured, improved, managed, and demonstrated. These are the characteristics which form the subject matter of the specified requirements referred to in ISO 9000. When the value of these characteristics is quantified or qualified they are termed *quality requirements* or *requirements for quality*. ISO 8402:1994 defines requirements for quality as *an expression of the needs or their translation into a set of quantitatively or qualitatively stated requirements for the characteristics of an entity to enable its realization and examination*. While rather verbose, this definition removes the confusion over quality requirements and technical requirements. (An additional definition is provided in Appendix A.) Technical requirements for a product or service are quality requirements. The requirements of ISO 9000 are quality system requirements.

Quality, reliability, and safety

There is a school of thought that distinguishes between quality and reliability and quality and safety. Quality is thought to be a non-time-dependent characteristic and reliability a time-dependent characteristic. Quality is thought of as conformance to specification regardless of whether the specification actually meets the needs of the customer or society. If a product or service is unreliable, it is clearly unfit for use and hence of poor quality. If a product is reliable but emits toxic fumes, is too heavy, or not transportable when required to be, it is of poor quality. Similarly, if a product is unsafe it is of poor quality even though it may meet its specification in other ways. In such a case the specification is not a true reflection of customer needs. A nuclear plant may meet all the specified safety requirements but if society demands greater safety standards, the plant is not meeting the quality requirements of society, even though it meets the immediate customer requirements. You therefore need to identify your real customers in order to determine the quality characteristics that need to be satisfied. Customers are not only the buyers. They may be users, consumers, shareholders, and society in general. The needs of all these people have to be satisfied in order for *quality* to be achieved. This is borne out by ISO 8402:1994 which defines the requirements of society as *the obligations resulting from laws, regulations, rules, codes, statutes, and other considerations* and the standard advises that all requirements of society should be taken into account when defining the requirements for quality.

Quality parameters

Differences in design can be denoted by grade or class but can also be the result of poor attention to customer needs. It is not enough to produce products that conform to the specifications or supply services that meet management's requirements. Quality is a

composite of three *parameters*: quality of design, quality of conformance, and quality of use:

- *Quality of design* is the extent to which the design reflects a product or service that satisfies customer needs and expectations. All the necessary characteristics should be designed into the product or service at the outset.
- *Quality of conformance* is the extent to which the product or service conforms to the design standard. The design has to be faithfully reproduced in the product or service.
- *Quality of use* is the extent by which the user is able to secure continuity of use from the product or service. Products need to have a low cost of ownership, be safe and reliable, maintainable in use, and easy to use.

Products or services that do not possess the right features and characteristics either by design or by construction are products of poor quality. Those that fail to give customer satisfaction by being uneconomic to use are also products of poor quality, regardless of their conformance to specifications.

Dimensions of quality

In addition to quality parameters there are three *dimensions of quality* which extend the perception beyond the concepts outlined previously:

- *The business quality dimension*. This is the extent to which the business services the needs of society. Customers are not only interested in the quality of particular products and services but judge suppliers by the general level of quality products they provide and continuity of supply, their care of the environment, and their adherence to health, safety, and legal regulations.
- *The product quality dimension*. This is the extent to which the products and services provided meet the needs of specific customers.
- *The organization quality dimension*. This is the extent to which the organization maximizes its efficiency and effectiveness, achieving minimum waste, efficient management, and good human relations. Companies that do not operate efficiently or do not meet their employees' expectations will generally find their failure costs to be high and will lose their best people. This directly affects all aspects of quality.

Many organizations only concentrate on the product quality dimension, but the three are interrelated and interdependent. Deterioration in one leads to a deterioration in the others, perhaps not immediately but eventually.

As mentioned previously, it is quite possible for an organization to satisfy the customers for its products and services and fail to satisfy the needs of society. Some may argue that the producers of pornographic literature, nuclear power, non-essential drugs, weapons, etc. harm society and so regardless of these products and services being of acceptable quality in themselves, they are not regarded by society as benefiting the quality of life. Within an organization, the working environment may be oppressive – there may be political infighting and the source of revenue so secure that no effort is made to reduce waste. Even so, such organizations may produce products and services which satisfy their customers. We must separate these three concepts to avoid confusion. When addressing quality, it is necessary to be specific about the object of our discussion. Is it the quality of products or services, or the quality of organization in which we work, or the business as a whole, about which we are talking? If we only intend that our remarks apply to the quality of products, we should say so.

Level of attention to quality

Whilst the decision to pursue ISO/TS 16949 registration will be an executive decision, the attention it is given at each level in the organization will have a bearing on the degree of success attained. There are three primary organization levels: the enterprise level, the business level, and the operations level¹. Between each level there are barriers.

At the enterprise level, the executive management responds to the voice of ownership and is primarily concerned with profit, return on capital employed, market share, etc. At the business level, the managers are concerned with products and services and hence respond to the voice of the customer. At the operational level, the middle managers, supervisors, operators, etc. focus on processes that produce products and services and hence respond to the voice of the processes carried out within their own function.

In reality, these levels overlap, particularly in small organizations. The CEO of a small company will be involved at all three levels whereas in the large multinational, the CEO spends all of the time at the enterprise level, barely touching the business level, except when major deals with potential customers are being negotiated. Once the contract is won, the CEO of the multinational may confine his/her involvement to monitoring performance through metrics and goals.

¹ Gregory H Watson, *Business Systems Engineering* (Wiley, 1994)

Quality should be a strategic issue that involves the owners as it delivers fiscal performance. Low quality will cause fiscal performance ultimately to decline.

The typical focus for a quality system is at the operations level. ISO 9000 is seen as an initiative for work process improvement. The documentation is often developed at the work process level and focused on functions. Much of the effort is focused on the processes within the functions rather than across the functions and only involves the business level at the customer interface, as illustrated in Table 2-1.

Organization Level	Principle Process Focus	Basic Team Structure	Performance Issue Focus	Typical Quality System Focus	Ideal Quality System Focus
Enterprise	Strategic	Cross-Business	Ownership	Market	Strategic
Business	Business	Cross-Functional	Customer	Administrative	Business Process
Operations	Work	Departmental	Process	Task Process	Task Process

Table 2-1 Attention levels

Achieving, sustaining, and improving quality

Several methods have evolved to *achieve, sustain, and improve quality*; they are quality control, quality improvement, and quality assurance, which collectively are known as *quality management*. This trilogy is illustrated in Figure 2.1. Techniques such as quality planning, quality costs, “Just-in-time”, and statistical process control are all elements of

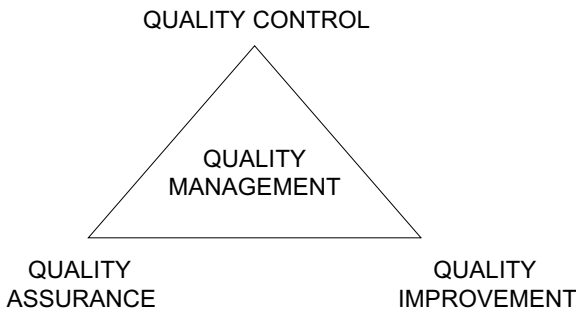


Figure 2.1 Quality management

these three methods. ISO 8402:1994 separates quality planning from quality control, quality improvement, and quality assurance but by including planning within the domain of each concept, one can focus on the purpose of planning more easily.

Quality management

The basic goal of quality management is the elimination of failure: both in the concept and in the reality of our products, services, and processes. In an ideal world, if we could design products, services, and processes that could not fail we would have achieved the ultimate goal. Failure means not only that products, services, and processes would fail to fulfill their function but that their function was not what our customers desired. A gold-plated mousetrap that does not fail is not a success if no one needs a gold-plated mousetrap!

We have only to look at the introductory clauses of ISO 9001 to find that the aim of the requirements is to achieve customer satisfaction by prevention of nonconformities. Hence quality management is a means for planning, organizing, and controlling the prevention of failure. All the tools and techniques that are used in quality management serve to improve our ability to succeed in our pursuit of excellence.

Quality does not appear by chance, or if it does it may not be repeated. One has to design quality into the products and services. It has often been said that one cannot inspect quality into a product. A product remains the same after inspection as it did before, so no amount of inspection will change the quality of the product. However, what inspection does is measure quality in a way that allows us to make decisions on whether to release a piece of work. Work that passes inspection should be quality work but inspection unfortunately is not 100% reliable. Most inspection relies on the human judgement of the inspector and human judgement can be affected by many factors, some of which are outside our control (such as the private life, health, or mood of the inspector). We may fail to predict the effect that our decisions have on others. Sometimes we go to great lengths in preparing organization changes and find to our surprise that we neglected something or underestimated the effect of something. We therefore need other means than *inspection* to deliver quality products. It is costly anyhow to rely only on inspection to detect failures – we have to adopt practices that enable us to prevent failures from occurring. This is what quality management is all about.

Quality management is both a technical subject and a behavioral subject. It is not a bureaucratic administrative technique. The rise in popularity of ISO 9000 has created some unhelpful messages such as the “document what you do” strategy. There has also been a perception in the service industries that ISO 9000 quality systems only deal with the procedural aspects of a service and not the professional aspects. For instance in a medical practice, the ISO 9000 quality system is often used only for processing patients

and not for the medical treatment. In legal practices, the quality system again has been focused only on the administrative aspects and not the legal issues. The argument for this is that there are professional bodies that deal with the professional side of the business. In other words, the quality system only addresses the non-technical issues, leaving the profession to address the technical issues. This is not *quality management*. The quality of the service depends upon both the technical and non-technical aspects of the service. Patients who are given the wrong advice would remain dissatisfied even if their papers were in order or even if they were given courteous attention and promptly informed of the decision. To achieve quality one has to consider both the product and the service. A faulty product delivered on time, within budget, and with a smile remains a faulty product.

Another often forgotten aspect of quality management is the behavior of people in an organization. Such behavior is formed by the core values to which that organization subscribes. The absence of core values that form a positive behavior may not have an immediate effect because individuals will operate according to their own personal values. When these conflict with the organization's values, an individual could resent being forced to comply and may eventually adopt the values of the majority or leave to find a more suitable company to work for.

The management of quality involves many aspects of an organization. In essence, quality management is concerned with the failure potential of processes, products, and services, as stated previously. Organizations comprise many functions and all must be essential for the organization to function efficiently and effectively. It follows therefore that if any function fails to perform, there will be a corresponding detrimental effect on the organization. Whether this failure has any effect on the products and services offered for sale depends on the time taken for the effect to be damaging. Some failures have an immediate effect where they contribute directly to the supply of products and services. Others have a long-term effect where their contribution is indirect, such as the behavioral aspects. People work best when management shows it cares about them. Neglect the people and you eventually impact product quality. A failure in a support function, such as office cleaning, may not affect anything initially, but if the office remains unclean for a prolonged period it will begin to have an effect on productivity.

If a Total Quality Management philosophy is to be adopted, every function in the organization – regardless of the magnitude of its effect on processes, products, and services – is brought into the system. ISO/TS 16949 only addresses those functions that contribute directly to the sale of products and services to customers. The difference is that ISO/TS 16949 and other standards used in a regulatory manner are not directly concerned with an organization's efficiency or effectiveness in delivering profit. However, they are concerned indirectly with nurturing the values that determine the behavior of the people who make decisions that affect product or service quality.

Quality control (QC)

The ISO definition states that *quality control* is the operational techniques and activities that are used to fulfill requirements for quality. This definition could imply that any activity, whether serving the improvement, control, management, or assurance of quality, could be a quality control activity. What the definition fails to tell us is that controls regulate performance. They prevent change and when applied to quality regulate quality performance and prevent undesirable changes in the quality standards. Quality control is a process for maintaining standards and not for creating them. Standards are maintained through a process of selection, measurement, and correction of work, so that only those products or services that emerge from the process meet the standards. In simple terms, quality control prevents undesirable changes being present in the quality of the product or service being supplied. The simplest form of quality control is illustrated in Figure 2.2. Quality control can be applied to particular products, to processes that produce the products, or to the output of the whole organization by measuring the overall quality performance of the organization.

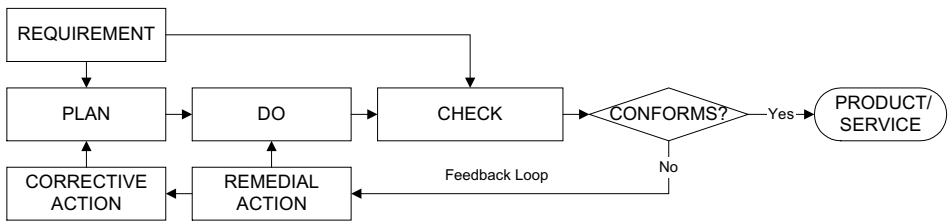


Figure 2.2 Quality control process

Quality control is often regarded as a post-event activity: i.e. a means of detecting whether quality has been achieved and taking action to correct any deficiencies. However, one can control results by installing sensors before, during, or after the results are created. It all depends on where you install the sensor, what you measure, and the consequences of failure.

Some failures cannot be allowed to occur and so must be prevented from happening through rigorous planning and design. Other failures are not so critical but must be corrected immediately using automatic controls or mistake-proofing. Where the consequences are less severe or where other types of sensor are not practical or possible, human inspection and test can be used as a means of detecting failure. Where failure cannot be measured without observing trends over longer periods, you can use information controls. They do not stop immediate operations but may well be used to stop further operations when limits are exceeded. The progressive development of controls

from having no control of quality to installing controls at all key stages from the beginning to the end of the life cycle is illustrated in Figure 2.3. As can be seen, if you have no controls, quality products are produced by chance and not design. The more controls you install the more certain you are of producing products of consistent quality but there is a need for balance to be achieved. Beware of the law of diminishing returns.

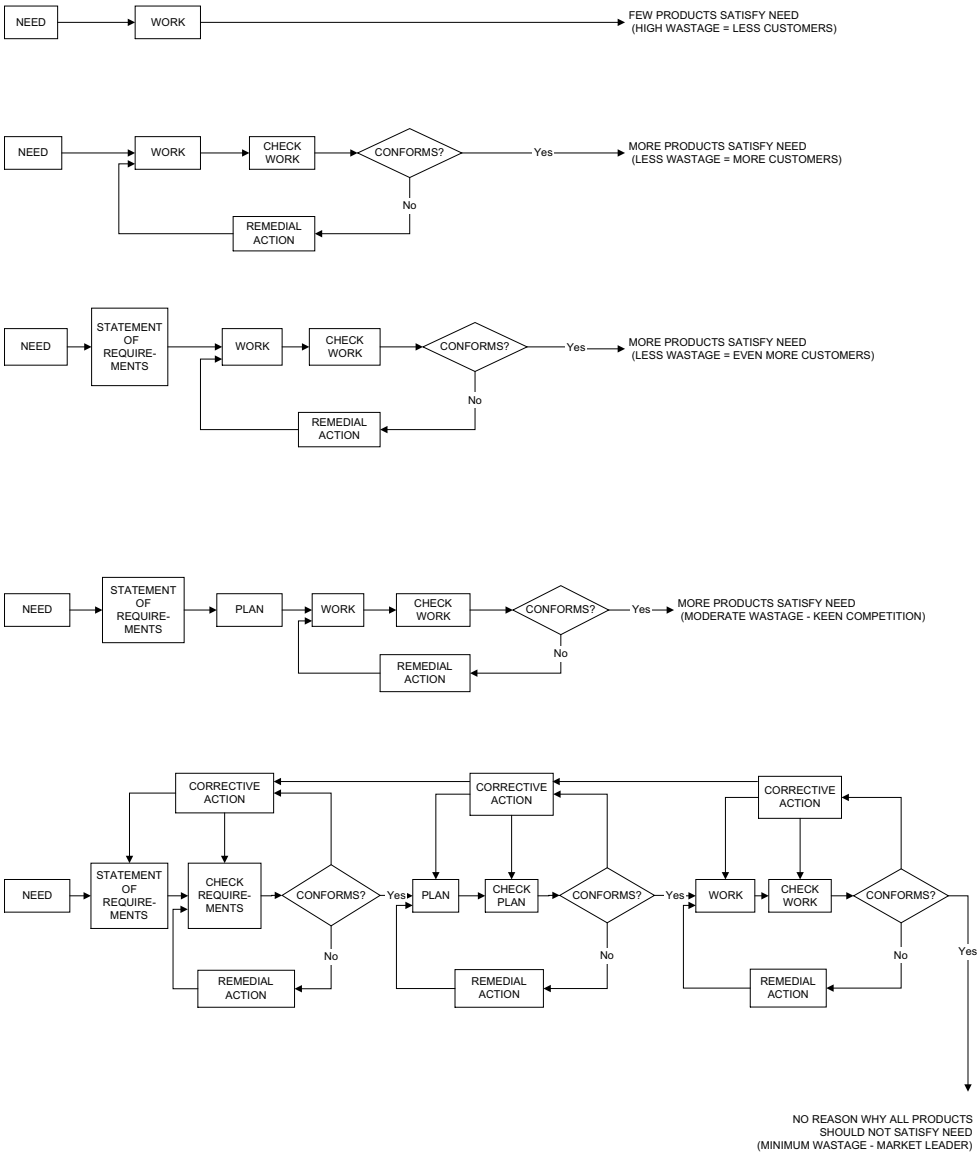


Figure 2.3 Development of quality controls

It is often deemed that quality assurance serves prevention and quality control detection, but a control installed to detect failure before it occurs serves prevention, such as reducing the tolerance band to well within the specification limits. So quality control can prevent failure. Assurance is the result of an examination whereas control produces the result. *Quality assurance* does not change the product, *quality control* does.

“Quality control” is also the term used as the name of a department. In most cases Quality Control Departments perform inspection and test activities and the name derives from the authority that such departments have been given. They sort good products from bad products and authorize the release of the good products. It is also common to find that Quality Control Departments perform supplier control activities, which are called Supplier Quality Assurance or Vendor Control. In this respect they are authorized to release products from suppliers into the organization either from the supplier’s premises or on receipt in the organization.

Since to control anything requires the ability to effect change, the title Quality Control Department is a misuse of the term, as such departments do not in fact control quality. They do act as a regulator if given the authority to stop release of product, but this is control of supply and not of quality. Authority to change product usually remains in the hands of the producing departments. It is interesting to note that similar activities within a Design Department are not called “quality control” but “design assurance” or some similar term. “Quality control” has for decades been a term applied primarily in the manufacturing areas of an organization and hence it is difficult to change people’s perceptions after so many years of the term’s incorrect use.

In recent times the inspection and test activities have been transferred into the production departments of organizations, sometimes retaining the labels and sometimes reverting to the inspection and test labels.

Control of quality, or anything else for that matter, can be accomplished by the following steps:

- 1 Determine what parameter is to be controlled.
- 2 Establish its criticality and whether you need to control before, during, or after results are produced.
- 3 Establish a specification for the parameter to be controlled which provides limits of acceptability and units of measure.
- 4 Produce plans for control which specify the means by which the characteristics will be achieved and variation detected and removed.

- 5 Organize resources to implement the plans for quality control.
- 6 Install a sensor at an appropriate point in the process to sense variance from specification.
- 7 Collect and transmit data to a place for analysis.
- 8 Verify the results and diagnose the cause of variance.
- 9 Propose remedies and decide on the action needed to restore the status quo.
- 10 Take the agreed action and check that the variance has been corrected.

Quality improvement (QI)

The ISO definition of *quality improvement* states that it is the actions taken throughout the organization to increase the effectiveness of activities and processes to provide added benefits to both the organization and its customers. In simple terms, quality improvement is anything that causes a beneficial change in quality performance. There are two basic ways of bringing about improvement in quality performance. One is by better control and the other by raising standards. We don't have suitable words to define these two concepts. Doing better what you already do is *improvement* but so is doing something new. Juran uses the term *control* for maintaining standards and the term *breakthrough* for achieving new standards. Imai uses the term *improvement* when change is gradual and *innovation* when it is radical. Hammer uses the term *re-engineering* for the radical changes. All beneficial change results in improvement, whether gradual or radical, so we really need a word that means gradual change or incremental change. The Japanese have the word *kaizen* but there is no English equivalent that I know of, other than the word *improvement*.

Quality improvement (for better control) is about improving the rate at which an agreed standard is achieved. It is therefore a process for reducing the spread of variation so that all products meet agreed standards. The performance of products or processes may vary due to either random or assignable causes of variation. By investigating the symptoms of failure and determining the root cause, the assignable causes can be eliminated and the random causes reduced so that the performance of processes becomes predictable. A typical quality improvement of this type might be to reduce the spread of variation in a parameter so that the average value coincides with the nominal value (i.e. bring the parameter under control). Another example might be to reduce the defect rate from 1 in 100 to 1 in 1,000,000. Another might be simply to correct the weaknesses in the registered quality system so that it will pass re-assessment.

Quality improvement (innovation), is about raising standards and setting a new level. New standards are created through a process that starts at a feasibility stage and progresses through research and development to result in a new standard, proven for repeatable applications. Such standards result from innovations in technology, marketing, and management. A typical quality improvement might be to redesign a range of products to increase the achieved reliability from 1 failure every 5,000 hours to 1 failure every 100,000 hours. Another example might be to improve the efficiency of the service organization so as to reduce the guaranteed call-out time from the specified 36 hours to 12 hours. A further example might be to design and install a quality system which complies with ISO 9001 in a company that had no formal quality system.

The transition between where quality improvement stops and quality control begins is where the level has been set and the mechanisms are in place to keep quality on or above the set level. In simple terms, if quality improvement reduces quality costs from 25% of turnover to 10% of turnover, the objective of quality control is to prevent the quality costs rising above 10% of turnover. This is illustrated in Figure 2.4.

Improvement by better control is achieved through the corrective action mechanisms described in Part 2 Chapter 14 and ISO 9004-4. Improvement by raising standards requires a different process, a process that results in new standards.

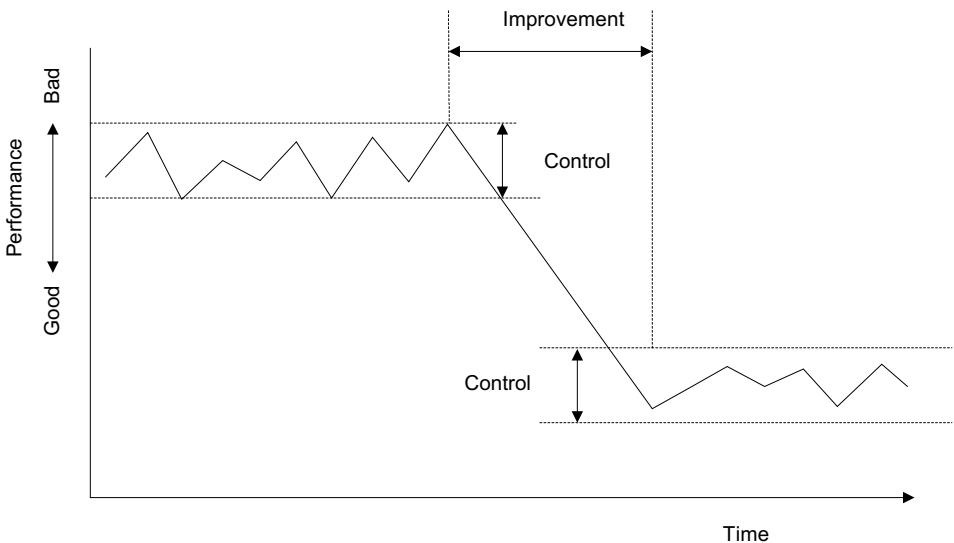


Figure 2.4 Quality improvement and quality control

Improving quality by raising standards can be accomplished by the following steps (illustrated diagrammatically in Figure 2.5):

- 1 Determine the objective to be achieved, e.g. new markets, products, or technologies, or new levels of organizational efficiency or managerial effectiveness, new national standards or government legislation. These provide the reasons for needing change.
- 2 Determine the policies needed for improvement, i.e. the broad guidelines to enable management to cause or stimulate the improvement.
- 3 Conduct a feasibility study. This should discover whether accomplishment of the objective is feasible and propose several strategies or conceptual solutions for consideration. If feasible, approval to proceed should be secured.
- 4 Produce plans for the improvement which specify the means by which the objective will be achieved.
- 5 Organize the resources to implement the plan.

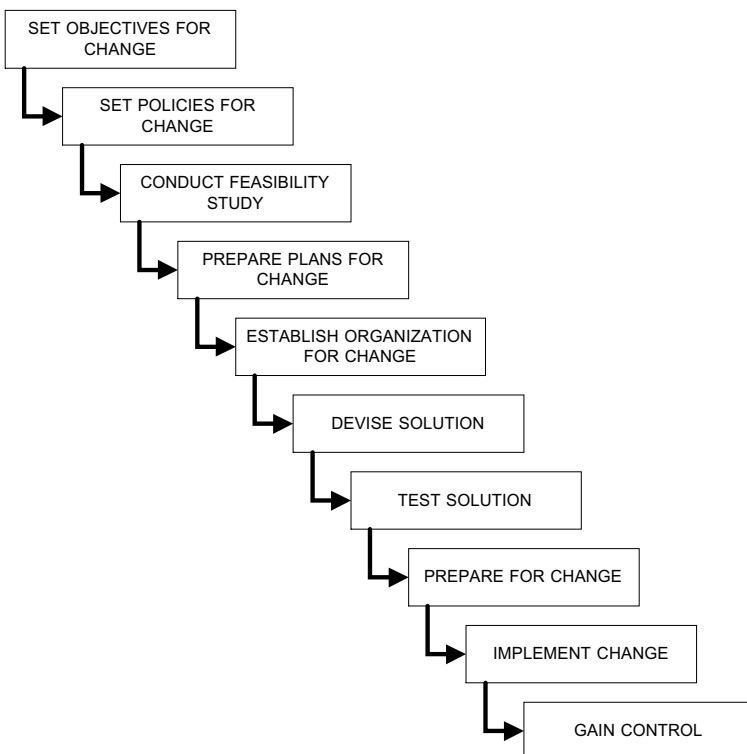


Figure 2.5 *The improvement process*

- 6 Carry out research, analysis, and design to define a possible solution and credible alternatives.
- 7 Model and develop the best solution and carry out tests to prove it fulfills the objective.
- 8 Identify and overcome any resistance to the change in standards.
- 9 Implement the change, i.e. put new products into production and new services into operation.
- 10 Put in place the controls to hold the new level of performance.

This improvement process will require controls to keep improvement projects on course towards their objectives. The controls applied should be designed in the manner described previously.

Quality assurance (QA)

The ISO definition states that *quality assurance* is all those planned and systematic actions necessary to provide adequate confidence that an entity will fulfill requirements for quality. Both customers and managers have a need for quality assurance as they are not in a position to oversee operations for themselves. They need to place trust in the producing operations, thus avoiding constant intervention.

Customers and managers need:

- 1 Knowledge of what is to be supplied. (This may be gained from the sales literature, contract, or agreement.)
- 2 Knowledge of how the product or service is intended to be supplied. (This may be gained from the supplier's proposal or offer.)
- 3 Knowledge that the declared intentions will satisfy customer requirements if met. (This may be gained from personal assessment or reliance on independent certifications.)
- 4 Knowledge that the declared intentions are actually being followed. (This may be gained by personal assessment or reliance on independent audits.)
- 5 Knowledge that the products and services meet your requirements. (This may be gained by personal assessment or reliance on independent audits.)

You can gain an assurance of quality by testing the product/service against prescribed standards to establish its capability to meet them. However, this only gives confidence in the specific product or service purchased and not in its continuity or consistency during subsequent supply. Another way is to assess the organization that supplies the products/services against prescribed standards to establish its capability to produce products of a certain standard. This approach may provide assurance of continuity and consistency of supply.

Quality assurance activities do not control quality, they establish the extent to which quality will be, is being, or has been controlled. This is borne out by ISO 8402:1994 where it is stated that quality control concerns the operational means to fulfill quality requirements, and quality assurance aims at providing confidence in this fulfillment both within the organization and externally to customers and authorities. All quality assurance activities are post-event activities and off-line and serve to build confidence in results, in claims, in predictions, etc. If a person tells you they will do a certain job for a certain price in a certain time, can you trust them or will they be late, overspent, and under spec? The only way to find out is to gain confidence in their operations and that is what quality assurance activities are designed to do. Quite often, the means to provide the assurance need to be built into the process, such as creating records, documenting plans, documenting specifications, reporting reviews, etc. Such documents and activities also serve to control quality as well as assure it (see also ISO 8402:1994). ISO 9001:1994 provides a means for obtaining an assurance of quality, if you are the customer, and a means for controlling quality, if you are the supplier.

Quality assurance is often perceived as the means to prevent problems but this is not consistent with the definition in ISO 8402:1994. In one case the misconception arises due to people limiting their perception of quality control to control during the event; and not appreciating that you can control an outcome before the event by installing mechanisms to prevent failure, such as automation, mistake-proofing, and failure prediction. Juran provides a very lucid analysis of control before, during, and after the event in *Managerial Breakthrough*.

In another case, the misconception arises due to the label attached to the ISO 9000 series of standards. They are sometimes known as the quality assurance standards when in fact, as a family of standards, they are quality system standards. The requirements within the standards do aim to prevent problems, hence the association with the term *quality assurance*. Only ISO 9001, ISO 9002, and ISO 9003 are strictly quality assurance standards. It is true that by installing a quality system, you will gain an assurance of quality, but assurance comes about through knowledge of what will be, is being, or has been done, rather than by doing it. Assurance is not an action but a result. It results from obtaining reliable information that testifies the accuracy or validity of some event or product. Labeling the prevention activities as quality assurance activities may have a negative effect, particularly if you have a Quality Assurance Department. It could send

out signals that the aim of the Quality Assurance Department is to prevent things from happening! Such a label could unintentionally give the department a law enforcement role.

Quality Assurance Departments are often formed to provide both customer and management with confidence that quality will be, is being, and has been achieved. However, another way of looking upon Quality Assurance Departments is as Corporate Quality Control. Instead of measuring the quality of products, they are measuring the quality of the business and by doing so are able to assure management and customers of the quality of products and services.

Assurance of quality can be gained by the following steps (illustrated diagrammatically in Figure 2.6):

- 1 Acquire the documents that declare the organization's plans for achieving quality.
- 2 Produce a plan that defines how an assurance of quality will be obtained, i.e. a quality assurance plan.
- 3 Organize the resources to implement the plans for quality assurance.
- 4 Establish whether the organization's proposed product or service possesses characteristics which will satisfy customer needs.
- 5 Assess operations, products, and services of the organization and determine where and what the quality risks are.
- 6 Establish whether the organization's plans make adequate provision for the control, elimination, or reduction of the identified risks.
- 7 Determine the extent to which the organization's plans are being implemented and risks contained.
- 8 Establish whether the product or service being supplied has the prescribed characteristics.

In judging the adequacy of provisions you will need to apply the relevant standards, legislation, codes of practice, and other agreed measures for the type of operation, application, and business. These activities are quality assurance activities and may be subdivided into design assurance, procurement assurance, manufacturing assurance, etc. Auditing, planning, analysis, inspection, and test are some of the techniques that may be used.

ISO 9001 is a quality assurance standard, designed for use in assuring customers that suppliers have the capability of meeting their requirements.

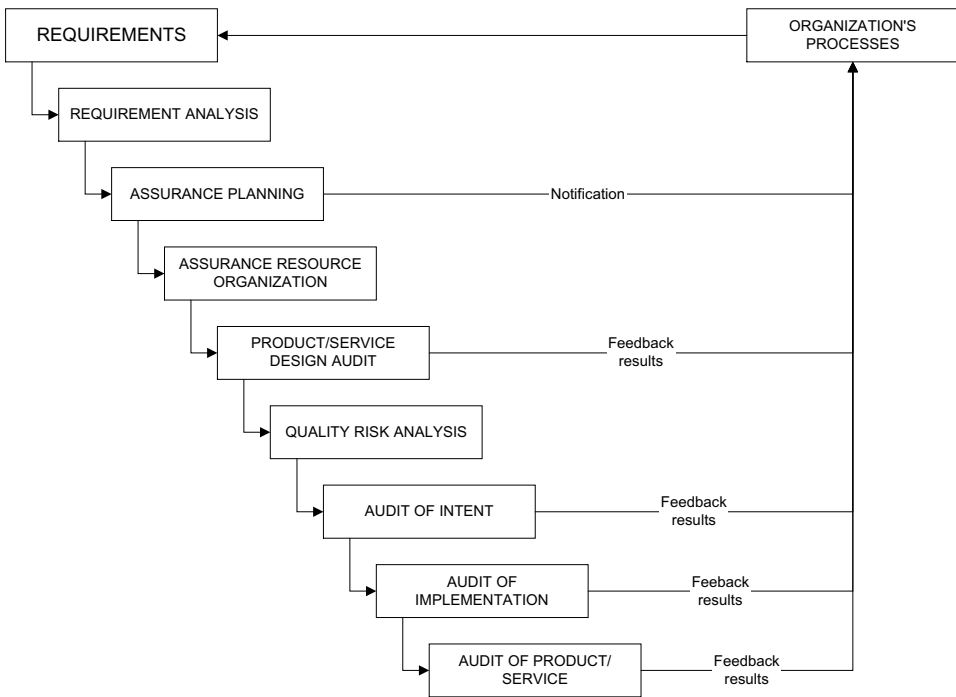


Figure 2.6 *The assurance process*

Quality goals

To control, assure, and improve quality you need to focus on certain goals. Let's call them the quality goals. Here are some key actions from which specific goals may be derived:

- Establish your customer needs.
- Design products and services with features that reflect customer needs.
- Build products and services so as to reproduce faithfully the design that meets the customer needs.
- Verify before delivery that your products and services possess the features required to meet the customer needs.
- Prevent supplying products and services that possess features that dissatisfy customers.

- Discover and eliminate undesirable features in products and services even if they possess the requisite features.
- Find less expensive solutions to customer needs because products and services that satisfy these needs may be too expensive.
- Make your operations more efficient and effective so as to reduce costs, because products and services that satisfy customer needs may cost more to produce than the customer is prepared to pay.
- Discover what will delight your customer and provide it. (Regardless of satisfying customer needs your competitor may have provided products with features that give greater satisfaction!)
- Establish and maintain a management system that enables you to achieve these goals reliably, repeatedly, and economically.

ISO 9001 addresses quality goals through the use of the term *quality objectives* but goes no further. ISO/TS 16949 addresses both goals and objectives and requires them to be defined and performance evaluated relative to the defined goals and objectives.

Quality systems

The purpose of a *quality system* is to enable you to economically achieve, sustain, and improve quality. It is unlikely that you will be able to produce and sustain the required quality unless you organize yourselves to do so. Quality does not happen by chance – it has to be managed. No human endeavor has ever been successful without having been planned, organized, and controlled in some way.

Depending on your strategy, quality systems should enable you to achieve all your quality goals. Quality systems have a similar purpose to financial control systems, information technology systems, inventory control systems, and personnel management systems. They organize resources so as to achieve certain objectives through processes which, if implemented and maintained, will yield the desired results. Whether it is the management of costs, inventory, personnel, or quality, systems are needed to focus the thought and effort of people towards prescribed objectives. Quality systems focus on the quality of what the organization produces, the factors which will cause the organization to achieve its goals, the factors which might prevent it satisfying customers, and the factors which might prevent it from being productive, innovative, and profitable. Quality systems should therefore *cause* conforming product and *prevent* nonconforming product.

Quality systems can address one of the quality goals or all of them, they can be as small or as large as you want them to be. They can be project-specific, or they can be limited to quality control: that is, maintaining standards rather than improving them. They can include Quality Improvement Programs (QIPs) or encompass what is called Total Quality Management (TQM).

Quality systems need to possess certain characteristics for them to be fit for their purpose. ISO/TS 16949 specifies functional requirements for quality systems rather than performance requirements. It specifies what a quality system must do but not how well it must do it. The performance required will however depend on the environment in which the system will be used. Some of these performance characteristics will be as follows:

Robustness	The ability to withstand variation in the way operations are carried out without system breakdown
Complexity	The number of interconnections, routings, pathways, variations, options, alternatives, etc. which give rise to multiple procedures
Maintainability	The ease and economy with which system changes can be made
Reliability	The extent to which the system produces consistent and predictable results
Flexibility	The ease with which the system can handle changing circumstances
Vulnerability	The extent to which the system is dependent upon certain resources
Consistency	The extent to which the system unifies communication (purpose and behavior)
Compliance	The extent to which the system complies with the requirements of ISO/TS 16949 or other prescribed requirements
Usability	The ease and economy with which the system enables users to determine the right things to do and to do these things in the right way the first time and every time
Traceability	The ease and economy with which the system enables information to be traceable to the governing requirements and vice versa

The quantitative measure of these characteristics may be difficult if not impractical, but nevertheless they provide a means of judging the effectiveness of the system once it is installed. The effectiveness of quality systems is also addressed in Part 2 Chapter 1.

Quality and ISO/TS 16949

Quality products are products that meet customer needs and expectations but, as has already been said, quality does not happen by chance. A quality system is the means by which organizations produce products that meet customer needs and expectations. Even if that system is not formalized, it is the combination of processes, resources, and organization that will deliver quality products. All ISO/TS 16949 does is define a minimum set of requirements which if met will enable an organization to satisfy its customers. It is a kind of framework for achieving product quality.

Should an organization have to change its practices to meet ISO/TS 16949, the resultant system should have a positive measurable impact on product quality. If there is no impact, either the organization was doing all the right things to start with and the documentation merely described what they were doing or the organization has not properly implemented the requirements. ISO/TS 16949 represents what the major vehicle manufacturers believe are the essential characteristics of an effective quality system. Leave any one out and product quality is believed to be at risk – maybe not immediately but eventually.

The requirements of the automotive industry are more demanding than some other industries. Automotive products have to be safe, reliable, and maintainable, protect the occupants, and have minimal impact on the environment in their manufacture, use, and disposal. The automotive sector is a very competitive market and as a consequence costs have to be optimized. There is little margin for excessive variation, as variation causes waste and waste costs money and time. Therefore several methods have evolved to reduce variation. Among them are SPC, FMEA, MSA, and many other techniques². The automotive industry believes that the more their suppliers adopt such variation reduction techniques the more likely it will be that the resultant product will be brought to the market more quickly and its production process be more efficient.

ISO/TS 16949 is not a set of requirements for producing documentation (as many perceive ISO 9000 to be). It contains requirements that address the key characteristics of a quality system which if not met will put product quality (and consequently customer satisfaction) at risk.

² See Appendix B for an explanation of acronyms.

A postscript on definitions

Many of the official definitions of quality terms are verbose, hard to understand at first reading, and often lack the clarity needed to convey the actions and decisions which the terms may imply. They seem to have been constructed so they could withstand the rigors of cross examination in a court of law. One of the perennial problems which faces the quality fraternity is that they continually come up with new terms and then spend decades defining them. The only reason for inventing a new term is when we have a new concept or set of concepts that we wish to communicate. The label we give the concepts needs to reflect the concepts without being ambiguous. In reality, new terms have emerged and eventually committees have got together to formulate a definition which often disappoints the practitioner. The definition appears after the practitioner has built a whole new set of concepts only to find they conflict with what everyone is now labeling them. Sometimes new definitions are found for existing terms which completely change their meaning, such as the change in the concept of quality assurance from being all activities concerned with the attainment of quality (circa 1970) to being limited to the activities which provide confidence that quality has been achieved (circa 1980). I can do no better than quote Juran who said on terminology³:

The prime need is to discover the realities under the labels, i.e. the deeds, activities or things which the other fellow is talking about. Once these are understood accurate communication can take place whether the labels are agreed on or not. In contrast, if communication is purely through labels, it is easy to be deluded into believing there is understanding despite the fact that each of the parties literally does not know what the other fellow is talking about.

Although I have defined terms such as *quality control* and *quality assurance* in this chapter, what is important is not the *definition* but the *deeds* which it imbues. Whether we call the set of principles I have listed under the heading *Quality assurance*, Quality Assurance, Quality Improvement or Quality Control makes no difference since it does not change the set of principles. We often seem to invent a term then decide what it means rather than invent or discover a set of principles and think of a suitable name which conveys exactly what we intend without confusing people. Instead of saying “Quality control is ...” or “TQM is ...” to which there will be many propositions, we should be asking: What should we call *this* group of principles so that we can communicate with each other more efficiently? As Shakespeare once said: “That which we call a rose/By any other name would smell as sweet.”

An extensive range of definitions in the field of quality management is provided in ISO 8402:1994 and Appendix A includes over 150 commonly-used terms, less verbose but consistent with the definitions found in ISO 8402:1994.

³ J M Juran, *Quality Control Handbook*

Chapter 3

The differences

Provisions of ISO/TS 16949

As stated in Chapter 1, ISO/TS 16949 harmonizes the quality system requirements of the automotive industry in the USA, Germany, France, and Italy. It does not contain all automotive quality system requirements. All participating organizations have customer-specific requirements in addition, which may be issued separately or included in individual contracts for the supply of products and services.

Unlike ISO 9000, which is a family of documents, ISO/TS 16949 is a single standard that references other standards and manuals. The three standards that form part of ISO/TS 16949 and are therefore requirements of the standard are:

ISO 8402	Quality management and quality assurance – Vocabulary
ISO 9001	Quality systems – Model for quality assurance in design, development, production, installation, and servicing
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories ¹

Although the requirements of ISO 9001 section 4 are embodied in ISO/TS 16949, sections 1, 2, and 3 of ISO 9001 – while excluded from the text of ISO/TS 16949 – remain requirements. Therefore the scope, references, and definitions apply.

Existing AIAG, ANFIA, FIEV, and VDA manuals are listed in a bibliography to ISO/TS 16949 and form part of the requirements to the extent specified in specific clauses. For example, suppliers to Ford, Chrysler, and General Motors will be required to apply the APQP Manual, FMEA Manual, etc.

¹ To be released 4th quarter of year 2000

Scope of the standard

ISO/TS 16949 applies to the design, development, production, and, when relevant, installation and servicing of automotive-related products. The standard primarily applies to suppliers and subcontractor “sites” that provide:

- Parts or materials
- Service such as heat treating, painting, plating, or other finishes
- Other customer-specified products

Certification to the standard will only be awarded to a site that has the *capability* to meet all the applicable requirements of ISO/TS 16949 for the products and services concerned. If some operations are carried at remote locations (e.g. design centers and corporate headquarters), such locations cannot receive separate certification and must be included within the certification awarded to the parent site possessing production capability.

It is stated in the standard that the standard can also be applied throughout the automotive supply chain. This implies that vehicle manufacturers should apply the requirements to their own operations, but obviously such application is voluntary. In due course, ISO/TS 16949 will become a condition of any contract to supply products and services to the vehicle manufacturers. The supply chain includes vehicle distribution and dealers. However, it is not intended that ISO/TS 16949 be applied beyond the vehicle manufacturers at this time.

Differences with ISO 9001

Section 4 of ISO 9001 is incorporated in ISO/TS 16949 in the form of boxed text under the appropriate headings. The sector-specific requirements are outside the boxes and hence the additional requirements are readily identifiable. The only change to the ISO 9001 text has been the head numbering to facilitate decimal numbering of the additional clauses. Various notes have been added to correct clause numbering within the ISO 9001 text and in 13 cases a requirement has been modified:

- 1 A note in clause 4.2.1 states that all the quality systems documents should be controlled.
- 2 The note in clause 4.4.5.1 states that the characteristics specified are designated as special characteristics.

- 3 The note in clause 4.4.9.1 states that design changes are to include changes to proprietary designs.
- 4 The note in clause 4.5.2.1 lists examples of documents that should be available at all locations where operations essential to the effective functioning of the quality system are performed.
- 5 A note in clause 4.7.1 points out that customer-owned returnable packaging is included in customer supplied product.
- 6 The note in clause 4.8 removes the words “where appropriate”, implying that procedures for product identification are required.
- 7 A note in clauses 4.10.1.1 and 4.12 explains that reference to the quality plan should be interpreted as control plan.
- 8 A note in clause 4.11.2 requires wear and frequency of use to be taken into account in establishing calibration frequency.
- 9 A note in clause 4.11.2 also accepts a serial number traceable to the device calibration record as meeting the intent of the requirement on calibration status indicator.
- 10 A note in clause 4.12 points out that location of product in the normal production flow does not constitute suitable indication of inspection and test status unless inherently obvious.
- 11 A note in clause 4.16.1 points out that disposition of quality records includes disposal and that quality records include customer-specified records.
- 12 A note in clause 4.18.1 points out that training applies to all employees at all levels of the organization.
- 13 The note in clause 4.19.1 points out that any after-sales product servicing provided under the OEM contract or order would constitute servicing.

Differences between existing automotive quality system requirements

The differences with the existing automotive quality system requirements need careful examination. There are additions, deletions, and movements that users of QS-9000 Third Edition, AVSQ '94, EAQF '94, and VDA 6.1:1998 need to be aware of, as they affect not only supplier quality systems but the internal and external auditing practices. As the national requirements are not similarly structured comparisons are impossible to illustrate in a single table. Readers are therefore advised to compare specific text in each to discover the actual differences. The source of the requirements is depicted in the tables that follow. A dash (-) indicates that there is no matching requirement.

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.1	Management responsibility	<i>Heading</i>				
4.1.1	Quality policy	<i>Heading</i>				
4.1.1.1	Quality policy	4.1.1	4.1.1	01.1	4.1.1a)	1.1
4.1.1.2	Objectives	–	–	01.2 Z1.1	4.1.1a)	1.3
4.1.1.3	Customer satisfaction	–	4.1.6	Z1.4 04.7	4.16b) 4.19e)	19.3
4.1.1.4	Continuous improvement	–	4.2.5	01.3 04.2	4.1.1b)	1.2
4.1.2	Organization	<i>Heading</i>				
4.1.2.1	Responsibility and authority	<i>Heading</i>				
4.1.2.1.1	Responsibility and authority	4.1.2.1	4.1.2	02.3	4.1.2.1a) 4.1.2.1b)	1.11 1.13
4.1.2.1.2	Customer representative	–	4.1.2f)	07.5	4.1.2.1c) 4.4.2m)	2.4
4.1.2.1.3	Quality responsibility	–	4.1.2a)	18.1 02.3	4.2.3b) 4.1.2.1b)	1.9 4.3
4.1.2.2	Resources	<i>Heading</i>				
4.1.2.2.1	Resources	4.1.2.2	4.1.2.2	02.1	4.1.2.2a) 4.1.2.2b)	1.7 1.14
4.1.2.2.2	Shift resources	–	–	01.4 02.3	4.1.2.2c)	1.12
4.1.2.3	Management representative	4.1.2.3	4.1.2.3	01.5	4.1.2.3	1.4
4.1.2.4	Organizational interfaces	–	4.1.2.4	02.4 02.5	4.4.2e) 4.4.2f) 4.4.2b)	

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.1.3	Management review	<i>Heading</i>				
4.1.3.1	Management review	4.1.3	4.1.3	01.6	4.1.3	1.8
4.1.3.2	Management review – supplemental	–	4.1.3.1	01.6 05.1 Z1.1	–	21.1 21.2
4.1.4	Business plan	–	4.1.4	Z1.1 01.2 Z1.3 07.1	–	–
4.1.5	Analysis and use of company level data	–	4.1.5	04.7 Z1.2 Z1.3	4.2.3b)	2.5 2.6
4.1.6	Employee motivation, empowerment, and satisfaction	–	–	04.6 Z1.5	4.4.4d) 4.18g)	18.6 18.7
4.1.7	Impact on society	<i>Heading</i>				
4.1.7.1	Product safety	–	4.2.3.4	06.3 06.1	4.22	22.1–22.4
4.1.7.2	Regulations	–	–	06.2	4.4.2i) 4.22a)	1.6
4.2	Quality system	<i>Heading</i>				
4.2.1	General	4.2.1	4.2.1	02.1	4.2.1	2.1
4.2.2	Quality system procedures	<i>Heading</i>				
4.2.2.1	Quality system procedures	4.2.2.1	4.2.2.1	02.1	4.2.2	2.2
4.2.2.2	Quality system documentation	–	–	02.1	–	–
4.2.3	Quality planning	<i>Heading</i>				
4.2.3.1	Quality planning	4.2.3	4.2.3	02.4	4.2.3a)	2.3, 2.6
4.2.3.2	Quality plan requirements	–	–	02.5 02.6	–	4.6
4.2.4	Product realization	<i>Heading</i>				
4.2.4.1	General	–	4.2.3.1	02.4 09.1 08.1 01.4	4.4.4d)	4.8
4.2.4.2	Measurements	–	–	02.5 09.4, 05.1	4.4.2m)	–
4.2.4.3	Review cycle	–	–	09.4	–	4.7
4.2.4.4	Multidisciplinary approach	–	4.2.3.1	02.5 09.1 09.4 09.5	4.4.2f)	4.1 4.2

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.2.4.5	Tools and techniques	–	4.2.3.1	02.5 09.3 06.3, 09.4 15.1, 02.6 14.2, 09.6 09.7	4.4.2l) 4.9b)	4.6
4.2.4.6	Computer aided design	–	4.4.4.1	09.3	4.4.2c)	4.25 4.19
4.2.4.7	Special characteristics	–	4.2.3.2	02.5 06.2 02.6, 09.2 09.3, 09.6	4.4.2g) 4.9b)	1.10 4.16
4.2.4.8	Feasibility reviews	–	4.2.3.3	09.3 09.7	4.3.2d)	3.5
4.2.4.9	Management of process design	–	–	–	–	1.5
4.2.4.9.1	General	–	–	09.1	–	–
4.2.4.9.2	Process design input data	–	–	09.3	–	–
4.2.4.9.3	Process design output data	–	–	09.6	–	–
4.2.4.9.4	Process verification	–	–	09.4 14.2	–	9.10 9.4
4.2.4.10	Control plan	–	4.2.3.7	02.6 09.6, 09.5 09.2, 09.3 10.3	4.9f)	9.6
4.2.4.11	Product approval process	–	4.2.4	09.3 09.5 14.2 11.3 02.5	4.6.4c) 4.9n)	9.11 9.8 9.10
4.2.5	Plant, facility, and equipment planning	–	4.2.6	02.5 01.3 03.4	4.8b) 4.9c)	9.18
4.2.6	Tooling management	–	4.2.6.2	01.4 14.4 11.1	4.9c)	9.18 9.20
4.2.7	Process improvement	–	4.2.5.1	01.3	–	–
4.2.8	Quality system performance	–	–	01.6 Z1.4	–	–
4.3	Contract review	<i>Heading</i>				
4.3.1	General	4.3.1	4.3.1	07.2	4.3.1	2.4, 3.1 3.2, 3.3
4.3.2	Review	<i>Heading</i>				

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.3.2.1	Review	4.3.2	4.3.2	07.2	4.3.2a) 4.3.2b) 4.3.2c) 4.3.2d)	3.3 3.4 3.5 3.6
4.3.2.2	Review – supplemental	–	–	07.3 07.4	–	–
4.3.3	Amendment to contract	4.3.3	4.3.3	–	4.3.3	3.6
4.3.4	Records	4.3.4	4.3.4	20.3 09.3	4.3.4	–
4.4	Design control	4.4	4.4	08.1	4.4	3.3, 3.6
4.4.1	General	4.4.1	4.4.1	08.1 09.1	4.4.1	4.1
4.4.2	Design and development planning	<i>Heading</i>				
4.4.2.1	Design and development planning	4.4.2	4.4.2	08.1 09.1	4.4.2a) 4.4.2b) 4.4.2c)	4.4 4.5 4.6
4.4.2.2	Required design skills	–	4.4.2.1	04.5	4.4.2c)	–
4.4.2.3	Research and development	–	–	–	4.4.2d)	4.11
4.4.3	Organizational and technical interfaces	4.4.3	4.4.3	02.4 08.5 08.7, 09.5 09.7	4.4.3a) 4.4.3b)	2.4 4.1 4.4
4.4.4	Design input	<i>Heading</i>				
4.4.4.1	Design input	4.4.4	4.4.4	08.1 08.2, 09.1	4.4.4a)	4.8 4.11–4.14
4.4.4.2	Reliability objectives	–	–	08.4	–	4.17
4.4.4.3	Use of information	–	4.4.1.1	08.7	4.4.4b) 4.4.4c)	4.13
4.4.5	Design output	<i>Heading</i>				
4.4.5.1	Design output	4.4.5	4.4.5	08.1 08.5 08.6 08.7, 09.1 09.5, 09.6 09.7	4.4.5a) 4.4.5b) 4.4.5c)	4.16 4.19
4.4.5.2	Design optimization	–	4.4.5.1	02.5 08.2	–	4.10 4.11
4.4.6	Design review	4.4.6	4.4.6	08.4 09.4	4.4.6	4.4 4.6 4.7

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.4.7	Design verification	4.4.7	4.4.7	08.3	4.4.7a) 4.4.7b) 4.4.7c)	4.7 4.13 4.18
4.4.8	Design validation	<i>Heading</i>				
4.4.8.1	Design validation	4.4.8	4.4.8	08.3 08.5 09.3, 09.5	4.4.8a) 4.4.8b)	4.9 4.15 4.20
4.4.8.2	Design validation – supplemental	–	4.4.8.1	02.5 08.3, 20.1 18.1, 18.3	–	–
4.4.8.3	Prototype program	–	4.4.10	02.5 08.4, 14.2 08.1	4.6.4d)	4.20 4.9 4.24
4.4.9	Design changes	<i>Heading</i>				
4.4.9.1	Design changes	4.4.9	4.4.9	08.1–08.7 09.1–09.7	4.4.9a)	4.27
4.4.9.2	Evaluation of design change	–	4.4.9.2	08.1 08.4	4.4.9b)	4.27
4.5	Document and data control	<i>Heading</i>				
4.5.1	General	4.5.1	4.5.1	10, 10.1	4.5.1	5.3, 22.2
4.5.2	Document and data approval and issue	<i>Heading</i>				
4.5.2.1	Document and data approval and issue	4.5.2	4.5.2	10.1 10.2 10.4	4.5.2a) 4.5.2b) 4.5.2c)	5.1 5.2 9.16
4.5.2.2	Engineering specifications	–	4.5.2.1	10.4 10.2	–	–
4.5.3	Document and data changes	4.5.3	4.5.3	10.2 10.5, 07.2	4.5.3a)	4.27, 5.1 5.2
4.6	Purchasing	<i>Heading</i>				
4.6.1	General	<i>Heading</i>				
4.6.1.1	General	4.6.1	4.6.1	11.2 11.3 11.4	4.6.1	6.4 6.7
4.6.1.2	Customer approved subcontractors	–	4.6.1.1	11.2 11.3 (VDA 2)	–	–
4.6.1.3	Regulatory compliance	–	4.6.1.2	08.2 11.1	–	–
4.6.2	Evaluation of subcontractors	<i>Heading</i>				

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.6.2.1	Evaluation of subcontractors	4.6.2	4.6.2	11.1 11.2 11.3 11.5	4.6.2a) 4.6.2b) 4.6.2c)	6.1, 6.4 6.5, 6.9 6.10
4.6.2.2	Subcontractor development	–	4.6.2.1	11.6	–	–
4.6.2.3	Scheduling of subcontractors	–	4.6.2.2	11.4 11.1, 11.6	4.9t)	–
4.6.3	Purchasing data	4.6.3	4.6.3	11.1	4.6.3a) 4.6.3b)	6.2 6.3
4.6.4	Verification of purchased product	<i>Heading</i>				
4.6.4.1	Supplier verification at subcontractor's premises	4.6.4.1	4.6.4.1	11.5 11.6	4.6.4a)	6.6
4.6.4.2	Customer verification of subcontractor's product	4.6.4.2	4.6.4.2	11.1 11.5, 11.6	4.6.4b)	6.4, 6.8
4.7	Control of customer supplied product	<i>Heading</i>				
4.7.1	Control of customer supplied product	4.7	4.7	12	4.7	7.1
4.7.2	Customer-owned tooling	–	4.7.1	12, 12.2	–	–
4.8	Product identification and traceability	4.8	4.8	06.3 11.7 13.1 13.6	4.8a) 4.8b) 4.8c)	8.1, 8.2 4.23, 8.3 22.4
4.9	Process control	<i>Heading</i>				
4.9.1	General	<i>Heading</i>				
4.9.1.1	General	4.9	4.9	9.1–9.7 13.2 13.3 13.4 13.7 14.1–14.4 14.6	4.9a) 4.9d) 4.9e) 4.9h) 4.9i) 4.9p) 4.9q) 4.9r)	4.21 4.22 4.24 4.25 4.26 8.1 9.1–9.14 9.17–9.20 18.6 18.7
4.9.1.2	Cleanliness of premises	–	4.9.b.1	03.4 14.6	–	9.12
4.9.1.3	Contingency plans	–	4.9.b.2	19.6 14.2	–	–
4.9.1.4	Designation of special characteristics	–	4.9.d.1	14.3 14.2	–	–

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.9.1.5	Preventive maintenance	–	4.9.g.1	14.4	4.9o)	9.2
4.9.2	Job instructions	–	4.9.1	09.2 14.2, 09.6	4.9o)	–
4.9.3	Maintaining process control	–	4.9.2	14.1 09.2 15.1, 14.3 15.4, 14.2	4.9i) 4.9n)	9.4
4.9.4	Verification of job set-ups	–	4.9.4	13.7 14.1	4.9m) 4.9o)	9.7 9.11
4.9.5	Appearance items	–	4.9.6	04.5 09.3, 15.2	–	–
4.10	Inspection and testing	<i>Heading</i>				
4.10.1	General	<i>Heading</i>				
4.10.1.1	General	4.10.1	4.10.1	11.6 15.2 15.3–15.6	4.10.1	10.1–10.3
4.10.1.2	Acceptance criteria	–	4.10.1.1	15.2 09.2	–	–
4.10.2	Receiving inspection and testing	4.10.2	4.10.2	15.3	4.10.2a) 4.10.2b) 4.10.2c)	10.1 12.2
4.10.2.4	Incoming product quality	–	4.2.10.4	11.5 15.3	–	–
4.10.3	In-process inspection and testing	4.10.3	4.10.3	15.4	4.10.3a) 4.10.3b) 4.10.3c)	10.2 12.2
4.10.4	Final inspection and testing	<i>Heading</i>				
4.10.4.1	Final inspection and testing	4.10.4	4.10.4	15.5	4.10.4a) 4.10.4b)	10.3 12.2
4.10.4.2	Layout inspection and functional testing	–	4.10.4.1	15.6 11.5	–	–
4.10.5	Inspection and test records	4.10.5	4.10.5	–	4.10.5a) 4.10.5b)	10.5
4.10.6	Laboratory requirements	–	4.10.7	15.6 15.1 16.2	–	–
4.11	Control of inspection, measuring, and test equipment	<i>Heading</i>				
4.11.1	General	<i>Heading</i>				
4.11.1.1	General	4.11.1	4.11.1	16.1	4.11.1a) 4.11.1b)	9.3 11.2

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.11.1.2	Measurement systems analysis	–	4.11.4	16.4	4.11.2d)	–
4.11.2	Control procedure	4.11.2	4.11.2	14.2 16.1 16.2 16.4 16.5 20.1 14.6, 13.4	4.11.2a) 4.11.2b) 4.11.2c) 4.11.2e) 4.11.2f)	9.4 9.15 11.1–11.5
4.11.3	Measurement records	–	4.11.3	16.1 16.5	–	–
4.12	Inspection and test status	4.12	4.12	13.1 15.4	4.12	12.1 12.2
4.13	Control of nonconforming product	<i>Heading</i>				
4.13.1	General	<i>Heading</i>				
4.13.1.1	General	4.13.1	4.13.1	17.1	4.13.1	13.1–13.3
4.13.1.2	Suspect material or product	–	4.13.1.1 4.13.1.2	17.1	–	–
4.13.1.3	Corrective action plan	–	4.13.2.1	21.3 17.1	–	–
4.13.2	Review and disposition of nonconforming product	4.13.2	4.13.2	17.1–17.3	4.13.2a) 4.13.2b) 4.13.2c)	13.4 15.3
4.13.3	Control of reworked product	–	4.13.3	17.3	–	–
4.13.4	Engineering approved authorization	–	4.13.4	17.2 13.5	–	–
4.14	Corrective and preventive action	<i>Heading</i>				
4.14.1	General	<i>Heading</i>				
4.14.1.1	General	4.14.1	4.14.1	18.1 19.4	4.14.1	14.1–14.5
4.14.1.2	Problem solving	–	4.14.1.1	18.3	–	–
4.14.1.3	Mistake-proofing	–	4.14.1.2	18.2	–	–
4.14.2	Corrective action	<i>Heading</i>				
4.14.2.1	Corrective action	4.14.2	4.14.2	17.4 18.1 18.3 21.3	4.14.2a) 4.14.2b) 4.14.2c)	14.2–14.5
4.14.2.2	Corrective action impact	–	4.14.2.2	18.3	–	–
4.14.2.3	Returned product test/analysis	–	4.14.2.1	18.3 18.4	–	–

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.14.3	Preventive action	4.14.3	4.14.3	18.2	4.14.3a) 4.14.3b)	14.2–14.5
4.15	Handling, storage, packaging, preservation, and delivery	<i>Heading</i>				
4.15.1	General	4.15.1	4.15.1	19.1 19.4	4.15.1	15.1 15.2 15.4 15.5
4.15.2	Handling	4.15.2	4.15.2	19.1	4.15.2	15.1
4.15.3	Storage	<i>Heading</i>				
4.15.3.1	Storage	4.15.3	4.15.3	19.1	4.15.3a) 4.15.3b)	15.2
4.15.3.2	Inventory	–	4.15.3.1	13.6 19.1	4.13.2d) 4.15.3b)	–
4.15.4	Packaging	<i>Heading</i>				
4.15.4.1	Packaging	4.15.4	4.15.4	19.2–19.4	4.15.4	15.4
4.15.4.2	Customer packaging standards	–	4.15.4.1	19.2	–	–
4.15.4.3	Labeling	–	4.15.4.2	19.2	–	–
4.15.5	Preservation	4.15.5	4.15.5	07.5 19.3	4.15.5	15.4
4.15.6	Delivery	<i>Heading</i>				
4.15.6.1	Delivery	4.15.6	4.15.6	07.5 19.3	4.15.6a)	15.5 9.18
4.15.6.2	Performance monitoring of supplier delivery	–	4.15.6.1	19.6	4.15.6a)	
4.15.6.3	Production scheduling	–	4.15.6.2	14.2 19.6	4.15.6a)	1.12
4.15.6.4	Electronic communication	–	4.15.6.3	09.3 19.6	4.15.6a)	–
4.15.6.5	Shipment notification system	–	4.15.6.4	19.6 13.6	4.15.6a)	–
4.16	Control of quality records	<i>Heading</i>				
4.16.1	Control of quality records	4.16	4.16	12.3 20	4.16a)	2.5, 6.9 16.1 16.2 18.7 19.3
4.16.2	Record retention	–	4.16.1	06.2	–	–
4.17	Internal quality audits	<i>Heading</i>				
4.17.1	Internal quality audits	4.17	4.17	03	4.17a)–d)	17

ISO/TS 16949 Clause		Source – Requirement/Clause Ref				
No.	Heading	ISO 9001	QS-9000	VDA 6.1	AVSQ '94	EAQF '94
4.17.2	Internal quality audit – supplementary	<i>Heading</i>				
4.17.2.1	General	–	4.17.1	03.1 03.2 03.3	–	17.1–17.3
4.17.2.2	System audit	–	4.17.1	03.2	–	–
4.17.2.3	Process audit	–	–	03.4	–	9.21
4.17.2.4	Product audit	–	4.10.4.2	03.4	4.10.4c)	10.4
4.17.3	Auditor qualification	–	–	03.1	–	17.2
4.18	Training	<i>Heading</i>				
4.18.1	Training	4.18	4.18	04	4.18a) 4.18b) 4.18e) 4.18f)	18.1–18.7
4.18.2	Training effectiveness	–	4.18.1	04.1	–	–
4.18.3	Training on the job	–	–	04.4 04.6	–	–
4.19	Servicing	<i>Heading</i>				
4.19.1	Servicing	4.19	4.19	21.1–21.5	4.19a)	19.1
4.19.2	Feedback of information from service	–	4.19.1	21.4	4.19d)	19.3
4.19.3	Servicing agreement with customer	–	–	21.5	–	19.2
4.20	Statistical techniques	<i>Heading</i>				
4.20.1	Identification of need	4.20.1	4.20.1	21.1 21.2 21.3 21.4	4.20.1	20.1
4.20.2	Procedures	4.20.2	4.20.2	21.1 21.2 21.3 21.4	4.20.2	20.2
4.20.3	Identification of statistical tools	–	4.20.3	22.1 22.2 22.3 22.4 22.5	–	–
4.20.4	Knowledge of basic statistical concepts	–	4.20.4	04.4	–	–

From this table one can see that all the additional requirements in ISO/TS 16949 were sourced from one or more of the four national quality system requirement documents. The location and wording of the requirements changed on incorporation into ISO/TS 16949. Many requirements from QS-9000 have been incorporated verbatim, whereas extracts from VDA, AVSQ, and EAQF were reworded so as to phrase the statements as requirements.

Additional requirements

In order to identify the differences in detail one would have to compare each of the four existing automotive quality system requirement documents with ISO/TS 16949. This is an exercise that forms part of the IATF Auditor Qualification Course and is not duplicated here. However, a summary of the 26 requirements that are additional to those in QS-9000 Third Edition are listed below:

- 4.1.1.2 Requirement for goals and objectives and measurements to deploy the quality policy to be defined in the business plan
- 4.1.2.1.3 Requirement for personnel responsible for quality to have authority to stop production
- 4.1.2.2.2 Requirement for all shifts to be staffed with personnel in charge of or delegated responsibility for quality
- 4.1.6 Requirement for a process for motivation of employees to achieve quality objectives
- 4.1.6 Requirement for a process for measurement of employee satisfaction and understanding of appropriate quality objectives
- 4.1.7.2 Requirement for a process to ensure compliance with all applicable government, safety, and environmental regulations
- 4.2.3.2 Requirement for a quality plan that includes customer requirements and references to appropriate technical specifications
- 4.2.4.2 Requirement for measurements at appropriate stages of product realization to be defined, analyzed, and reported
- 4.2.4.3 Requirement for the status of product realization to be reviewed at appropriate stages
- 4.2.4.9.1 Requirement for documented procedures to develop and verify the design of processes used in product realization

- 4.2.4.9.2 Requirement for process design input requirements to be identified, documented, and reviewed
- 4.2.4.9.3 Requirement for process design output to be expressed in terms that can be verified and validated against process design input
- 4.2.4.9.4 Requirement for process design output to be verified against design input requirements
- 4.2.8 Requirement for the performance of the quality system to be evaluated to verify the effectiveness of its operation
- 4.3.2.2 Requirement for a process for identification of cost elements or price as appropriate in developing quotations
- 4.4.2.3 Requirement for the supplier to have access to research and development facilities
- 4.4.4.2 Requirement for product life, durability, and maintainability objectives to be included in design inputs
- 4.10.6 Requirement for the supplier's inspection and testing laboratories to comply with ISO/IEC 17025
- 4.11.3 Requirement for records of customer-owned gages
- 4.13.1.3 Requirement for the customer to be promptly informed in the event that nonconforming product is shipped
- 4.15.3.2 Requirement for obsolete product to be controlled in a similar manner to nonconforming product
- 4.17.2.3 Requirement for audit of product realization and production processes to determine the effectiveness of process performance
- 4.17.3 Requirement for compliance with customer requirements for internal system and process auditor qualification
- 4.18.3 Requirement for provision of on-the-job training in any new or modified job affecting quality that includes supplier and contract personnel
- 4.18.3 Requirement for personnel affecting quality to be informed about the consequences for the customer of nonconformities with quality standards
- 4.19.3 Requirement for the effectiveness of servicing to be verified

Removed requirements

There are a number of requirements and guidelines in QS-9000 Third Edition that have not been carried over into ISO/TS 16949; in fact 32 notes have been removed. Overall the omissions have no impact as they remove detail without changing the intent of the requirement or remove duplication and explanation. There are some omitted requirements that may have some impact:

- 4.1.6.1 *Certification body notification.* However, this could still be imposed as a customer-specific requirement.
- 4.2.5.1 *Shall continuously improve price.* Replaced by *improvement in cost* which changes the emphasis so that price could remain the same if costs fall and the increase in profit can be justified in order to fund development.
- 4.2.5.3 *Shall demonstrate knowledge of continuous improvement techniques.* Limited to use of appropriate measures, which is less onerous.
- 4.2.6 *Shall maximize value-added floor space.* Replaced by *optimize*.
- 4.4.9.1 *Design changes shall have written customer approval or waiver prior to production implementation.* This requirement, although removed, is implicit in the product approval requirements.
- 4.4.10 *Performance tests shall consider and include as appropriate product life, reliability, and durability.* This requirement, although removed, is implicit in the requirement for reliability objectives to be included in design outputs and subsequent design validation.
- 4.9.g.1 *The (preventive maintenance) system shall include a procedure that describes planned maintenance activities and a procedure providing for packaging etc.* The new requirement calls for a system, not procedures.
- 4.10.6.2 *Laboratory personnel.* Requirement addressed by ISO/IEC 17025.
- 4.10.6.3 *Laboratory product identification and testing.* Requirement addressed by ISO/IEC 17025.
- 4.10.6.4 *Laboratory process control.* Requirement addressed by ISO/IEC 17025.
- 4.10.6.5 *Laboratory testing and calibration methods.* Requirement addressed by ISO/IEC 17025.
- 4.10.6.6 *Laboratory statistical methods.* Requirement addressed by ISO/IEC 17025.
- 4.16.1 *Production part approvals, tooling records, etc shall be maintained for the length of time that the part is active for production plus one calendar year, unless otherwise specified.* This requirement, although removed, is implicit in the new requirement for record retention. However, the note on including purchase orders as quality records is removed, implying that they are not considered quality records but are documents and retained until obsolete.
- 4.16.1 *The supplier shall eventually dispose of records.*

Chapter 4

Implementing ISO/TS 16949

Many organizations will not be reaching for ISO/TS 16949 without having put in place either an ISO 9000 compliant quality system or a quality systems that meets QS-9000, VDA 6.1, AVSQ '94, or EAQF '94. The few that may be motivated to use ISO/TS 16949:1999 rather than wait for ISO 16949:2001 should start out by adopting the process approach¹ and resist any temptation to build an element-based quality system².

It is relatively easy to take each requirement (a *shall* statement), produce a response, and document it in your quality system documentation but that is not an effective approach. For one thing, it suggests you are doing all the right things and that a quality system is merely a set of documents, which of course it isn't. A quality system is a subsystem of the management system and there is one realistic way in which to view a management system and that is illustrated in Figure 4.1.

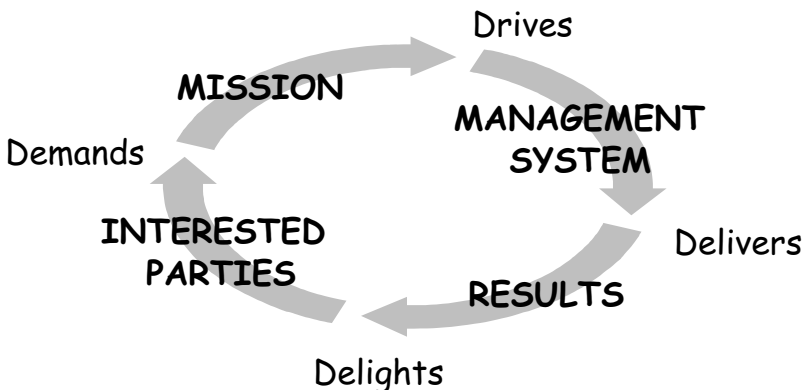


Figure 4.1 *The role of the management system*

¹ A system built around the organization's core processes – see *ISO 9000 Quality System Development Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

² A system designed around the 20 elements of the standard.

The diagram shows that there is a direct link between the mission of the organization, the system that delivers the mission, and the results that satisfy your customers. ISO/TS 16949 demonstrates the linkage by requiring:

- Goals to deploy the quality policy (clause 4.1.1.2)
- Plans to implement the goals (clause 4.1.4)
- Processes that implement the plans (clause 4.2.4)
- Analysis of data to determine whether goals are being achieved (clause 4.1.5)
- Monitoring of achievement of goals (clauses 4.1.3.2 and 4.2.8)
- Determining customer satisfaction (clause 4.1.1.3)

Step 1 Coherence check

The existing quality system requirements do have some of the above requirements but it is ISO/TS 16949 in which the full impact of their relationship is evident. It follows therefore that in making the transition from your existing system to an ISO/TS 16949 compliant system, the first step is to establish the extent to which your existing system possesses these linkages and feedback loops – a sort of coherence check to verify your system is not just a “bolt-on” extra.

Step 2 Cultural analysis

The principal reason why quality initiatives fail is that they fail to take into account the culture and climate into which changes are being introduced. Documenting policies and procedures is a fruitless activity without the motivation and commitment being present in the organization to implement them. ISO/TS 16949 is no exception; in fact there are many new requirements in this technical specification that organizations will be unable to implement unless the climate for change is right. Measuring employee motivation and employee satisfaction requires much more than a documented procedure. That is the easy bit. The difficult bit is to change the behavior of managers and supervisors so that they implement any such procedure willingly, taking the right attitude and acting upon the results in the manner intended – not throwing them in the bin when they don't like what they found.

The second step is therefore to analyze the culture and climate in the organization in order to detect any characteristics that may impede the successful implementation of the requirements. It is often difficult for those inside the organization to be objective in per-

forming such analysis and therefore an independent assessor is much better at obtaining the information. Staff are more likely to talk freely to an outsider than another employee. One can use questionnaires³ or structured interviews but the latter is by far the best. The only problem is that it takes time and produces masses of data. The topics addressed in the interview could be selected from the following, the intention being to discover the perception of the staff to these characteristics:

- Authority and power
- Commitment
- Concern for people
- Continual improvement
- Decision making
- External relationships (customers, suppliers, society)
- Leadership
- Objectives
- Problem solving
- Respect
- Rewards
- Technology
- Autonomy
- Communication
- Consensus
- Control
- Ethics
- Integrity
- Measurement
- Planning
- Reputation
- Responsibility
- Teamwork
- Trust

Certain rites and rituals may act to impede progress and conflict with the requirements of ISO/TS 16949. In fact the degree of prescription in the standard may well be far too much for certain types of organizations that regard culture as the most important factor. Quality system standards are accepted more readily by organizations that perceive themselves as machines – organizations that are autocratic rather than democratic, driven by rules rather than behavior. Political organizations shy away from standards. They may accept them in public but in private managers operate behind closed doors plotting the next conflict, how they can maneuver their department or themselves into powerful positions.

Step 3 System analysis

The next step is to assess whether your existing system possesses all the additional processes that are required. The following are some of the key processes that may not be addressed by existing automotive quality systems:

³ A list of topics and questions is given in Chapter 3 of the *ISO 9000 Quality System Development Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

- Employee motivation (clause 4.1.6)
- Regulation capture (clause 4.1.7.2)
- Product realization (clause 4.2.4)
- Process design (clause 4.2.4.9.1)
- Preventive maintenance (clause 4.9.1.5)
- Measurement systems analysis (clause 4.11.1.2)
- Process audit (clause 4.17.2.3)
- Product audit (clause 4.17.2.4)

Step 4 Process analysis

Having designed the additional processes, you need to examine existing processes and establish the extent to which they are compliant with the relevant requirements of ISO/TS 16949. Remember that the requirements are a framework. They are not exhaustive. Your processes should possess characteristics that are compliant but are likely to possess many other characteristics that are not addressed by the requirements.

Step 5 System integration

One significant observation made by the IATF was that many organizations do perform SPC, MSA, FMEA, APQP, etc. but invariably do not feed back the results into the processes for which they were intended. The activities tend to be performed in isolation from design or production rather than as an integral part of design and production. There is clearly no point in performing an FMEA and not using the results to improve the design. An FMEA is not just a tool to verify that a sound design has been produced, it is an aid to producing a sound design – as is SPC in production and MSA in verification. The use of these tools and techniques has to be demonstrated as being effective. The next step is therefore to assess the use of the tools and the results and ensure the results are directly integrated into the processes that are intended to benefit from them. In making the linkages it would be prudent to establish records that demonstrate that the actions have been taken.

Other steps are no different to any quality system development and further guidance is given in Part 2 of this handbook and in the *ISO 9000 Quality System Development Handbook*.

Chapter 5

Third party assessment

The certification business has grown enormously in the last ten years. The International Accreditation Forum (IAF) recorded 616 accredited certification bodies in January 1999. The experience of the vehicle manufacturers with ISO 9000 certification led them to question the wisdom of so many certification bodies chasing the same business in a competitive market. The results seemed to indicate that cost reductions by the certification bodies led to a decline in the quality of auditing and that was the opposite of what the vehicle manufacturers wanted. The vehicle manufacturers had *not* seen a significant rise in product quality as a result of ISO 9000 and they believed this was partially due to the quality of the accreditation and certification schemes being operated as well as inadequacies in the quality system standard. When the four national automotive schemes were launched, great emphasis was placed on regulating more closely the accreditation and certification schemes. From a customer perspective, the ISO 10011 scheme had some particular problems:

- The competency of auditors in specific industry sectors is not verified – knowledge and experience is all that is necessary.
- The certification bodies adhere to EN 45012, which is a general standard that does not provide for specific industry sectors to tailor the requirements to their needs.
- The accreditation body rather than the industry determines which certification bodies are qualified to issue certificates.
- The certificates issued by the certification body are not subject to independent verification by the industry.
- Audits are carried out on behalf of the organization seeking certification, not on behalf of the industry that created the requirements, and hence requirements are prone to an interpretation to suit clients and retain business.
- Although the schemes exist to satisfy the needs of industry, industry has no power to verify that the standards are being maintained by the accreditation and certification bodies.

The ISO/TS 16949 certification scheme

The IATF have designed a certification scheme in which they are the regulator for the automotive-specific requirements, and hence have the ability to ensure greater uniformity in ISO/TS 16949 certification than has hitherto been the case with ISO 9000. The IATF regulates certification bodies and auditors performing ISO/TS 16949 certification audits. As a result “opportunists” in the certification business, without the required automotive credentials, will have nothing to offer except a certificate not recognized by subscribing IATF members. There is a penalty, however, as it can also rule out credible certification bodies that do not have a sufficient number of clients in the automotive sector to qualify. As will be seen later in the chapter, the IATF scheme will remove from the automotive sector third party auditors who cannot demonstrate their competency to independent examiners. In effect, the scheme puts in place conditions which require automotive auditors to possess a license to practice and, unlike ISO 9000 auditors, this license has to be renewed every three years.

In brief, the auditor has to be qualified by IATF to perform the audits and, to be eligible for qualification, the auditor has to be sponsored by an IATF-approved certification body that is subject to witness audits performed by qualified auditors from vehicle manufacturers. Such measures will inevitably improve the quality of certification offered by certification bodies and will be good for the global automotive industry.

Certification bodies

The IATF initially intends to contract a limited number of certification bodies to perform ISO/TS 16949 certification in order to reduce variation in auditing. Where certification bodies have several offices, only one can be designated and approved by IATF as the contracted office for the group. In order to qualify, a certification body must conform to the *Rules for Achieving IATF Recognition* – a document specifying the conditions under which ISO/TS 16949 certificates are issued. To qualify, certification bodies must perform at least 25 automotive quality system audits each year and agree to be bound by the IATF rules.

Trade associations

The trade associations that are members of IATF perform an assurance function and have set up a panel to administer certification activities in their country. This involves witness audits of certification bodies to verify that they are adhering to the IATF agreement. They will monitor the scheme on behalf of the vehicle manufacturers in ensuring that certificates are only awarded to organizations that are 100% compliant with the requirements. These activities should provide added confidence that the certification bodies are fulfilling their obligations.

The trade associations will also process applications for IATF recognition and for auditor qualification. A central database of auditors will be maintained so that auditor competency can be monitored. Auditor qualification and re-qualification results, complaints, and movements will be stored so that the validity of auditor certificates can be ascertained.

Third party auditors

Most certification body auditors who are currently performing audits against one or more of the national automotive quality system requirements (QS-9000, VDA 6, AVSQ, or EAQF) will qualify. To qualify, auditors need to:

- Have an education acceptable to the IATF
- Have minimum work experience acceptable to IATF that includes at least three years full-time appropriate practical experience in the automotive or associated industry including two years dedicated to quality assurance activities completed in the last six years
- Have performed at least eight first or second party audits in the automotive sector in the last three years at a minimum of 24 audit days and led at least two of these audits
- Be qualified according to ISO 10011 part 2
- Successfully complete the IATF-sanctioned Auditor Qualification Course

Existing automotive auditors must have performed at least 15 third party audits to one of the four automotive quality system requirements in the last three years at a minimum of 45 audit days with two of these as a lead auditor.

In order to take the IATF-sanctioned Auditor Qualification Course, the auditor has to be:

- Sponsored by an IATF-contracted certification body
- An auditor nominated by an IATF member body

Experience in the automotive industry is obviously open to interpretation. This does not mean that only auditors who have worked in GM, Ford, BMW, etc. will be eligible. Auditors with Tier 1 and Tier 2 suppliers to the OEMs will also be eligible as will those who have worked for industries that produce products or materials used by the automotive industry. Therefore if an auditor has worked in the steel industry, electronics industry, or other manufacturing industry, such experience could be acceptable. During

the development of the scheme it was mooted that only auditors with recent experience in such industries should be eligible but such conditions would require all auditors to return to industry periodically to upgrade their knowledge. This is practiced in some countries but was felt impractical to impose on a global basis. Even those auditors who have worked in the automotive sector may not necessarily have carried out SPC and other techniques on the production line or performed an FMEA in the design office. Many may have been managers or supervisors whose job was to get work done – not do it themselves.

The IATF Auditor Qualification Course is not strictly a training course and hence any auditors designated to attend such a course should not expect to be trained if they are not already competent. It is a course designed to screen auditors so that only those deemed competent emerge qualified. It is a two-day course with the first day covering ISO/TS 16949 and the differences between it and the other automotive quality system requirements. The aim is to provide insight into the nature of the change and what auditors should look at and look for in verifying compliance. The first day also covers the rules of the scheme with a focus on the auditors' responsibilities. On the second day auditors take a written examination and an oral examination and perform simulated audits during which their performance as auditors is evaluated. The courses are delivered by IATF-approved trainers from IATF-approved training providers.

Effect of the rules

On auditors

The rules of the scheme contain requirements covering such topics as:

- Accreditation
- Certification body's quality system
- Scope of certification
- Remote locations
- Nonconformities
- Audit team composition
- Audit process
- Surveillance audits
- Consultancy
- Auditor database
- Auditor qualification
- Audit reports
- Minimum audit man-days

Within the rules are some significant requirements that impact the way auditors will plan, conduct, and report their audits. These are covered in more detail in Part 1 Chapter 6.

Requirement	Implication for the auditor
<p>These requirements are binding on certification bodies approved by IATF.</p>	<p>If the auditor does not adhere to the rules such conduct may result in the CB being disqualified.</p>
<p>More than one pre-audit on any one site in the same company shall be considered consulting.</p>	<p>The auditor must decline requests by the supplier to return to the site to confirm that pre-audit observations have been satisfactorily resolved before commencing the certification audit.</p>
<p>Consulting is the provision of training, documentation development, or assistance with implementation of quality systems to a specific supplier.</p>	<p>An auditor who also performs training cannot provide training to a specific supplier but is permitted to provide public training even if the only participants are from a single supplier. It also means that an auditor cannot offer assistance to a supplier to implement a quality system either during a gathering of suppliers or with one supplier.</p>
<p>The scope of certification shall include all products supplied to customers subscribing to the certification of ISO/TS 16949.</p>	<p>A supplier cannot exclude products and services from the audit scope if any such products and services are provided to subscribing members – hence the auditor needs to know who the subscribing members are.</p>
<p>The certification shall address all ISO/TS 16949 requirements according to Annex 1.</p>	<p>Auditors cannot sample requirements of ISO/TS 16949. All requirements have to be checked within the sample of operations chosen during the audit and the sample has to take in sufficient operations and processes that will enable all requirements to be checked.</p>
<p>Any site may elect to pursue third party certification to ISO/TS 16949; however, such sites shall have demonstrated capability to conform to all ISO/TS 16949 requirements.</p>	<p>The auditor has to confirm that the site has a capability to meet all ISO/TS 16949 requirements and, if not, the other sites providing the missing capability have to be included in the certification audit.</p>

Requirement	Implication for the auditor
<p>Conformance with ISO/TS 16949 for third party certification shall be based on objective evidence of meeting each applicable requirement including customer-specific requirements at the time of the audit.</p>	<p>The auditor needs to determine specific customer requirements that apply and verify compliance with each requirement – not a sample. If the supplier has several different customers then compliance with the requirements of each customer has to be demonstrated.</p> <p>This also implies that verification of conformity cannot be extended over several audits – each requirement has to be verified on the initial audit.</p>
<p>Remote locations shall be included in the initial and ongoing surveillance audits as addressed in the annual audit plan.0</p>	<p>The auditor has to establish what constitutes a site and a remote location for a specific supplier.</p>
<p>Remote locations shall be audited as they support a site but cannot obtain independent ISO/TS 16949 certification.</p>	<p>A division that does not have the capability to meet all requirements cannot seek ISO/TS 16949 certification: e.g. Personnel, Purchasing divisions cannot be registered separately as they could be under ISO 10011.</p>
<p>Remote locations where design function is performed shall undergo surveillance audits at least once within each consecutive 12-month period.</p>	<p>Surveillance audits cannot exclude a remote design site more than once each year.</p>
<p>The entire quality system shall be assessed at a minimum of once every three years.</p>	<p>The audit plan for a supplier has to cover all requirements, all sites, all locations, all operations, all functions, all customers, all processes, all procedures at least once in a three-year cycle, unless it is an upgrade certification (see clause 4.6). Hence the sample of operations taken on each audit has to cover at least 1/6th of the whole.</p>

Requirement	Implication for the auditor
<p>It is permissible for each surveillance audit to re-examine part of the system so that the equivalent of a total assessment is completed within each three-year cycle.</p>	<p>The auditor needs to establish what constitutes the system and establish the identity of its associated parts (see also Annex 1 of the <i>Rules</i> on Final Report) so that it can be demonstrated that all parts are audited at least once every three years.</p> <p>This requirement also implies that a repeat certification audit does not have to be performed once every three years if it can be demonstrated that the whole system has been audited within the three-year cycle.</p>
<p>Quality systems shall not be registered to ISO/TS 16949 if open minor or major non-conformities to ISO/TS 16949 exist.</p>	<p>Auditors cannot clear minor nonconformities on the first surveillance visit following the initial audit – hence additional visits may be necessary before the first surveillance audit.</p>
<p>After certification, when a nonconformity is identified by the certification body, then the de-certification process shall be initiated.</p>	<p>The auditor needs to know how to initiate the CB's de-certification process.</p>
<p>Such identification (of nonconformities) can occur as a result of a customer complaint.</p>	<p>The auditor needs to assess all customer complaints and determine if they arose from a system nonconformity and if so initiate the de-certification process.</p> <p>This implies that the customer provides third parties with evidence of nonconformity.</p>
<p>A major nonconformity is one of the following: . . .</p>	<p>When read in conjunction with Annex 1.3 of the <i>Rules</i>, the only reason to classify a nonconformity as major is when making a decision to terminate the audit.</p> <p>However, if a nonconformity could not be closed within the 90-day period, it becomes a major nonconformity, implying that the auditor has to resolve the classification with the QMR prior to the Closing Meeting.</p>

Requirement	Implication for the auditor
<p>A major nonconformity is the absence or total breakdown of a system to meet an ISO/TS 16949 requirement.</p>	<p>The auditor has to find several instances of where a requirement of ISO/TS 16949 has not been addressed or has not been implemented. One instance of noncompliance in a sample does not indicate an absence or a total breakdown.</p> <p>The implication is that a failure to meet one <i>shall</i> statement is a major nonconformity.</p> <p>It also implies that not all major nonconformities are indicative of a failure of the quality system to prevent shipment of defective product.</p>
<p>A major nonconformity is a noncompliance that judgement and experience indicate is likely either to result in the failure of the quality system or to materially reduce its ability to assure controlled processes and products.</p>	<p>The auditor needs to be able to judge when the quality system fails to fulfill its purpose.</p>
<p>The audit plan must include all elements of the supplier's quality system that meet the needs of those customers recognizing ISO/TS 16949 certification of their suppliers, even when these requirements go beyond ISO/TS 16949.</p>	<p>Auditors need to appreciate that suppliers may choose to design a quality system for a purpose other than meeting automotive customer needs.</p> <p>Where a supplier has non-automotive customers or automotive customers that have not recognized ISO/TS 16949, any elements of the system that are specifically tailored to those customers must be excluded from the audit plan.</p> <p>Where a supplier has a quality system that covers the whole business, the audit plan must not include elements that are not implemented for automotive customer needs: e.g. elements of Human Resources, Accounting, Finance, IT, Legal, Marketing, Sales, Public Relations may not serve automotive customers' needs but company needs.</p> <p>Any nonconformity that arises from an audit of such areas is invalid.</p>

Requirement	Implication for the auditor
<p>The audit plan shall include evaluation of all supplier quality system elements for effective implementation of ISO/TS 16949 requirements as well as for effectiveness in practice.</p>	<p>The implication is that the audit should focus on performance and not on conformance. It is therefore not sufficient to verify conformity with a supplier's documented policies and practices. The auditor should examine the documented system for compliance with all requirements and examine operations to verify the results achieved are those required by the policies and practices and by the standard.</p>
<p>Assessment shall evaluate the effectiveness of the system, its linkages, its performance, and its requirements.</p>	<p>The auditor should establish that the supplier has made provision to link all the processes and should follow trails through departments and processes to verify correct use of outputs from interfacing processes: e.g. use of SPC charts, FMEA, MSA, control plans and changes to these when the products or processes change.</p>
<p>Part of the evidence required is the result of at least one complete internal audit and management review cycle.</p>	<p>The auditor should verify that all elements have been subject to internal audit during the initial audit and, if not, a nonconformity is warranted.</p>
<p>Effectiveness determination should consider how well the system is deployed.</p>	<p>The auditor should establish the extent to which the policies have been deployed to all levels and the extent to which staff are familiar with all procedures applicable to their operations.</p>
<p>Each on-site audit, including initial and surveillance audits, shall include a review of supplier internal audit and management review results and actions and progress made toward continuous improvement targets.</p>	<p>During the initial audit evidence of progress on audit and review actions, and progress toward CI targets has to be demonstrated. Hence it is not sufficient for the supplier to have defined CI targets, and not sufficient for internal audits and management reviews to have been conducted – there has to be evidence of achievement.</p>
	<p>Repeated failure to meet specified targets, especially customer-specified targets, would constitute a nonconformity.</p>

Requirement	Implication for the auditor
<p>All ISO/TS 16949 audit teams including surveillance shall consist of IATF-qualified auditors.</p>	<p>The Team Leader has to ensure that the audit team comprises only IATF-qualified auditors – hence if the CB has only two qualified auditors, the audit days have to be extended.</p>
<p>For consistency at least one auditor of the initial audit team should participate in all visits of a three-year cycle.</p>	<p>By using the word <i>should</i>, the requirement is rendered non-mandatory and hence acknowledges that people may leave CBs.</p>
<p>The certification body shall regularly evaluate auditor performance in determining effective implementation of ISO/TS 16949.</p>	<p>Auditors should expect their performance to be regularly evaluated by their CB and that the person performing the evaluation is a qualified auditor.</p>
<p>The audit report shall provide a full report on the operations audited consistent with the content of Annex 1 of the <i>Rules</i>.</p>	<p>The audit report has to contain more detail than an equivalent ISO 10011 audit report (see also Annex 3 requirements).</p>
<p>Third party auditors shall identify opportunities for improvement.</p>	<p>Auditors have to examine records and make a judgement as to whether results indicate unacceptable trends.</p>
<p>Authorization to provide the final report to the IATF shall be specified in the certification contract.</p>	<p>The auditor needs to advise the supplier at the Closing Meeting that a copy of the full report will be supplied to the IATF. This also implies that the IATF is the auditor's customer.</p>
<p>Consultants to the supplier cannot participate in the audit.</p>	<p>It should also be noted that the Final Report is not the initial report but the report containing the supplements that indicate all actions to be satisfactorily completed.</p> <p>The auditor needs to establish whether consultants are present and if so what role the supplier intends them to perform. Consultants can be observers but cannot answer questions posed by third party auditors.</p>

Requirement	Implication for the auditor
<p>Certification body shall notify the IATF of all scheduled audits including witness audits and shall allow IATF members or their designates to attend.</p> <p>Upgrading of a current automotive certificate by one of the IATF contacted certification bodies will be taken into account . . .</p>	<p>Auditor should expect to be informed that an IATF member may attend. If the date of the audit has to be changed it cannot be extended by more than three months from the date of document review (see Annex 1 of the <i>Rules</i>).</p> <p>The auditor needs to establish whether the supplier intends the ISO/TS 16949 audit to be an upgrade of current certificate and if so to advise them that unless it is performed by the same CB there can be no reduction in the audit man-days.</p>
<p><i>Annex 1 Rules for auditing quality systems according to ISO/TS 16949</i></p> <p>This annex of the <i>Rules</i> contains a flowchart identifying the key stages in the audit process from the initial request for certification through to issue of the certificate.</p>	<ul style="list-style-type: none"> ● Existing audit process may need to be modified. ● Pre-audit is not a documentation audit. ● Supplier must provide all required data prior to site visit. ● Man-days do not include pre-audit man-days. ● Audit must be completed within three months from document review. ● Multiple visits for initial audit are not permitted. ● Audit has to cover all shifts. ● Auditor has to submit audit plan to CB prior to audit. ● Cannot sample requirements or sites. ● Nonconformities are not OFIs – hence an OFI is an area where the supplier is compliant but performance is below industry norm. ● Draft report is not the same as the Final Report.

Requirement	Implication for the auditor
	<ul style="list-style-type: none"> ● Not essential to get supplier to acknowledge NC before leaving the site. ● Auditor has to advise supplier to conduct root cause analysis on all NCs. ● Within 90 days the supplier is required to close NCs. It is not 90 days for the supplier to submit a response.
<i>Annex 2 Criteria for third party auditor qualification to ISO/TS 16949</i>	<ul style="list-style-type: none"> ● Criteria are greater than for ISO 9000 auditors. ● All existing automotive auditors must perform 15 automotive audits in three years and seek qualification to ISO/TS 16949 before the other standards are withdrawn.
<i>Annex 3 Audit man-days for certification to ISO/TS 16949</i>	<ul style="list-style-type: none"> ● An auditor auditing the day and evening shift may accumulate more than 8 hours in one day, therefore man-days are not calendar days but divisions of 8 audit hours. ● Actual man-days have to be reported in the audit report.

On suppliers

Suppliers will see some significant changes in the way the audit is planned, conducted, and reported. Here are some of the changes:

- Probably the most significant change you will see is that the certification bodies are representing the IATF. The certification bodies are not strictly your suppliers although you pay for the privilege. The auditors are the eyes of your customer, who is relying on them to verify whether the quality system is effective in both its design and its implementation.
- You will receive information from your customers advising you that they subscribe to the IATF and recognize ISO/TS 16949 certification as equivalent to QS-9000, AVSQ '94, VDA 6, and EQAF '94. You need to retain this letter as evidence of which of your products and services will be governed by ISO/TS 16949 certification.

- You need to identify all sites and remote locations and re-assess current certifications to establish that your registered sites have the capability to meet all ISO/TS 16949 requirements. If you have remote design, purchasing, personnel, calibration, sales, or other functions to which ISO/TS 16949 applies, you may need to merge registrations if they are currently registered separately or bring the locations within the scope of registration if currently unregistered.
- If your organization is registered to one or more of the existing automotive quality system requirements and the scope is unchanged, the required man-days for the initial audit may be reduced by 50%, but if you decide to change certification body or have changed the scope, there will be no reduction.
- You will not receive any certificate until you have resolved all nonconformities.
- A nonconformity will only be classified as *major* in order to determine whether an audit should be terminated prematurely or de-certification effected.
- You will be subject to de-certification if nonconformities are detected after initial certification.
- Customer complaints can warrant de-certification action by the certification body if the complaint was as a result of a system nonconformity.
- If the nonconformity is not resolved within 90 days of its detection, de-certification will be enacted.
- Auditors will look especially for linkages between the processes and your objectives and between studies and analyses and processes. It will no longer be sufficient to show you have performed an analysis – you will need to show a consequential impact on performance.
- You will need to provide evidence of internal audits and management review from the previous 12 months with your application for certification.
- You will need to provide lists of qualified internal auditors, customers, and their specific requirements with your application for certification.
- You will need to provide evidence of effective management of customer complaints with your application for certification.
- You will need to provide evidence of continual improvement since the previous audit.

- If you subcontract design, you must be able to demonstrate you have the appropriate capability to ensure your subcontractor meets the design control requirements of ISO/TS 16949.
- You can expect to receive both accreditation body witness auditors and IATF witness auditors on any initial audit and subsequent surveillance audit but not at the same time.
- You can expect the auditor to identify opportunities for improvement but not offer advice as to how such opportunities may be realized.
- You will be required to perform a root cause analysis on each detected nonconformity.
- The audit report will be released to the IATF.

Summary

In summary there are some radical but welcome differences between ISO 9000 audits and ISO/TS 16949 audits:

- The auditors have demonstrated competency in auditing to the requirements of the automotive industries.
- Auditor competency is evaluated every three years.
- The auditors perform audits on behalf of the IATF and its subscribing members.
- The industry regulates the certification bodies, in addition to them being regulated by accreditation.
- The industry regulates the certification bodies authorized to certify suppliers.
- Certificates cannot be issued if there are any outstanding nonconformities.
- The pre-audit is not a documentation review.

Chapter 6

Self assessment

This questionnaire addresses all the key requirements of ISO/TS 16949 and will help you determine the margin between where you are now and where you need to be to achieve ISO/TS 16949 registration. If your business is the provision of services rather than products, replace the word *product* with *service* in the following questions.

Element	Question	Yes	No
1 4.1	Have the quality policy, quality objectives, and commitment to quality been defined and documented by executive management?	<input type="checkbox"/>	<input type="checkbox"/>
2 4.1	Is the quality policy understood, implemented, and maintained at all levels in the organization?	<input type="checkbox"/>	<input type="checkbox"/>
3 4.1	Has a process been established for determining customer satisfaction?	<input type="checkbox"/>	<input type="checkbox"/>
4 4.1	Are continuous improvement measures and methodologies employed and do these cover all aspects of the quality system?	<input type="checkbox"/>	<input type="checkbox"/>
5 4.1	Is the responsibility, authority, and interrelationship of all personnel who manage, perform, and verify work affecting quality defined and documented?	<input type="checkbox"/>	<input type="checkbox"/>
6 4.1	Have individuals been appointed who have authority to represent the customer in internal functions?	<input type="checkbox"/>	<input type="checkbox"/>
7 4.1	Have adequate resources been provided for management, performance of work, and verification activities?	<input type="checkbox"/>	<input type="checkbox"/>
8 4.1	Have the personnel assigned to management, operational, and verification activities been properly trained?	<input type="checkbox"/>	<input type="checkbox"/>
9 4.1	Have all shifts been staffed with personnel with authority for accepting product as meeting customer requirements?	<input type="checkbox"/>	<input type="checkbox"/>
10 4.1	Has a representative of management been appointed to ensure that the requirements of ISO/TS 16949 are implemented and maintained?	<input type="checkbox"/>	<input type="checkbox"/>

Element	Question	Yes	No
11 4.1	Are multidisciplinary teams employed to manage product realization and production phases?	<input type="checkbox"/>	<input type="checkbox"/>
12 4.1	Do executive management establish the continuing suitability and effectiveness of the quality system through periodic reviews?	<input type="checkbox"/>	<input type="checkbox"/>
13 4.1	Do trends in performance lead to action that provides solutions to customer-related problems and long-term planning?	<input type="checkbox"/>	<input type="checkbox"/>
14 4.1	Are processes employed that motivate employees in achieving quality objectives and continuous improvement?	<input type="checkbox"/>	<input type="checkbox"/>
15 4.1	Are measures taken which minimize risks to employees, customers, and users of the product and its impact upon the environment?	<input type="checkbox"/>	<input type="checkbox"/>
16 4.1	Are processes employed to ensure compliance with all relevant government regulations?	<input type="checkbox"/>	<input type="checkbox"/>
17 4.2	Are the means used to ensure that product conforms to specified requirements documented in the form of a quality manual and quality system procedures?	<input type="checkbox"/>	<input type="checkbox"/>
18 4.2	Have the means by which the requirements for quality will be met for specific products, projects, or contracts been defined and documented?	<input type="checkbox"/>	<input type="checkbox"/>
19 4.2	Will the processes for product realization consistently deliver conforming products on time to customers?	<input type="checkbox"/>	<input type="checkbox"/>
20 4.2	Is FMEA and mistake-proofing applied to each product and process and are the results used to effect beneficial changes to these products and processes?	<input type="checkbox"/>	<input type="checkbox"/>
21 4.2	Are process studies conducted to verify process capability on all new processes?	<input type="checkbox"/>	<input type="checkbox"/>
22 4.2	Is process design subjected to the same controls as applied to product design?	<input type="checkbox"/>	<input type="checkbox"/>
23 4.2	Is the development of plant, facilities, and equipment undertaken by multidisciplinary teams?	<input type="checkbox"/>	<input type="checkbox"/>
24 4.3	Are tenders, contracts, and subsequent amendments reviewed in accordance with documented procedures prior to submission or acceptance as appropriate?	<input type="checkbox"/>	<input type="checkbox"/>
25 4.3	Are quotations developed through a process in which cost elements are identified?	<input type="checkbox"/>	<input type="checkbox"/>
26 4.3	Do the reviews ensure that the customer requirements are adequately defined and that the company has the capability to meet them prior to submitting a tender or the acceptance of a contract?	<input type="checkbox"/>	<input type="checkbox"/>
27 4.4	Is product design controlled in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>

Element	Question	Yes	No
28 4.4	Is the design team staffed with personnel possessing the necessary qualification to implement the requirements of ISO/TS 16949?	<input type="checkbox"/>	<input type="checkbox"/>
29 4.4	Do design staff have access to research and development facilities?	<input type="checkbox"/>	<input type="checkbox"/>
30 4.4	Do the design controls ensure that design inputs are documented and reflect customer needs and expectations?	<input type="checkbox"/>	<input type="checkbox"/>
31 4.4	Do the design controls ensure that design and development activities are planned so as prevent failure and secure success?	<input type="checkbox"/>	<input type="checkbox"/>
32 4.4	Do the design controls ensure that design outputs are documented and in a form suitable for procurement, manufacture, verification, and installation?	<input type="checkbox"/>	<input type="checkbox"/>
33 4.4	Do the design controls ensure that design reviews and design verification and validation are recorded and demonstrate the product meets the design input and user requirements?	<input type="checkbox"/>	<input type="checkbox"/>
34 4.4	Is data from previous designs and competitor analysis deployed in the design of new products?	<input type="checkbox"/>	<input type="checkbox"/>
35 4.4	Are measures taken to simplify, optimize designs, reduce waste, and minimize risks?	<input type="checkbox"/>	<input type="checkbox"/>
36 4.4	Is design verification and validation performed using the same subcontractors, tooling, and processes as will be used in production?	<input type="checkbox"/>	<input type="checkbox"/>
37 4.5	Are all internal and external documents that relate to the requirements of ISO 9001 controlled in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
38 4.5	Are all documents and data and changes thereto reviewed and approved by authorized personnel prior to issue?	<input type="checkbox"/>	<input type="checkbox"/>
39 4.5	Are all obsolete or invalid documents removed from use, or suitably identified?	<input type="checkbox"/>	<input type="checkbox"/>
40 4.6	Is product purchased in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
41 4.6	Are subcontractors selected on the basis of their ability to meet subcontract requirements?	<input type="checkbox"/>	<input type="checkbox"/>
42 4.6	Is assistance and encouragement given to subcontractors to comply with ISO/TS 16949?	<input type="checkbox"/>	<input type="checkbox"/>
43 4.6	Are all subcontractors required to meet 100% on-time delivery?	<input type="checkbox"/>	<input type="checkbox"/>
44 4.6	Are records of acceptable subcontractors maintained?	<input type="checkbox"/>	<input type="checkbox"/>
45 4.6	Do purchasing documents clearly describe the product ordered and, where applicable, the on-site verification arrangements?	<input type="checkbox"/>	<input type="checkbox"/>
46 4.7	Is customer supplied product verified, stored, and maintained in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>

Element	Question	Yes	No
47 4.7	Is lost, damaged, or unsuitable customer supplied product recorded and reported to the customer?	<input type="checkbox"/>	<input type="checkbox"/>
48 4.8	Is product identified in accordance with documented procedures when the identity is not inherently obvious?	<input type="checkbox"/>	<input type="checkbox"/>
49 4.9	Are the production, installation, and servicing processes that directly affect quality identified and planned?	<input type="checkbox"/>	<input type="checkbox"/>
50 4.9	Are production, installation, and servicing carried out in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
51 4.9	Do the production, installation, and servicing controls include the use of suitable equipment and a suitable working environment?	<input type="checkbox"/>	<input type="checkbox"/>
52 4.9	Are reference standards, procedures, and criteria for workmanship defined and complied with?	<input type="checkbox"/>	<input type="checkbox"/>
53 4.9	Are process parameters monitored and processes and equipment approved?	<input type="checkbox"/>	<input type="checkbox"/>
54 4.9	Is equipment maintained to ensure continued process capability?	<input type="checkbox"/>	<input type="checkbox"/>
55 4.9	Are statistical techniques used to determine process and product variation and are the results used to consistently reduce variation?	<input type="checkbox"/>	<input type="checkbox"/>
56 4.9	Are measures taken to maintain or exceed process capability required by the customer?	<input type="checkbox"/>	<input type="checkbox"/>
57 4.10	Are incoming products, semi-finished products, and finished products inspected and tested in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
58 4.10	Are the required inspections and tests and the records to be produced detailed in documented procedures or quality plans?	<input type="checkbox"/>	<input type="checkbox"/>
59 4.10	Do the inspections and tests verify that incoming products, semi-finished products, and finished products conform to specified requirements before use, processing, or dispatch?	<input type="checkbox"/>	<input type="checkbox"/>
60 4.10	Are the acceptance criteria for attribute data sampling set at zero defects?	<input type="checkbox"/>	<input type="checkbox"/>
61 4.10	Are records maintained to provide evidence that product has been inspected and tested and meets the specified requirements?	<input type="checkbox"/>	<input type="checkbox"/>
62 4.10	Are all in-house inspection, testing, and calibration laboratories compliant with the requirements of ISO/IEC 17025?	<input type="checkbox"/>	<input type="checkbox"/>
63 4.10	Are all external inspection, testing, and calibration laboratories compliant with the requirements of ISO/IEC 17025?	<input type="checkbox"/>	<input type="checkbox"/>
64 4.11	Are the devices used to demonstrate conformance of product with specified requirements controlled, calibrated, and maintained in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>

Element	Question	Yes	No
65 4.11	Is measuring equipment selected on the basis of the accuracy and precision required and do all measurements have a known relationship to National Standards?	<input type="checkbox"/>	<input type="checkbox"/>
66 4.11	Are statistical studies conducted to analyze the variation present in each type of measurement system and are the results used to effect a reduction in variation?	<input type="checkbox"/>	<input type="checkbox"/>
67 4.12	Is product identified in a way that indicates its conformance or nonconformance with regard to inspections and tests performed?	<input type="checkbox"/>	<input type="checkbox"/>
68 4.13	Are documented procedures employed to prevent the inadvertent use or installation of nonconforming products?	<input type="checkbox"/>	<input type="checkbox"/>
69 4.13	Are reworked or repaired products subject to re-inspection in accordance with documented procedures prior to release?	<input type="checkbox"/>	<input type="checkbox"/>
70 4.14	Are customer complaints and reports of product nonconformities handled in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
71 4.14	Are documented procedures employed to determine the cause of nonconformities in products, processes, and the quality system and to prevent their recurrence?	<input type="checkbox"/>	<input type="checkbox"/>
72 4.14	Are documented procedures employed to detect and eliminate potential causes of nonconformance and prevent their occurrence?	<input type="checkbox"/>	<input type="checkbox"/>
73 4.15	Is the handling, storage, packaging, preservation, and delivery of product carried out in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
74 4.15	Does the inventory management system optimize inventory turns over time and assure stock rotation?	<input type="checkbox"/>	<input type="checkbox"/>
75 4.15	Do the measures taken prevent damage or deterioration of product in handling, storage, and delivery?	<input type="checkbox"/>	<input type="checkbox"/>
76 4.15	Do delivery systems support 100% on-time deliveries to meet customer production and service requirements?	<input type="checkbox"/>	<input type="checkbox"/>
77 4.16	Are quality records collected, indexed, accessed, filed, stored, maintained, and dispositioned in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
78 4.16	Is the retention time for quality records established and recorded?	<input type="checkbox"/>	<input type="checkbox"/>
79 4.16	Are quality records maintained which demonstrate conformance to specified requirements and the effectiveness of the quality system?	<input type="checkbox"/>	<input type="checkbox"/>
80 4.17	Are internal quality audits planned and implemented in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
81 4.17	Do the internal audits verify whether quality activities and related results comply with planned arrangements?	<input type="checkbox"/>	<input type="checkbox"/>
82 4.18	Are training needs identified in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>

Element	Question	Yes	No
83 4.18	Are the personnel performing specific assigned tasks qualified on the basis of appropriate education, training, and/or experience?	<input type="checkbox"/>	<input type="checkbox"/>
84 4.18	Is the effectiveness of training evaluated periodically?	<input type="checkbox"/>	<input type="checkbox"/>
85 4.18	Are supplier staff and contractors subject to training when jobs affecting quality are introduced or modified?	<input type="checkbox"/>	<input type="checkbox"/>
86 4.19	Is product servicing performed and reported in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>
87 4.19	Are measures taken to communicate servicing concerns to manufacturing, engineering, and design staff?	<input type="checkbox"/>	<input type="checkbox"/>
88 4.20	Are mechanisms in place to identify the need for statistical techniques required for verifying the acceptability of process capability and product characteristics?	<input type="checkbox"/>	<input type="checkbox"/>
89 4.20	Is the application of statistical techniques controlled in accordance with documented procedures?	<input type="checkbox"/>	<input type="checkbox"/>

Part 2

Satisfying ISO/TS 16949 requirements

Foreword

This part of the book addresses each subsection of section 4 of ISO/TS 16949 and analyzes the principal requirements, each taking a separate chapter, 20 in total. Within each chapter there is an explanation of the scope of the requirements in terms of what they apply to, their purpose and meaning. Where the requirements omit aspects that should be considered, these are also addressed. Each chapter then addresses the individual requirements of each sub-clause of the standard by dissecting them into their component parts. The subheadings act as indicators to the subject of the requirement. Recommendations are given for implementation of each individual requirement, the procedures to be produced, the aspects that are important, and problems to look out for. Examples are given for both products and services in the automotive sector. The principle adopted has been to interpret the requirements as they are stated and not as one might like them to be stated. Much may be implied by the standard but if it is not stated it is not a requirement; no competent auditor should insist on a company taking corrective action against nonconformities that do not exist.

ISO/TS 16949 embodies section 4 of ISO 9001 in its entirety within boxed text, with the additional requirements that apply to the automotive sector outside the boxes. As the original ISO 9001 text has not been changed except as stated in Part 1 Chapter 3, there are several instances where an additional requirement amplifies, extends, or modifies the original ISO 9001 requirement. In general the additional requirements have been addressed in this book under separate headings so that the reader has an explanation of the ISO 9001 requirement and, in a subsequent paragraph, an explanation of the additional requirement.

At the end of each chapter is a task list which summarizes the main tasks that need to be carried out to fulfill the requirements. Where a task list is given within the chapter this

is not repeated. Care should be taken when using the task list as it is not exhaustive and does not list tasks in any particular sequence.

Next is a questionnaire which only covers the specific requirements of the standard. This breaks down the requirements into their individual components where it is likely that the solutions for each part will be different. It can be used as a basic checklist for verifying that the quality system you have designed addresses all the requirements, or as a means of creating policy or of assessing conformity.

At the end of each chapter is a list of do's and don'ts, which attempts to identify some of the principal things that you should and should not do. Again it summarizes much of the advice given within the chapter but often includes aspects that have not been covered.

Doing all the things that are listed will not guarantee ISO/TS 16949 registration, but not doing any of them will almost certainly guarantee failure.

Quality management is not an exact science. There are no hard and fast rules. Each situation in each organization will produce new problems which demand perhaps different solutions to those that are presented here. The knowledge that has enabled this book to be produced was gained over a period of nearly 30 years in industry, mainly in the "high tech" field but subsequent consultancy and training assignments in a range of industries in Europe, the USA, the Middle East, India, and South East Asia has added greatly to this knowledge. When management is receptive and unquestioning, you may wonder what all the fuss is about. But there will be many out there who are having difficulty in convincing their managers of the need for some of the things that have to be done to meet the requirements of ISO/TS 16949. It is hoped that the following chapters will provide solutions to those who have problems and forearm those who do not.

Chapter 1

Management responsibility

Scope of requirements

The requirements for management responsibility do not prescribe any particular organization but are rules that govern the management and allocation of work. They apply to all levels of management and supervision although where the organization is divided into separate divisions, groups, or departments, there may be justification for limiting some of the requirements to specific levels. The requirements should not be seen as all embracing as there are many other rules that ought to be followed if an organization is to become a world leader. They apply only to product/service quality responsibilities and not to other responsibilities, although it may be difficult to separate them. These requirements are amongst the most important in the standard. Without management's acceptance of responsibility for quality, its achievement, control, and improvement, quality will remain an illusive goal.

It is not *mandatory* that you have documented procedures for forming the quality policy and the quality objectives, defining the responsibility of personnel, identifying resources, or conducting management reviews. However, section 4 of the standard is titled *Quality system requirements* and section 4.2 requires that a quality manual be prepared covering the requirements of the standard. It follows therefore that you need to address the requirements of section 4.1 in your quality manual. You have a choice of how you address the requirements providing they are documented.

The requirements in element 4.1 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 1.1.

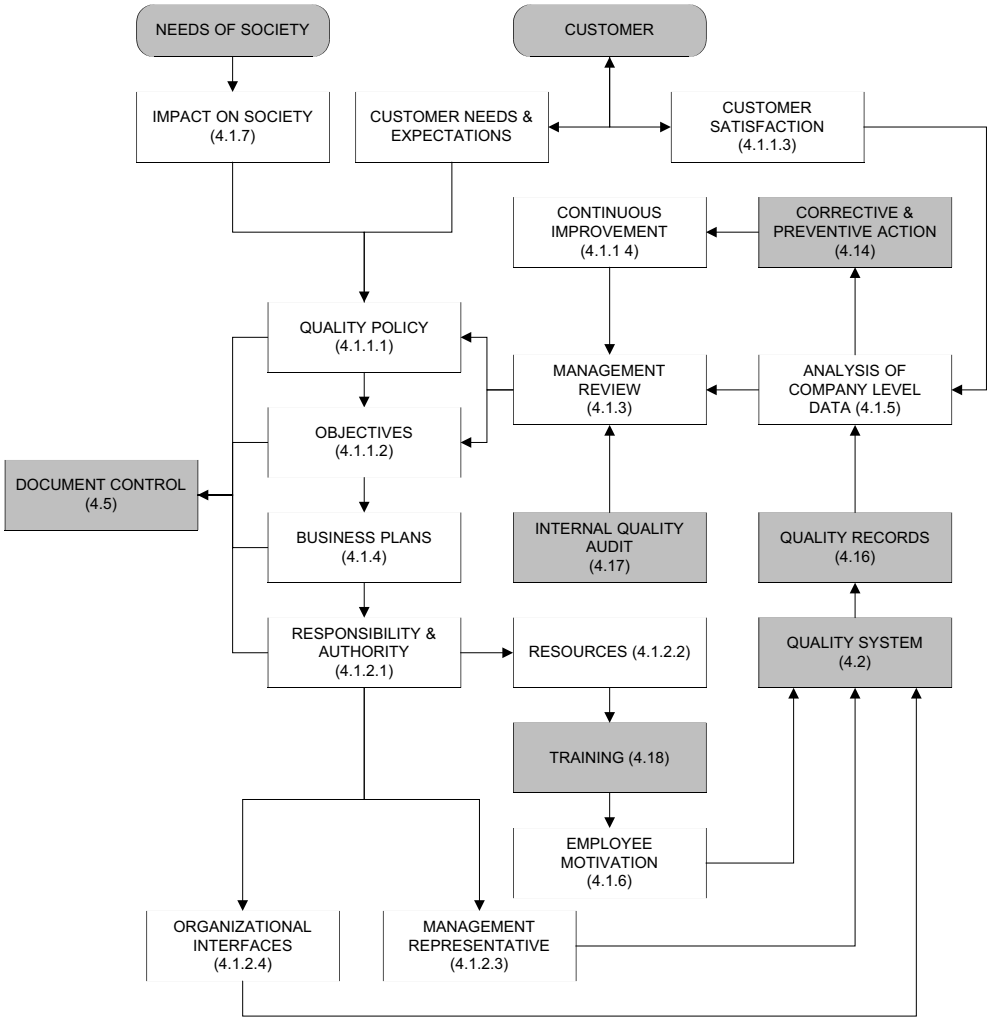


Figure 1.1 Clause relationship with management system responsibility

Quality policy (4.1.1.1)

Although under a single heading of *Quality policy*, this clause in fact contains three quite different requirements: one concerning *policy*, another concerning *objectives*, and a third on *commitment*. You can have policies on setting objectives but commitment is not something for which you can legislate (more on this later). Objectives are also addressed in clause 4.1.1.1 but will be treated together under *Quality objectives*.

Defining policies (4.1.1.1)

The standard requires that *the supplier's management with executive responsibility define and document its policy for quality.*

Executive responsibility

Before examining what is meant by policy, ISO 9001 specifically refers to management with executive responsibility. Management is such a general term that it could apply to almost any group of persons with staff reporting to them. Those managers with executive responsibility sit at the top of the tree. These are the people who make policy decisions affecting the whole organization and may include the person with the title Quality Manager, but will not and should not be exclusive to this position. One reason for specifically requiring management with executive responsibility to define the quality policy is that if it is defined at some other level there may well be conflict with the organization's other goals.

In order to clarify who in the organization has executive responsibility, it will be advantageous to specify this in the quality manual. It is then necessary to ensure that the positions of the personnel appointing the management representative and reviewing the quality system are those persons with executive responsibility. In some organizations, there are two roles, one of management representative and another of Quality Manager, with the former only having executive responsibility.

Types of quality policy

You will note that the heading of this section of the standard is *Quality policy*, and not *Quality policies*, as if there should be only one policy. Many companies do have a single quality policy statement at the front of their quality manual, but this is more of a quality philosophy rather than a policy of a form that will guide conduct (see also *Commitment*).

Any statement made by management at any level which is designed to constrain the actions and decisions of those it affects is a policy. ISO 9001 could therefore be requiring policy on quality at all levels to be defined. It is only by consulting ISO 8402:1994 that the level of policy required is clarified.

ISO 8402:1994 defines quality policy as the overall quality intentions and direction of an organization with regard to quality, as formally expressed by top management; it adds that the quality policy forms one element of corporate policy and is authorized by top management. The quality policy that is required to be defined is therefore the corporate quality policy and not lower-level policies. However, there are different types of policy and it is important that they are not confused so that a policy purporting to be a

quality policy is actually an operational policy, marketing policy, etc. Types of policy include:

- Government policy, which applies to any commercial enterprise
- Corporate policy, which applies to the business as a whole and may cover, for example:
 - * Environmental policy – our intentions with respect to the conservation of the natural environment
 - * Financial policy – how the business is to be financed
 - * Marketing policy – to what markets the business is to supply its products
 - * Investment policy – how the organization will secure the future
 - * Expansion policy – the way in which the organization will grow, both nationally and internationally
 - * Personnel policy – how the organization will treat its employees and the labor unions
 - * Safety policy – the organization's intentions with respect to hazards in the work place and to users of its products or services
 - * Social policy – how the organization will interface with society
 - * Quality policy – the organization's intentions with respect to meeting customer requirements, needs, and expectations
- Operational policy, which applies to the operations of the business, such as design, procurement, manufacture, servicing, and quality assurance. This may cover, for example:
 - * Pricing policy – how the pricing of products is to be determined
 - * Procurement policy – how the organization will obtain the components and services needed
 - * Product policy – what range of products the business is to produce
 - * Inventory policy – how the organization will maintain economic order quantities to meet its production schedules
 - * Production policy – how the organization will determine what it makes or buys and how the production resources are to be organized
 - * Servicing policy – how the organization will service the products its customers have purchased

- Department policy, which applies solely to one department, such as the particular rules a department manager may impose to allocate work, review output, monitor progress, etc.
- Industry policy, which applies to a particular industry, such as the codes of practice set by trade associations for a certain trade

In the context of ISO 9001, the quality policy referred to in clause 4.1.1 is one of the corporate policies. It is characterized by a single policy statement which declares the organization's commitment to quality and the strategy adopted to discharge this commitment.

Does ISO 9001 require the other types of policies to be defined and documented? There is no requirement in clause 4.1.1 but in clause 4.2.2 there is a requirement to prepare a quality manual covering the requirements of the standard and this is where you should document your operational policies. While the quality manual could simply contain the quality system procedures, the guidelines given in ISO 10013 clearly indicate that whether or not this is the case, the manual should describe the organization's policies for meeting the requirements of the standard. These aspects are addressed in Part 2 Chapter 2.

Subject matter of corporate quality policy

The following are some typical quality policy statements:

- * *We will perform exactly like the requirement or cause the requirement to be officially changed.*
- * *We will satisfy our customers' requirements on time, every time, and within budget.*
- * *Our aim is to give customer satisfaction in everything we do.*
- * *We shall not knowingly ship defective products.*

Some quality policy statements are as simple as these, others are much longer (see below) but all seem to be accommodated by a single page. Very short statements tend to become slogans which people chant but they rarely understand their impact on what they do. Their virtue is that they rarely become outdated. Long statements confuse people because they contain too much for them to remember. Their virtue is that they not only define what the company stands for but how it will keep its promises.

NISSAN UK's Quality Policy

We will comply with NML's policies and procedures for quality assurance activities. In addition we will develop our own ideas to improve upon NML requirements. We will set quality targets and objectives in line with corporate standards. In support of achieving customer satisfaction we will seek to achieve product conformity by carrying out quality assurance activities at all stages of vehicle manufacture – from planning through to vehicle sales.

These activities will involve all relevant departments based on the concepts of the Plan, Do, Check, Action Cycle, Right First Time, and that each employee has a role to play in achieving product quality.

NISSAN UK's Quality Philosophy

We aim for total customer satisfaction. Customers are those who buy our products: our suppliers, our staff, and all people with whom we have contact. We will treat each other with care and respect and strive for excellence in all we do to provide a high level of service to all customers, internal and external. We will thereby provide finished products and services to the highest standards of quality, safety, reliability, and durability.

Delphi Chassis Systems Quality Policy

Delphi Chassis Systems will provide products and services to global markets that will meet or exceed customer expectations through people, teamwork, and continuous improvement.

While these and many other contemporary quality policies would not need to be publicized 20 or so years ago, policy statements are not something new to the automobile industry. The General Motors of the 1920s under the direction of Alfred P Sloan used corporate policy as a means of coordinating the efforts of several divisions. GM's quality policy was to build quality products sold at fair prices and in setting up an Executive Committee Sloan wrote on the subject of quality, "A carefully designed policy should be

enunciated that will convey to each division a complete understanding of the general quality of product that should be attained or maintained and all major alterations of design should be submitted to the Executive Committee for approval from this standpoint.” He goes on to state: “In general, the activity of the Executive Committee should be guided along the lines of establishing policies and laying the same down in such clear cut and comprehensive terms as to supply the basis of authorized executive action ...” Clearly, this strategy focuses on the key purpose of the Executive Management in policy matters and is fundamental to choosing the direction in which the organization is to pursue its business.

The purpose of corporate quality policies is to direct everyone in a particular direction regarding quality, to give them a sound basis for their actions and decisions. In the above cases, if you cannot meet the requirement, get it changed or hand the job to someone else. If by taking a particular action you will upset your customer, don't do it. One of the problems with quality policies is that there will always be occasions when you can't adhere to the policy. When something goes wrong, as it always does, you may need to exceed the budget to put things right, to deviate from one requirement in order to meet another. It is no use management having a vision of a perfect world while having to work with imperfect people and materials. They have to accept human imperfections and compensate for them. Remember, the policy is only a guide. It is not a law, a rule that must not be broken. There is no penalty for not meeting the policy in the odd instance. However, if the policy is frequently ignored then slowly but surely the company will decline.

There is no guidance in ISO 9000:1994 on the subject matter of corporate quality policies. However, in the Committee Drafts (CD) of ISO 9000:2000 there is now some useful information. It is recommended that the quality policy should be consistent with the overall policy and goals of the organization and should provide a framework for the setting of quality objectives and quality targets. For the first time in these standards, a link has been made between policy and objectives so that policies are not merely motherhood statements but intentions for action. By deriving objectives from the policy you initiate a process for bringing about compliance with policy.

Since publication of the 1994 edition of the ISO 9000 series, TC176 has been busy formulating some basic principles of quality management. These principles are recommended as the basis for establishing the quality policy. The eight quality management principles are:

- Customer-focused organization
- Leadership
- Involvement of people

- Process approach
- Systems approach to management
- Factual approach to decision making
- Continual improvement
- Mutually beneficial supplier relationships

If we were to build policy statements from these principles we would find that an organization's quality policy would:

- Declare the intention to identify and satisfy customer requirements.
- Declare the intention to establish and communicate a clear vision of the organization's future.
- Declare the intentions to involve people at all levels in the improvement of the policy and strategies of the organization.
- Declare the intention to utilize defined processes throughout the organization in order to achieve more predictable results.
- Declare the intention to achieve the organization's objectives through a managed system of interconnected processes.
- Declare the intention to continually improve quality, service, cost, and technology (see also *Continuous improvement* below).
- Declare the intention to base decisions at all levels on an analysis of accurate data and information.
- Declare the intention to develop strategic alliances or partnerships with suppliers.

In addition quality policies may include the following:

- Declare the intentions regarding the law, national and international standards, industry practices, human safety, reliability, natural resource conservation, and the environment.
- Declare the intentions regarding the use of a documented quality system and its certification to national standards.

- Declare the scope of the policy and the quality system if applying to all operations of the business.
- Declare management commitment to the policy.

There are several things the policy should not include:

- Quantitative targets or limits, as these are the domain of quality objectives
- The responsibilities of any particular manager, as implementation of the policy will become the burden of this manager rather than all the managers
- Any method for deviating from the policy, as it signals management flexibility and reduces the original intent

Expressing quality policy

Note how the policies are phrased in the above examples. They are not expressed as vague statements or emphatic statements using the words *may*, *should*, or *shall*, but clear intentions by use of the word *will* – thus expressing a commitment.

Statements of reality

While it is important that management show commitment towards quality, these statements can be one of two things: *worthless* or *obvious*. They are worthless if they do not reflect what the organization already believes and is currently implementing. They are obvious if they do reflect the current beliefs and practices of the organization. It is therefore foolish to declare in your quality policy what you would like the organization to become. If you are already doing it, publishing the policy merely confirms that this is your policy. If the organization does not exhibit the right characteristics, change the culture first before publishing the policy, otherwise you may create an impossible goal. Commitment and understanding are extremely important aspects in making the quality policy work and these are dealt with next.

Commitment (4.1.1.1)

The standard requires that *management with executive responsibility define and document its commitment to quality*.

As stated above, commitment is not something for which you can legislate. The management has to be committed to quality; in other words it must not knowingly ship defective products or give inferior service. It must do what it says it will do and no less.

A manager who signs off waivers without customer agreement is not committed to quality, whatever the reasons. It is not always easy, however, for managers to honor their commitments when the chips are down and the customer is screaming down the phone for supplies that have been ordered. The standard only requires that commitment is defined and documented. It does not require that it is honored or tested but that will emerge as objective evidence is gathered over a period of time. The proof that managers are committed to quality will be self evident from their actions and decisions. When they start spending time and money on quality, diverting people to resolve problems, motivating their staff to achieve performance standards, listening to their staff and to customers, there is *commitment*. It will also be evident from customer feedback, internal and external audits, and sustained business growth. Increased profits do not necessarily show that the company is committed to quality. Profits can rise for many reasons, not necessarily because of an improvement in quality. Managers should not just look at profit results to measure the success of the quality program. Profits may go down initially as investment is made in quality system development. If managers abandon the program because of short-term results, it shows not only a lack of commitment but a lack of understanding. Every parent knows that a child's education does not bear fruit until he or she is an adult.

A commitment is an obligation that a person (or a company) takes on in order to do something. It very easily tested by examination of the results.

<p>■ Commitment means doing what you say, not saying what you do.</p>
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A commitment exists if a person agrees to do something and informs others of their intentions. A commitment that is not communicated is merely a personal commitment with no obligation except to one's own conscience.

Commitment can be defined and documented either through the quality policy statement or through a Vision and Values Statement that defines management values with respect to:

- Doing what you say you will do
- Not accepting work below standard
- Not shipping product below standard
- Improving processes
- Honoring plans, procedures, policies, promises

- Listening to the workforce
- Listening to the customer

Once communicated, a commitment can be tested by:

- Establishing if resources have been budgeted for discharging the commitment
- Establishing that resources are allocated when needed
- Establishing that performance of the tasks to which the person has given his/her commitment is progressed, monitored, and controlled
- Establishing that deviations from commitment are not easily granted

In managing a quality system, such tests will need to be periodically carried out even though it will be tedious to both the person doing the test and the person being subjected to it. It is less tedious if such tests are a feature of the program that the management has agreed to, thereby making it impersonal and by mutual consent.

Many organizations document their commitment to quality by issuing a Corporate Policy Statement of the form described previously. These statements are really the creed or philosophy of the company and thereby a statement of the company's commitment to quality. However, any policy statement agreed by management is a commitment by the company, for example the principal managers signing the documents containing the corporate and operational quality policies. There does not need to be a single statement but if management declares its quality philosophy and displays it in a prominent place, it can help focus attention.

A signed statement by management without its approval to the quality system documented policies and procedures will indicate that it is not committed to honoring the policies and procedures. Managers need to approve the documents within the quality system that prescribe activities for which they themselves are responsible. This serves to demonstrate that they agree with the manner in which the policy has been interpreted and are prepared to provide the resources needed to implement the documented practices.

Ensuring the relevance of quality policy (4.1.1.1)

The standard requires that *the quality policy be relevant to the supplier's organizational goals and the expectations and needs of its customers.*

The goals of the organization may be driving it in one direction and the quality policy in another. This situation can arise when the organizational goals are defined by top management and the quality policy by a lower level of management, as indicated previously. The only way to ensure there is no conflict is for the executive management that defines the organizational goals to define the quality policy.

The supplementary requirement in clause 4.1.1.1 for goals to deploy the quality policy creates an ambiguity because it is unclear as to whether these *goals* are the same “*organizational goals*” referred to in clause 4.1.1 or some other *goals*. For clarity, *goals* are addressed separately under *Quality objectives* in this chapter.

Ensuring that the policy is relevant to the expectations and needs of the organization’s customers is a little more difficult. Companies need to predict what their customer expectations and needs are (now a requirement in clause 4.1.4 under *Business plans*). They may be beyond what they specify in contracts although they may in fact be identical to such specifications. For companies to create satisfied customers they not only need to meet requirements specified by the customer but meet national and international legislation and have consideration for the needs and expectations of society. As explained in Part 1 Chapter 1 on *Quality characteristics*, customers are not only the buyers but comprise several other interested parties. You need to provide a means of determining what the customer expectations and needs are and then subject the written quality policy to a review against those expectations and needs to determine if there is any conflict. As part of your business planning procedure you should indicate how you determine your customer’s current and future needs and expectations.

Ensuring that the policy is understood (4.1.1.1)

The standard requires that the supplier *ensures that its quality policy is understood at all levels of the organization*.

This is perhaps the most difficult requirement to achieve. Any amount of documentation, presentations by management, and staff briefings will not necessarily ensure that the policy is understood. Communication of policy is about gaining understanding but you should not be fooled into believing that messages delivered by management are effective communication. Effective communication consists of four steps: attention, understanding, acceptance, and action. It is not just the sending of messages from one source to another. So how do you *ensure* (i.e. make certain) that the policy is understood?

Within your quality system you should prescribe the method you will employ to ensure that all the policies are understood at all levels in the organization, but it is not manda-

tory as all you need to document and define is the quality policy, the quality objectives, and your commitment to quality.

One method is for top management to do the following:

- Debate the policy together and thrash out all the issues. Don't announce anything until there is a uniform understanding among the members of the management team. Get the managers to face the question, "Do we intend to adhere to this policy?" and remove any doubt before going ahead.
- Announce to the workforce that you now have a quality policy that affects everyone from the top down.
- Publish the policy to the employees (including other managers).
- Display the quality policy in key places to attract people's attention.
- Arrange and implement training/instruction for those affected.
- Test understanding at every opportunity: for example, at meetings, when issuing instructions/procedures, when delays occur, when failures arise, when costs escalate.
- Audit the decisions taken that affect quality and go back to those who made them if they do not comply with the stated policy.
- Take action every time there is misunderstanding. Don't let it go unattended and don't admonish those who may have misunderstood policy. It may not be their fault!
- Every time there is a change in policy, go through the same process. Never announce a change and walk away from it. The change may never be implemented!
- Give time for understanding to be absorbed. Use case studies and current problems to get the message across.

The audit program is another method of testing understanding and is a way of verifying whether the chosen method of ensuring understanding is effective.

In determining whether the policy is understood, auditors should not simply ask "What is the quality policy?" All this will prove is whether the auditee remembers it! The standard does not require that everyone knows the policy, only that it be understood. To test understanding therefore, you need to ask, for example:

- How does the quality policy affect what you do?
- What happens if you can't accomplish all the tasks in the allotted time?
- What would you do if you discovered a nonconformity immediately prior to delivery?
- How would you treat a customer who continually complains about your products and services?
- What action would you take if someone requested you to undertake a task for which you were not trained?
- What are your objectives and how do they relate to the quality policy?
- What action would you take if you noticed that someone was consuming food and drink in a prohibited area?
- What action would you take if you noticed that product for which you were not responsible was in danger of being damaged?

Ensuring that the policy is implemented (4.1.1.1)

The standard requires that the supplier *ensures that its quality policy is implemented at all levels of the organization.*

Publishing the quality policy alone will not ensure it is implemented. People don't use such documents to carry out their duties. As stated previously, policies set boundary conditions for the actions and decisions and therefore it is through defined objectives and procedures that actions and decisions are taken. However, jumping from a corporate quality policy statement directly to procedures is often too large a step to take and most organizations introduce an intermediate level which we will call the operational policies. These are often documented in a quality manual (see Part 2 Chapter 2). Some procedures will implement a policy directly, other procedures may be constrained by more than one policy. It is therefore necessary to trace policies through to the procedures which serve to control work processes and in the review of these procedures ensure that the applicable policies have been complied with. In some cases no procedure may be necessary to implement a policy, its implementation being met by the existence of a record, a post in the management structure, a piece of equipment, etc.

The quality system should be designed to implement the corporate quality policy and hence the operational policies need to be consistent with the corporate policy. Often the

operational policies are merely a paraphrasing of the requirements of ISO 9001 and in such cases there can be no direct relationship between the two. Care should be taken to ensure that there is traceability from corporate quality policy to operational policy and in so doing you may need to deviate from a strict paraphrasing of ISO 9000. In fact paraphrasing ISO 9001 is often not a suitable approach to take (see Part 2 Chapter 2).

■ **Ensuring means making certain and you can't make certain without having control over that which causes the results.**

Ensuring that the policy is maintained (4.1.1.1)

The standard requires that the supplier *ensures that its quality policy is maintained at all levels of the organization.*

Maintenance is concerned with retaining something in or restoring something to a state in which it can perform its required function. However, the standard does not require that the maintenance of policy is to be preventive or corrective. In other words it does not require that maintenance of the quality policy should be carried out before or after it is changed. Even so, it is advisable to maintain documented policies in line with your beliefs and to do this:

- Don't change the policy by any other means than by changing the quality manual. Having declared that your quality policy is documented in the quality manual, you have imposed limits on what you can do. If you want to allow changes ahead of changing the manual, you will need to do it formally through a written procedure. It is unwise to permit the use of memoranda to promulgate policies as they are uncontrolled documents: much better to use a formal change notice. It should take no longer to produce, is official, and can be more easily controlled.
- Review the policy periodically to ensure that it remains current and relevant to the business (see later under *Management review*).
- Don't allow any deviations from the policy unless authorized in writing by those who sanctioned the original policy. By allowing deviations you are not maintaining the status quo. The requirement applies to defining and implementing as well as documenting the policies so the three need to be in concert.

The standard does not require you to document how you maintain your quality policy but the requirements of clause 4.5.1 place the quality policy into the category of documents which need to be governed by documented control procedures and hence all changes must be reviewed and approved.

Defining quality objectives (4.1.1.1, 4.1.1.2, and 4.1.4)

The supplementary requirements modify considerably the ISO 9001 requirement for quality objectives and in order to clarify the intent, the two requirements have been merged as follows.

The standard requires that *the management with executive responsibility define and document in the business plan its goals, objectives, and measurements to deploy the quality policy.*

Goals

There are two requirements for goals: the one mentioned above and that specified in clause 4.1.4 under *Business plans*. Quite why goals are addressed twice is a mystery, but clearly one needs to specify goals before one can start to produce a business plan. However it is not uncommon to find business plans comprising nothing else but goals and objectives, with no substance at all on how these goals and objectives are to be accomplished.

Goals reflect the intended destination of the organization. They could be such destinations as:

- To be a world class producer of ball bearings
- To capture 50% of the market in high temperature lubricants
- To be first to market with innovative solutions in automobile safety

These destinations capture the imagination but without planning they are mere pipe dreams. They also focus on intentions that are optional. For instance, meeting customer needs and expectations is not an option and therefore not a goal. If you made it a goal you would send out the wrong signal. It gives the impression that you do not currently meet customer needs and expectations but intend to do so at some point in the future. This is an intention but not a destination and therefore a policy.

Note that clause 4.1.4 requires goals to cover short term (1 to 2 years) and long term (3 years or more). The standard implies that in order to establish your goals you are required to:

- Analyze competitor products where available.
- Benchmark inside and outside the industry and the supplier's commodity.

Objectives

The term *objectives* is not defined in ISO 8402 but in ISO/DIS 9000:2000 (soon to replace ISO 8402) *quality objectives* are defined in ISO 9004 as key elements of quality such as fitness of use, performance, safety, and reliability. It also mentions the calculation and evaluation of costs associated with all quality objectives. It goes on to suggest that specific quality objectives be documented and be consistent with quality policy as well as other objectives of the organization. You can then go on to set new objectives.

Policies, Goals, and Objectives

- * Policies are intentions that guide action and decision.
- * Policies are implemented – goals and objectives are achieved.
- * Policies remain in force until changed – objectives remain in force until achieved.
- * Goals are your intended destination.
- * Objectives are the milestones you intend to reach en route towards your goals.

In this way, a quality system can drive you forward towards world class quality. It is not a static system but a dynamic one, if properly designed and implemented.

In order to become a world class producer you may need to reduce nonconformities, improve customer feedback, improve skill training, improve product reliability, reduce quality costs, etc.

The requirement for defining objectives is one of the most important requirements. Without quality objectives there can be improvement and no means of measuring how well you are doing. There are two classes of quality objectives: those serving the control of quality and those serving the improvement of quality.

The objectives for quality control should relate to the standards you wish to maintain or to prevent from deteriorating. At the corporate level these objectives will address strategic issues such as safety and reliability or customer care. Although you will be striving

for improvement it is important to avoid slipping backwards with every step forwards. One might question whether the addition of passenger air bags was a step forward in passenger safety when it is claimed that people are being killed by the airbag itself when the vehicle is in collision. At the lower level, objectives for quality control will address tactical issues such as delivery performance, level of imperfections, and customer returns.

Quality improvement objectives are often limited to reducing errors and reducing waste, but if we ask why a company develops new products and services or breaks into new markets we find that it is to create new customers and satisfy new needs and therefore quality objectives are being set. You can improve the quality of your products and services in two ways: remove nonconformities in existing products (improving control) or develop new products with features that more effectively satisfy customer needs (improving performance). A product or service that meets its specification is only of good quality if it satisfies customer needs and requirements. Eliminating all errors is not enough to survive – you need the right products and services to put on the market.

Types of quality objectives

There are five types of quality objectives within each class (control or improvement):

- Objectives for business performance – addressing markets, the environment, and society
- Objectives for product or service performance – addressing customer needs and competition
- Objectives for process performance – addressing the capability, efficiency and effectiveness, use of resources, and controllability
- Objectives for organization performance – addressing the capability, efficiency and effectiveness of the organization, its responsiveness to change, the environment in which people work, etc.
- Objectives for worker performance – addressing the skills, knowledge, ability, motivation, and development of workers

Whether you address all five of these subjects for quality objectives depends on your strategy but all need to be defined in the business plan and all need to deploy the quality policy, thereby making a standalone statement of objectives unnecessary.

Subject matter of quality objectives

The subject matter of quality objectives is prescribed by the quality policy to some extent. Hence an appropriate method would be to derive one or more statements of objectives from each statement in the quality policy. If you adopt the eight quality management principles as your framework, having eight groups of quality objectives would not be unreasonable (see previously under *Subject matter for quality policy*).

ISO 9001:1994 does not actually require you to plan and organize for meeting these objectives or in fact monitor achievement but this is corrected in ISO/TS 16949 in clause 4.1.4 (*Business plan*).

Expressing quality objectives

The note in clause 4.1.1.1 clearly indicates that the objectives should be achievable within a defined time period. Therefore quality objectives should be expressed in the form *what is to be achieved and by when*.

<p>■ Objectives are results to be achieved by a certain date.</p>
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Measurements

The standard requires *measurements to be defined to deploy the quality policy*. This is a rather odd requirement as measurements cannot deploy anything. What is intended here is that the objectives be expressed in measurable terms. The extent to which the quality policy is being implemented can thus be measured from tracking achievement of quality objectives.

Customer satisfaction (4.1.1.3)

The standard requires *a documented process for determining customer satisfaction, including the frequency of determination and how objectivity and validity are assured*.

Customer satisfaction determination process

The integrity of your process for determining customer satisfaction is paramount, otherwise you could be misled by the data and believe customers are satisfied when they are not. The process therefore needs to be free from bias, prejudice, and political influence.

A way of determining customer satisfaction is to:

- Seek the opinions of customers about your organization's products and services provided through questionnaires or interview checklists.
- Seek opinions from the people within the customer's organization, such as Marketing, Design, Purchasing, Quality Assurance, Manufacturing, etc.
- Target key product features as well as delivery, price, and relationships.
- Collect and analyze customer feedback, particularly complaints to target areas for improvement.
- Conduct customer focus meetings to gather opinion and recommendations for action, using data gathered from questionnaires and periodic customer feedback.
- Report back the findings to particular customers to secure understanding.
- Summarize the data to identify trends and conditions that indicate improvement opportunities.
- Compute customer satisfaction indices as an aid to measuring change.
- Use the data to derive the business, product development, and quality plans for current and future products and services.

To document this process you should develop a customer satisfaction procedure that details:

- The sources from which information is to be gathered and the forms, questionnaires, and interview checklists to be used
- The actions and decisions to be taken and those responsible for the actions and decisions
- The methods to be used for computing the customer satisfaction index
- The records to be created and maintained
- The reports to be issued and to whom they should be issued

It should be noted that questionnaires by themselves are not an effective means of gathering customer opinion. Customers don't like them and are not likely to take them

seriously unless they have a particular issue they want to bring to your attention. It is much better to talk face to face with your customer using an interview checklist. Think for a moment how a big customer like Ford or GM would react to thousands of questionnaires from their suppliers. They would either set up a special department just to deal with the questionnaires or set a policy that directs staff not to respond to supplier questionnaires. Economics alone will dictate the course of action customers will take.

A customer satisfaction index (CSI) that is derived from data from an independent source would indeed be more objective. Such schemes are in use in North America, Sweden, and Germany. A method developed by a Professor Claes Fornell has been in operation for 12 years in Sweden and is now being used at the National Quality Research Center of the University of Michigan Business School. Called the American Customer Satisfaction Index (ACSI) it covers seven sectors, 40 industries, and some 200 companies and government agencies. It is sponsored by the ASQC and the University of Michigan Business School with corporate sponsorship from AT&T, General Motors, and others. Using data obtained from customer interviews, sector reports are published indicating a CSI for each listed organization, thereby providing a quantitative and independent measure of performance useful to economists, investors, and potential customers. A pan-European scheme is being developed through EOQ and is currently on trial.

Frequency of measurement

Frequency also needs to be adjusted following changes in models and major changes in organization structure, such as mergers, downsizing, and plant closures. Changes in fashion and public opinion should also not be discounted. Repeating the survey after the launch of new technology, new legislation, or changes in world economics affecting the automotive industry may also affect customer perception and hence satisfaction.

Trends

To determine trends in customer satisfaction and dissatisfaction you will need to make regular surveys and plot the results, preferably by particular attributes or variables. The factors will need to include quality characteristics of the product or service as well as delivery performance and price. The surveys could be linked to your improvement programs so that following a change, and allowing sufficient time for the effect to be observed by the customer, customer feedback data could be secured to indicate the effect of the improvement.

Customer dissatisfaction will be noticeable from the number and nature of customer complaints collected and analyzed as part of your corrective action procedures (see Part 2 Chapter 14). This data provides objective documentation or evidence and again can be reduced to indices to indicate trends.

By targeting the final customer using data provided by intermediate customers, you will be able to secure data from the users but it may not be very reliable. A nil return will not indicate complete satisfaction so you will need to decide whether the feedback is significant enough to warrant attention. Using statistics to make decisions in this case may not be a viable approach since you will not possess all the facts!

Considering internal and external customers (4.1.1.3)

The note attached to clause 4.1.1.3 needs to be interpreted carefully otherwise you will have every individual setting up systems to monitor their relationship with the people to whom they provide product or information. Everyone needs to be aware of their relationships with others but formal systems are only necessary between organizations. If your organization receives formal orders from other parts of the same company then there may be benefit in treating this as a customer-supplier relationship and monitoring customer satisfaction.

It is common when adopting the TQM philosophy to regard *all* human interfaces as customer-supplier interfaces. When executed wisely this can have a beneficial effect on internal efficiency and effectiveness, but there are pitfalls to avoid. In a customer-supplier chain, the expectations of the external customer can be modified with each transaction, as illustrated in Figure 1.2.

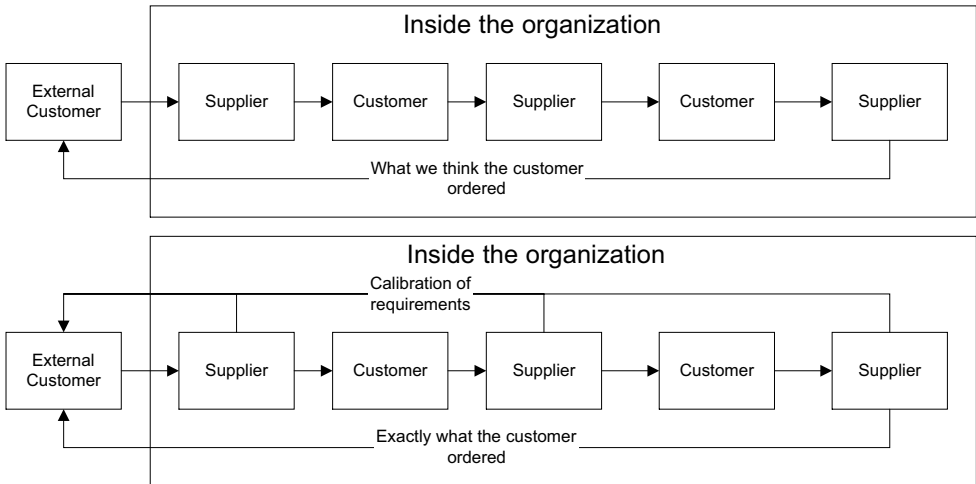


Figure 1.2 Internal customer-supplier relationships

In the upper diagram each supplier individually interprets the customer's requirements and either imposes additional requirements or neglects to pass on requirements. The net result at the end of the chain is that the external customer (the one who buys from the organization) does not get satisfaction from the transaction. In the lower diagram, each supplier refers back to the external customer's requirements to calibrate the internal customer's demands. This ensures that the net result matches exactly what the customer ordered. In reality, such calibration should not be necessary if the internal customers demonstrate traceability to external customer requirements. This can be achieved through process reviews performed in each process before instructions are transmitted to subsequent processes.

Continuous improvement (4.1.1.4)

The standard requires that *continuous improvement in quality, service, cost, and technology be provided for in the quality policy*.

The standard also requires *opportunities for quality and productivity improvement to be identified and appropriate improvement projects implemented*.

Ambiguity in the requirement

It has become fashionable to use the term *continuous improvement* rather than *continual improvement*. *Continuous* means without breaks or interruption – such as continuous stationery. *Continual* means repeated regularly and frequently – a term that fits the concept of improvement rather better and will be used in ISO 9000:2000.

The first two statements in clause 4.1.1.4 create an ambiguity when read together. The first calls for improvements in quality, service, cost, and technology (but not productivity) to be provided for in the quality policy but not implemented and the second calls for improvement in quality and productivity to be identified and implemented with no mention of cost, service, or technology.

Quality, service, cost, and technology are not mutually exclusive. One can't distinguish between a quality improvement and a service or technology improvement. It was necessary only to mention *quality* and *cost*, as an improvement in service must be an improvement in either the quality or cost of the service – all other factors come within the definition of quality. Improvements in technology are also improvements in quality or cost. Such improvements may improve the quality of design, quality of conformance, or quality of use (see Part 1 Chapter 1 under *Quality parameters*) or may cause a reduction in cost while not providing any change in product or service characteristics.

Productivity is a measure of productive efficiency calculated as the ratio of what is produced to what is required to produce it. Productivity can therefore be considered as a characteristic of a process, and therefore a measure of the quality of a process. Consider two process each producing the same product but one delivers the result using less resources and hence as a consequence has a higher productivity. The process with the higher productivity could thus be regarded as being of better quality. However, measuring resource consumption alone would not be a valid means of comparison as inputs could be vastly different. Hence *productivity* is a quality characteristic.

■ **If you are not maintaining or improving quality, delivery, or cost, the action you are taking adds no value.**

Improvements in product quality

Improvement in business performance is essential for growth and profit, but the ISO/TS 16949 requirements are not concerned with your growth and profits; they are concerned with product quality, and one definition of product quality that signals improvement potential is “freedom from defects”. Achieving quality become a quest to eliminate defects and in so doing reduces variation in the operational processes, but even when there are no defectives, there will still be variation. One might well question the need to reduce variation when there are no defectives but by reducing variation you will have fewer breakdowns, fewer errors, less space allocated to inventory, less waste, etc.: in fact fewer problems and increased profit as a result.

The starting point in building this system of values is *self analysis*. It is of little use to declare a policy of continual improvement if the will to implement it does not exist. Many organizations are content to meet the specification every time and, once achieved, believe they have made all the improvement to which resources should be committed. There are four questions that each manager should be able to answer:

- Can we make it OK?
- Are we making it OK?
- Have we made it OK?
- Could we make it better?

Meeting the specification every time means that you have obtained satisfactory answers to the first three questions – but why stop there? Could you make it better? Often the answer is “yes” but it will cost a lot of money and after all, why should we want to make

it better? Some reasons for pursuing improvement beyond achievement to specification are given in Part 1 Chapter 1 on the subject of *Quality goals*.

Improvement on cost

The price charged for products is a function of cost, profit, and what the market will pay. Sometimes price is much higher than cost and in other cases only slightly higher.

■ **Control change and you control cost.**

In your particular business, it may be profitable to sell some products below cost as an enticement to capture further business where you can make more profit. This will create a force to drive down costs. Remember that if you control change you control cost, so the more stable your processes the less they cost.

If you find that you cannot absorb increases in labor and raw material costs, then you may have to look for alternative approved sources, alternative materials, alternative methods or consider alternative designs. By including price in the improvement formula, it will act as a driving force.

Improvements in productivity

Your general aim should be to improve product quality, increase productivity, and reduce the cost of development and manufacture. However, productivity is not easy to measure with multiple products on multiple lines, each at a different stage of maturity. This makes comparisons to detect changes in productivity difficult, if not impossible. However there may be factors common to all product lines, such as labor costs. Merely outsourcing manufacture to developing countries may not improve your productivity. The labor costs may reduce but rework and warranty claims increase. Productivity is only improved if product quality has been maintained. Certain processes may also be common to more than one product line and hence improving productivity of common processes can have wide-ranging impact.

Time is also a resource and therefore reducing cycle time impacts productivity. Often the administration and design processes are a source rich in cycle time improvements, such as the time taken to change a document, a design, a policy, etc. or the time taken to place an order, arrange a training course, authorize budgets and expenditure, etc. Reaction time is also important as in servicing, maintenance, customer support, etc. How long does it take to get management to react to a situation that requires their atten-

tion? There are priorities of course, but question these priorities if you believe they hinder continuous improvement!

A need for productivity improvement may arise because your standards were made difficult to achieve although possible to attain. As a result this has the effect of encouraging initiative and resourcefulness and using the capabilities of your personnel. Many improvement opportunities will be identified by those who are eager to seek easier ways of doing things.

Opportunities for improvement can be identified through:

- Process and product measurement systems
- System audits
- Customer and supplier surveys
- Suggestion schemes
- Research
- Experiments
- Benchmarking

You need an improvement system that causes improvement opportunities to be identified. Relying on chance encounters will not create the conditions needed for continuous improvement. The data that needs to be analyzed will be generated by a particular process and this process governed by particular documented procedures. By having already placed instructions in these procedures for certain data to be transmitted to your data analysts, you can cause opportunities to be identified. Other opportunities that are less dependent on product or process data may arise from the audit process and particular projects such as benchmarking, customer and supplier surveys.

Use of appropriate improvement methodologies (4.1.1.4)

The standard requires *the use of appropriate continuous improvement measures and methodologies*.

A list showing examples of possible continuous improvement techniques is included in the standard. These techniques and many more are defined in Appendix A and a bibliography is provided in Appendix C.

In demonstrating knowledge of these techniques an auditor would be looking for evidence that:

- Staff have received adequate training in continuous improvement methodologies.
- Information is available to enable staff to select and use the appropriate techniques.
- The technique to be used for identifying improvement opportunities is specified for each quality objective.

Just because a technique exists does not imply that you have to use it, but you should understand the advantages and disadvantages of using a particular technique.

Responsibility and authority (4.1.2.1)

The requirements on responsibility and authority are in two parts: one general and the other relating to people with particular roles. Each is treated separately.

Identifying work that affects quality (4.1.2.1.1)

The standard requires that *the responsibility, authority, and interrelation of personnel who manage, perform, and verify work affecting quality be defined and documented.*

The key to this requirement is determining what work affects quality; i.e. if you can identify any work that does *not* affect quality, you are not obliged to define in your quality system the responsibilities and authority of those who manage, perform, or verify it.

In principle, everyone's work affects the quality of the products and services supplied by the organization, some directly, others indirectly. Work can be divided into result-producing, support, and housekeeping activities. All are essential to the business but only the result-producing and support activities affect the quality of the products and services supplied. The result-producing activities are those which directly bring in revenue and which contribute to results, such as sales, marketing, development, manufacture, and maintenance. The support activities are usually those which set standards, create vision, produce information needed by the result-producers, provide teaching, training, and advice, such as research, computer services, quality assurance, training, and personnel. Housekeeping activities are those which do not contribute to results but their malfunction could harm the business, such as health and safety, security, catering, travel, medical, general maintenance, etc.

Apart from result-producing activities, there are several other activities that could affect quality:

- A failure to observe government health and safety regulations could close a factory for a period and hence result in late delivery to customers.
- Health and safety hazards could result in injury or illness, place key personnel out of action for a period, and hence result in work not being done or being done by personnel who are not competent.
- A failure to take adequate personnel safety precautions may put product at risk.
- A failure to safely dispose of hazardous materials and observe fire precautions could put plant at risk.

If there are personnel involved with the identification, interpretation, promulgation, and verification of such regulations then their responsibilities and authority will need to be defined in the quality system.

What is “responsibility and authority”?

Defining the responsibility and authority of personnel can be achieved in several ways but first let’s look at what we mean by *responsibility and authority*.

Responsibility is in simple terms an area in which one is entitled to act on one’s own accord. It is the obligation of staff to their managers for performing the duties of their jobs. It is thus the obligation of a person to achieve the desired conditions for which they are accountable to their managers. If you caused something to happen, you must be responsible for the result just as you would if you caused an accident – so to determine a person’s responsibility, ask “What can you cause to happen?”

Authority is in simple terms the right to take actions and make decisions. In the management context it constitutes a form of influence and a right to take action, to direct and coordinate the actions of others, and to use discretion in the position occupied by an individual, rather than in the individual themselves. The delegation of authority permits decisions to be made more rapidly by those who are in more direct contact with the problem.

It is necessary for management to define who should do what in order that the designated work is assigned to someone to carry out. It is not cost effective to have duplicate responsibilities or gaps in responsibility as this leads to conflict or tasks being overlooked.

A person's job can be divided into two components: actions and decisions. Responsibilities and authority should therefore be described in terms of the actions assigned to an individual to perform and discretion delegated to an individual: that is, the decisions they are permitted to take along with the freedom they are permitted to exercise. Each job should therefore have core responsibilities, which provide a degree of predictability, and innovative responsibilities, which in turn provide the individual with scope for development.

In defining responsibilities and authority there are some simple rules that you should follow:

- Through the process of delegation, authority is passed downward within the organization and divided among subordinate personnel, whereas responsibility passes upwards.
- A manager may assign responsibilities to a subordinate and delegate authority; however, they remain responsible for the subordinate's use of that authority.
- When managers delegate responsibility for something, they remain responsible for it. When managers delegate authority they lose the right to make the decisions they have delegated but remain responsible and accountable for the way such authority is used. Accountability is one's control over the authority one has delegated to one's staff.
- It is considered unreasonable to hold a person responsible for events caused by factors that they are powerless to control.
- Before a person can be in a state of control they must be provided with three things:
 - i) Knowledge of what they are supposed to do: i.e. the requirements of the job, the objectives they are required to achieve.
 - ii) Knowledge of what they are doing, provided either from their own senses or from an instrument or another person authorized to provide such data.
 - iii) Means of regulating what they are doing in the event of failing to meet the prescribed objectives. These means must always include the authority to regulate and the ability to regulate both by varying the person's own conduct and by varying the process under the person's authority. It is in this area that freedom of action and decision should be provided.

- The person given responsibility for achieving certain results must have the right (i.e. the authority) to decide how those results will be achieved; otherwise, the responsibility for the results rests with those who stipulate the course of action.
- Individuals can rightfully exercise only that authority which is delegated to them and that authority should be equal to that person's responsibility (not more or less than it). If people have authority for action without responsibility, it enables them to walk by problems without doing anything about them. Authority is not power itself. It is quite possible to have one without the other! A person can exert influence without the right to exert it.
- In the absence of the delegation of authority and assignment of responsibilities, individuals assume duties that may duplicate those duties assumed by others. Thus jobs that are necessary but unattractive will be left undone. It also encourages decisions to be made only by top management, resulting in an increasing management workload and engendering a feeling of mistrust in the workforce.

Defining responsibilities and authority (4.1.2.1.1)

ISO 9001 requires responsibilities and authority to be documented in addition to being defined, as one can define such things in dialog with one's staff without documenting them. This is indeed a common way for staff to discover their responsibilities. Sometimes you may not be aware of the limits of your authority until you overstep the mark. By documenting the responsibility and authority of staff, managers should be able to avoid such surprises.

There are four principal ways in which responsibilities and authority can be documented:

- In an organization structure diagram, or *organigram*
- In job descriptions
- In terms of reference
- In procedures

The standard does not stipulate which method should be used. In very small companies a lack of such documents defining responsibility and authority may not prove detrimental to quality provided people are made aware of their responsibilities and adequately trained. However, if you are going to rely on training, there has to be some written material which is used so that training is carried out to consistent standards.

Organigrams are a useful way of showing interrelationships (see below) but imprecise as a means of defining responsibility and authority. They do illustrate the lines of authority and accountability but only in the chain of command. Although organigrams can define the area in which one has authority to act, they do not preclude others having responsibilities within the same area; for example, the title “Design Manager – Computer Products” implies the person could be responsible for all aspects of computer product design when in fact they may not have any software, mechanical engineering, or reliability engineering responsibilities. Titles have to be kept brief as they are labels for communication purposes and are not usually intended for precision on the subject of responsibilities and authority. One disadvantage of organigrams is that they do not necessarily show the true relationships between people within the company. Horizontal relationships can be difficult to depict with clarity in a diagram. They should therefore not be used as a substitute for policy.

Job descriptions or job profiles are useful in describing what a person is responsible for; however, it rather depends upon the reason for having them as to whether they will be of any use in managing quality. Those produced for job evaluation, recruitment, salary grading, etc. may be of use in the quality system if they specify the objectives people are responsible for achieving and the decisions they are authorized to take.

Terms of reference are not job descriptions but descriptions of the boundary conditions. They act as statements that can be referred to in deciding the direction in which one should be going and the constraints on how to get there. They are more like rules than a job description and more suited to a committee than an individual. They rarely cover responsibilities and authority except by default.

Procedures are probably the most effective way of defining people’s responsibilities and authority as it is at the level of procedures that one can be specific as to what someone is required to do. Procedures specify individual actions and decisions. By assigning actions or decisions to a particular person you have assigned to them a responsibility or given them certain authority. Procedures do present problems however. It may be difficult for a person to see clearly what his/her job is by scanning the various procedures because procedures often describe tasks rather than objectives. When writing procedures never use names of individuals as they will inevitably change. The solution is to use position or role titles and have a description for a particular position or role that covers all the responsibilities assigned through the procedures. Individuals only need to know what positions they occupy or roles they perform. Their responsibilities and authority are clarified by the procedures and the position or role descriptions¹.

¹ An explanation of roles and the advantages of applying the concept of roles in a quality system is given in the *ISO 9000 Quality System Development Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

Within ISO/TS 16949 there are several requirements for an assignment of responsibility. These include the responsibility and authority for:

- Defining the quality policy and objectives (clauses 4.1.1.1 and 4.1.1.2)
- Determining customer satisfaction (clause 4.1.1.3)
- Representing the needs of the customer (clause 4.1.2.1.2)
- Stopping production to correct quality problems (clause 4.1.2.1.3)
- Assigning trained personnel (clause 4.1.2.2.1)
- Appointing the management representative (clause 4.1.2.3)
- Reviewing business plans (clause 4.1.4)
- Promoting quality awareness (clause 4.1.6)
- Promoting safety awareness (clause 4.1.7.1)
- Conducting the management review (clause 4.1.3.1)
- Quality planning (clause 4.2.3.1)
- Assigning the project manager (clause 4.2.4.1)
- Reporting product realization measurements to management (clause 4.2.4.2)
- Conducting project reviews (clause 4.2.4.3)
- Carrying out FMEA (clause 4.2.4.5)
- Performing process studies (clause 4.2.4.5)
- Performing process design verification (clause 4.2.4.9.4)
- Developing control plans (clause 4.2.4.10)
- Submitting product approval requests (clause 4.2.4.11)
- Accepting contracts (clause 4.3.2.1)

- Reviewing product designs (clause 4.4.6)
- Performing product design verification and validation (clauses 4.4.7 and 4.4.8.1)
- Reviewing product design changes (clause 4.4.9.1)
- Reviewing and approving documents and changes thereto (clauses 4.5.2.1 and 4.5.3)
- Evaluating and selecting subcontractors (clause 4.6.2.1)
- Subcontractor assessment (clause 4.6.2.1)
- Reviewing and approving purchasing documents (clause 4.6.3)
- Verifying product at subcontractor's premises (clause 4.6.4.1)
- Reporting lost or unsuitable customer supplied product to customers (clause 4.7.1)
- Planning production, installation, and servicing processes (clause 4.9.1.1)
- Verifying job set-ups (clause 4.9.4)
- Verifying product (clauses 4.10.2, 4.10.3, and 4.10.4)
- Performing layout inspection (clause 4.10.4.2)
- Checking comparative references (clause 4.11.1.1)
- Calibrating inspection, measuring, and test equipment (clause 4.11.2)
- Notifying customers of nonconforming product shipment (clause 4.13.1.3)
- Reviewing and disposing of nonconforming product (clause 4.13.2)
- Obtaining authorization to deviate from customer approved specifications (clause 4.13.4)
- Handling customer complaints (clause 4.14.2.1)
- Investigating the cause of nonconforming product (clause 4.14.2.1)
- Determining corrective and preventive actions (clauses 4.14.2.1 and 4.14.3)

- Receiving product into and dispatching product from storage areas (clause 4.15.3.1)
- Issuing shipment notifications to customers (clause 4.15.6.5)
- Planning, conducting, and reporting on internal quality audits (clause 4.17.1)
- Identifying training needs and providing training (clause 4.18.1)
- Reviewing training effectiveness (clause 4.18.2)
- Reporting that servicing meets requirements (clause 4.19.1)
- Identifying the need for statistical techniques (clause 4.20.1)

In organizations that undertake projects rather than operate continuous processes or production lines, there is a need to define and document project-related responsibilities and authority. These appointments are often temporary, being only for the duration of the project. Staff are assigned from the line departments to fulfill a role for a limited period. To meet the requirement for defined responsibility, authority, and interrelationships for project organizations you will need Project Organization Charts and Project Job Descriptions for each role (such as Project Manager, Project Design Engineer, Project Systems Engineer, and Project Quality Engineer).

As project structures are temporary, there needs to be a system in place that controls the interfaces between the line functions and project team. Such a system would include:

- Policies that govern the allocation of work to projects
- Policies that govern the allocation of work to staff on these projects
- Job descriptions for each role, stating responsibilities, authority, and accountability
- Procedures that identify the roles responsible for each task and for ensuring that information is conveyed to and from these staff at the appropriate time
- Procedures that consolidate information from several disciplines for transmission to the customer when required
- Monitoring procedures to track progress and performance
- Procedures that ensure the participation of all parties in decisions affecting the product and its development and production
- Procedures for setting priorities and securing commitment

- Procedures that include the management of subcontractor programs during development and deal with the transmission of information to and from the subcontractors, what is to be transmitted, by whom, in what form, and with whose approval

Some organizations have assigned responsibility for each element of the standard to a person, but such managers are not thinking clearly. For some elements, the assignment of responsibility may appear possible, as in the case of clause 4.4 on *Design control* and 4.6 on *Purchasing*, but when you come to examine it more closely you will find that the task is not so easy. If we look at purchasing we find that it is made up of many actions and decisions, such as defining the technical requirement, evaluating the supplier, choosing the supplier, placing the order, monitoring the supply, inspecting the goods on receipt, etc. No one person other than the CEO is responsible for all of these actions, unless it is a small company. The Purchasing Manager may not accept responsibility for errors in the technical specification invoked in the purchase order if he/she did not prepare or approve the technical specification. When auditors ask “Who is responsible for purchasing?” ask them to specify the particular activity they are interested in. Remember you have a system that delegates authority to those qualified to do the job.

Defining the interrelation of personnel (4.1.2.1.1)

Defining individual responsibilities and authority alone will not define how personnel relate to one another. Interrelation means to place in mutual relationship, so what is needed is a definition of the relationships between all staff with quality responsibilities. The primary reason for defining interrelationships is to establish channels of communication so that work proceeds smoothly without unplanned interruption. Staff need to know from whom they will receive their instructions, to whom they are accountable, to whom they should go to seek information to resolve difficulties, and to whom information or product should be submitted when complete.

Personnel within a company are related in several ways:

- By position in a reporting hierarchy
- By position in a chain of operations as internal customers and suppliers of information, product, or service
- By position in a salary-grading structure
- By job title, profession, type of work
- By location, i.e. being on the same site but not in the same department, group, or division

In order for personnel to achieve a common objective (product or service quality) they must relate to one another – they must interact. Work passes from one person to another, from one department to another and often this relationship is quite different from the hierarchical relationship of personnel in the company. In order to meet this particular requirement it is therefore necessary to:

- Define the structure of the company, preferably in diagrammatic form showing each department and section whose work affects quality. (You don't have to define all parts of the company.)
- Define the location of work, departments, groups, and divisions.
- Define the processes that manage, specify, achieve, and control product/service quality and who performs each stage in the process, preferably in the form of flow diagrams.

An organization may respond to these requirements in several ways, so in managing the quality system a list of the documents is needed which contains the definition of people's responsibilities and authority. The difficulty arises in keeping all such documents compatible and so it is often better to limit the documents to the three types above, if possible.

Personnel with organizational freedom (4.1.2.1.1)

The second part of the responsibility and authority requirement requires the supplier to *define the responsibility, authority, and interrelation of personnel who need the organizational freedom and authority to:*

- a) *Initiate action to prevent the occurrence of any nonconformities relating to product, process, and quality system.*
- b) *Identify and record any problems relating to the product, process, and quality system.*
- c) *Initiate, recommend, or provide solutions through designated channels.*
- d) *Verify the implementation of solutions.*
- e) *Control further processing, delivery, or installation of nonconforming products until the deficiency or unsatisfactory condition has been corrected.*

Who are these personnel who need organizational freedom and why do they warrant a special mention? This is not meant to imply that you should set up a separate quality department. The standard does not in fact require all personnel to have organizational freedom but it suggests that some people will *need* organizational freedom to do certain things.

Personnel who initiate action to prevent nonconformity (4.1.2.1.1a)

Initiating action to prevent something is not the same as preventing something from taking place. You can prevent something from happening either by not starting the process or by stopping it before a nonconformity has occurred. The only people who should prevent the occurrence of product or process nonconformity are those in control of the process – those operating the machines, producing the results, doing the work – or those people who manage or supervise such people. It would not be right for anyone not responsible for the process to exert power over it, such as stopping the process or changing the material, the documentation, the instructions, or the personnel. In addition to the managers of the process, the management representative and the quality auditors should be given the authority to initiate action to prevent nonconformity (i.e. the organizational freedom) but if you do this, such authority should override that of those in control of the process. In other words if the auditor requires some action to be taken to prevent the recurrence of nonconformity, he has to do more than notify those in control of the process, otherwise such notification could be ignored or any agreement abandoned. The reason for doing this is so that the management representative can discharge responsibility for *ensuring* that the requirements of the standard are met (see later in this chapter). Authority to initiate means authority to cause someone to take action. It does not give the initiator the right to specify what action to take. However, the receiver of the instruction must either obey it or escalate it to higher management.

Regarding nonconformities relating to the quality system, anyone should be permitted to request a change to the quality system documentation to prevent the occurrence of nonconformities; however, only a person's manager should be permitted to issue instructions to his/her staff enforcing compliance with the documented quality system. The management representative can and should, however, instruct other managers to comply with the agreed policies and practices.

Personnel who identify and record problems (4.1.2.1.1b)

A problem is the difference between the way things are and the way things ought to be, as perceived by the one identifying it. A problem relating to the product, process, or quality system (or quality problem) is therefore a difference between what has been achieved and what is required. There is no requirement in this clause for you to actually identify and record such problems (see below). You are only required to define the

responsibilities and authority of those personnel in your organization who need to identify and record such problems.

Should anyone *need* organizational freedom and authority to identify and record problems? Any organization should provide an environment which encourages all employees to contribute to the business, but unfortunately this is not so in many organizations. There may well be some merit in limiting such freedom in order that management is not swamped with fictitious problems. It all comes down to deciding who is in a position to be able to tell whether a situation is a problem and whether it affects quality. Certainly managers and professional staff should be free to identify problems because they should have the knowledge to report only problems that can be resolved.

To provide staff with the necessary organizational freedom you will need one or more problem-reporting procedures and some policies that give staff the freedom to identify, record, and report problems relating to the product, process, and quality system.

The requirement does not cross refer to clause 4.16 on *Quality records*, clearly indicating that there is no requirement in this clause for problems to be recorded, as other clauses such as 4.10, 4.13, and 4.14 cover this. However, these clauses only relate to problems in not meeting the specified requirements and therefore may exclude types of problems not governed by specified requirements. So having identified the responsibilities of these personnel there may be no compulsion to provide a means for such problems to be documented, resolved, and prevented from recurrence.

Personnel who initiate, recommend, or provide solutions (4.1.2.1c)

There is no requirement to implement solutions, only to initiate, recommend, provide, and verify them. Initiating, recommending, and providing have three quite different meanings. Initiating in this context means causing a solution to be implemented and has more power than a recommendation, which can be ignored, as can solutions provided by others. Managers of the functions concerned should have authority to initiate solutions to problems arising in their areas of responsibility. Experts and other personnel used in an advisory capacity should also be given authority to make recommendations and provide solutions. However, you may wish to limit such powers. You will not want just anyone to influence those resolving the problems. Those not qualified to give advice on certain subjects should not have authority to do so. There have been many cases where a person has taken unqualified advice to find that they should not have done so. Hence the requirement that solutions be provided through *designated channels*. You will therefore need some policy to ensure that the credentials of those giving advice are checked before the advice is accepted. Likewise, there should be a policy that ensures staff take the advice given by qualified personnel unless they can justify otherwise. There is no point in an organization employing experts and then allowing their advice to be ignored. If the experts are no good it is better to replace them!

Personnel who verify the implementation of solutions (4.1.2.1.1e)

The person resolving the problem should be the person who caused it or, if this is not possible or appropriate, it should be the person responsible for the result. This person should also verify that they have implemented the solution correctly, but there may be a need for others to verify that the solution resolves the problem; for example, the person detecting the problem may be a customer. Quite often the solution implemented may not in fact resolve the original problem. This could be due to poor communication or to politics. In addition, the designer of the solution may decide to take the opportunity to change things that were perhaps not perfect but found them less costly to change in conjunction with other changes. Where such changes may result in the problem not being solved, it becomes more important that the verification be carried out by someone other than the designer. You will need to define who has the authority to verify certain types of solutions, such as new products, design changes, policy changes, planning changes, procedures changes, or process changes. They may be the same people who verified the original designs, plans, procedures, etc. but could be different if you have a product support, maintenance, or post-design organization.

Personnel who control further processing, delivery, or installation of nonconforming product (4.1.2.1.1e)

There are three separate requirements here. Control of further processing involves stopping the process and, as explained previously, should be carried out only by those responsible for the process. Controlling further delivery is somewhat different, as the authority to deliver may not be vested in the same person who performed the processing.

Delivery decisions are more than decisions about conformance to specification. They are about conformance to contract and those responsible for the production processes may not be able to determine whether contractual conditions have been met. Much more may hang on the resolution of a problem than mere conformance to specification. The decision in some circumstances may be taken by the CEO. There may have been a safety problem or a product liability problem so your system needs to recognize these fine distinctions. Those making the delivery decisions need possession of all the information required to protect the company as well as meet customer needs.

Installation decisions are similar to process decisions and the decision to start or stop further installation work should rest with those responsible for installation. If the materials have not been delivered they cannot be installed, so the key decision in this case is the delivery decision.

Customer representative (4.1.2.1.2)

The standard requires that *appropriate individuals be assigned to represent the needs of the customer in internal functions.*

Whatever your business you cannot operate as though you are a field of corn, letting the wind blow you in different directions. Each customer may have slightly different requirements, many of them often having no impact on product quality but on the presentation of information. If you characterize products and processes too closely to specific customer requirements, you run the risk of introducing inefficiencies and reducing productivity. You can, however, maintain productivity and respond to your customer's varying demands through an interface function. Appointing a person as your customer liaison representative provides an opportunity to develop someone in your organization who knows as much about what the customers need and why it is needed than the customers themselves. This person is then able to translate specific customer requirements into your language and back again. So rather than change all your processes to suit all your customers, translate customer requirements onto your own paperwork and use this throughout the process. At the end of the chain of processes translate your paperwork onto customer forms and supply these to your customer. Where a customer wants something that others have not yet demanded, consider the overall benefits and if it does provide added value change your processes. If not, find a compromise that is mutually beneficial.

The appointed customer representative will need to spend some time with the customer to learn their ways, and understand their language, needs, and expectations. Hence if the native tongue of your staff is English and you do business with Swedish, Italian, and French companies you may need people who can speak these languages and who are familiar with the appropriate subject vocabulary. Beware, however, that in appointing such a person you choose wisely. It also has to be someone you can trust to represent your interests. You will need a means of calibrating this person so that he/she does not get carried away with enthusiasm and start to impose requirements that are no more than personal likes and dislikes.

Quality responsibility (4.1.2.1.3)

Notification of nonconformities (4.1.2.1.3)

The standard requires *management with responsibility and authority for corrective action to be promptly informed of products or processes which become noncompliant with specified requirements.*

The requirement in clause 4.13.1 of ISO 9001 requires the supplier's nonconforming product controls to provide for notifying the functions concerned. This supplementary

requirement expands this requirement to include nonconforming processes. The requirement is also misplaced as its subject is not *responsibility and authority* but *notification*. The responsibility and authority of those personnel who have been notified of noncompliant products or processes is covered by clause 4.1.2.1.1(c).

Authority to stop production (4.1.2.1.3)

The standard requires *personnel responsible for quality to have the authority to stop production to correct quality problems*.

This supplementary requirement is unnecessary because clause 4.1.2.1.1(e) addresses this point by requiring the responsibility, authority, and interrelation of personnel who control further processes of nonconforming product to be defined and documented. Apart from being unnecessary, the requirements also contain a fundamental inconsistency. The notion that there are some personnel responsible for quality and others who are not is a nonsense. Everyone is responsible for the quality of their results. The question is, what results are being addressed in this requirement? Clearly, operators on a production line cannot take full responsibility for the quality of the product because they may not have designed it, selected the materials, set up the machines, etc. They cannot be responsible for anything over which they have no control. Operators can only take responsibility for what they do or cause to happen. What the requirement tries to address is that having assigned a responsibility for certain results, management should also delegate authority to personnel to control the processes that produce the results for which they are responsible – thereby authorizing them to stop production if need be. It is imperative that you avoid the situation whereby management has told someone he/she is responsible for quality without clarifying his/her authority.

Resources (4.1.2.2)

Identifying and providing adequate resources (4.1.2.2.1)

The standard requires that the supplier *identify resource requirements for management, performance of work, and verification activities and provide adequate resources*.

The term *resource* is often used to imply only *human resources* when there are in fact other types of resources. The standard is not specific although resources would normally include time, manpower, machines, materials, finance, plant, facilities: in fact, any means available to the supplier for implementing the quality system. So when ISO 9001 requires that you provide adequate resources it requires that you provide all the human, finance, and material resources necessary to implement your quality system, including the allocation of sufficient time.

Resource management is a common feature of all organizations and while it may be known by different titles, the determination and control of the resources to meet customer needs is a fundamental requirement and fundamental to the achievement of all other requirements.

There are two types of resource requirements: those needed to run the business and those needed to execute particular contracts or sales. The standard is not specific, but a glance at ISO 9004-1 will reveal that it is more than those needed for a particular contract and less than needed to run the business. ISO 9004-1 limits the resources to those needed to implement the quality policy and meet quality objectives. It will be very difficult for companies to distinguish between those resources which serve quality and those which serve other objectives. There may be some departments that can be eliminated, such as the legal, insurance, catering, medical, or publicity departments, but in a company-wide quality culture all departments etc. will be included.

The way many companies identify resource requirements is to solicit resource budgets from each department covering a 1 to 5 year period. However, before the managers can prepare budgets they need to know what requirements they will have to meet. They will need access to the corporate plans, sales forecasts, new product development plans, marketing plans, production plans, etc. as well as the quality policies, objectives, and procedures.

The standard does not require the resource requirements to be documented or that documented procedures be established and maintained for resource management, or that records of resource utilization be kept. However, without such documentation it will be difficult to demonstrate that you have allocated adequate resources to implement your quality system. While neither clause 4.1.2.2 nor 4.1.4 on *Business plans* require resource plans to be documented, problems may arise if you rely on verbal communication. By documenting your resource plans you would be taking the necessary steps to deal with problems requiring preventive action, as indicated in clause 4.14.2.1(b). Therefore a business plan and a business planning procedure does serve to prevent problems that will have significant impact on the business.

A practical way of ensuring that you have adequate resources to implement the quality system is to assign cost codes to each category of work and include the management and verification activities among these. Quality system management activities are often deemed as an overhead, but the costs may be difficult to identify among all the other overheads. Unless you can identify what you spent on internal audits, for instance, how can you allocate sufficient resources for future programs? Allocating and collecting costs does not inhibit you from moving resources around to resolve immediate problems and

gives you more effective control of the business. Providing a means for staff to charge their time is often a practical way of overcoming resistance to the policies and procedures².

It is quite normal to provide sufficient resources to produce product. However, when it comes to verifying that you have done what you say you will do, there is a tendency to underestimate or to cut verification resources when costs escalate. These cuts are often seen as a risk worth taking. Another common weakness is defining requirements that are desirable rather than essential and then not verifying that they have been implemented. Being able to demonstrate provision of adequate verification resources is another sign of commitment to quality (see *Defining commitment to quality* above).

Assigning trained personnel (4.1.2.2.1)

The standard requires that *trained personnel be assigned for management, performance of work, and verification activities including internal quality audits.*

Training is covered by section 4.18 of the standard where it requires the training of all personnel performing activities affecting quality. However, the clause on resources gives a certain perspective to the identity of these personnel. They have to include management and verification personnel including internal auditors (further clarification is given in section 18 of ISO 9004-1). You are free to determine the training necessary for such personnel but it should be commensurate with the level of responsibility, the complexity of the task, and the experience and qualifications of the person.

It should be recognized that there is no requirement for auditors to be trained as Lead Assessors or Registered Internal Quality Auditors. Staff need only to be trained sufficient to carry out the task given to them.

Shift resources (4.1.2.2.2)

The standard requires that *all shifts be sufficiently staffed with personnel in charge of or delegated responsibility for quality.*

You cannot assume that if the process is stable at the end of the day shift it will remain so throughout the night shift. Tools may wear out or break, the process may go out of control, materials may need to be replenished, etc. All of these require decisions. The reason for this requirement is so that there are staff on each shift who are authorized to:

² Further details are provided in the *ISO 9000 Quality System Development Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

- Make process acceptance decisions.
- Make machine set-up decisions.
- Make product acceptance decisions.
- Stop production in the event of an out-of-control situation developing.
- Change the sampling criteria in the event of an out-of-control situation developing.

Management representative (4.1.2.3)

The standard requires that *the supplier's management with executive responsibility appoints a member of its own management with responsibility for ensuring that quality system requirements are established, implemented, and maintained in accordance with ISO 9001, and for reporting on the performance of the quality system to management for review and as a basis for improvement of the quality system.*

The requirements of ISO 9001 do not apply solely to one department. As everyone in some way contributes to the quality of the products and services provided by the supplier, everyone shares the responsibility for the quality of these products and services. Every manager within an organization makes a unique contribution towards the organization's purpose and mission. The achievement of quality, however, is everyone's job but only in so far as each person is responsible for the quality of what they do. You cannot hold each person accountable for ensuring that the requirements of ISO 9001 are implemented and maintained, as the requirements apply to the organization as a whole and not to any specific individual. It is a trait of human nature that there has to be a leader for an organization to meet an objective. It does not do it by itself or by collective responsibility – someone has to lead; hence the purpose of this requirement.

Employee or contractor

In the standard the term management representative appears only in the title of the requirement. The emphasis has been put on management appointing a member of its own management, indicating that the person should have a managerial appointment in the organization. This implies that the role cannot be filled by a contractor or external consultant. It also implies that the person should already hold a managerial position and be on the payroll. However, it is doubtful that the intention is to exclude a person from being promoted into a managerial position as a result of a person being available for the appointment or in fact preclude the authority of the management representative being delegated to a contractor, providing responsibility for the tasks is retained within the company.

Figurehead or practitioner

There is a note in clause 4.1.2.3 of ISO 9001 which states: *The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.*

Logically, a representative carries the wishes of the people they represent to a place where decisions are taken that affect them – this is the case for Members of Parliament, Union Representatives, Committee Members, etc. The “note” would appear to address the need for representation outside the business. Inside the business, the representative represents management to the workforce but not in the same sense. The person carries the wishes of management (i.e. the policies) to the workforce so that the workforce makes decisions that take into account the wishes of management.

There are, however, two schools of thought. One is that the management representative is a figurehead rather than a practitioner and is a role established solely to meet ISO 9000. Hence the CEO would either take on the role or would appoint one of the executive directors as the management representative in addition to his/her regular job, the role being to satisfy themselves that a quality system is being established, implemented, and maintained. Such a person may not necessarily employ the resources to do this. These resources would be dispersed throughout the organization. While the system is being developed, a project manager is assigned to coordinate resources and direct the project towards its completion. After the system is fully operational, a quality system manager takes over to maintain and improve the system, who with a small staff manages the audit and improvement programs.

The other school of thought views the management representative as a practitioner and not a figurehead. Here you would appoint a senior manager as a quality director and assign him/her the role of management representative. This director takes on the role of project manager during the development phase and quality system manager during the maintenance and improvement phase. He/she acts as the management representative with the customer and registrar and in effect is the eyes of the customer inside the organization. Depending on the size and complexity of the organization, there may be one person doing all of these jobs. In some cases a fairly large team of engineers, auditors, analysts, statisticians, etc. may be appropriate.

If you have one quality system, the roles of management representative and quality director become difficult to separate and can cause a conflict of interest unless the management representative is the CEO. In large organizations with multiple sites, each with separate ISO 9000 registrations, a more appropriate solution is to have a management representative for each site and one quality director for the whole organization.

As with all assignments of responsibility one has firstly to define the actions and decisions for which the person is to be responsible, ensuring no conflict with others and then ensuring that you give a person the necessary authority to control the results for which they are responsible.

Responsibilities and authority of the management representative

Primarily, the designated person is the system designer for the quality system. This person may not produce the policies and procedures but operate as a system designer. He/she lays down the requirements needed to implement the corporate quality policy and verifies that they are being achieved. It is also necessary to have someone who can liaise with customers on quality issues, who can coordinate the assessment and subsequent surveillance visits, who can keep abreast of the state of the art in quality management. The person should be an adviser to the top management who can measure the overall performance of the company with respect to quality.

The role

To ensure the quality system is established, implemented, and maintained and report on quality system performance the management representative, whether he/she is an executive director or a department manager, needs the right to:

- Manage the design, development, implementation, and evaluation of the quality system including the necessary resources (the managerial role)
- Determine whether proposed policies and practices meet the requirements of the standard, are suitable for meeting the business needs, are being properly implemented, and cause noncompliances to be corrected (the regulatory role)
- Determine the effectiveness of the quality system (the analysis role)
- Report on the quality performance of the organization (the scorekeeper role)
- Identify opportunities for improvement in the quality system (the innovative role)
- Cause beneficial changes in quality performance (the leadership role)
- Liaise with external bodies on quality matters (the role of ambassador)

Organizational interfaces (4.1.2.4)

The standard requires *systems to be in place to ensure management of appropriate activities during concept development, prototype, and production according to customer advanced product quality planning and control plan manual or project management manual.*

What this requirement implies is that the organization has to set up product-oriented teams comprising staff from each of the disciplines that will be involved. These teams should be formed during the conceptual phase of product development and operate throughout the development and production phases. What is required is *project management* through development and *product management* through production.

The standard requires *a system in place*, but what would constitute such a system? The organization maintains its line and staff departments and allocates staff to each product. Where the products of the organization cover several ranges it is often practical to divide the staff into divisions, each equipped with its own set of disciplines. Such a system would include:

- Policies that govern the allocation of work to the divisions
- Policies that govern the allocation of work to staff in these divisions
- Job descriptions for each role stating responsibilities, authority, and accountability
- Procedures that identify the roles responsible for each task and for ensuring that information is conveyed to and from these staff at the appropriate time
- Procedures that consolidate information from several disciplines for transmission to the customer when required
- Monitoring procedures to track progress and performance
- Procedures that ensure the participation of all parties in decisions affecting the product and its development and production
- Procedures for setting priorities and securing commitment
- Procedures that include the management of subcontractor programs during development and deal with the transmission of information to and from the subcontractors, what is to be transmitted, by whom, in what form, and with whose approval

Multidisciplinary approach for decision making (4.1.2.4)

The standard requires suppliers to *use a multidisciplinary approach for decision making and have the ability to communicate necessary information in a language used by the customer.*

If you have adopted use of either the APQP manual or Project Management Manual, then you will have formed multidisciplinary teams that are dedicated to a particular project and who make decisions associated with that project. If you have appointed customer representatives as defined in clause 4.1.2.1.2, you will have put in place the means by which effective communication with the customer can take place. There are, however, two additional requirements. The first is for the team to make project decisions. Hence, once the contract has been accepted and resources allocated, the project team should have the authority to decide how and when those resources are utilized. The second requirement is for the team to communicate with the customer in a language used by the customer. This may require at least one person on the team being fluent in the customer's native language. During product design there will be a lot of liaison with the customer and therefore it may be more effective if all project documents are in the customer's native language so that the expense of translation is avoided and only incurred when more resources are brought in during the prototype phase.

Management review (4.1.3)

Purpose of review (4.1.3.1 and 4.2.8)

The standard requires that *the quality system be reviewed at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of ISO 9001 and the supplier's stated quality policy and objectives.* There is also a supplementary requirement in clause 4.2.8 for *the performance of the system to be evaluated to verify the effectiveness of its operation.*

Although termed a management review the requirement is strictly referring to a review of the quality system and not the Corporate Plan.

A review is another view of something. There is a need for the supplier's management with executive responsibility, as the sponsors of the system, to look again at the data the system generates and determine whether the system they installed is actually doing the job they wanted it to do. These are big issues and most of the time management only wants to be told of the exceptions. One of the reasons that the management review may not work is when it is considered something separate to management's job, separate to running the business, a chore to be carried out just to satisfy the standard. This is par-

tially due to perceptions about quality (see Part 1 Chapter 2). If managers perceive quality to be about the big issues, like new product or service development, major investment programs for improving plant, for installing computerization, etc., the management review will take on a new meaning. If on the other hand it looks only at audit results it will not attract a great deal of attention, unless of course the audits also include the big issues.

The requirement for the review to ensure that the quality system satisfies the quality policy and objectives emphasizes that compliance with ISO 9001 alone is insufficient and that the system has to meet business needs as well. However, the effectiveness of the system is dependent upon what you defined as its purpose. If the purpose of the system is merely to ensure customers are supplied with products and services which meet their requirements, its effectiveness is judged by how well it does this and not how much it costs to do it. However, ISO/TS 16949 goes beyond this as it requires continuous improvement in quality, cost, technology, and process performance. This implies you develop a quality system with the purpose of minimizing waste, improving efficiency, reducing operating costs, etc. Hence the effectiveness of an ISO/TS 16949 quality system will be judged by how well it does these things. The standard does not simply require the system to be effective. It requires the system to be effective in satisfying the requirements of the standard and your stated policies and objectives. This is measurable, whereas the former statement is not. (See also Part 1 Chapter 2 for a means of measuring system effectiveness.) The supplementary requirement in clause 4.2.8 adds little to the original ISO 9001 requirement, as effectiveness of operation is determined by the extent to which the system enables implementation of the quality policy and achievement of the quality objectives.

Although there is no requirement for you to have a documented procedure for management review, you need to ensure that certain information is brought before the review and the review produces certain results. As you are going to conduct these reviews frequently you may want to ensure they follow a repeatable process and an obvious way to achieve this is through a documented procedure.

Scope of review

Elements of the system

There are three references to the management review in other sections of the standard: preventive action information (clause 4.14.3), internal audit results (clause 4.17.1), and changes to procedures (clause 4.14.1.1) are required to be submitted for management review.

Clause 4.1.3.1 requires the quality system to be reviewed. However, there are only two other references in the standard that hint at what should be covered in such a review. There is a note in clause 4.17.1 suggesting that audit results form an integral part of the input to management review. There is a requirement in clause 4.14.3(d) for information on (preventive) actions taken to be submitted for management review. These two statements led the authors of ISO/TS 16949 to add a supplementary requirement pointing out that the review shall include all elements of the quality system and its performance. Its inclusion appears as a result of an ambiguity arising out of there being only two cross references to input data for management review in ISO 9001.

Components of the system

The elements of the system can be construed to be the 20 elements of ISO 9001. The components of the system are different. ISO 8402 states that a quality system is the organizational structure, procedures, processes, and resources for implementing quality management. It therefore follows that in reviewing the quality system one needs to review each of these aspects.

Monitoring strategic objectives and quality costs

There is also a supplementary requirement in clause 4.1.3.2 for the management review to include *the monitoring of strategic quality objectives and the regular reporting and evaluation of the cost of poor quality*.

After expressing your quality objectives in measurable terms you need to put in place procedures for collecting performance data that can be used to show whether these objectives are being achieved. By including objectives for reducing quality costs and again collecting relevant data, you will also be able to report regularly on the cost of poor quality.

Quality costs are the costs incurred because failure is possible. These costs comprise three types:

- Prevention costs – cost incurred in preventing failure, such as planning, training, FMEA, FTA, SPC, MSA
- Appraisal costs – cost incurred in detecting failures, such as reviews, assessments, inspections, audits, tests including test and diagnostic equipment
- Failure costs – costs incurred in recovering from failure, such as rework, repair, modification, warranty claims

Although the costs of poor quality are specifically required, a more accurate presentation of trends is provided when prevention, appraisal, and failure costs are reported together.

A more comprehensive treatment is given in ISO/TR 10014:1998 *Guidelines for managing the economics of quality*.

Meeting or activity

The management review is not a meeting. Management review is an activity aimed at assessing information on the performance of the quality system. When you have a real understanding of the intentions of the review you will realize that its objectives cannot be accomplished entirely by a meeting. The review should be in three stages. Stage one is collecting and analyzing the data, stage two is reviewing the data, and stage three is meeting to discuss the results and decide on a course of action. A typical review process flow is illustrated in Figure 1.3.

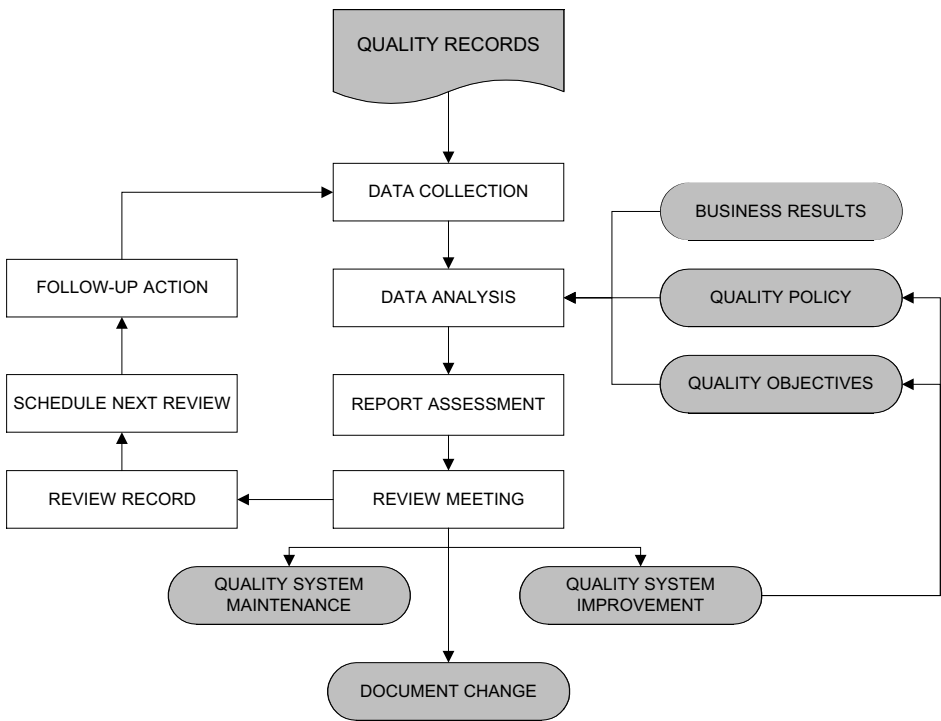


Figure 1.3 Management review process flow

The management review should do several things:

- Establish whether the system is being used properly.

You can determine this by providing the results of all quality audits of the system, of processes, and of products.

- Establish whether the audit program is effective.

You can do this by providing the evidence of previous audit results and problems reported by other means.

- Establish whether customer needs are being satisfied.

You can determine this by providing the evidence of customer complaints, market share statistics, competitor statistics, warranty claims, customer satisfaction surveys, etc.

- Establish whether the defined quality objectives are being met.

Analysis of the data the system generates should reveal whether the targets are being achieved.

- Establish whether there is conflict between the stated quality policy, the quality objectives, and the organizational goals and expectations and needs of your customers.

- Establish whether the quality philosophy is being honored.

An analysis of managerial decisions should reveal whether there is constancy of purpose or lip service being given to the policy.

- Establish whether the system requires any change to match changing business needs.

You can do this by assessing the proposed changes in business against the known capability of the system.

- Establish whether the system provides useful data with which to manage the business.

This can be done by providing evidence showing how business decisions have been made. Those made without using available data from the quality system show either that poor data is being produced or management is unaware of its value.

The key questions to be answered are: “Is the system effective?” and “Is it suitable to continue without change?” At every meeting of the review team these questions should be answered and the response recorded.

What are defined intervals?

The periodicity of management reviews should be matched to the evidence that demonstrates the effectiveness of the system. Initially the reviews should be frequent, say monthly, until it is established that the system is effective. Thereafter the frequency of reviews can be modified. If performance has already reached a satisfactory level and no deterioration appears within the next three months, extend the period between reviews to six months. If no deterioration appears in six months extend the period to twelve months. It is unwise to go beyond twelve months without a review as something is bound to change that will affect the system. Shortly after a reorganization (the launch of a new product/service, breaking into a new market, securing new customers, etc.), a review should be held to establish if performance has changed. After new technology is planned, a review should be held before and afterwards to measure the effects of the change. Your procedures need to state the criteria for scheduling the reviews. Don't set them at a specific period, other than a maximum interval, as it limits your flexibility. You can define the interval between reviews in the minutes of the review meeting, thereby giving you the flexibility to change the frequency when desirable.

Maintaining records of management reviews (4.1.3.1 and 4.2.8)

There are two requirements addressing records of the management review which when combined require firstly that *records of management review be maintained* and secondly that *these records provide as a minimum evidence of the achievement of objectives specified in the quality policy and the business plan and evidence of customer satisfaction with product supplied*.

The supplementary requirements provide a welcome addition to this somewhat inadequately specified clause of ISO 9001. However the reference to clause 4.1.1.2 with respect to objectives specified in the quality policy is somewhat ambiguous. Clause 4.1.1.2 does not require objectives to be included in the policy; this is required in clause 4.1.1.1. As stated previously, system effectiveness is judged by how well the system enables implementation of policy and achievement of objectives. Therefore, requiring records that contain evidence of this is a logical interpretation. Such records need to identify the matters reviewed, the results, the actions, and the decisions taken, together with the names of those responsible and the date by which actions are to be completed. The records should also contain the data used to conduct the review as the basis upon which the decisions have been made and so that comparisons can be made at later

reviews when determining progress. Finally, the records should declare the extent to which the quality system is meeting its objectives and is effective in maintaining control of quality.

Business plans (4.1.4)

The standard requires that *a formal, documented, comprehensive business plan be utilized* and lists several aspects that should be included.

While the plan itself is not auditable by third parties, it may be auditable by second parties: i.e. customers. The third party or registrar is entitled to examine the plan to ascertain that it is what it proclaims to be. The particulars are of no concern except those aspects relating to quality, such as the resources, quality objectives, customer satisfaction plans, and performance metrics. Whatever is stated on these aspects, the auditors will expect to see evidence that the business plan is not merely a “wish list” and that provisions have been made to enable implementation through the quality system.

It should be noted that the business plan is a document that relates to the requirements of the standard and therefore should be under document control (although your controls may be different to those used for controlling other types of documents).

Time-scale of plans

The standard requires that *goals and plans cover short-term and longer term and be based on analysis of competitive products and on benchmarking inside and outside the automotive industry and the supplier's commodity.*

The requirement for goals seems misplaced as goals are also addressed under quality objectives. Plans however, should contain provisions made to accomplish goals. Including the goals in the plan would therefore be appropriate but basing the plan as well as the goals on an analysis of competitive products and on benchmarking does seem illogical. It would appear that what is intended is that the goals be based on *competitive products and on benchmarking* and a plan be produced that defines the provisions made to meet these goals. It is quite common to produce separate business plans of the following types:

- Annual business plan
- Three-year business plan
- Five-year plus business plan

There are many books³ and organizations you can turn to for advice on benchmarking. With benchmarking you analyze your current position, find an organization that is performing measurably better and learn from them what they are doing that gives them the competitive edge. You then change your processes as a result of what you learn and implement the changes.

Determination of customer expectations

The standard requires *methods to be in place to determine current and future customer expectations*.

Putting methods in place

The most significant aspect of this requirement is that it extends the quality system beyond the processes required to satisfy current customers and clearly brings the marketing process into the quality system. The marketing process is primarily concerned with finding out what customers want and attracting them to the organization that can satisfy those wants. However, this requirement does not require every aspect of marketing be brought within the system. The aspect of marketing that deals with determining current and future customer needs is market research. Therefore the methods and processes used to conduct market research need to be defined and documented and brought under control.

Using an objective and valid process

The standard requires that *an objective and valid process is used to define the scope and collection of information on current and future customer expectations at a defined frequency*.

Decisions affecting the future direction of the organization and its products and services are made from information gleaned through market research. Should this information be grossly inaccurate, over optimistic or pessimistic the result may well be the loss of many customers to the competition. It is therefore vital that objective data is used to make these decisions. The data can be primary data (data collected for the first time during a market research study) or secondary data (previously collected data). However, you need to be cautious with secondary data, as it could be obsolete or have been collected on a different basis than needed for the present study.

³ Sylvia Codling, *Benchmarking* (Gower, 1998); M Zaire and P Leonard, *Practical Benchmarking, The Complete Guide* (Chapman & Hall)

The marketing information primarily identifies either *problems* or *opportunities*. *Problems* will relate to your existing products and services and should indicate why there has been a decline in sales or an increase in returns. In order to solve these problems a search for possible causes should be conducted and one valid method for doing this is to use the Cause and Effect Diagram. *Opportunities* will relate to future products and services and should indicate unsatisfied wants. There are three ways of collecting such data: by observation, survey, and experiment.

Observation studies are conducted by actually viewing the overt actions of the respondent. In the automotive industry this can either be carried out in the field or in the factories, where subcontractors can observe their customer using their materials or components.

Using surveys is the most widely used method for obtaining primary data. Asking questions that reveal their priorities, their preferences, their desires, their unsatisfied wants, etc. will provide the necessary information. Information on the profile of the ultimate customers with respect to location, occupation, life style, spending power, leisure pursuits, etc. will enable the size of market to be established. Asking questions about their supplier preferences and establishing what these suppliers provide that you don't provide is also necessary. Customers will expect more than they will require. Expectations are brought about by previous experiences. One is given a free sample with two inquiries and so one begins to expect free samples with every inquiry. Knowing what the customer will pay more for is also necessary, as many will expect features that were options to be provided as standard.

A method used to test the potential of new products is the *controlled experiment* – using prototypes, alpha models, etc. distributed to a sample of known users. Over a limited period these users try out the product and compile a report, which is returned to the company for analysis.

A source of secondary data can be automotive trade press reports and independent reviews. Reading the comments about other vehicles can give you some insight into the needs and expectations of potential customers.

For a more comprehensive treatment of market research the reader is advised to consult the many books available that will provide a range of methods for determining customer expectations.

Following the business plan

The standard requires *methods to track, update, revise, and review the business plan to ensure it is followed and communicated throughout the organization.*

A plan is more than a list of goals, a bar chart, or a schedule of activities. For the business plan to be effective it needs to define how the measures it covers are to be achieved and the resources to achieve them obtained. There may well be supplementary plans for this purpose. The plan or plans also need to define who is to be responsible for achieving the goals and implementing the plans. Once this is done and the provisions communicated to those affected, a method of tracking achievement can be put in place. To track performance effectively the implementation of the plan needs to be phased such that target dates are set for the determination and acquisition of resources, the issue of detail implementation plans, the organization of work, and the completion of individual tasks.

It is often the case in business that strategic plans remain unchanged even though circumstances may change and that business planning is an annual event rather than a continual event. ISO/TS 16949, however, does not permit this approach as it requires the plan to be updated, revised, and reviewed. Suppliers therefore need to schedule regular reviews of the plan and of the progress of its implementation. Most organizations will already perform monthly or quarterly business reviews so this requirement will not be onerous apart from updating and revising the plan. The terms *update* and *revise* may appear to be one and the same requirement. However, *updating* means keeping current so that it reflects current circumstances, whereas *revising* means changing for whatever reasons. Some reasons for revision may arise out of current circumstances, such as extending the scope of the plan, correcting errors, or refining objectives and goals as more accurate data emerges.

Communicating the plan throughout the organization requires careful thought. The standard does add the rider “as appropriate” so you do not have to send copies of the plan to everyone – only those who have a responsibility to implement it. Where staff are assigned responsibilities for implementing parts of the plan through other directives, they only need what is essential to their needs and no more. This does require, however, that should data be taken from the plan and conveyed to staff in another form – e.g. in a task directive – then you have to maintain control of the data so that, if as a result of the business planning review the data changes, the data in the task directives also needs to be changed. This is governed by clause 4.5.1 of the standard.

Analysis and use of company level data (4.1.5)

The standard requires *trends in quality, operational performance (productivity, costs of poor quality, efficiency, effectiveness) and current quality levels for key product and service features to be documented.*

This requirement is similar to that in clause 4.14.3 under *Preventive action* since the data collected for preventive action serves a similar purpose. In one case an analysis of company-level data serves to identify overall trends and predict potential failures that will affect achievement of the goals. In the preventive action case, the data serves to identify local and overall trends and predict potential failures that will affect achievement of specified requirements for the product, process, and quality system. It would be sensible to develop a data collection and analysis system that serves all levels in the organization, with criteria at each level for reporting data upwards as necessary. You should not treat this requirement separately from that for preventive action since the same data should be used. However, the explanation given in clause 4.1.5 of *Operational performance* does include some factors that may not be addressed in your preventive action procedures.

Productivity is addressed under *Continuous improvement* and in order to improve productivity you will need to collect data generally in the form of resource/part produced. Resource can be hours, costs, weight, or volume of material consumed. Graphs showing the productivity trend over time for plants, products, and processes would satisfy this requirement.

Costs of poor quality were addressed under *Management review* and in order to provide adequate data for review, the prevention, appraisal, and failure costs need to be collected. Graphs showing the trend in quality costs for the plants, products, and processes would satisfy this requirement.

Efficiency and effectiveness are broad terms that encompass the others. *Productivity* is a measure of efficiency and *quality costs* a measure of effectiveness, but there are others. Customer satisfaction is also a measure of effectiveness.

Quality levels are the result of a ratio of parts defective to parts produced. The current trend is to use parts per million (ppm) but this is not always practical for some processes. Painting processes for instance cannot achieve blemish-free surfaces in the order of one blemish per million parts painted!

A general plan of action would cover the following:

- 1 Identify the key parameters to be measured.

- 2 Locate where in the process they are achieved.
- 3 Install data collection method in relevant procedures.
- 4 Collect and analyze the data.
- 5 Use suitable presentation techniques to draw attention to the results.
- 6 Determine priorities.
- 7 Get management buy-in to action.

In collecting the data care should be taken to avoid data paralysis (see Part 2 Chapter 14). The various quality tools can be used to prioritize the identified problems and corresponding decisions. As with all data collection tasks, you should show a direct correlation between what you are collecting and the goals to be achieved and all conclusions should lead to positive action, otherwise the effort has been futile.

Employee motivation, empowerment, and satisfaction (4.1.6)

Employee motivation process (4.1.6)

The standard requires *a process for the motivation of employees to achieve quality objectives and make continuous improvements to be established.*

Everything achieved in or by an organization ultimately depends upon the activities of its workforce. It is therefore imperative that the organization is staffed by people who are motivated to achieve its goals. Everyone is motivated but not all are motivated to achieve their organization's goals. Many may be more interested in achieving their personal goals. Motivation is key to performance. The performance of a task is almost always a function of three factors: environment, ability, and motivation. To maximize performance of a task, personnel have not only to have the necessary ability to perform it but need to be in the right surroundings and have the motivation to perform it⁴. Motivation comes from within. Employees therefore cannot be altered at will by a manager, despite what they may well believe to be the case.

So what is motivation? It has been defined as an inner mental state that prompts a direction, intensity, and persistence in behavior⁵. It is therefore a driving force within an

⁴ V H Vroom, *Work and Motivation* (John Wiley, New York, 1964)

⁵ Rollinson, Broadfield, and Edwards, *Organizational Behaviour and Analysis* (Addison Wesley, 1998)

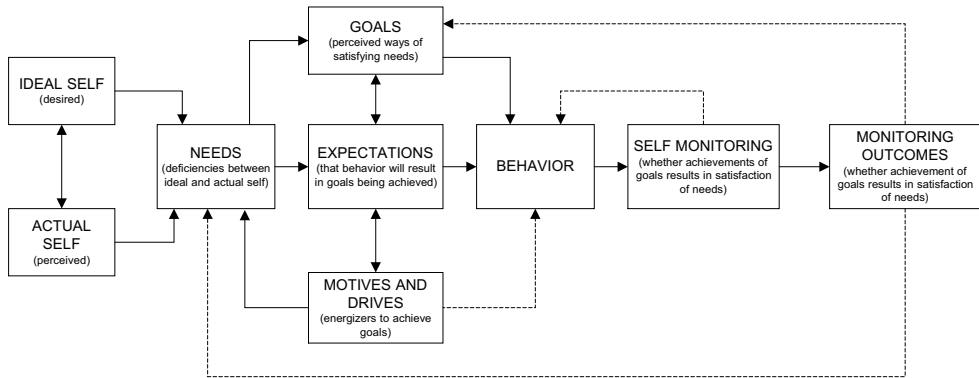


Figure 1.4 *Motivation process*

individual that prompts him/her to achieve some goal. There is a motivation process – not an organizational process but a process operating inside the individual. This process is illustrated in Figure 1.4.

From this diagram it will be observed that motivation comes from satisfying personal needs and expectations of work. Therefore the motivation to achieve quality objectives must be triggered by the expectation that achievement of objectives will lead to a reward that satisfies a need of some sort. This does not mean that you can motivate personnel solely by extrinsic rewards such as financial incentives. It requires a good understanding of an individual's pattern of needs. People desire psychological rewards from the work experience or like to feel a part of an organization or team. People can be motivated by having their efforts recognized and appreciated or included in discussions. However, this will only occur if the conditions they experience allow them to feel this way.

If a person knows which quality objectives need to be achieved and has the ability to achieve them, and the environment in which the work is to be performed provides the right conditions, the role of the manager in enabling the person to be motivated is that of removing barriers to work motivation. There are two types of barriers that cause the motivation process to break down. The first barrier is job-related; i.e. there is something about the job that prevents the person from being motivated. An example is boring and monotonous work in mass production assembly lines. The second barrier is goal related; that is, attainment of the goals is thwarted in some way, which results in frustration and a decline in the motivation to continue.

Common barriers are:

- Fear of failure, of reprisals, of rejection, of losing, of conflict, of humiliation, of exploitation

- Distrust of management, favoritism, discrimination
- Work is not challenging or interesting
- Little recognition, respect, reward
- No authority and responsibility

Empowerment is said to motivate employees as it offers a way of obtaining higher level of performance without the use of strict supervision. However, it is more theory and rhetoric than a reality. To *empower* employees, managers not only have to delegate authority but put at their disposal resources to use as they see fit and trust their employees to use the resources wisely. If you are going to empower your employees, remember that you must be willing to cede some of your authority but also, as you remain responsible for their performance, you must ensure your employees are able to handle their new authority. Employees not only have to be trained to perform tasks but need a certain degree of experience in order to make the right judgements. Some employees may acknowledge that they are willing to accept responsibility for certain decisions but beware, they may not be ready to be held accountable for the results when they go sour. It is also important that any changes arising from the empowering of employees to improve the process be undertaken under controlled conditions. However, empowerment does not mean that you should give these individuals the right to change policies or practices that affect others without due process.

Managers therefore need to understand and analyze human behavior rather than establish a process for motivating employees.

Quality awareness (4.1.6)

The standard requires *the employee motivation process to include promotion of quality awareness on all levels.*

As indicated above, the motivation process is not an organizational process; the intention is that personnel be made aware of quality and all aspects of its management. It would be better to call the process the *communication process* since that is all it can achieve. You can take a horse to water but you can't make it drink, so the saying goes. It is the same with people! Making them aware of the quality issues and how important they are to the business and consequently to themselves may not motivate certain individuals. The intention is to build an understanding of the collective advantages of adopting a certain style of behavior. It is therefore more important to modify behavior than promote awareness.

A good example is to look at what has happened with smoking in the USA. Once an expected behavior in all but places of worship, it has now been driven out of most public places by pressure from society. It has become, certainly in some states, unacceptable behavior of the worst kind. However, smokers have been aware of the dangers and unsociable effects for years but have not been motivated to change their behavior. Those that changed did so either because they were ostracized by their friends or acknowledged that they were damaging their health or they had no option as they realized their life was in immediate danger unless they stopped. Now these are rather drastic measures but if you can gain *commitment* to *quality* you may find this is sufficient to motivate people to achieve quality, to prevent errors, and to look continually for improvements.

Measuring employee satisfaction and understanding (4.1.6)

The standard requires *a process for measurement of employee satisfaction and employee understanding of appropriate quality objectives.*

Many companies carry out employee surveys in an attempt to establish their needs and expectations and whether they are being satisfied. It is a fact that unsatisfied employees may not perform at the optimum level and hence product quality may deteriorate. Like customer satisfaction surveys, employee satisfaction surveys are prone to bias. If the survey hits the employee's desk following a reprimand from a manager, the result is likely to be negatively biased. The results of employee satisfaction surveys are also often disbelieved by management. Management believe their decisions are always in their employees' best interests, whereas the employees may not believe what management says when management's track record has not been all that great. Employee satisfaction has less to do with product quality and more to do with relationships. However employee relationships can begin to adversely affect product quality if no action is taken.

By all means install a process for measuring employee satisfaction but design the survey with great care and treat the results with caution as they cannot be calibrated. A common method for measuring satisfaction is to ask questions that require respondents to check the appropriate box on a scale from "strongly agree" to "strongly disagree".

Measuring employee understanding of appropriate quality objectives is again a subjective process. Through the data analysis carried out to meet the requirements of clause 4.1.5 and 4.2.8 you will have produced metrics that indicate whether your quality objectives are being achieved. If they are being achieved you could either assume your employees understand the quality objectives or you could conclude that it doesn't matter. However, it does matter as the standard requires a measurement. Results alone are insufficient evidence. The results may have been achieved by pure chance and in six months' time your performance may have declined significantly. The only way to test

understanding is to check the decisions people make. This can be done with a questionnaire but is more effective if one checks decisions made in the workplace. Is their judgement in line with your objectives or do you have to repeatedly adjust their behavior?

For each quality objective you should have a plan that defines the processes involved in its achievement. Assess these processes and determine where critical decisions are made and who is assigned to make them. Audit the decisions and ascertain whether they were contrary to the objectives. A simple example is where you have an objective of decreasing dependence upon inspection. By examining corrective actions taken to prevent recurrence of nonconformities you can detect whether a person decided to increase the level of inspection in order to catch the nonconformities or considered alternatives. Any person found making such a decision has clearly not understood the quality objective.

Impact on society (4.1.7)

Product safety (4.1.7.1)

The standard requires *product safety to be addressed in the supplier's design control and process control policies and practices with special attention to due care and means to minimize potential risks to employees, customers, users, and the environment.*

Product safety and environmental protection is already covered in design control because safety and environmental impact are two of many characteristics that products possess. Products have to meet legal requirements but not all countries do have safety and environmental legislation. This supplementary requirement therefore does indicate that risks have to be minimized regardless of there being safety legislation in the country of origin. Where this requirement departs from ISO 9001 is in extending the safety and environmental requirements to employees. In ISO 9001 only the effect on the product is given consideration under *Process control*, hence environmental cleanliness is important. There are good reasons for including this requirement in the standard. The commitments made by major automobile manufacturers to their customers cannot be met without an assurance of supplies of parts and materials from their suppliers. Integrity through the supply chain is vital. Customers cannot switch suppliers if one fails to deliver since it would be too disruptive to production. Although it may be possible to order competing parts if both parts can be supplied to different models of vehicles, the pressure to drive down costs and hence prices makes this almost out of the question except for high risk parts. Assurance of supply depends not only on product quality but on the supplier remaining in business and acting in a manner that does not compromise the customer.

The implications are that:

- The product has to be safe during use, storage, and disposal.

- The product has to present minimum risk to the environment during use and disposal.
- The materials used in manufacture of the product have to be safe during use, storage, and disposal.
- The materials used in manufacture of the product have to present minimum risk to the environment during use and disposal.

Safety and environmental policies need to be established and approved by executive management. Practices for implementing the policy need to be established, documented, implemented, and evaluated for continued suitability and effectiveness. These practices have to be planned, organized, and controlled so that they achieve their purpose.

Some of the topics your safety and environmental management practices should address are as follows:

- Methods for assessing the health and safety hazards and environmental effects present in your organization, its products, and its operations
- Safety and environmental objectives and targets based on the results of the safety and environmental assessment
- A program for achieving the safety and environmental objectives
- Methods for making staff aware of their safety and environmental responsibilities, the benefits of compliance, and the consequences of a failure to comply
- Methods for alerting staff to hazardous situations
- Methods for creating controlled conditions in which safety hazards and adverse environmental effects are a minimum
- Methods for dealing with accidents, incidents, and emergency situations, investigating their cause, and preventing recurrence
- Methods of measuring the achievement of safety and environmental objectives and targets

Instructions concerning safety and environmental issues should be integrated into the control and operating procedures such that the instructions are given at the stage in the process when they apply. In this way staff do not have to consult several documents and the chance of error is reduced.

Compliance with applicable regulations (4.1.7.2)

The standard requires a process to ensure compliance with all applicable government safety and environmental regulations including those concerning storage, handling, recycling, eliminating, or disposing of materials.

In addition to the methods developed to meet the product safety requirements of clause 4.1.7.1 you will need to provide the following to ensure compliance with applicable regulations:

- Methods for capturing the relevant safety and environmental regulations and ensuring you are kept up-to-date with revisions
- Methods for conveying the regulations through policies and practices to the point of implementation
- Methods for monitoring conformance with the policies and practices and for assessing the extent of compliance with the regulations
- Maintenance of records to demonstrate compliance with the prescribed regulations and effective operation of the management system

There are lots of regulations and no guarantees of finding them all. However, you can now search through libraries on the Internet and consult bureaus, trade associations, and government departments to discover those that apply to you. Ignorance of the law, they say, is no excuse. So here are a few consequences related to the automobile industry that you may rather avoid:

- A failure to observe government health and safety regulations could close a factory for a period.
- Health and safety hazards could result in injury or illness and place key personnel out of action for a period.
- Environmental claims made by the automakers to customers regarding conservation of natural resources, recycling, etc. may be compromised if environmental inspections of suppliers show disregard for such regulations.
- The unregulated discharge of waste gases, effluent, and solids may result in public concern in the local community and enforce closure of the plant by the authorities.
- A failure to take adequate personnel safety precautions may put product at risk.

- A failure to dispose of hazardous materials safely and observe fire precautions could put plant at risk.
- A failure to provide safe working conditions for personnel may result in public concern and local and national inquiries that may harm the reputation of the supplier.

The solution is to perform an FMEA on the product and the process and identify the critical products, processes, and regulations.

Task list

- 1 Define, agree, and publish your corporate quality policy.
- 2 Define, agree, and publish operational policies for meeting each of the requirements of the standard and publish them in a policy manual.
- 3 Define your quality objectives, document, and publish them in a business plan.
- 4 Initiate seminars and meetings to gain understanding of the policies and objectives.
- 5 Define management values.
- 6 Audit commitment and understanding of the policies and objectives periodically.
- 7 Establish customer needs and expectations and define organizational goals and record them in the business plan.
- 8 Establish a customer satisfaction determination process.
- 9 Conduct customer satisfaction surveys to detect whether the quality policy is being maintained.
- 10 Produce improvement plans for each quality objective.
- 11 Introduce a procedure for changing and deviating from the agreed policies.
- 12 Conduct periodic reviews of your policies and objectives.
- 13 Create, agree, and publish rules for the assignment of responsibilities and delegation of authority.
- 14 Produce, agree, and publish organization charts.

- 15 Produce, agree, and issue to those concerned job descriptions for each defined position.
- 16 Appoint customer representatives.
- 17 Ensure responsibilities are clearly understood and documented and clarify who is accountable for the resolution of quality problems.
- 18 Check that authority matches responsibility.
- 19 Produce, agree, and publish flow diagrams of the processes that contribute to the achievement of quality and identify the interfaces and responsibilities.
- 20 Produce and agree resource budgets for management, productive work, and verification activities.
- 21 Assign trained personnel to all tasks.
- 22 Create staff lists that indicate competency to perform tasks and use techniques within a job.
- 23 Create project management procedures (where applicable) that define interfaces with line departments, customers, and suppliers.
- 24 Appoint a management representative to manage the quality system and define, agree, and publish the responsibilities and authority.
- 25 Collect and analyze data on quality performance.
- 26 Conduct periodic reviews of the quality system using the collected data.
- 27 Carry out corrective actions to improve the effectiveness of the quality system.
- 28 Maintain records of the management reviews.
- 29 Prepare business plans for each aspect of the business where performance is critical to its success.
- 30 Carry out competitor analysis and benchmarking inside and outside the company.
- 31 Create procedures for determining customer expectations.
- 32 Create procedures for determining customer satisfaction.
- 33 Create procedures for developing and maintaining business plans.
- 34 Conduct employee surveys.
- 35 Train your managers in organizational behavior and analysis.

Management responsibility questionnaire

- 1 In what document is your corporate policy for quality and your commitment to quality defined?
- 2 In what document do you define your quality goals and objectives?
- 3 How do you ensure that the corporate quality policy is relevant to your organizational goals and the expectations and needs of your customers?
- 4 How do you ensure that your corporate policy for quality is understood at all levels in the organization?
- 5 How do you ensure that your corporate policy for quality is implemented at all levels in the organization?
- 6 How do you ensure that your corporate policy for quality is maintained at all levels in the organization?
- 7 In what document do you express your commitment to continuous improvement?
- 8 How do you identify opportunities for improvement in quality, cost, technology, and productivity?
- 9 In what documents do you define the responsibility and authority of personnel who manage, perform, and verify work affecting quality?
- 10 How do you ensure that, when needed, personnel have the organizational freedom to identify and record product, process, and quality system problems, provide solutions and initiate action to prevent the occurrence and recurrence of any nonconformities?
- 11 How do you ensure that those responsible for results have the organizational freedom necessary to control processing, delivery, or installation of product?
- 12 In what document do you define the interrelation of all personnel who manage, perform, and verify work affecting quality?
- 13 Whom have you appointed as your customer representatives and what responsibility and authority have you given them?
- 14 How do you identify resource requirements?
- 15 How do you ensure that adequate resources are provided?
- 16 How do you ensure that trained personnel are assigned for management, productive work, and verification activities?
- 17 Whom have you appointed to ensure that a quality system is established, implemented, and maintained?

- 18 How do you ensure your management representative remains a member of your own management?
- 19 In what document is the management representative's authority and responsibility defined?
- 20 What system is used for managing the concept development, prototype, and production phases?
- 21 Which functions participate in decision making for each product line?
- 22 How does your management ensure the continuing suitability and effectiveness of the quality system?
- 23 What information is used to determine the effectiveness of the quality system?
- 24 What evidence demonstrates that your quality system is suitable and effective in satisfying ISO/TS 16949 and your stated quality policy and objectives?
- 25 In what documents are the provisions defined that you have made to achieve your short-term and long-term goals?
- 26 How do you determine the current and future expectations of your customers?
- 27 How do you determine customer satisfaction and dissatisfaction and where is it recorded?
- 28 In what documents are trends in quality and operational performance recorded?
- 29 What measures are taken to provide conditions in which employees will feel motivated to achieve your quality objectives?
- 30 What measures are taken to minimize risks to customers, users, employees, and the environment from use, storage, and disposal of your product?
- 31 How do you ensure compliance with regulatory requirements that apply to your product?
- 32 What methods are used to communicate, track, review, update, and revise your business plans?

Do's and don'ts

- ⊗ Don't issue edicts or directives that violate the declared policies.
- ⊗ Don't write procedures that violate published policies.
- ⊗ Don't publish policies that your managers cannot or will not abide by.

- ⊗ Don't grant concessions without giving time limits and valid reasons.
- ⊗ Don't sign documents unless you have the necessary authority to do so.
- ⊗ Don't allocate funds for managing the quality system without providing a means of collecting the costs or time spent.
- ⊗ Don't let your management reviews degenerate into a talking shop.
- ⊗ Don't let the action list from the management review become a wish list!
- ⊗ Don't use customer procedures and forms within your processes. Translate customer requirements into your language and visa versa.
- ⊗ Don't allow process improvements to be made in isolation without assessing their impact on the system.
- ⊗ Don't collect and analyze data just because it is accessible. Only collect data that will lead to action to improve the product, process, or system
- ☺ Do ensure your staff know their responsibilities and what decisions they are permitted/not permitted to take.
- ☺ Do ensure the managers know their objectives and have plans to meet them.
- ☺ Do ensure signatures are legible and traceable to those with the necessary authority.
- ☺ Do ensure that job descriptions and procedures are compatible.
- ☺ Do ensure all your staff know where to find the quality policies.
- ☺ Do ensure everyone knows the source of their requirements.
- ☺ Do ensure that everyone knows what to do if they can't meet the requirements.
- ☺ Do ensure there is no conflict between the responsibilities and authority of different managers.
- ☺ Do ensure staff know who has the right to stop the process.
- ☺ Do ensure you have sufficient resources to carry through your plans.
- ☺ Do give your management representative the authority to get things done.
- ☺ Do keep the management reviews separate from other meetings.
- ☺ Do drive out fear so that employees are not deterred from offering suggestions for change.
- ☺ Do encourage staff to identify improvements in products, processes and organizational structures.
- ☺ Do remove barriers to communication and to effective and efficient working.

Chapter 2

Quality system

Scope of requirements

Although there are only two basic requirements in ISO/TS 16949 for the establishment and maintenance of a quality system, they are perhaps the most important requirements of all. The quality system is a tool to enable you to achieve, sustain, and improve quality. It implements your quality policy and enables you to achieve your quality objectives either for control or for improvement. Quality systems, like any other system, need to be managed and so quality system management is a function of the business. This function consists of four principal processes:

- Quality system design and development, addressed by clauses 4.2.1 and 4.2.2
- Quality system implementation, addressed by clauses 4.2.2 and 4.18
- Quality system evaluation, addressed by clauses 4.1.3 and 4.17
- Quality system maintenance, addressed by clauses 4.2.1, 4.5, and 4.16

These elements of ISO/TS 16949 are linked together as shown in Figure 2.1. In the figure, document control and management are functions common to other elements of the business, and the education and training process is shown separately as it operates in both the implementation and the design phase.

The standard does not require you to demonstrate that you meet all the requirements of the standard. It only requires a quality system to be documented, implemented, and maintained. While clause 4.16 on quality records does in fact require you to demonstrate the effective operation of the quality system, it does not dictate how you should

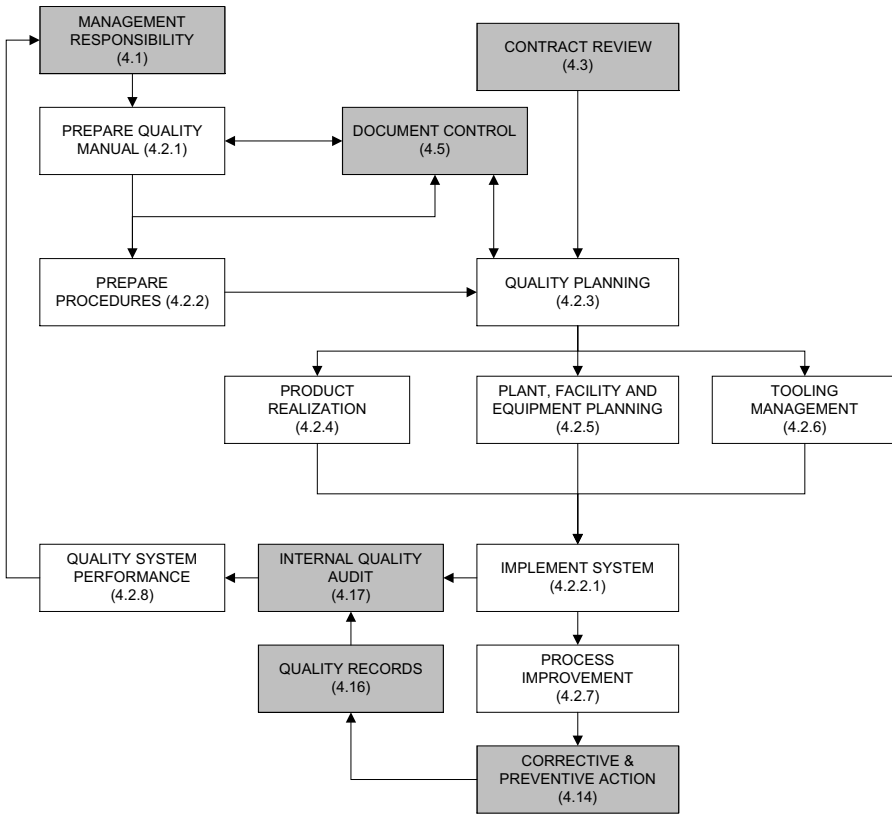


Figure 2.1 Clause relationships with quality system element

do this. As the purpose of the system is to ensure that product conforms to specified requirements, an unblemished record of zero customer complaints and a healthy order book would appear to indicate that your quality system is effective.

In the *Introduction* to ISO 9001 it states that the quality assurance models represent three distinct forms of quality system suitable for the purpose of a supplier demonstrating its capability and for the assessment of such capability by external parties. In other words, the standard is suitable for contractual as well as for assessment purposes, but it does not actually require demonstration of capability to the assessor or purchaser unless required by the contract.

Establishing a documented quality system (4.2.1)

The standard requires suppliers to *establish and document a quality system as a means of ensuring that product conforms to specified requirements*.

To *establish* means to set up on a permanent basis, and the requirement therefore emphasizes that the quality system should form part of the infrastructure of the organization.

This requirement clearly defines the purpose of a quality system, that of ensuring that products conform to specified requirements. One of the principal differences between ISO 9000 and ISO/TS 16949 is the emphasis placed on internal efficiency and effectiveness. Implementing the requirements of ISO/TS 16949 will cause the waste, errors, and internal costs to be minimized. Unlike ISO 9001, ISO/TS 16949 requires the system to enable the organization to implement its quality policy and achieve its quality objectives, which after all is its purpose. This fundamental shift in concept is also behind the changes being made to ISO 9000 in the year 2000 edition.

One of the first decisions to take should be to define the purpose of the quality system, what you want it to do, why you want to create it. Your reasons for creating a documented quality system may be to:

- Ensure products and services satisfy customer requirements
- Maintain the standards which you have been successful in achieving
- Improve standards in those areas where performance is lacking
- Harmonize policies and practices across all departments
- Improve efficiency
- Create stability and minimize variance
- Eliminate complexity and reduce processing time
- Benchmark current performance
- Focus attention on quality
- Ensure products and services are delivered on time
- Reduce operating costs

These are only some of the reasons for creating a quality system. Whatever your reasons are, define and document them and review them frequently. When you evaluate the system these reasons will help determine whether your system is effective (see Part 2 Chapter 17).

A system is an ordered set of ideas, principles, and theories or a chain of operations that produces specific results; to be a chain of operations, the operations need to work together in a regular relationship. A quality system is not a random collection of procedures (which many quality systems are) and therefore quality systems, like air conditioning systems, need to be designed. All the components need to fit together, the inputs and outputs need to be connected, sensors need to feed information to processes which cause changes in performance and all parts need to work together to achieve a common purpose: i.e. to ensure that products conform to specified requirements. You may in fact already have a kind of quality system in place. You may have rules and methods which your staff follow in order to ensure product conforms to customer requirements, but they may not be documented. Even if some are documented, unless they reflect a chain of operations that produces consistent results, they cannot be considered to be a system.

Many suppliers will already have methods in place that cover many of the requirements of ISO/TS 16949. What they may not have done, however, is to integrate these methods into a system that will cause conformity and prevent nonconformity. The ISO 8402 definition of a quality system makes it clear that a quality system is not just a set of procedures. It is the organization structure, processes, and resources to manage the achievement, control, and improvement of quality.

Preparing the quality manual (4.2.1)

The standard requires the supplier to *prepare a quality manual covering the requirements of the standard* and also requires *the quality manual to include or make reference to the quality system procedures and outline the structure of the documentation used in the system.*

The structure of the quality manual

If we look at ISO 10013, which is referenced for guidance in preparing a quality manual, we will see that it shows that the quality manual is a top-level document containing the stated quality policy, the quality objectives, and a description of the quality system (see Figure 2.2). The definition in ISO 8402 supports this concept and the requirement aligns with this definition. However, ISO 8402, ISO 10013, and the above requirement from ISO 9001 provide a choice as to whether the manual contains or refers to procedures.

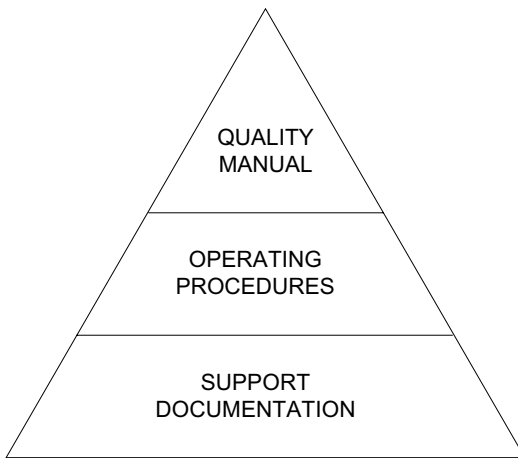


Figure 2.2 Levels of quality system documentation

For a quality manual to be a “manual” it should contain the procedures and instructions, as does a computer manual or a car maintenance manual, so whether one volume of the manual contains or refers to other documents does not prevent the collection of documents being referred to as the *quality manual*. Manuals tend to include operating instructions, hence the word *manual*. The quality manual should therefore contain all the policies and practices but not necessarily in one volume.

Some organizations divide their quality system documentation into three levels: a quality manual, a set of operating procedures, and the support documentation.

The problem with this approach is that the term *supporting documentation* fails to convey what might be included. In many cases the supporting documentation has been limited to the work instructions but in reality there are many different types of documents that are needed to produce quality products (see Part 2 Chapter 5).

Figure 2.3 shows the model given in ISO/TS 16949 but it does possess some anomalies. The quality manual is shown at the top of the pyramid but the manual can be a collection of documents, not a type of document. The ISO 8402 definition of a quality manual is that it is a document stating the quality policy and describing the quality system of an organization. Clearly the description of the quality system is not complete unless it includes Levels 1, 2, and 3. Only high-level responsibilities will be defined in the quality manual but most of the responsibilities will be defined in the *procedures*. The quality manual should define more than an approach. It should define the operational policies for implementing the requirements of the standard and hence for achieving the quality

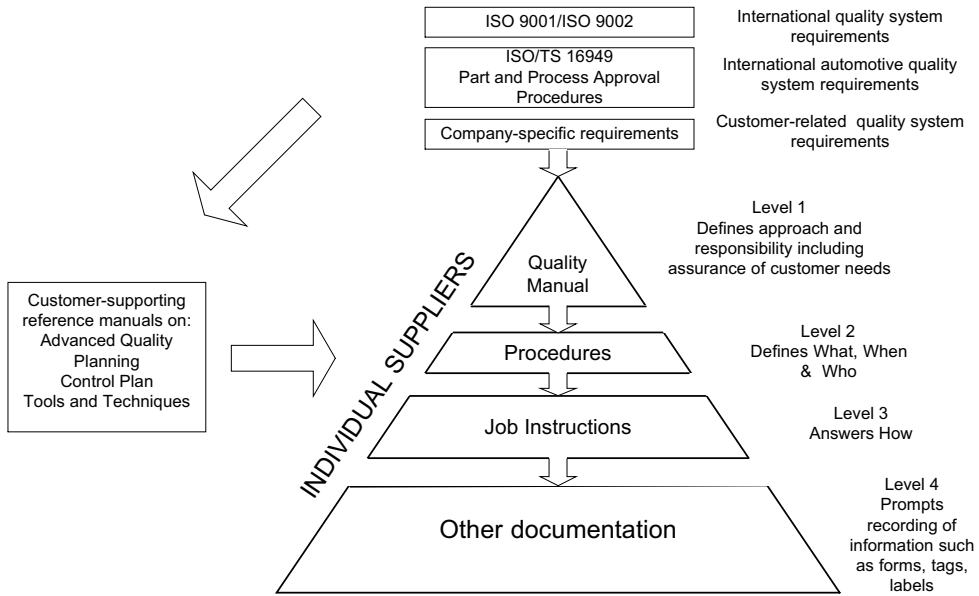


Figure 2.3 Quality system documentation progression

objectives. Company-specific requirements are not those of suppliers but of specific automakers such as Ford, BMW, Fiat, etc. and hence should be customer-specific requirements as indicated to the right of the diagram.

The reference manuals to the right of the diagram indicate these are *supporting* and not *governing* documents and that they impact all documentation levels.

It is unclear where supplier specifications, drawings, and other engineering documents sit in the progression as they will be produced by implementing policies and practices at Levels 1, 2, and 3, but they are clearly not Level 4 documents as they don't prompt recording of information and are not records themselves. Specifications, plans, drawings, etc. are not *job instructions* but may be referred to within job instructions. Hence the diagram lacks clarity but it is difficult to show the engineering documents in such a progression. The issue becomes clearer when we move away from triangles, as illustrated in Figure 5.1 in Part 2 Chapter 5. An alternative pyramid is shown in Figure 2.4, identifying more clearly the specific types of documents.

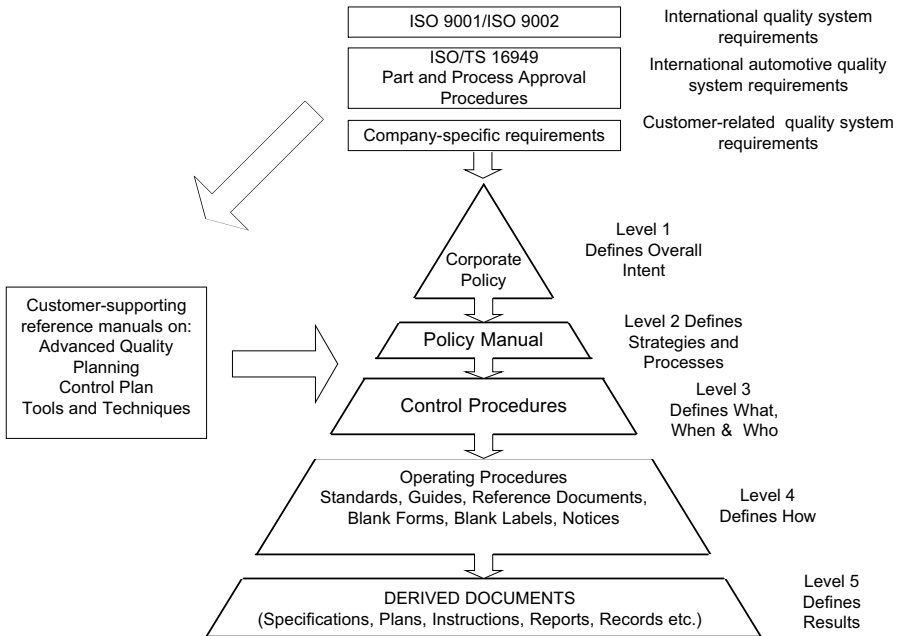


Figure 2.4 *Alternative documentation progression*

The 1987 version of ISO 9001 required the quality policy and the quality system procedures and instructions to be documented, clearly identifying three levels of documents; in practice, organizations produced an intermediate level between the quality policy statement and the procedures which addressed the requirements of the standard and cross-referenced the associated procedures. This intermediate level together with the quality policy statement was often referred to as the *quality manual*. However, some manuals merely paraphrased the requirements of the standard, some described the quality system, and others confined the manual to the organization's operational policies. The guidance given in clause 5.3.1 of ISO 9004-1 suggests that the quality system documentation consists of policies and procedures. Clearly these policies are of a somewhat lower level than the corporate quality policy addressed in Part 2 Chapter 1.

There is no requirement for you to state the policies to meet each clause of the standard but many organizations in fact do just this. ISO 9001 requires the manual to cover the requirements of the standard and ISO 10013 gives an example of how this may be done. ISO 10013, however, points you in the direction of producing a quality manual which is structured in the sequence of the key elements of the standard rather than the operations of your business. This is fine for third party auditors but not for your staff, who will probably want to know your policy on some aspect of your operations in order to make a certain decision. This is where you need operational quality policies organized around the operations of the business – such an approach is deemed acceptable in ISO 10013.

It would be sensible to document your quality policies separately from your quality objectives and keep these separate from the other quality system documentation. A solution is to have:

- A Policy Manual containing the corporate and operational quality policies
- A Quality Improvement Plan containing the quality objectives and plans to achieve them (see Part 2 Chapter 1)
- An Exposition containing a description of the system
- A Procedures Manual containing the documented procedures

The reason for an Exposition is so that there is a description of the system showing how it works and how it controls the achievement of quality. This is different from the policies and procedures. The policies are a guide to action and decision and as such are prescriptive. The procedures are the methods to be used to carry out certain tasks and as such are task related. They need to be relatively simple and concise. A car maintenance manual, for example, tells you how to maintain the car but not how the car works. Some requirements, such as those on traceability and identification, cannot be implemented by specific procedures although you can have specific policies covering such topics. There is no sequence of tasks you can perform to achieve traceability and identification. These requirements tend to be implemented as elements of many procedures which when taken as a whole achieve the traceability and identification requirements. In order that you can demonstrate achievement of such requirements and educate your staff, a description of the system rather than a separate procedure would be an advantage. The Exposition can be structured around the requirements of ISO/TS 16949 and other governing standards¹. It is a guide or reference document and not auditable.

¹ A specimen Exposition is included in the *ISO 9000 Quality System Development Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

Contents of the quality manual

The quality manual will typically include the following sections:

- Introduction, covering purpose, scope, applicability, and definitions
- Business overview, describing the nature of the business (not required but extremely useful)
- Corporate policy, covering the mission, vision, values, objectives, and quality policy
- Operational management, covering planning, organization, and management control including quality system management, audits, reviews, and improvement
- Operational policies, structured to align with the sequence of key processes from receipt of customer inquiry through to delivery and after-sales support, referencing the implementing control procedures
- Cross-reference matrix between manual and ISO/TS 16949

Operational policies

Any statement made by management at any level which is designed to constrain the actions and decisions of those it affects is a *policy*. Policies serve to guide the actions and decisions required to achieve objectives and are not therefore objectives in themselves. Policies set boundary conditions so that actions and decisions are channeled along a particular path in pursuit of an objective. Many see policies as requirements to be met – they are requirements but only in so far as an enabling mechanism. Policies enable management to operate without constant intervention and once established enable others to work within a framework without seeking decisions or guidance from above.

Staff do not work to policies but in fact work in accordance with procedures which themselves direct actions and decisions within the framework of the stated policies. In order to make the decisions required in the procedures, staff will often need to know the company policy on a particular subject, such as procurement, recruitment, release of product, licensing agreements, agreeing design changes, etc. Can they or can they not do something and if so what criteria would they satisfy?

When one deviates from procedure one may not in fact be violating a policy as the procedure may describe one of several ways of doing something. Where top management dictates that all work be conducted in accordance with certain procedures it puts itself in a position of having to authorize deviations when the procedures cannot be followed. It

is therefore more effective use of time if top management prescribes the policies to be met by its direct subordinates rather than for all levels.

There are many sound reasons for documenting your operational policies:

- Corporate policy needs to be translated into practical terms which can be implemented through procedures.
- Every job has constraints surrounding it – without written policies people would be left to discover them by trial and error, the organization would become a disorganized mess, its managers lacking any means to direct and harmonize their staff's activities.
- Policies enable managers and their subordinates to be left in no doubt about what they are actually responsible for, the boundaries within which they need to work, and the demands upon them to which they will be expected to respond.
- Policies set clear boundaries for people's jobs so that everyone knows in advance what response they will get from others when making decisions.
- Policies create a baseline to which subsequent change can be referred and enable changes in the way things are done to be clearly defined.
- Policies enable managers to determine whether a subordinate's action or decision was simply poor judgement or an infringement of the rules. If no rule exists, subordinates cannot be criticized for using their judgement, however poorly it is used. If a rule exists, one has to establish whether it was accidentally or deliberately broken, for the latter is a disciplinary offence. Without written policy no one knows where they stand and any decision may create an unwanted precedent.
- Policies provide freedom to individuals in the execution of their duties to make decisions within defined boundaries and avoid over-control by managers. If people are uncertain about where the limits of their job lie they cannot feel free to act. Without a clearly defined area of freedom there is no real freedom at all.
- Policies enable managers to exercise control by exceptions rather than over every action and decision of their subordinates and therefore enable self-control by subordinates.
- Policies enable managers to control events in advance. Before the action begins, people know the rules and so are more likely to produce the right results first time. Without policies, one is forced to control events in arrears, after something has happened to cause dissatisfaction. Alternatively, one has to be on the scene of the event to respond as soon as the situation approaches the limits. This is a costly use of managers' time.

However, one does not need to write *everything* down, as policies are needed only for important matters where the question of right or wrong does not depend upon circumstances at the time, or when circumstances only rarely come into the picture.

■ **Policies that don't cause action are not policies.**

In documenting your operational policies to meet ISO/TS 16949 you need to address each requirement in the standard where it is relevant to your business in terms that enshrine the above principles. Procedures implement policies – therefore the policies do not need to stipulate *how* things are carried out. In order to be effective, the policies should state *what* is to be done and the rules that constrain the actions and decisions connected with it.

A common practice is to paraphrase the requirements of ISO/TS 16949 as operational policy statements. Whilst this approach does provide direct correlation with ISO/TS 16949 it does not by itself add any value since users can read the same things by referring to ISO/TS 16949. Operational policies should respond to the requirements, not paraphrase them, and they should provide solutions appropriate to the organization, as given in the following examples²:

- On responsibility and authority: “The responsibility and authority of all personnel shall be defined and documented within the procedures that apply to the operations they perform. In addition, the responsibilities, authority, and accountabilities for those holding specific positions or carrying out a particular trade or profession shall be defined in Job Profiles.”
- On resources: “The manpower, material, facilities, and plant needed to execute a particular contract shall be established, documented, and agreed with senior management prior to submission of any tender, bid, or offer. The estimate shall include the resources to manage and carry out the work required and in addition the resources required to verify that work has been completed in accordance with the contractual requirements.”

■ **Policies limit choice where choice is available.**

While procedures implement policies there will be occasions when one level of procedure contains policies that are to be implemented by a lower level, as may be the case with large companies with several divisions.

² Further operational policies are provided in the *ISO 9000 Quality System Development Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

It is often difficult to separate quality policies from other policies such as finance, personnel, and marketing. To avoid duplication, overlap, and possible conflict (as well as simplify maintenance) a single policy manual would be preferable.

Referencing procedures in the quality manual

There are a number of ways to show traceability between policy and procedures:

- Number the procedures so that they relate to the section of the quality manual that has been implemented.

The limitations with this method are that you can only add new sections to the end of the quality manual, otherwise the procedure numbers would need to change. Also you cannot relate a procedure to a specific policy unless the section contains only one policy.

- List the procedures at the end of the appropriate section of the quality manual.

The limitations with this method are that you cannot relate a procedure to a specific policy unless the section contains only one policy. However, it is the most common solution.

- Produce a matrix showing the relationship between procedures and policies.

To make this method better than the others, you would need to number all your policies.

- Cross-reference the procedures within the text of the quality manual.

This is the only method that matches specific policies with specific procedures, other than numbering each policy. Note that this is not practical for policies that are implemented through many procedures.

Once you have matched the policies with the procedures (a one-off activity), implementation is assured by verifying that the procedures are being adhered to by those to whom they apply. Simply auditing procedures will not ensure that policies are implemented unless you verify that the procedures themselves comply with the appropriate policies.

Handling non-applicable requirements

It is required that the *quality manual cover the requirements of the standard*. However, not all requirements may apply to your business so how should you proceed? There are

several ways of handling requirements that are not applicable. You can include a cross-reference matrix showing the relationship between the sections of the manual and ISO/TS 16949 and indicate which elements of the standard are not applicable. This method is the simplest but is only a rough guide as one can only identify complete elements such as 4.20 or clauses such as 4.6.4.1. One cannot identify individual requirements such as those pertaining to test software in clause 4.11. Another method is to refer to the non-applicable requirements within the introductory sections of the manual, either in the statement defining the scope of the quality system or in the section profiling the organization. Alternatively, you can refer to non-applicable requirements in the relevant sections of the policy manual but this may not be practical, especially if you have structured your manual around your business rather than the standard. Of course you can omit any reference to those requirements which are not applicable but you will in all probability receive inquiries from the third party auditors so it is advantageous to have your answers prepared. A more robust solution is to prepare a separate document which provides a response to each of the requirements. The questionnaires included at the end of each chapter in Part 2 of this book provide the questions you need to address. Where the requirements do apply, your response could be a cross reference to the policy manual and/or procedures manual. Where the requirements do not apply, an explanation can be given to justify its exclusion from your system.

Quality systems which go beyond ISO/TS 16949

The standard only requires the documentation covering the requirements of the standard to be defined in a quality manual. If your quality system covers areas outside the scope of ISO/TS 16949, as it may if you have used ISO 9004 as the basis for designing the system, or if you have included more functions of the business than addressed in ISO/TS 16949, this raises several questions:

- Where should you put such documentation, in the quality manual or in a separate manual?
- Will the assessment of the system extend to such documents?
- If the assessment does extend to such documents, and the auditors find nonconformities in the areas outside the scope of the standard, will they count?
- If such nonconformities count, could they be deemed major nonconformities and thus result in failure to achieve certification or re-certification?

The rules of the scheme require the third party auditors to cover all elements of your system including those that go beyond the standard, if they form part of your quality system. The rationale is that the operations you declare in your quality system are those

needed to provide products and services that meet customer requirements. If you include such operations as marketing, administration, and accounting in your quality system, you are declaring they are essential to meet customer requirements, and if you are not properly implementing your declared policies and practices in these areas there is a nonconformity. If you exclude them, the opposite is true. If the auditor finds you have omitted essential operations this too is a nonconformity.

Maintaining a quality system (4.2.1)

The standard requires suppliers to *maintain a quality system as a means of ensuring that product conforms to specified requirements.*

As stated in Part 2 Chapter 1, maintenance is concerned with retaining something in or restoring something to a state in which it can perform its required function. Quality systems comprise the organization, resources, and processes as well as the documentation needed for achieving quality, so you need to maintain more than the documentation.

In maintaining a quality system you need to:

- Keep the quality system documents updated with the needs of the business.
- Keep copies of the documents updated with the latest amendments.
- Keep the policies and procedures up-to-date with the latest industry practices and technologies.
- Keep staff training up-to-date with current policies and procedures.
- Change policies and procedures to prevent the recurrence of problems.
- Keep the description of the organization (including the associated responsibilities and authority) compatible with the actual staff relationships and their responsibilities and authority.
- Keep the resources required to implement the policies and procedures compatible with the actual resources available.

Why should all this be necessary to maintain the quality system? The answer can be found in ISO 8402 which defines a quality system as *the organizational structure, responsibilities, procedures, processes, and resources needed to implement quality man-*

agement. In maintaining the quality system you are therefore doing more than maintaining pieces of paper.

Business changes

In order to keep the system up-to-date with the needs of the business you will need to review the system when changes occur in the business. This review may be carried out at the same time as the management reviews described in Part 2 Chapter 1; however, as these reviews may be scheduled on a periodic basis, you should not allow the system to become outdated. The system should always reflect what you do and should remain ahead of actual practice rather than lag behind it. You should therefore integrate your system review with the business review so that changes in the business are implemented through the quality system rather than as an afterthought.

Amendments

It is a fact of life that people don't give a high priority to installing amendments to documents in their possession. Some will carry out the amendments immediately on receipt while others will allow them to pile up in the pending tray (out of sight, out of mind). To keep copies of your documents up-to-date you should adopt a method of issuing changes that minimizes the effort required to amend copies of documents. There are several options:

- Reissue documents in their entirety instead of employing manuscript amendment or page replacement techniques.
- Make one particular individual responsible for updating all the manuals.
- Place the manuals in the custody of secretaries or clerks instead of the users.
- Limit the number of copies to those who need regular access and provide a library copy for casual users.
- Structure your documentation so that it consists of a number of volumes, each addressing a particular department or phase of operations. Limit the distribution of the relevant volume to staff affected and only keep one complete set.

Each of these options has advantages and disadvantages depending on the type, size, and dispersal of staff in the organization.

State of the art changes

To keep your policies and procedures up-to-date with the latest industry practices you should provide a means of identifying new developments. This can be done by scanning journals, attending seminars and conferences, and generally maintaining an awareness of developments in quality management and technologies relevant to your business.

Staff changes

When you set up your quality system as part of its implementation you should train staff in the application and use of the various documents. The system may not change as frequently as the staff so as new staff enter the organization or change roles, they need to be trained to carry out their jobs as well as possible. This training needs to be a continuous process if the standards of quality are to be maintained with a mobile workforce. You will therefore need a means of identifying when staff changes occur so as to enable you to schedule their training. These training plans are as much a part of quality system maintenance as staff induction and development. Therefore, provision needs to be made in your procedures to ensure this occurs.

Improvement changes

Internal audits, corrective action plans, and management reviews may all indicate a need for the documented policies to be changed or staff to be trained in order to prevent the recurrence of problems. This is by far the most frequent cause of change – certainly until your system has stabilized. You will need a method of making such changes promptly if the problems are not to recur. Often the change control system may be too bureaucratic and inject delays while management procrastinates over policy and procedure changes. As a result, a manager may issue a memo instructing a change in practice to overcome a particular problem and possibly at the same time initiate a formal change to the system documentation. This method should be prohibited by the system as the memo is an uncontrolled vehicle which may set unwanted precedents as well as cause your documented system to diverge from the system in operation. Your *change procedures* should be such that they are the quickest way to change the system. It should be possible to issue a change note within a working day (see Part 2 Chapter 5). Walk it around the managers if the internal mail takes too long, call a meeting, or invoke the manager's deputy if the manager is unavailable. If the managers cannot agree, no change should be made and certainly not by a memo.

Organization changes

A common failing of many quality systems is that the organization structure, job titles, and responsibilities become out of date shortly after the documentation has been issued. Managers often believe that the organization charts in the quality manual are there simply as a publicity aid and not as a definitive statement. Managers also prefer to be free to change their organization when it suits them and not to be constrained by a bureaucratic system. Most managers will announce a change in their organization, then rely on the quality manager to change the charts in the quality manual. To avoid conflicts you need a method whereby managers change the charts then announce the changes in their organization, and not vice versa. Again, if you employ a quick change procedure such as that described above, managers will find no advantage in by-passing the system. One way of limiting the effects that organizational changes have on the quality system is to make the system immune to such changes. By avoiding job titles, locations, department names, and other labels that are prone to change you can minimize the impact of organizational changes on the documentation. To achieve such immunity you need to use terms such as *design authority*, *manufacturing authority*, *inspection authority*, etc. instead. If you need to be specific, you can do so in a Quality Plan or Organization Manual which translates the authorities into department names or job titles. Thus in the case of reorganization you need only change one document instead of many. Processes often remain the same after a reorganization as only the names and positions may have changed.

Resource changes

The implementation of policies and procedures, including the processes they define, requires human, material, and financial resources. When you introduce the policies and procedures for the first time, you need to take into account the resources that will be needed. It is of no use to issue a new procedure that requires new equipment, new skills, and many more people if no one has made provision for them. Likewise, when procedures change you need to consider the impact on resources and when resources are reduced you need to consider the impact on the procedures. Managers may inadvertently dispose of old equipment or acquire new equipment without giving consideration to the procedures or instructions which specify the equipment. Some procedures may have been designed around a certain facility or around a particular department, section, or even a particular person or skill, although every attempt to make them immune to such changes was taken. In times of a recession certain pruning may need to occur which may affect the implementation of the procedures. You therefore need to be vigilant to identify the effects of these changes on your procedures and take prompt action to maintain them in line with current circumstances. Rather than dispose of procedures that have become obsolete due to such changes, archive them because you *may* be able to resurrect them when circumstances improve.

Quality system procedures (4.2.2)

Preparation of documented procedures and instructions (4.2.2.1a)

The standard requires the supplier to *prepare documented procedures consistent with the requirements of this international standard and the supplier's stated quality policy.*

What are procedures?

A procedure is a sequence of steps to execute a routine task. ISO 8402 defines a procedure as a *specified way to perform an activity*. It prescribes how one should proceed in certain circumstances in order to produce a desired result. Sometimes the word can imply formality and a document of several pages but this is not necessarily so. A procedure can be five lines, where each line represents a step to execute a task.

Quality system procedures are a certain type of procedure. They implement the operational policies and regulate processes that produce an output, the quality of which is essential to the business. Procedures do not in fact achieve quality – it is people who do that. Procedures do not take decisions, it is people who do that. So you could have the best procedures in the world and still not achieve quality. It has to be a combination of both for you to achieve the desired quality.

The standard only refers to procedures as the category of quality system documentation. If we use the term *documented practices* we have a wider choice as to the types of documents we put into the quality system. Many documents are not procedures. They do not tell us how to proceed or specify a way to perform an activity. They specify criteria we must meet or provide guidance in conducting a task. They may, however, give examples or define rules to follow.

Types of documented practices

There are various types of documented practices:

- Divisional procedures apply to more than one division of a company and regulate common activities.
- Control procedures control work on product as it passes between departments or processes. These should contain the forms which convey information from department to department and reference the operating procedures that apply to each task.

- Operating procedures prescribe how specific tasks are to be performed. Subcategories of these procedures may include test procedures, inspection procedures, installation procedures, etc. These should reference the standards and guides (see below) which are needed to carry out the task, document the results, and contain the forms to be used on which to record information.
- Standards define the acceptance criteria for judging the quality of an activity, a document, a product, or a service. There are national standards, international standards, standards for a particular industry, and company standards. Standards may be in diagrammatic form or narrative form or a mixture of the two. Standards need to be referenced in control procedures or operating procedures and be a part of the quality system. These standards are in fact *your* quality standards. They describe features and characteristics which all *your* products and services must possess. Some may be type-specific, others may apply to a range of products or types of products, and some may apply to all products whatever their type. These standards are not the drawings and specifications that describe a particular product but are the standards that are invoked in such drawings and specifications and are selected when designing the product.
- Guides are aids to decision-making and to the conduct of activities. They are useful as a means of documenting your experience and should contain examples, illustrations, hints, and tips to help staff perform their work as well as possible.
- Work instructions define the work required in terms of who is to perform it, when it is to commence and to be completed, what standard it has to meet, and any other instructions which constrain the quality, quantity, delivery, and cost of the work required. Work instructions are the product of implementing a control procedure, an operating procedure or a document standard (see further explanation below).

The relationship between these documents and the policies described in Part 2 Chapter 1 is illustrated in Figure 2.5.

By having several types of quality system document you can place the mandatory provisions in the control and operating procedures, select the standards that are appropriate to the task, and place all the other material in the guides. You will therefore not be committed to doing things that are not essential. The third party auditors should assess you only against the mandatory procedures and the appropriate standards and not the guides unless the guides are invoked in the contract when you will need to justify to your customer any alternative approach taken.

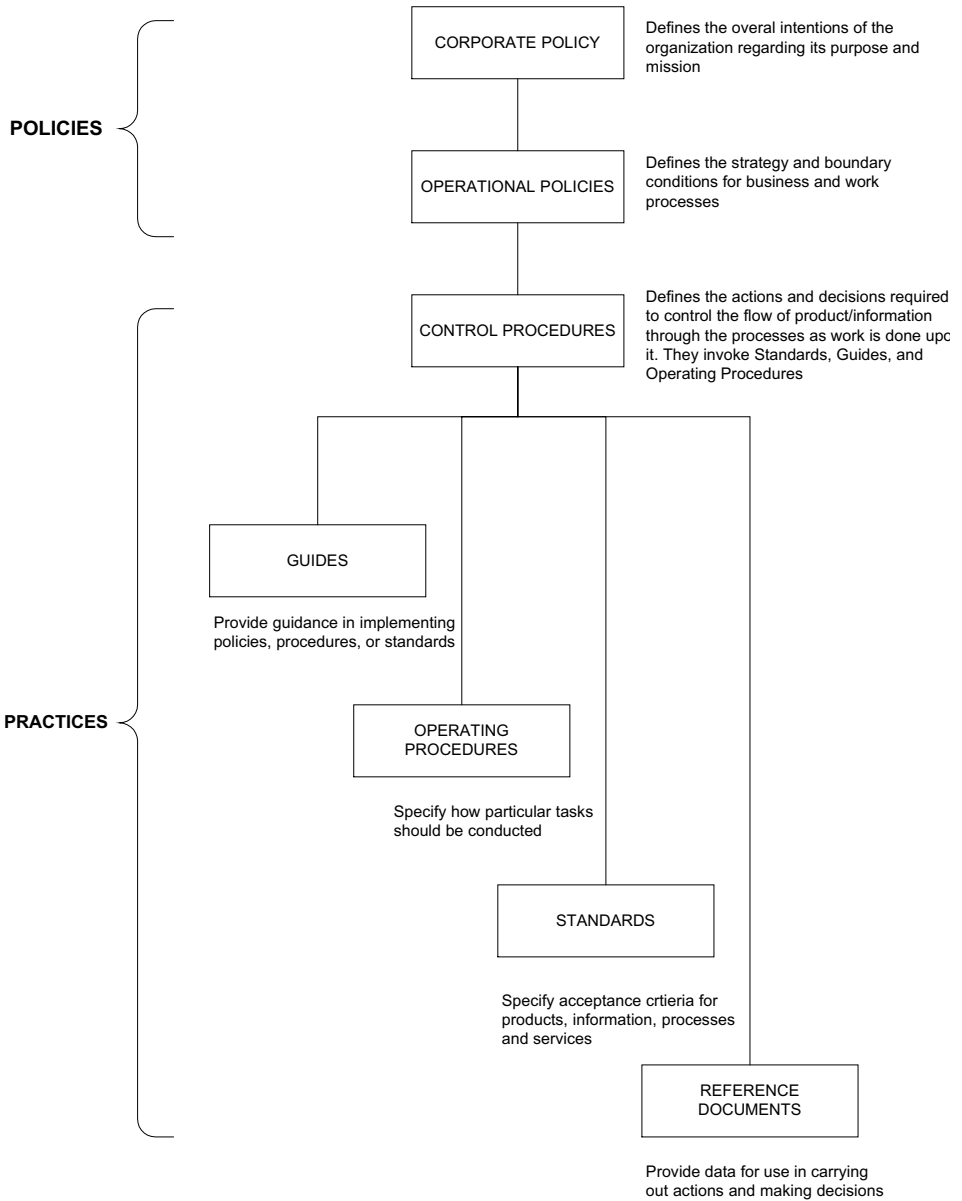


Figure 2.5 Relationship between policies and practices

What are the differences between procedures and instructions?

Work instructions are identified in a Note to clause 4.2.2 of ISO 9001 and in clause 4.9.2 in ISO/TS 16949 where it states that *job instructions* are equivalent to *work instructions*. In ISO 9001 it implies that work instructions *define how an activity is performed* but in ISO 8402:1994 a procedure is defined as a *specified way to perform an activity*. There isn't enough difference between these two definitions to warrant a change in the term and its inclusion may well create much confusion, especially as ISO 9004-1 does not refer to work instructions or any other type of instructions. The list of topics that should be addressed by job instructions in clause 4.9.2 of ISO/TS 16949 certainly does not by itself imply that job instructions *define how an activity is performed!*

In simple terms, *instructions* command work to be done, *procedures* define the *sequence* of steps to execute the work to be done. Instructions may or may not refer to procedures that *define how an activity is performed*. In some cases an instruction might be a single command such as "Pack the goods". Procedures, on the other hand, define how one should proceed to execute a task. Procedures are documented when the activities that need to be performed are likely to be performed regularly or routinely. For example, you may issue an instruction for certain goods to be packed in a certain way on a particular date and the package to be marked with the contents and the address to which it is to be delivered. So that the task is carried out properly you may also specify the methods of packing in a *procedure*. The procedure would not contain specific details of a particular package – this is the purpose of the instruction. The procedure is dormant until the instruction to use it is initiated or until personnel are motivated to refer to it.

Not all instructions need to be documented – it depends upon the nature of the message being conveyed. Many types of forms have been conceived to convey instructions. Purchase Orders, Change Requests, Amendment Instructions, Engineering Orders, and Print Requisitions are all instructions that cause people to do work and hence are work instructions rather than procedures.

It follows therefore that the idea of calling documents *procedures* when they only apply to interdepartmental activities and calling documents *work instructions* when they apply to departmental activities is ill-conceived. Both types of documents are in fact *procedures*. In both cases work instructions may be needed to initiate work and procedures may be needed to define the sequence in which the work is to be executed, where the instructions alone are insufficient³.

³ Further details are provided in the *ISO 9000 Quality Systems Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

What should be documented? (4.2.2.1a)

The standard advises that *the range and detail of the procedures that form part of the quality system depend upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.*

Clause 4.9 of the standard requires procedures only where the absence of such procedures would adversely affect quality. This phrase is often taken out of context and used as a valid reason for not documenting aspects of the quality system. There has to be a limit on what you proceduralize. At school we are taught reading, writing, and arithmetic, so procedures should not attempt to define these functions. The procedures need only detail what would not be covered by education and training. A balance should be attained between training and procedures. In order to provide training of consistent quality, it too should be documented in the form of training manuals, training aids, and facilities. If you rely on training rather than employing documented procedures, you will need to show that you have control over the quality of training to a level that will ensure its effectiveness. We expect staff to know how to do the various tasks that comprise their trade or profession, how to write, how to design, how to type, how to answer the telephone, how to paint, how to lay bricks, etc. You may feel it necessary to provide handbooks with useful tips on how to do these tasks more economically and effectively and you may also use such books to bridge gaps in education and training but these are not your procedures. The quality system has to be documented in your procedures, standards, guides, or manuals.

Not everything you do can be proceduralized. Some policies can be implemented without a procedure. The following are examples of such policies:

- All communication with suppliers shall be with the approval of the purchasing authority
- Positive feedback from customers shall be recorded, filed with client data, and posted on the company noticeboard
- No deviations from the policies stated in the policy manual will be permitted without written authorization of the Managing Director

In many organizations, procedures for such policies would not be necessary as the policy is concise enough for effective implementation. In other organizations procedures may well be required to limit the number of possible variables in carrying out such simple tasks.

As a minimum you should document your response to the requirements of the standard – the general requirements as well as each individual requirement. Some requirements

will be addressed in your policy statements, others will be addressed directly in your procedures. It is within the framework of systematic procedures that experience and judgement produce successful results and a reputation for managerial excellence. Procedures can only work, however, where judgement is no longer required or necessary.

How many procedures and how big do they need to be?

The standard requires *documented procedures to be prepared consistent with the requirements of this international standard*, but what does this mean? Preparing procedures consistent with the requirements of the standard means preparing those procedures where the standard requires them. Outside ISO 9001, ISO/TS 16949 does not use the same wording to require procedures. In some clauses it requires a process and in others it requires methods or a methodology or a system. Although systems are not procedures, procedures are not processes and methods are not necessarily procedures, systems, or processes. Some methods, however, will inevitably need one or more procedures. By including systems, methods, and processes, the standard now requires 43 documented procedures directly.

The table below identifies these procedures indicating the clause numbers, with the * denoting those which are applicable only when the requirement applies. In Appendix B are a further 144 topics which your procedures need to address in order to demonstrate that you have *documented* your quality system.

	Procedures requirements	Clause
1	Determination of customer satisfaction	4.1.1.3
2	Continuous improvement	4.1.1.4
3	Determination of current and future customer expectations	4.1.4
4	Business plan review and revision	4.1.4
5	Employee motivation	4.1.6
6	Employee satisfaction	4.1.6
7	Regulation capture and compliance tracking	4.1.7.2
8	Product realization	4.2.4.1
9	Process design	4.2.4.9.1
10	Process development	4.2.4.9.1
11	Process verification	4.2.4.9.1
12	Tooling management	4.2.6
13	Contract review procedures	4.3.1
14	Design control procedures	4.4*

Procedures requirements		Clause
15	Document and data control procedures	4.5.1
16	Customer document review	4.5.2.2
17	Purchasing procedures	4.6.1.1
18	Subcontractor performance monitoring	4.6.2.3
19	Product identification procedures	4.8*
20	Traceability procedures	4.8*
21	Production procedures	4.9.1.1*
22	Installation procedures	4.9.1.1*
23	Servicing procedures	4.9.1.1*
24	Preventive maintenance	4.9.1.5
25	Inspection and test procedures	4.10.1.1
26	Control of inspection, measuring, and test equipment	4.11.1.1
27	Calibration of inspection, measuring, and test equipment	4.11.1.1
28	Maintenance of inspection, measuring, and test equipment	4.11.1.1
29	Control of nonconforming product	4.13.1.1
30	Corrective action procedures	4.14.1.1
31	Preventive action procedures	4.14.1.1
32	Handling procedures	4.15.1
33	Storage procedures	4.15.1
34	Packaging procedures	4.15.1
35	Preservation procedures	4.15.1
36	Delivery procedures	4.15.1
37	Delivery performance monitoring procedures	4.15.6.2
38	Control of quality records	4.16.1
39	Internal quality audits	4.17.1
40	Identification of training needs	4.18.1
41	Servicing management procedures	4.19.1*
42	Communication of servicing concerns	4.19.3
43	Application of statistical techniques	4.20.2

The standard doesn't require a procedure for Management Review and while it does require procedures for Design Control it does not specify that a Design Review Procedure is required. The phrases "consistent with" and "in accordance with" have the same meaning as both imply compatibility and agreement. If you restrict yourself to a literal interpretation of the standard, you need produce no more than 43 documented procedures – possibly less if some aspects do not apply to your business. You can combine several procedures in one document, the size of which depends on the complexity of your business. The more complex the business the greater the number of quality system documents. The more variations in the ways that work is executed, the larger the quality system will need to be. If you have a small business and only one way of carry-

ing out work your system will tend to be small. Your quality system may be described in one document of no more than 30 pages. On the other hand a larger business may require several volumes and dozens of procedures of over 10 pages each to adequately describe your system.

Control procedures need to be user friendly and so should be limited in size. Remember you can use other documents, such as guides, standards, and operating procedures, to extend what you have written in the control procedures. The procedures should not, however, be so short as to be worthless as a means of controlling activities. They need to provide an adequate degree of direction so that the results of using them are predictable. If you neglect to adequately define what needs to be done and how to do it, don't be surprised that staff don't know what to do or constantly make mistakes. It is also important to resist the desire to produce manuals that are impressive rather than practical. Printing the documents on expensive paper with colored logo does not improve their effectiveness and if they are not written simply and understood by a person of average intelligence, they will not be used.

To determine the procedures you need you should design the system from the top down. Some requirements will apply to many operations such as document control, corrective action, and quality records whereas other requirements may apply to only one operation, such as auditing and management review. A matrix showing this relationship is given in Appendix D.

Reasons for not documenting procedures

If you can't predict the course of action or sequence of steps you need to take, you can't write a procedure. You can't plan for unforeseen events and as the unexpected will happen sooner or later, it would be wasteful of resources to produce procedures for such hypothetical situations. If you do not use statistical techniques, for instance, it is a waste of time writing a procedure that will not be used even though the standard requires one.

There are several other good reasons for not documenting procedures. Management may have no objection to doing many sensible things but may well resist declaring them as policy or prescribing them in published procedures. Management may take this attitude for several reasons:

- Customers may use evidence of noncompliance, no matter how trivial, to terminate a contract or decline a tender.
- There may be many instances where the policy or procedure doesn't apply.
- Management may wish to safeguard against over-zealous auditors or assessors.

- Managers may wish to choose the most appropriate action for given circumstances.
- Managers may wish to avoid overkill, avoid doing more than is necessary.
- The practices may not have any effect on product or service quality.
- The practices may rely on skills acquired through training where judgement is necessary to produce the desired result.

Making the system effective

The standard does not in fact require you to design an *effective* system. It does require the system to be reviewed to ensure its continuing effectiveness but if the system was not designed properly in the first place, the review may simply result in a series of minor improvements that are never ending and do not deal with the system as a *whole*. Many initiatives for quality improvement attack parts of the system but not the *whole* system. Improvement in processes is often made without considering the effects on other processes. This is certainly true with document changes where the effects of changes on other documents are not usually considered before authorizing the change.

How do you then design an effective system? There are several techniques you can use. Failure Modes and Effect Analysis (FMEA), Fault Tree Analysis (FTA), and Theory of Constraints (TOC) are but three. The FMEA is a bottom-up approach, the FTA a top-down approach, and TOC a holistic approach.

One way of applying the FMEA technique to the quality system is to take each procedure objective and establish the probability of it not being achieved, the likely cause and effect on the system, and the probability of the failure being detected by the downstream controls. The analysis may show up key activities for which there are no safeguards, activities that rely on one person doing something for which there are no checks that it has been done. The quality system is a collection of interrelated processes; therefore by chasing the effect along the chain you may find single point failures (parts of the system which affect the performance of the whole system).

The FMEA approach is a bottom-up approach, looking at component failures and establishing their effect on the system. An alternative approach is to use a top-down approach such as Fault Tree Analysis to postulate system failure modes and establish which processes, procedures, or activities are likely to cause such failures.

The third method is not new but not widely used. The Theory of Constraints developed by Eliyahu M. Goldratt in the 1980s examines the system as an interconnection of processes and focuses on the one constraint that limits overall system performance. The

theory is founded on the principle that if all parts are performing as well as they can, the system as a whole may not be. Each process links with others in a chain and therefore by improving one process you may degrade the performance of another. It looks for the weakest link in the chain of processes that produce organizational performance and seeks to eliminate it. Once eliminated, it looks for the next constraint on the system. Many of the constraints may not be physical. There may well be policy constraints that govern many of the actions and decisions being made. What may have to change is the *policy* for improvement in system performance to be achieved. In this way TOC is similar to FTA but goes beyond the physical boundaries of the system.

Ensuring effective implementation (4.2.2.1b)

The standard requires the supplier to *effectively implement the quality system and its documented procedures*.

This requirement implies the quality system may well consist of more than just the documented procedures. It also implies that documented procedures do not form part of the quality system, as it was deemed necessary to mention both. Without speculating on what the drafting team had in mind, the message conveyed by the requirement is that the system needs to be implemented, including the documented procedures. Hence all policies and practices defined within the system need to be implemented. Effectively, *implement* in this case means to implement the policies and practices in such a way that they achieve their purpose. Slavishly following a policy or procedure that is clearly misguided and failing to achieve the intended results is demonstrating ineffective implementation.

Effective implementation is also following what is stated, not changing your procedures after changing your practice. However, one can argue that effective implementation is trying out the new practice first and then documenting it but it is stretching a point to bring your procedures in line with your current practice as a regular event, because they should not be out of line in the first place.

A common failing with the implementation of procedures is that they are not sold to the workforce before they become mandatory. Also, after spending much effort in their development, procedures are often issued without any thought given to training or to verifying that practices have in fact been changed. As a result, development is often discontinued after their release. It then comes as a shock to managers to find that all their hard work has been wasted. An effectively-managed program of introducing new or revised procedures is a way of overcoming these shortfalls.

The process of implementing a new procedure or one that requires a change in practice is one that is concerned with the management of change. It has to be planned and resourced and account taken of attitudes, culture, barriers, and any other resistance there may be. One must not forget that those who are to implement the procedure may not have participated in its development and may therefore be reluctant to change their practices. The process of introducing a new or revised practice consists of Preparation, Commissioning, Implementation, and Qualification. Once the qualification exercise has proved that the procedure effectively fulfills its purpose one may resort to periodic auditing to confirm continued effectiveness⁴.

The way in which these phases of quality system development are related is illustrated in the quality system life cycle model shown in Figure 2.6. This diagram has some important features. Note that the design input to the system comprises internal and external requirements. The system requirements are ISO/TS 16949 plus customer-specific system requirements. The customer needs and expectations include the product and process requirements and the business objectives include product, process, personnel, resource, and other objectives that affect the manner in which quality will be achieved, sustained, and improved. Note that on the right-hand side there is improvement in conformity, meaning getting better at doing what you said you would do, and improvement in the system, meaning correcting aspects of the system that are found noncompliant with the requirements. On the left-hand side, the emphasis is on performance not conformance. Here, performance data is collected and compared with objectives and either the system design modified or more challenging objectives established. On the right is tweaking and on the left is advancement.

In ensuring the effective implementation of the quality system you should continually ask:

- Does the quality system fulfill its purpose?
- Do the results of the audits indicate that the system is effective?
- Are procedures being used properly?
- Are policies being adhered to?
- Are the customers satisfied with the products and services provided?

If the answer is “Yes” your system is operating effectively. If your answer is “No” to any of these questions, your quality system is not being effectively implemented.

⁴ Further guidance on implementing a quality system can be found in Part 1 Chapter 5 and the *ISO 9000 Quality System Development Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

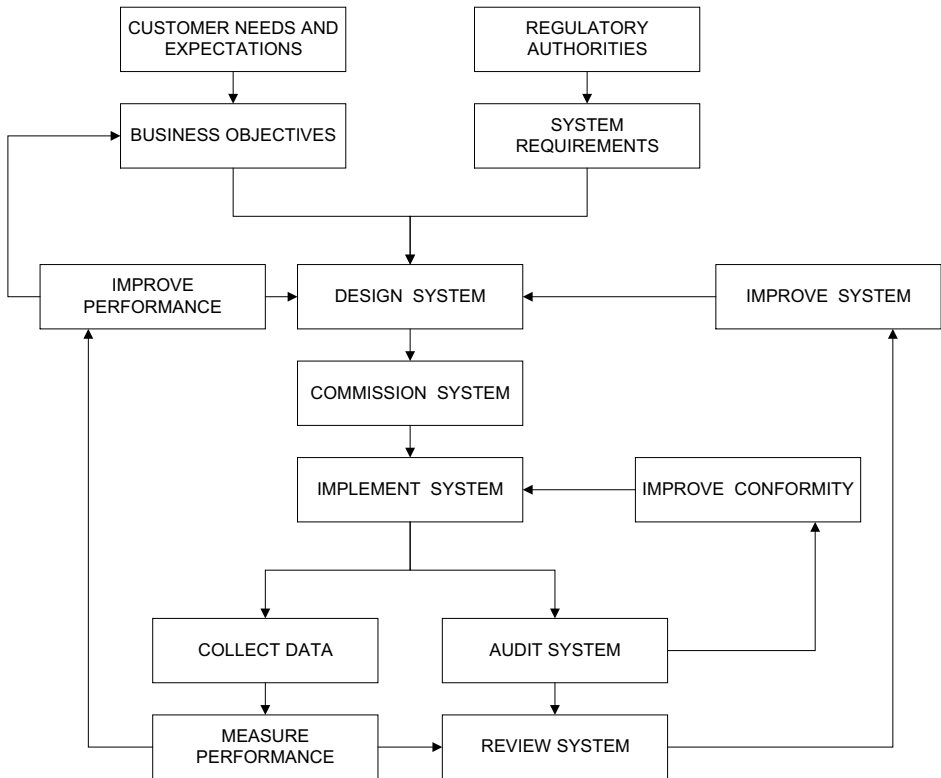


Figure 2.6 *System life cycle model*

Quality system documentation (4.2.2.2)

The standard requires all the requirements of ISO/TS 16949 *to be addressed in the quality system documentation but not necessarily by individual procedures.*

This requirement acknowledges that not all the requirements of the standard can be addressed by procedures. As described previously in this chapter, quality system documentation consists of several types of documents with procedures being one type. The requirement is therefore sending out a strong message that the supplier should not produce procedures to address each element of the standard or each clause.

Quality planning (4.2.3)

Defining how requirements for quality will be met (4.2.3.1)

The standard requires the supplier to *define and document how the requirements for quality will be met*.

The quality system developed to meet the requirements of ISO/TS 16949 is likely to be a generic system, not specific to any particular product, project, or contract other than the range of products and services which your organization supplies. By implementing the policies and procedures of the documented quality system, product, project, or contract specific plans, procedures, specifications, etc. are generated. ISO 9001 contains a series of quality system requirements, not product quality requirements. For a given product, project, or contract there will be specific product, project, or contract requirements and it is these requirements to which this clause of the standard refers.

The term “requirements for quality” is defined in ISO 8402 as *an expression of the needs or their translation into a set of quantitatively or qualitatively stated requirements for the characteristics of an entity to enable its realization and examination*.

Quality requirements are not the requirements contained in ISO/TS 16949. These are quality system requirements; they apply to quality systems, not to products and services. A product cannot conform with ISO/TS 16949 as it contains no product requirements (see also Part 1 Chapter 2).

The requirements for quality are the objectives which the organization is committed to achieving through the contract. They may relate to products, services, or both. The vehicle for you to define and document how these objectives will be met is called a *quality plan* but may be known by other names such as a *project plan* or *contract plan*. In some cases the requirement may be met in the form of a technical proposal by the supplier to the customer.

Ensuring consistency with other quality system requirements (4.2.3.1)

The standard requires that *quality planning be consistent with all other requirements of the quality system*.

The quality system you have developed should have made all the necessary provisions to enable the products and services you normally supply to conform to customer

requirements. It is therefore essential that the provisions made for any particular product, service, project, or contract do not conflict with the authorized policies and procedures. There is often a temptation when planning for specific contracts to change the policies and procedures where they are inflexible, invent new forms, change responsibilities, by-pass known bottlenecks, etc. You need to be careful not to develop a mutant quality system for specific contracts. If the changes needed are good for the business as a whole, they should be made using the prescribed quality system change procedures. This is another good reason for having a *fast* method of making authorized changes to approved documents. Changes to meet specific contractual requirements should be made without causing conflict with existing practices. If special procedures are needed which replace existing procedures in the quality system, a mechanism needs to be developed which authorizes staff to deviate from the existing procedures.

Documenting quality planning (4.2.3.1)

The standard requires *quality planning to be documented in a format to suit the supplier's method of operation*.

Although the standard does not specifically require a quality planning procedure, to ensure that such planning is carried out in a manner which avoids conflict with existing practices and in a format which suits your operations, you will need to prescribe the method to be employed in a procedure. Some contracts may stipulate a particular format for contract-specific procedures, especially when they are to be submitted to the customer for approval. If these procedures are only used by the project team, this may not cause any conflict. However, if they are to be used by staff in the line departments, you may have to reach a compromise with the customer so that any differences in format do not create implementation problems.

Planning to meet specified requirements (4.2.3.1)

The standard requires that *the supplier gives consideration* to a number of activities as appropriate but does not define when such consideration should be given. If you intend submitting a fixed price tender to a customer, preparing detailed plans of what you are going to do for the price *before* you submit your bid is giving “appropriate consideration” to planning. Likewise, identifying controls, ordering equipment and materials, etc. in good time before you need them is giving “appropriate consideration”; i.e. anticipating what you may need and initiating its acquisition beforehand will prevent you from having delays and problems when you embark upon the work.

Preparing quality plans (4.2.3.1a and 4.2.3.2)

ISO 9001 requires consideration to be given to the preparation of quality plans. However, the supplementary requirement in ISO/TS 16949 requires the supplier to *have a quality plan which includes customers' requirements and references to appropriate technical specifications*.

Quality plans are needed when the work you intend to carry out requires detailed planning beyond that already planned for by the quality system. The system will not specify everything you need to do for every job. It will usually specify only general provisions which apply in the majority of situations. You will need to define the specific documentation to be produced, tests, inspections, and reviews to be performed, and resources to be employed. The contract may specify particular standards or requirements that you must meet and these may require additional provisions to those in the quality system. Although ISO/TS 16949 requires the plan to include customers' requirements, the intention is not that these requirements are reproduced if provided in a documented form by the customer, but that a cross reference is made in the plan together with any other relevant specifications referred to in the contract. However, when constructing the plan, it would make sense to refer to specific customer requirements and provide a response that indicates your intentions regarding those requirements.

Guidance in preparing quality plans is given in ISO 9004-6, but these guidelines are based on the structure of ISO 9001 and your quality system may not in fact be structured in this manner. However, the guidance given in ISO 9004-6 is indeed sound advice and it identifies many of the aspects which need to be planned when applying your quality system to a specific product, project, or contract. The note at the end of section 4.2.3.1 in the standard recognizes that a quality plan may in fact be no more than a list of procedures which apply to a particular product, project, or contract. If your system is structured so that you can select the appropriate procedures, this is by far the simplest method. However, in addition to the procedures, you may need to specify when particular reviews, inspections, and tests, etc. are to be carried out and in what sequence. Where a procedure provides an option, an alternative route, or for activities and decisions to be based on particular contract, product, or project requirements, these aspects need to be addressed in your quality plan.

Identifying and acquiring controls (4.2.3.1b)

In planning for a contract or new product or service, the existing quality system needs to be reviewed against the customer or market requirements. One can then identify whether the system provides an adequate degree of control. Search for unusual requirements and risks to establish whether any adjustment to procedures is necessary. This

may require you to introduce new forms, provide additional review, test, and inspection stages and feedback loops, or prepare contingency plans.

One technique you can use to identify the new controls is to establish a list of critical items or areas by analyzing the design. Such items may include:

- Long lead items, i.e. items that need to be procured well in advance of the main procurement
- Risky suppliers, i.e. single-source suppliers or suppliers with a poor quality record for which there is no alternative
- High reliability items and single-point failure items
- Limited life items, fragile items, or hazardous items

For each item you should:

- Provide a description.
- State the nature of criticality.
- Identify the failure modes and the effects.
- Determine the action required to eliminate, reduce, or control the criticality.

New controls may also be needed if there are unusual contractual relationships, such as overseas subcontractors, international consortia, or in-plant surveillance by the customer. There may be language problems, translation work, harmonization of standards, and other matters arising from international trade.

Once the criticality has been eliminated or reduced by design, choosing the right quality controls is key to the achievement of quality. You need to:

- Analyze the items or activities to determine the key characteristics the measurement and control of which will ensure quality.
- Install provisions that will ensure that these characteristics are achieved.
- Define methods for evaluating the selected characteristics.
- Establish when to perform the measurements and what to do if they are not achieved.

Another method of identifying the controls needed is to describe the result-producing processes in flow diagram format. This will enable you to identify where the verification stages need to be added and the feedback loops inserted⁵.

Identifying and acquiring processes (4.2.3.1b)

You need to identify very early in the program any new processes and one way is to establish a list of processes. The list would identify:

- The process by name
- The process specification
- Manufacturer, if relevant
- Existing qualification data for required application
- Required qualification for the application

Such items may be allocated to several different departments or suppliers and if their acquisition is not coordinated you may find that all the right materials, equipment, resources, processes, etc. are not available when you need them.

Identifying and acquiring equipment (4.2.3.1b)

You will need to review the requirements and the resultant design to identify any special equipment, tools, test software, and test or measuring equipment required. Once identified, plan for its design, manufacture, procurement, verification, and certification. One way of doing this is to produce a list that contains the following details:

- Nomenclature of the equipment or software
- What it is to be used for
- Reference to its specification
- The location of any design data
- Manufacturer

⁵ David Hoyle, *ISO 9000 Quality System Development Handbook* (Butterworth-Heinemann, 1998).

- The date it was proven fit for use
- Reference to any release certificates

In the service industries, you may need to install new information controls for management to determine whether the services are giving customer satisfaction. This may require new equipment to record, collect, and transmit the data.

Identifying and acquiring fixtures (4.2.3.1b)

Fixtures, jigs, and other tools required can be identified in a similar manner. One advantage in producing separate lists is that they serve as a coordination and tracking tool.

Identifying and acquiring resources (4.2.3.1b)

Resources are an available supply of equipment, environment, machines, materials, processes, labor, documentation, and utilities, such as heat, light, water, power etc., which can be drawn upon when needed. This therefore requires detailed planning and logistics management and may require many lists and subplans so that the resources are available when required. Inventory management is an element of such planning.

Identifying skills needed to achieve quality (4.2.3.1b)

You need to identify any new skills required to operate the processes, design new equipment, perform new roles. For example, if the company hasn't carried out an automotive project before, you may need to train a project manager specifically for the job. If the project language is not limited to your own language you may need to provide language courses for your staff. Remember, any additional staff need to be trained and qualified before work commences if quality problems are to be minimized. You will also need to identify those skills upon which the success of the project depends and ensure they are not lost to other work. No one is indispensable but a key player leaving at a critical point in the program because of dissatisfaction with working conditions is avoidable!

Ensuring the compatibility of the design, the production process, etc. (4.2.3.1c)

It is necessary to verify that all the documentation needed to produce and install the product is compatible; that you haven't a situation where the design documentation requires one thing and the production documents require another or that details in the

design specification conflict with the details in the test specification. Incompatibilities can arise in a contract which has been compiled by different groups. For example, the contract requires one thing in one clause and the opposite in another. Many of the standards invoked in the contract may not be applicable to the product or service required. Production processes may not be qualified for the material specified in the design – the designer may have specified materials that are unavailable!

In order to ensure compatibility of these procedures, quality planning reviews need to be planned and performed as the new documentation is produced. Depending on the type of contract, several quality planning reviews may be necessary, each scheduled to occur prior to commencing subsequent stages of development, production, installation, or servicing. The quality planning reviews during product development can be held in conjunction with the design stage reviews required in section 4.4.7 of ISO 9001. At these reviews the technical and program requirements should be examined to determine whether the existing quality system provisions are adequate, compatible, and suitable to achieve the requirements; if necessary, additional provisions should be put in place.

Updating quality control and inspection and testing techniques (4.2.3.1c)

You should review the contract and the detail specifications to identify whether your existing controls will regulate quality within the limits required. You may need to change the limits, the standards, the techniques, the methods, the environment, and the instruments used to measure quality characteristics. One technique may be to introduce “Just-in-time” as a means of overcoming storage problems and eliminating receipt inspection. Another technique may be Statistical Process Control as a means of increasing the process yield. The introduction of these techniques needs to be planned and carefully implemented.

Development of new instrumentation (4.2.3.1d)

Should you need any new instrumentation, either for monitoring processes or for measuring quality characteristics, you need to make provision for its development. You will need to develop detail specifications of the instrumentation, and design, manufacture, inspect, and install the instruments under controlled conditions which meet the requirements of the standard.

Identifying new measurement capabilities (4.2.3.1e)

By assessing the specifications, you may come across a parameter that cannot be measured using state of the art instrumentation. You have three choices: to change the

design, renegotiate the contract, or develop some new measurement techniques. The customer should be informed, as he may well be able to relax or change the parameters. Should this not be possible, you will need to develop a new measurement capability. This may require a separate contract with all the attendant coordination problems of ensuring that the supplier comes up with the goods when you need them. More often than not, as with all new endeavors, there will be unforeseen problems, so keep your customer informed and ensure you are covered contractually when you hit trouble.

Identifying verification requirements (4.2.3.1f)

Identifying verification requirements is an important aspect of quality planning. Often all that needs to be defined in a quality plan are the verification requirements such as the inspection and tests to be performed on a particular product. While clauses 4.4.7 and 4.10 deal with verification procedures during design, production, installation, and servicing, a vital aspect of quality planning is the application of these procedures to determine what the verification requirements are, when, and on what size and nature of sample the verification activities are to be carried out. The verification procedures are unlikely to define these aspects for a specific product or service so they need to be determined in the planning phase. This requirement does not, however, take into account the validation process in clause 4.4.8. It would appear that this requirement is also partially addressed in clause 4.11.2 on *Inspection, measuring, and test equipment*. In this section you are required to determine the measurements to be made to demonstrate the conformance of product to the specified requirements. Clearly you can't do this without having identified what you need to verify.

To give this appropriate consideration you will need to do two things: define the requirements the product/service has to meet and define how these requirements are to be verified.

If all the key features and characteristics of your product/service can be verified by a simple examination on final inspection or at the point of delivery, the requirement is easily satisfied. On the other hand if you can't do this, while the principle is the same, it becomes more complex.

Generically there are two types of requirements: defining requirements and verification requirements. *Defining requirements* specify the features and characteristics required of a product, process, or service. (Within the standard these are termed *specified requirements*.) These may be wholly specified by the customer or by the supplier or a mixture of the two. *Verification requirements* specify the requirements for verifying that the defining requirements have been achieved and again may be wholly specified by the customer or by the supplier or a mixture of the two. With verification requirements, how-

ever, other factors need to be taken into consideration, depending on what you are supplying and to whom you are supplying it. In a contractual situation, the customer may specify what he wants to be verified and how he wants it verified. In a non-contractual situation, there may be statutory legal requirements, compliance with which is essential to avoid prosecution. Many of the national and international standards specify the tests which products must pass rather than performance or design requirements, so identifying the verification requirements can be quite a complex issue. It is likely to be a combination of:

- What your customer wants to be verified to meet the need for confidence. (The customer may not demand you demonstrate compliance with all customer requirements, only those which he/she judges as critical.)
- What you need to verify to demonstrate that you are meeting all your customer's defining requirements. (You may have a choice as to how you do this, so it is not as onerous as it appears.)
- What you need to verify to demonstrate that you are meeting your own defining requirements. (Where your customer defines the product/service in performance terms, you will need to define in more detail the features and characteristics that will deliver the specified performance and these will need to be verified.)
- What you need to verify to demonstrate that you are complying with the law (product safety, personnel health and safety, conservation, environmental, and other legislation).
- What you need to verify to obtain confidence that your subcontractors are meeting your requirements.

Verification requirements are not limited to product/service features and characteristics. One may need to consider who carries out the verification, where and when it is carried out, and under what conditions and on what quantity (sample or 100%) and standard of product (prototype or production models).

You may find that the only way you can put your product on the market is by having it tested by an independent test authority. You may need a license to manufacture it or to supply it to certain countries and this may only be granted after independent certification. Some verification requirements only apply to the type of product/service, others to the process or each batch of product, and others to each product or service delivery. Some requirements can only be verified under actual conditions of use. Others can be verified by analysis or similarity with other products that have been thoroughly tested (see Part 2 Chapter 4). The range is so widespread it is not possible in this book to explore all examples, but as you can see, this small and innocuous requirement contains

a minefield unless you have a simple product or unless the customer has specified everything you need to verify.

There are a number of ways of documenting verification requirements:

- By producing defining specifications that prescribe requirements for products or services and also the means by which these requirements are to be verified in-house in terms of the inspections, tests, analyses, audits, reviews, evaluations, and other means of verification
- By producing separate verification specifications that define which features and characteristics of the product or service are to be verified and the means by which such verification is to be carried out
- By producing a quality plan or a verification plan that identifies the verification stages from product conception to delivery and further as appropriate, and refers to other documents that define the specific requirements at each stage
- By route-card referencing drawings and specifications
- By inspection and test instructions specific to a production line, product, or range of products

In fact you may need to employ one or more of the above techniques to identify all the verification requirements. The standard does not limit the requirements to production.

Clarification of standards of acceptability (4.2.3.1g)

In order to verify that the products or services meet the specified requirements you will need to carry out tests, inspections, assessments, etc. and these need to be performed against unambiguous standards of acceptability. You need to establish for each requirement that there are adequate criteria for judging compliance. You need to establish how reliable is “reliable”, how safe is “safe”, how clean is “clean”, how good is “good quality”. Specifications often contain subjective statements such as good commercial quality, smooth finish, etc., and require further clarification in order that an acceptable standard can be attained. The secret is to read the statement then ask yourself if you can verify it. If not, select a standard that is attainable, unambiguous, and acceptable to both customer and supplier.

Identification and preparation of quality records (4.2.3.1h)

While procedures should define the quality records that are to be produced, these are the records that will be produced if these procedures are used. On particular contracts only those procedures that are relevant will be applied and therefore the records to be produced will vary from contract to contract. Special conditions in the contract may make it necessary for additional quality records. Records represent the objective evidence with which you are going to demonstrate compliance with the contractual requirements. It would therefore be expedient, although not essential, to list all the records that will be produced and where they will be located. The list does not need to detail every specific record, providing it identifies types of records and all new records to be produced.

Product realization (4.2.4)

Product realization process (4.2.4.1)

The standard requires the supplier to *have a process for product realization to deliver products on time to customer requirements* including product design where applicable.

The product realization process is the process that transforms customer requirements into a series of proven specifications that will consistently deliver conforming product. Product realization therefore includes product planning, design, development, design proving, production planning, and production proving. Why it involves so many separate processes is that product realization is not complete until product approval has been granted and product approval will not be granted until the production processes have been proven to be capable of producing conforming product. Product realization is the most exciting phase of any endeavor. It's not boring because operations have not settled into a routine and it's where all the lessons are learnt and successes secured.

Product realization in the automotive industry is either called *advanced product quality planning (APQP)* or *project management*. In terms of their objectives there is no difference. In terms of the mechanics there may be some differences, depending on the methodologies employed by the organization.

Project management approach (4.2.4.1)

The standard requires that *if a project management approach is used, a project manager and project team be assigned, that appropriate resources be allocated, and any special responsibilities and organizational interfaces be defined.*

In some respects this requirement is ambiguous as there are no equivalent requirements for when the APQP approach is used. The APQP manual merely offers guidance. With the APQP approach the equivalent of the *project manager* is the *project team leader* and the equivalent of the *project team* is the *product quality planning team*.

It is suggested that the project organization be described in the quality plan regardless of whether an APQP or project management approach is used. (See Part 2 Chapter 1 for a discussion on resource documentation.)

Ensuring confidentiality of customer-contracted products and projects (4.2.4.1)

The standard requires the supplier to *ensure the confidentiality of customer-contracted products and projects under development and related product information*.

A problem that may face many suppliers to the automotive industry is that of having multiple customers that are competitors, thus creating a need to preserve confidentiality. Customers are naturally concerned that their information or product does not reach their competitors.

In responding to this requirement you need to define how you intend to ensure confidentiality. How you do this is not as easy as getting everyone to sign a declaration. The declaration is useful in a prosecution but that will be after confidentiality has been breached! Things you can do to minimize a breach in confidentiality are:

- Employ a classification system for identifying information that requires different security measures.
- Denote the identity of the customer on classified information.
- Control filing/storing of customer data.
- Identify customer data with the name of customer.
- Control photocopying machines where access to customer data can be obtained.
- Destroy data by shredding and secure disposal.
- Remove labels from obsolete product before disposal.
- Escort and record visitors on site.
- Create project offices for new product development.
- Advise staff never to discuss company matters in a public place.

Defining, analyzing, and reporting measurements (4.2.4.2)

The standard requires that *measurements be defined, analyzed, and reported to management at appropriate stages of product realization and that these measurements include quality risk, costs, lead times, critical paths, and others as appropriate.*

The intent of this requirement is to provide a means for assuring management of performance and alerting them to potential and actual problems. Management need to know whether projects are proceeding on course and hence periodic reporting is necessary to provide management with factual data on which to make decisions. The results of these measurement should be reported at the planned project reviews as required by clause 4.2.4.3.

“Appropriate stages” in this case means that the measurements should be performed so that the results are available at the planned project reviews.

The kind of measurements you can make are:

- The extent to which planned tasks are being completed on time
- The degree of slippage or slack in the program
- The critical paths and changes in criticality
- Lead times and effect of changes on advanced procurement
- Resource utilization
- Spend versus budget
- Estimated spend to completion
- Quality risks in terms of potential and actual failures that affect critical tasks

Project review cycle (4.2.4.3)

The standard requires *the status of product realization to be reviewed at appropriate stages and suitable action taken.*

This requirement is linked to that above on measurement. A review cannot take place unless some measurement has been performed.

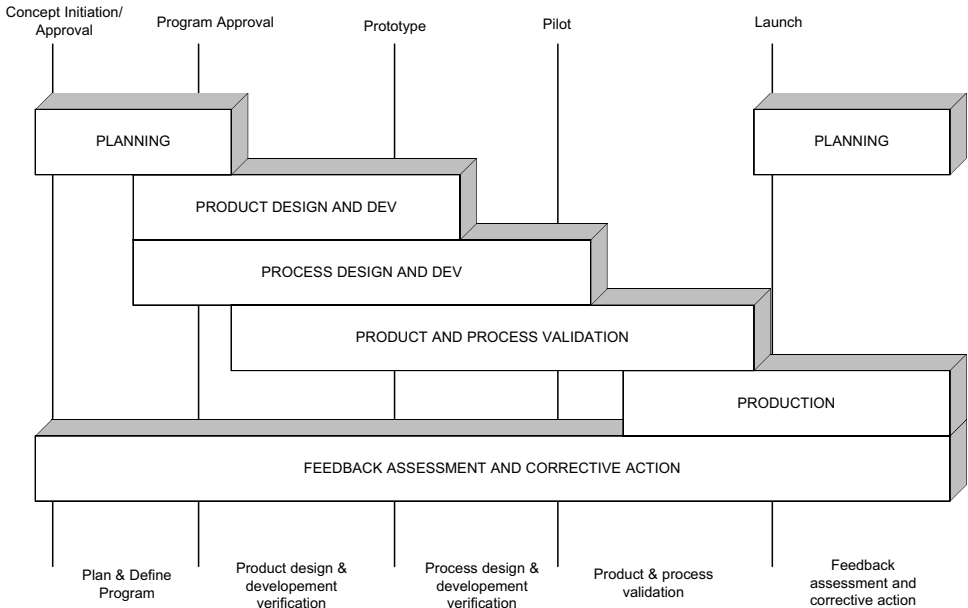


Figure 2.7 Product quality planning timing chart

The precise staging of the reviews will depend on the nature of the project. However, the principle is to hold a review prior to a major decision that dictates the direction of the project or at a stage in a project where the nature of work changes (see Figure 2.7). Alternatively, reviews can be held monthly, providing a project review precedes the change in phase of work.

Appropriate stages might be the following:

- Project launch
- Program approval
- Start and end of product design
- Start and end of process design
- Start and end of prototype manufacture
- Start and end of product verification
- Start and end of process verification
- Product approval

Project reviews are not design reviews. Project reviews assess performance of the project and take into account timing, costs, organization, work assignments, subcontracts, etc. Design reviews look back at the technical aspects of design and look forward to the technical aspects of the design tasks ahead.

Using a multidisciplinary approach (4.2.4.4)

The standard requires *the use of a multidisciplinary approach to prepare for product realization including development and review of special characteristics, FMEA, and control plans.*

A multidisciplinary approach is another term for a *cross-functional team* or a *project team*. Such teams comprise representatives from each line and staff department so that decisions are taken close to the development work by those who will need to implement the decisions or verify their implementation. Such teams facilitate communication and overcome delays that often occur when reliant upon line-staff relationships. If you have adopted the project management approach this requirement is not additional to that in clause 4.2.4.1.

The project organization has been used for several decades as an effective means of organizing knowledge-based staff, pooling ideas, obtaining consensus, and making decisions that don't need to be sold to the line departments, since they are usually well represented. They do have some disadvantages as several project teams may call upon a single resource at the same time and this is where upper management need to prioritize projects. Also, if standards for each project differ, errors can occur as staff juggle with different requirements for the same piece of work. (See also Part 2 Chapter 1 under *Organizational interfaces.*)

Use of tools and techniques (4.2.4.5)

Advanced product quality planning (4.2.4.5)

The standard requires the supplier to *use tools and techniques identified in the customer reference manual on advanced product quality planning.*

The APQP manual does include mandatory requirements by use of the words *shall*, *will*, and *must* as well as an advisory approach indicated by the word *should*. However, use of the word *will* is not consistent since in some cases it has a future implication such as "There will be assumptions ..." Other styles are also used, such as "is responsible" and while many of the provisions are advisory, the lists of inputs and outputs, having no preceding instruction, are neither mandatory nor advisory so you should consult your

customer if in doubt. Certain topics in ISO/TS 16949 are also covered in the APQP manual and thus convert advice into mandatory requirements. However, in the final analysis, the auditor will judge so be prepared to justify adequately why you have not done something that is addressed in the manual! There is much good advice in the manual, which is commended to readers. It is not the purpose of this handbook to cover the detail of the supplementary manuals, as they speak for themselves. The development cycle shown as a bar chart is illustrated in Figure 2.8.

Analysis of potential nonconformities (4.2.4.5)

The standard requires the supplier to *carry out analysis of potential nonconformities and to implement appropriate action.*

There is one technique widely used in the automotive industry for detecting and analyzing potential nonconformities: Failure Modes and Effects Analysis (FMEA). There are Design FMEAs and Process FMEAs. The technique is the same – it is only the focus that is different. As clause 4.14 addresses potential nonconformities, the subject of FMEAs is treated in Part 2 Chapter 14.

Utilizing mistake-proofing methods (4.2.4.5)

The standard requires suppliers to *utilize appropriate mistake-proofing methods during the planning of processes, facilities equipment, and tooling.*

Mistake-proofing is a preventive action and like FMEA is addressed in Part 2 Chapter 14.

Process studies (4.2.4.5)

The standard requires the supplier to *perform process studies on all new processes to verify process capability and provide additional input for process control.*

Process capability and related studies are addressed in Part 2 Chapter 9.

Documenting the results of process studies (4.2.4.5)

The standard requires *the results of process studies to be documented with specifications for means of production, measurement and test, and maintenance instructions.*

Prior to conducting process studies a statement of objectives, the methods to be used, and the form in which the results are to be recorded should be defined. This might be called a Process Study Plan and be an output of process development (see clause 4.2.4.9). During process studies the results should be recorded in terms of measure-

ments taken, the results achieved, and the actions taken in adjusting process parameters to improve performance. Following completion of the study, a report should be compiled that presents the results and the conclusions relative to the specification of parameters. The allowable variation that has been proven to achieve the desired aim and which is to be maintained during production should be defined in the report.

Computer-aided design (4.2.4.6)

The standard requires the supplier to *have the appropriate resources and equipment (when specified in the contract) to utilize computer-aided product design, engineering, and analysis that is compatible with the customer's and subcontractor systems.* It is also required that the supplier *be able to use numerical design and drawing data, by computer-aided methods for the manufacture of production tooling and prototypes.*

When it is a contractual requirement it is likely that your customer will require design information to be transmitted electronically to their location. There are many types of computer-aided design equipment and therefore potential for incompatibility. If your existing equipment is incompatible with that of the customer, it could be very costly to replace and therefore necessary that you enter a dialog with your customer on an approach that is mutually acceptable. You obviously do not want to spend money on upgrading your equipment if it is not essential. The standard does not specifically require that these resources be used under controlled conditions – i.e. that there be documented procedures covering their use, application, maintenance, modification, and improvement – but clearly it would be sensible to employ such controls in order to guard against substandard output produced as a result of inferior facilities. If the facilities are used to establish and verify product characteristics the need for them to be controlled is covered by clause 4.11.

If the computer-aided engineering activities are to be subcontracted you will then need to convey the appropriate requirements of your contract to your subcontractor (especially the requirements for special characteristics), impose the controls established to meet clause 4.6, and devise a means of verifying that the subcontractor has met your requirements. As the data stored in the CAE system is vital to your business, you need to ensure its protection and control. You need to ensure that the systems used by the subcontractor are not unique and that the data can be migrated to another subcontractor. Insist also on duplicate copies as a safeguard against the subcontractor terminating his business. Where such data is transmitted directly to your customer, you need to verify its integrity, including computer virus protection, prior to its transmission.

Numerical design and drawing data may be in the form of magnetic tape or disk for numerically controlled machines. Clearly you would not enter into a contract unless you had the type of NC machines required to process this data.

Identifying special characteristics (4.2.4.6)

The standard requires the supplier to *apply the appropriate methods to identify special characteristics, to include these characteristics in the control plan, and to comply with any specific definitions and symbols the customer may use.*

During the planning phase, a preliminary list of special product characteristics should be produced. Special characteristics are those characteristics of products and processes designated by the customer and/or selected by the supplier through knowledge of the product and the process. They are special because they can affect the safe functioning of the vehicle and compliance with government regulations, such as flammability, occupant protection, steering control, braking, emissions, noise, EMC, etc. During the product design and development phase, the list should be refined and reviewed, and consensus reached. The output should be documented in the prototype control plan. During process design and development, the list should be converted into a matrix that displays the relationship between the process parameters and the manufacturing stations and this documented in the production control plan.

The standard also requires *documents such as FMEA, control plans, etc. to be marked with the customer's specific symbols to indicate those process steps that affect special characteristics.* As the characteristics in question will be specified within documents, the required symbols should be applied where the characteristic is mentioned rather than on the face of the document. For drawings, the symbol should be applied close to the appropriate dimension or item. Alternatively, where a document specifies processes that affect a special characteristic, the appropriate symbol should be denoted against the particular stage in the process that affects that characteristic. The symbols therefore need to be applied during document preparation and not to copies of the document. The instructions to apply these symbols should be included within the procedures that govern the preparation of the documents concerned.

Feasibility reviews (4.2.4.8)

The standard requires the supplier to *investigate and confirm the manufacturing feasibility of proposed products in contract review and to record the results of the review.*

This is a very sensible requirement and should have been included in ISO 9001 (see Part 2 Chapter 9). However, it should have been placed either under the heading *Design control* or under *Process control*, since the feasibility review in this context is not concerned with the feasibility of the project before commencing design but the feasibility of manufacturing the product following completion of design.

Details on what is required are given in section 2 of the APQP manual. However, the design reviews carried out at strategic stages during development should address manufacturability and so, rather than conduct one feasibility review, you should plan a review as part of each design review.

Management of process design (4.2.4.9)

Procedures for process design (4.2.4.9.1)

The standard requires the supplier to *establish and maintain documented procedures to develop and verify the design of processes used for product realization.*

This requirement applies to the processes used in product realization, production, installation, and servicing and hence is not intended to be applied to management and procurement processes.

It is therefore necessary to develop a process design procedure. A typical sequence might be as follows:

- 1 Define process requirements, including space, feed, and timing requirements.
- 2 Outline the process flow from input to output.
- 3 Identify where measurements are to be made of product and process.
- 4 Identify the inputs for each step.
- 5 Determine the origin of these inputs and how they will be transmitted to the workstation.
- 6 Determine how the inputs will be transformed into the output for each step in terms of equipment needed.
- 7 Determine what resources are needed and what constraints apply to process the product.
- 8 Determine what resources are needed and what constraints apply to measure the product and the process.
- 9 Determine the destination of the outputs (including waste) and how they will be transmitted to the next workstation or be disposed of.

- 10 Produce floor plan.
- 11 Determine how materials will be held awaiting processing and after processing.
- 12 Determine health, safety, and environmental precautions.
- 13 Determine handling methods.
- 14 Determine measurement methods.
- 15 Perform process FMEA and mistake-proofing.
- 16 Conduct maintainability analysis.
- 17 Conduct simulation to establish provisional resource consumption including time, materials, labor, etc.
- 18 Produce process specification.
- 19 Produce process operating instructions.

Process design results in the design output, following which the process has to be constructed or installed, personnel trained capability studies conducted, and process verification performed. It will therefore be necessary to generate several other procedures dealing with each of these topics.

In addition you will need a process development plan in which you define who does what, when, and how for each new process from conception through to process approval.

A process development plan should address:

- Timeline from concept through to process approval
- Development tasks and responsibilities
- Make or buy decisions addressing what you will make in-house and what will be purchased
- Construction, installation, and commissioning tasks and responsibilities
- Tests and trials and responsibilities

- Competency development and responsibilities
- Process development trials, process capability studies, and analyses
- Process verification and process approval

A process development team should be established to manage the development of any new processes. The team may be formed from the project team but you may need additional specialists. If several new processes are to be developed, several teams will be needed. By building a team for each process you will focus the efforts of staff more clearly than loading several new jobs onto the same individuals, but if you lack resources you may have no option.

Identifying process design input requirements (4.2.4.9.1)

The standard requires the supplier to *identify, document, and review the process design input requirements*.

The primary input data is product design data consisting of:

- Design FMEA
- Design for Manufacturability and Assembly Plan
- Design review reports
- Prototype control plan
- Engineering drawings and specifications
- Material specifications
- New equipment, tooling, and facilities requirements
- Statement of special product and process characteristics
- Gages and testing equipment requirements
- Feasibility review report

These inputs will come from the product design activities and should already be documented. On receiving these inputs the process development team should review them and begin to produce the process development plan.

Expressing process design output data (4.2.4.9.2)

The standard requires the process design output *to be expressed in terms that can be verified and validated against process design input requirements.*

Process design output should include the following:

- Process specifications
- Process flowchart
- Floor plan
- Packaging specifications
- Process FMEA
- Process instructions including set-up and set-up verification
- Handling requirements
- Operator competency requirements
- Measurement systems analysis plan

These may change after tests and trials and therefore need to be brought under change control following the document approval.

Verifying process design output (4.2.4.9.3)

The standard requires the supplier to *verify process design output against process design input requirements and record the results.*

Once the process has been commissioned (i.e. set to work) trials can be conducted to optimize the process parameters. When special causes of nonconformity have been removed, process verification can commence. Process verification consists of a number of activities:

- Process capability studies (see Part 2 Chapter 9)
- Mistake-proofing verification
- Competency verification
- Equipment health, safety, and environmental verification

- Tooling and equipment reliability and maintenance verification
- Packaging evaluation
- Measurement systems evaluation

The records of all tests, inspections, analyses, and demonstrations should be generated which demonstrate that the process is safe, meets environment legislation, is reliable, stable, capable, and maintainable and produces products that meet engineering standards. The next step is product approval.

Control plans (4.2.4.10)

The standard requires the supplier to *develop control plans using a multidisciplinary approach at the system, subsystem, component, and/or material level for pre-launch and production and prototype when required.*

The purpose of the control plan is to ensure that all process outputs will be in a state of control by providing process monitoring and control methods to control product and process characteristics. The control plan is covered in section 6 of the APQP manual. It consists of forms containing data for identifying process characteristics and helps to identify sources of variation in the inputs that cause product characteristics to vary. The APQP manual provides excellent guidance on the compilation and use of the control plan so no further guidance is given here.

Three types of control plan are required. During the product design and development phase, a prototype control plan is required to be produced. During the process design and development phase, a pre-launch or pilot production control plan is required, and during the product and process validation phase, the production control plan is to be issued.

Pre-launch occurs after prototype testing and prior to full production. Additional inspections and tests may be needed until the production processes have been validated and process capability assured. The additional checks serve to contain nonconformities until variation has been brought within acceptable limits for production.

A sample format for a control plan is illustrated in Figure 2.8.

Figure 2.8 Control plan format

<input type="checkbox"/> Prototype <input type="checkbox"/> Pre-launch <input type="checkbox"/> Production Control Plan Number			Contact				Date Created		Date Revised		
Part Number/Revision Level		Core Team					Customer Eng Approval Date				
Part Name/Description						Supplier/Plant Approval Date		Customer Quantity Approval Date			
Supplier Plant				Supplier Code		Other Approval Date		Other Approval Date			
Part/Process Number	Process Name/Operation Description	Machine, Device, Jig, Tools, for Mfg	Characteristics			Special Char Class	Methods				Reaction Plan
			No	Product	Process		Product/Process Specification Tolerance	Evaluation Measurement Technique	Sample		
										Size	Freq

Maintenance of control plans (4.2.4.10)

The standard requires control plans *to be reviewed and updated as appropriate when certain conditions arise*.

This requirement should have been unnecessary since clause 4.2.1 requires the quality system to be maintained. However, what it does do is overcome any ambiguity by defining the occasions when the control plan has to be updated.

Product approval process (4.2.4.11)

Product approval procedures (4.2.4.11)

The standard requires the supplier to *comply with a product and process approval procedure recognized by the customer*.

The product approval process, or PPAP as it is known in QS-9000, is intended to validate that products made from production materials, tools, and processes meet the customer's engineering requirements and that the production process has the potential to produce product meeting these requirements during an actual production run at the quoted production rate.

The process commences following design and process verification during which a production trial run using production-standard tooling, subcontractors, materials, etc. produces the information needed to make a submission for product approval. Until approval is granted, shipment of production product will not be authorized. If any of the processes change then a new submission is required. Shipment of parts produced to the modified specifications or from modified processes should not be authorized until customer approval is granted.

When one considers the potential risk involved in assembling unapproved products into production vehicles, it is hardly surprising that the customers impose such stringent requirements. The process is similar in other industries but more refined and regulated in mass production where the risks are greater.

The requirements for product approval are defined in the reference manuals. You may not need to prepare product approval submissions for *all* the parts you supply. The applicability of product approval procedures is affected by several factors so definitive solutions cannot be offered. The fundamental requirement is that if you supply product to the automotive customers you need a product approval procedure in place to gain ISO/TS 16949 registration. If you have been supplying parts for some time without product approval then you should confirm with your customer that you may continue to do so.

The requirements in clause 4.2.4.11 are linked with other elements of the standard, even when there is no cross reference. This relationship is illustrated in Figure 2.8.

The documentation required varies but is likely to include the following:

- Production part submission warrant – a form that captures essential information about the part and contains a declaration about the samples represented by the warrant
- Appearance approval report – a form that captures essential information about the appearance characteristics of the part
- Design records, including specifications, drawings, and CAD/CAM math data
- Engineering change orders not yet incorporated into the design data but embodied in the part
- Dimensional results using a pro forma or a marked up print
- Test results
- Process flow diagrams
- Process FMEA
- Design FMEA where applicable
- Control plans
- Process capability study report
- Measurement systems analysis report

The data on which the product approval submission is based should be generated during the process verification phase.

Applying product approval (4.2.4.11)

The standard requires the supplier to *apply the product approval process to subcontractors*.

Your subcontractors may not need to supply product approval submissions for all parts they supply but there are situations where subcontractor product approval submissions are required. For example, GM requires product approval of all commodities supplied by subcontractors to first tier suppliers. The standard does point out that suppliers are

responsible for subcontracted material and services so if your submission relies on your subcontractors operating capable processes, you should be requesting a product approval submission from them.

Verification of changes (4.2.4.11)

The standard requires the supplier to *verify that changes are validated (including all subcontractor changes) and, when required by the customer, additional verification/identification requirements shall be met.*

Following product approval any change to the product or the processes producing it needs to be assessed for its impact on the conditions of product approval. You need close contact with your subcontractors because you need to capture any changes they make and perform an impact assessment. This can be difficult if you are using proprietary products. Your contract with your supplier needs to require the supplier to notify you of any changes in product or process. Quite minor changes may have significant effect on the product you supply to your customer. In some cases, suppliers may not accommodate your requirements, especially if the order value is small.

Notification of changes (4.2.4.11)

The standard requires *all changes to be notified to customers which may require customer approval.*

Customer approval is likely when:

- Products are modified.
- A discrepancy on a previously submitted part has been corrected.
- Changes are made to the production process, materials, tooling, subcontractors, etc.
- Production has been inactive for 12 months or more.
- Shipment has been suspended due to quality problems.

Plant facility and equipment planning (4.2.5)

Plant layouts (4.2.5)

The standard requires *plant layouts to minimize material travel and handling, synchronize material flow, and optimize value added use of floor space and to use a multidisciplinary approach for developing plant facility and equipment plans.*

For some types of production, the facility housing the equipment and machinery needed to create, move, and store product has to be designed. The pathways for raw materials and semi-finished product need to be thought out and the gangways for staff movement need careful planning to prevent hazard.

The term *plant* relates to the collection of buildings and equipment designed for a particular industrial purpose, whereas the term *facility* is a smaller collection of machines, equipment, and tools within a plant to facilitate particular operations or processes. Plant design cannot commence until conceptual design of the product and the process flow have been worked out and the planned production targets determined. You need to know what quantities of material and product need to be stored and moved plus the limitations on your current layout and determine whether changes are needed to minimize material travel and handling. This can cause some difficult decisions since plant design decisions tend to be long term and cannot be implemented without considerable disruption to existing facilities. This is one advantage of cellular manufacturing, where a complete cell can be redesigned without affecting other cells.

You should develop a documented procedure for the facility planning activity that will ensure the provision of adequate information on which to base plant design decisions. The procedures should provide for a separate development plan with allocation of responsibilities for the various tasks to be undertaken and should cover the layout, specification, procurement, installation, and commissioning of the new or revised plant.

Evaluation methods (4.2.5)

The standard requires the supplier to *develop methods for evaluating the effectiveness of existing operations* and recommends *appropriate metrics are identified and defined*.

Your procedures should detail your plant evaluation methods and require consideration to be given to the overall plan of the plant, automation, ergonomics, operator and line balance, inventory levels, and value added labor content. Reports of the evaluation should be required so that they facilitate analysis by management and auditors.

The layout of your plant and facilities should be documented to facilitate its analysis. Detailed installation drawings and commissioning procedures should be prepared in order to ensure completion on time. Plant dimensions and movement times should be recorded and the constraints imposed by handling-equipment, safety and environmental regulations registered. The documents should be brought under document control since their revision is necessary whenever the layout is changed. Out-of-date plans will hinder future planning activities so their maintenance is a preventive action (clause 4.14.3).

Tooling management (4.2.6)

The standard requires the supplier to *provide appropriate technical resources for tool and gage design, fabrication, and verification activities, establish a system for tooling management, and implement a system to track and follow-up tooling management activities if any work is subcontracted.*

An item is a tool when it comes into contact with a part and produces a change to that part. Clearly if tooling is not adequately controlled, product quality will not be maintained.

Many general-purpose tools used in manufacturing industry are designed by tool manufacturers. The purchase of these tools is governed by clause 4.6 and their use governed by clause 4.9(b). If you subcontract the design of tooling, clause 4.6 again applies.

Apart from general-purpose cutting tools, hand tools, and gages, most of the shaping, forming, pressing, and molding tools, inspection gages, etc. may need to be especially designed and fabricated. This will probably require a tool design office where the tools, jigs, fixtures, and gages are designed and a toolroom where the tools are manufactured and inspected. Control of tooling is extremely important as in some cases you will be reliant on the contour of the tool to form the part and you will be unable to check the part economically by other means. In such cases it is simpler to check the tool frequently in order to detect wear before it produces a nonconforming part.

You need to possess either the necessary competence to design and make tools or the ability to control any subcontractors you employ to do this work for you. You need appropriate numbers of staff to do the job, equipped with design and manufacturing resources that enable them to deliver effective tools when needed. Tooling engineers should participate in design reviews during the product design and development phase and undertake the following activities where appropriate:

- Design review of tooling
- Mistake-proofing using the results of failure modes analysis
- Tool wear analysis
- Tool accuracy analysis
- Tool maintenance planning
- Preparation of tool set-up instructions

Certain tools are perishable; i.e. they are consumed during the process. Others are reusable after maintenance and this is where adequate controls need to be in place. The tool control system needs to cover tool selection, set-up, tool change, and tool maintenance. You will need procedures for withdrawing maintainable tools from service, performing the maintenance, and then putting the tools back into service. You need to build in safeguards that prevent worn tools being used and to replenish tools when their useful life has expired.

If you do subcontract tool maintenance, you need to keep track of assignments so that you are not without vital tools when you need them.

Process improvement (4.2.7)

The standard requires that *continuous improvement extend to product characteristics and process parameters with the highest priority on special characteristics.*

This requirement illustrates some ambiguity over terminology. Clause 4.1.1.4 mentions improvement in quality which implies improvement in product and process characteristics, thereby making this additional requirement superfluous. Little more is needed than was given in Part 2 Chapter 1 except to state that when setting priorities for improvement you need to focus on the special characteristics first.

Quality system performance (4.2.8)

The standard requires the supplier to *evaluate the performance of the quality system to verify the effectiveness of its operation.* It also requires *the results to be used for continuous improvement or corrective action as appropriate.*

Although the wording is different, this requirement adds very little to that in clause 4.1.3 for management review. However, there are some significant differences. The action required is not a review but an evaluation, implying that the evaluation is performed first and followed by a review of the results. The evaluation does not need to be performed by management with executive responsibility. It can be performed by any qualified personnel. It extends the ISO 9001 requirement for quality objectives by requiring there to be evidence of the achievement of those specified in the quality policy. The objectives in the business plan should be strategic objectives and are therefore also addressed in clause 4.1.3.2. The determination of customer satisfaction is dealt with in clause 4.1.1.3 and the requirements of the results to be used for continuous improvement are also dealt with in clause 4.1.3.2.

Task list

- 1 Define what you want your quality system to do – define its purpose.
- 2 Create a plan of how you intend to design, develop, introduce, and evaluate the quality system.
- 3 Determine the resources required to design, develop, introduce, and evaluate the quality system.
- 4 Determine training needs for developing, implementing, and evaluating the quality system.
- 5 Determine the operational policies needed to implement the corporate quality policy and place these in a policy manual with the corporate quality policy.
- 6 Create a system manual that describes your quality system and how it works and references all the procedures, standards, etc. that implement your quality policies.
- 7 Determine the hierarchy of documentation which you intend to produce to define your quality system (the number and content of the volumes of procedures etc.)
- 8 Define what types of document constitute your quality system.
- 9 Design the quality system from the top down by analyzing your business processes and then implement from the bottom up, starting with customer complaints.
- 10 Produce a glossary of terms covering the concepts, documents, and activities to be used in developing and implementing the quality system.
- 11 Identify the control procedures you need to control what you do now and prepare a document development plan.
- 12 Compare what you do now with the requirements of ISO/TS 16949 and identify additional procedures and changes to your existing procedures.
- 13 Set up a quality system development team.
- 14 Determine methods for authorizing the preparation of new quality system documents.
- 15 Produce procedures for preparing, reviewing, approving, publishing, and distributing quality system documents.
- 16 Produce procedures for introducing, commissioning, qualifying, changing, filing, and withdrawing quality system documents.
- 17 Implement the document development plan.

- 18 Determine how you intend to maintain the system.
- 19 Determine how you intend to capture potential changes that will affect your quality system.
- 20 Install the procedures, standards, and guides into the business operations on a progressive basis.
- 21 Monitor the introduction of new practices.
- 22 Commence change control practices.
- 23 Qualify quality system documents for their application.
- 24 Remove all obsolete documents from operational use.
- 25 Launch the internal audit program.
- 26 Collect and analyze the data which the system generates.
- 27 Use the data for improving the effectiveness of the system.
- 28 Create a mechanism for preparing quality plans if your quality system has to be tailored to suit each product, contract, or project.
- 29 Produce and agree resource budgets for implementing the quality plan.
- 30 Review quality plans at each stage of the product/project life cycle for continued suitability.
- 31 Establish a product realization process that covers the phases from product conception to product approval.
- 32 Set up a mechanism to preserve the confidentiality of customer documentation and products.
- 33 Establish project reviews as separate reviews from design reviews.

Quality system questionnaire

- 1 What is the purpose of the quality system and where is it defined?
- 2 What is the scope of the quality system and where is it defined?
- 3 In what document are the requirements of ISO/TS 16949 addressed?
- 4 In what document are the quality system procedures either contained or referenced?
- 5 In what document is the outline structure of the documentation used in the quality system described?
- 6 How do you prepare the quality system procedures?
- 7 How do you determine the degree of documentation required?
- 8 How do you ensure your quality system procedures are consistent with the requirements of ISO/TS 16949 and your quality policy?
- 9 How do you ensure that the documented quality system is implemented effectively?
- 10 How is the quality system maintained?
- 11 In what manner do you define and document how the requirements for quality will be met?
- 12 How do you ensure that quality planning is consistent with other requirements of the quality system?
- 13 How do you identify and acquire any controls, processes, equipment, fixtures, resources, and skills that may be needed to achieve the required quality?
- 14 How do you determine whether a quality plan is necessary?
- 15 How do you ensure that the design, production process, installation, servicing, inspection, and test procedures and applicable documentation are compatible with the specified requirements?
- 16 How do you identify whether any quality control, inspection and testing techniques, and instrumentation requires updating to meet specified requirements?
- 17 How do you identify measurement requirements involving a capability that exceeds the known state of the art in sufficient time for the capability to be developed?
- 18 How do you identify verification requirements and plan their implementation at the appropriate stages?

- 19 How do you ensure that standards of acceptability for all features, including those containing a subjective element, are clarified before work commences?
- 20 How do you identify and prepare any new quality records that are needed to meet specified requirements?
- 21 How do you manage the product realization process so that it delivers products and processes that meet customer requirements?
- 22 What approach do you take to manage product realization?
- 23 How do you ensure confidentiality of customer data and product?
- 24 What measurements do you perform to determine the progress and success of product realization?
- 25 What disciplines comprise your multidisciplinary or project teams?
- 26 How do you manage the development of new processes?
- 27 How do you manage the design, development, and maintenance of tooling?

Do's and don'ts

- ⊗ Don't attempt anything unless you have the commitment and the funding to carry it through.
- ⊗ Don't start by defining new ways of doing things.
- ☺ Do document what you do now before considering new practices.
- ⊗ Don't let your consultants write all the documents.
- ⊗ Don't abdicate the preparation of documents to others.
- ☺ Do keep it simple and avoid unnecessary complexity.
- ☺ Do set targets for developers to aim for.
- ☺ Do review progress often.
- ⊗ Don't let the standard dictate what you must do – let the business do that.
- ⊗ Don't use cross-referencing between documents unless it is to the whole document.
- ⊗ Don't put people's names, titles, and locations in your procedures.
- ⊗ Don't divorce the quality system documents from other documents of your business – develop an integrated system.
- ⊗ Don't accept any application for a new procedure until you have determined where it fits in the system and how it will interface with other procedures.
- ☺ Do publish a glossary of terms to those involved before you commence procedure preparation.
- ☺ Do depict the system by diagrams and flowcharts as well as by text.
- ⊗ Don't try to anticipate everything – if it fits 80% of situations publish it.
- ☺ Do obtain prior approval before issuing new procedures for use.
- ☺ Do circulate draft documents for comment before submitting for approval.
- ⊗ Don't ignore people's comments – you may need their support in implementing the procedure later.
- ⊗ Don't stop development after registration.
- ⊗ Don't produce project/product specific procedures that conflict with the established quality system.
- ⊗ Don't include functions in your quality system unless they are essential to achieving customer requirements – they will be subject to third party audit otherwise.

Chapter 3

Contract review

Scope of requirements

This chapter deals with contracts placed on the supplier by customers, rather than contracts placed by the company on its suppliers. This can be a source of confusion for those unfamiliar with marketing and sales functions.

If you don't have contracts, you can't have a record of contract reviews. However, if the organization being certified to ISO 9001 is part of a larger organization, it may receive orders from other divisions of the same organization and these transactions can be interpreted as "contracts" for the purpose of ISO 9001 certification. In such cases you will need Service Agreements with the other divisions which will be governed by the requirements of this clause of the standard. If you obtain services from other divisions of the same organization, these will need to be treated as "subcontractors" and governed by the requirements of clause 4.6 of the standard.

The purpose of the requirements is to ensure that you have established the requirements you are obliged to meet before you commence work. This is one of the most important requirements of the standard. The majority of problems downstream can be traced either to a misunderstanding of customer requirements or insufficient attention being paid to the resources required to meet customer requirements. Get these two things right and you are halfway there to satisfying your customer needs and expectations.

Many organizations do business through purchase orders or simply orders over the telephone or by mail. Some organizations may not be required to enter into formal contracts by their customers. However, a contract does not need to be written and signed by both parties to be a binding agreement. Any undertaking given by one party to another for the provision of products or services is a contract whether written or not. An example of how these requirements can be applied to a simple over-the-counter transaction is given at the end of the chapter.

In this competitive environment, product design may well be carried out during the tendering phase and yet ISO/TS 16949 does not require all aspects of the tendering phase to be performed under controlled conditions. However, customers need confidence that the supplier's tender was produced under controlled conditions. That is, there is more to the words in the tender than mere promises – the facts have been checked and validated; any proposed solution to the requirements will if implemented actually satisfy all the accepted requirements.

The requirements in element 4.3 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 3.1.

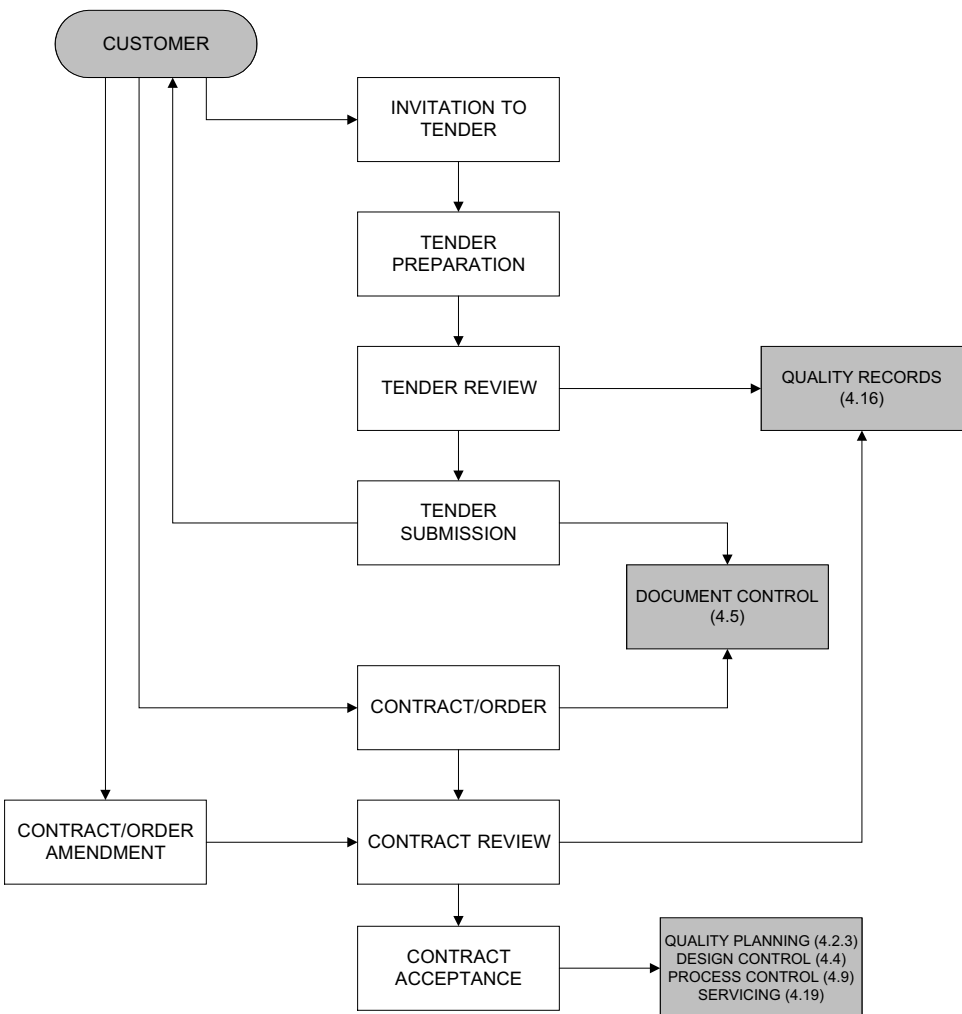


Figure 3.1 Element relationships with the contract review element

Procedures for contract review (4.3.1)

The standard requires firstly that the supplier *establishes and maintains documented procedures for contract review*.

Contract review is but one of the tasks in the contract acquisition process. These are marketing, prospect acquisition, tendering, contract negotiation, contract award, and then contract review. However, in a sales situation, you may simply have a catalog of products and services and a sales office taking orders over the telephone or over the counter. The contract review element of this operation takes a few seconds while you determine if you can supply the item requested. In an organization that produces products to specific customer requirements you may in fact carry out all the tasks in the contract acquisition process. Rather than isolate the contract review task and produce a procedure for this, your business may benefit more from a procedure or series of procedures that covers the contract acquisition process as a whole.

Your contract acquisition procedures need to define as appropriate:

- How potential customers are persuaded to place orders or invitations to tender
- How invitations to tender and customer orders are dealt with
- How proposals and quotations are generated, reviewed, and approved
- How contracts are negotiated
- How contracts are accepted, promulgated, and communicated to those concerned
- How changes to contract are initiated
- How changes to contract are agreed, promulgated, and communicated to those concerned
- What channels of communication should be established between supplier and customer
- The authority and responsibility of those who are permitted to interface with the customer

The standard specifies when contract reviews should be undertaken: before submission of a tender or acceptance of a contract. However, having reviewed it once, there is an ongoing requirement for you to ensure you remain capable of satisfying the require-

ments to which you have agreed. For contracts of short duration this will not be necessary. However, where the contract duration extends over several months or years, it is necessary to review periodically the requirements and your capability of meeting them. In project work these are known as *project reviews* and may be held at planned stages: monthly, quarterly, yearly, or when the nature of the subsequent work is to change; for instance:

- At the end of conceptual design prior to commencing detail design
- At the end of detail design prior to commencing production
- At the end of production prior to commencing installation
- At the end of installation prior to hand-over into service

Coordinating contract review activities (4.3.1)

The standard requires that the supplier *establishes documented procedures for coordinating contract review activities*.

In over-the-counter sales situations there is nothing to coordinate. However, in the contracting business, where several departments of the organization have an input to the contract and its acceptability, these activities do need coordinating. When you enter into contract negotiations, the activities of your staff and those of your customer will need coordinating so that you are all working with the same set of documents. You will need to collect the contributions of those involved and ensure they are properly represented at meetings. Those who negotiate contracts on behalf of the company carry a great responsibility. A sales person who promises a short delivery to win an order invariably places an impossible burden on the company. A company's capability is not increased by accepting contracts beyond its current level of capability. You need to ensure that your sales personnel are provided with reliable data on the capability of the organization, do not exceed their authority, and always obtain the agreement of those who will execute the contractual conditions before accepting them on their behalf.

One aspect of a contract often overlooked is shipment of finished goods. You have ascertained the delivery schedule, the place of delivery, but how do you intend to ship it: by road, rail, ship, or air. It makes a lot of difference to the costs. Also delivery dates often mean the date on which the shipment arrives not the date it leaves. You therefore need to build into your schedules an appropriate lead time for shipping by the means agreed to. If you are late then you may need to employ speedier means but that will

incur a premium for which you may not be paid. Your financial staff will therefore need to be involved in the contract review.

Having agreed to the contract, you need to convey all the contractual requirements to their point of implementation in sufficient time for resources to be acquired and put to work.

Ensuring that the requirements are adequately defined and documented (4.3.2.1a)

The standard requires that *before submission of a tender, or acceptance of a contract or order (statement of requirement), the tender, contract, and order are reviewed to ensure that the requirements are adequately defined and documented.*

There will be some organizations that deal with such predictable orders that a formal documented review before acceptance will be an added burden. But however predictable the order it is prudent to establish that it is what you believe it to be before acceptance. Many have been caught out by the small print in contracts or sales agreements such as the wording: “This agreement takes precedence over any conditions of sale offered by the supplier.”

If the customer is choosing from a catalog or selecting from a shelf of products, you need to ensure that the products offered for sale are properly described. Such descriptions must not be unrepresentative of the product, otherwise you may be in breach of national laws and statutes. In other situations you need some means of establishing that the customer requirements are adequate.

Although ISO 8402 defines quality as *the totality of characteristics of an entity that bears on its ability to satisfy a stated or implied need*, ISO 9001 does not require the required characteristics to be specified. Note 2 of clause 4.3.4 defines a contract and accepted order as *agreed requirements* but not *specified requirements* as used elsewhere in the standard. It would have made for less ambiguity if the term *customer requirements* had been used throughout and then there would be no doubt as to what requirements and to whose requirements these clauses refer.

You could be forgiven for restricting your quality system to the products or services you supply because all the requirements in the standard except clause 4.3 focus on an end product or service conforming to specified requirements. Contract or order requirements will go beyond end product or service requirements. They will address delivery, quantity, warranty, payment, and other legal obligations. With every product one provides a service; for instance one may provide delivery to destination, invoices for payment,

credit services, inquiry services, warranty services, etc. and the principal product may not be the only product either. There may be packaging, brochures, handbooks, specifications, etc. With services there may also be products such as brochures, replacement parts and consumables, reports, certificates, etc. The definition given in ISO 8402 for product provides for a product being a combination of products and services; therefore, when conducting your contract review you should be addressing all products and services you provide to your customer.

■ Each product has associated services and each service associated products.

In ensuring that the contract requirements are adequately defined, you should establish where applicable that:

- There is a clear definition of the purpose of the product or service you are being contracted to supply.
- The conditions of use are clearly specified.
- The requirements are specified in terms of the features and characteristics that will make the product or service fit for its intended purpose. A list of typical features and characteristics is given in Part 1 Chapter 1 for both products and services.
- The quantity and delivery are specified.
- The contractual requirements are specified, including: warranty, payment conditions, acceptance conditions, customer supplied material, financial liability, legal matters, penalties, subcontracting, licenses, and design rights.
- The management requirements are specified, such as points of contact, program plans, work breakdown structure, progress reporting, meetings, reviews, interfaces.
- The quality assurance requirements are specified, such as quality system standards, quality plans, reports, customer surveillance, and concessions.

An adequately documented requirement would be a written contract, schedule of work, and/or specification. However simple the requirement, it is wise to have it documented in case of a dispute later. The document needs to carry an identity and if subject to change, an issue status. In the simple case this is the serial numbered invoice and in more complicated transactions, it will be a multi-page contract with official contract number, date, and signatures of both parties.

The standard allows for undocumented verbal orders but requires that the order requirements are agreed before their acceptance. The third party auditor cannot confirm conformity with this requirement as there will be no objective evidence to substantiate the transaction other than the payment invoice. If the supplier confirms the agreement in writing a written statement of requirement exists. The standard does not stipulate that the agreement has to be documented only that the requirements need to be documented regardless of who produced them. The only evidence that the requirements were adequately defined is therefore the payment from the customer against the supplier's invoice.

Resolving differences (4.3.2.1b)

The standard requires that *before submission of a tender, or acceptance of a contract or order (statement of requirement), the tender, contract, and order are reviewed to ensure that any contract or accepted order requirements differing from those in the tender are resolved.*

There is a slight conflict in this clause as it requires that before acceptance of an order, you need to ensure that any differences between your tender and the accepted order requirements are resolved. Clearly if you have not accepted the order you don't need any accepted order requirement. But this small ambiguity doesn't detract from the essence of the requirement.

Whether or not you have submitted a formal tender, any offer you make in response to a requirement is a kind of tender. Where a customer's needs are stated and you offer your product, you are implying that it responds to your customer's stated needs. You need to ensure that your "tender" is compatible with your customer's needs otherwise the customer may claim you have sold a product that is not "fit for purpose". If the product or service you offer is in any way different than the requirement, you need to point this out to your customer in your tender or in negotiations and reach agreement. Always record the differences in the contract. Don't rely on verbal agreements as they can be conveniently forgotten when it suits one party or the other.

Ensuring that the supplier has the capability to meet contractual requirements (4.3.2.1c)

The standard requires that *before submission of a tender, or acceptance of a contract or order (statement of requirement), each tender, contract, and order be reviewed to ensure that the supplier has the capability to meet contract or accepted order requirements.*

You must surely determine that you have the necessary capability before accepting the contract as to find out afterwards that you haven't the capability to honor your obligations could land you in deep trouble. It is important that those accepting a contract are in a position to judge whether the organization has the capability of executing it. You have to consider that:

- You have access to the products and services required.
- You have a license to supply them if appropriate.
- You have the technology to design, manufacture, or install the product.
- You have the equipment to utilize the data in the form that the customer may provide to you (e.g. CAD/CAM, NC Tapes, Advanced Shipment Notification).
- You have the skills and knowledge to execute the work required in the time required and to the specified standards.
- There is sufficient time to accomplish the task with the resources you have available.
- You have access to appropriate subcontractors and suppliers.
- There is a secure supply of the necessary materials and components.
- You can meet the terms and conditions imposed by your customer.
- You are prepared to be held to the penalty clause (if specified).

If you don't have any of the above, you will need to determine the feasibility of acquiring the relevant license, the skills, the technology, etc. within the time-scale. Many organizations do not need staff on waiting time, waiting for the next contract. It is a common practice for companies to bid for work for which they do not have the necessary numbers of staff. However, what they need to ascertain is from where and how quickly they can obtain the appropriate staff. If a contract requires specialist skills or technologies that you don't already possess, it is highly probable that you will not be able to acquire them in the time-scale. It is also likely that your customer will want an assurance that you have the necessary skills and technologies before the contract is placed. No organization can expect to hire extraordinary people at short notice. All you can rely on is acquiring average people. With good management skills and a good working environment you may be able to get these average people to do extraordinary things but it is not guaranteed!

In telephone sales transactions or transactions made by a sales person without involving others in the organization, the sales personnel need to be provided with current details of the products and services available, the delivery times, prices, and procedures for varying the conditions.

Identifying cost elements (4.3.2.2)

The standard requires the supplier to *have a process for identifying the cost elements or price in developing quotations*.

This requirement is an extension of clause 4.3.2.1. It places further constraints on the tendering process.

Customers need confidence that supplier quotations have been developed using valid data. They want to be sure that you are capable of maintaining the price quoted and not underestimating or inflating material costs. By employing a process for developing quotations using established metrics you reduce variations when quotations need to be frequently produced by different people. An approach to take would be to establish a database of pricing data that includes:

- Labor costs
- Component and material costs
- Overheads
- Packaging costs
- Transportation costs
- Development recovery costs
- Profit margins
- Handling costs, where incoming material is stored and shipped without value added
- Discounts for quantity

The process would need to include:

- Means to capture pricing data from suppliers

- Means to capture internal cost elements
- Means to select product/service specification variables and associated prices
- Means to update the data periodically
- Means to generate quotations using the data

The third party auditor is entitled to look at the elements making up the quotation to verify that all appropriate elements have been included, but will not examine the values attributed to these elements.

Meeting customer-specific requirements (4.3.2.2)

The standard requires that the supplier *ensure that any customer-specific requirements are met.*

Customers may have specific requirements that apply to the contract acquisition processes, such as limitation on profit, special quotation forms, validity of quotation, etc. VDA 6.1, for example, has a requirement for the marketing function to be incorporated into the operational organization.

Amendments to contract (4.3.3)

The standard requires suppliers to *identify how an amendment to a contract is made and correctly transferred to the functions concerned.*

There may be several reasons why a customer needs to amend the original contract – customer needs may change, your customer’s customer may change the requirement, or details unknown at the time of contract may be brought to light. Whatever the reasons you need to provide a procedure for amending existing contracts under controlled conditions. On contracts where liaison with the customer is permitted between several individuals – e.g. a project manager, contract manger, design manager, procurement manager, manufacturing manager, quality assurance manager – it is essential to establish ground rules for changing contracts, otherwise your company may unwittingly be held liable for meeting requirements beyond the funding that was originally predicted. It is often necessary to stipulate that only those changes to contract that are received in writing from the contract authority of either party will be legally binding. Any other changes proposed, suggested, or otherwise communicated should be regarded as being

invalid. Agreement between members of either project team should be followed by an official communication from the contract authority before binding either side to the agreement.

Having officially made the change to the contract, a means has to be devised to communicate the change to those who will be affected by it. You will need to establish a distribution list for each contract and ensure that any amendments are issued on the same distribution list. The distribution list should be determined by establishing who acts upon information in the contract and may include the technical or design managers, the production and procurement managers, the test, commissioning, and installation managers, and the quality manager or management representative. Once established, the distribution list needs to be under control because the effect of not being informed of a change to contract may well jeopardize delivery of conforming product.

Maintaining records of contract reviews (4.3.4)

The standard requires *records of contract reviews to be maintained*.

Each order or contract should be signed by a person authorized to accept such orders or contracts on behalf of the organization. You should also maintain a register of all contracts or orders and in the register indicate which were accepted and which declined. If you prescribe in your contract acquisition procedures the criteria for accepting a contract, the signature of the contract or order together with this register can be adequate evidence of contract review. If contract reviews require the participation of several departments in the organization, their comments on the contract, minutes of meetings, and any records of contract negotiations with the customer represent the records of contract review. It is important, however, to be able to demonstrate that the contract being executed was reviewed for adequacy, for differences in the tender, and for supplier capability before work commenced. As stated previously, if you don't have written contracts you can't have records of contract reviews. The minimum you can have is a signature accepting an assignment to do work or supply goods but you must ensure that those signing the document know what they are signing for.

Application of requirements

Consider, for example, the transaction made between a person purchasing a replacement lamp for a motor vehicle. How might these requirements apply in such a case?

- The customer inquires whether the supplier has a lamp for a motor vehicle.

- The supplier obtains details of the type, model, and year of the vehicle, which lamp in which position, and then accesses the stock computer to identify the part number.
- The supplier then confirms with the customer that the correct lamp has been located. (The supplier is ensuring that the requirements are adequately defined. There is no document unless the customer makes the transaction by mail and there is no tender because the customer did not request one. These requirements of clause 4.3.2.1 are therefore not applicable.)
- The supplier then establishes that the identified part is in stock. (The supplier is now establishing the capability of meeting the requirement.)
- Having determined that the item is in stock and informed the customer of the price, the supplier presents the lamp together with an invoice to the customer for payment. (The invoice is the record of the contract review.)
- Should the customer change the requirement, a new transaction will commence. (This new transaction is the method by which amendments to contract are made.)

Task list

- 1 Define what constitutes a contract for your organization.
- 2 Determine when a formal review of a contract is necessary.
- 3 Determine what constitutes a review of a contract.
- 4 Prepare a procedure for conducting formal contract reviews.
- 5 Determine which functions in the organization should participate in contract reviews.
- 6 Decide how you will obtain input, comment, and participation in contract reviews.
- 7 Determine who should receive copies of the contract.

- 8 Establish criteria for determining whether sufficient information has been provided in the contract.
- 9 Establish a means for the reviewers to determine whether your organization has the capability to meet the contract requirements.
- 10 Prepare a contract amendment procedure covering incoming and outgoing amendments.
- 11 Establish who will hold the records of contract reviews, where they will be filed, and who will have access to them.
- 12 Establish a tendering process in which cost elements are identified, captured, and used to provide valid quotations.

Contract review questionnaire

- 1 How do you review tenders, orders, and contracts?
- 2 How do you coordinate contract reviews?
- 3 In what documents are the channels of communication and interface with the customer defined?
- 4 How do you ensure that requirements are adequately documented before they are accepted?
- 5 How do you ensure that requirements differing from those in the tender are resolved before contract or order acceptance?
- 6 How do you ensure that you have the capability to meet the contractual requirements before accepting a contract or order?
- 7 How are amendments to contracts made and correctly transferred to the functions concerned?
- 8 In what documents do you record the results of contract reviews?
- 9 How do you ensure that valid cost elements and values are utilized in developing quotations?

Do's and don'ts

- ⊗ Don't accept any contract unless you have established that you have the capability to satisfy its requirements, and you have agreement on the payment to be made on completion and when completion is required.
- ☺ Do establish what constitutes acceptance by the customer.
- ☺ Do ensure that those determining compliance with contracts have access to current versions of the contract.
- ☺ Do read the small print and any reference documents before you accept the contract.
- ☺ Do declare any areas where your offer differs from that required and state the reasons in terms advantageous to the customer.
- ☺ Do establish the boundaries affecting what you and the customer are responsible for.
- ⊗ Don't make promises to your customer that your staff will not be able to honor.
- ☺ Do check your sources of data, prices, technical specification, etc., and that they are current and applicable to the specific terms of the contract.
- ☺ Do issue contract amendments on the same distribution list as the original contract.
- ⊗ Don't imply acceptance of a change to contract in any communication other than a formal contract amendment.

Chapter 4

Design control

Scope of requirements

This chapter deals with requirements for the control of any design activities carried out by design-responsible suppliers. *Design-responsible suppliers* are those with authority from the customer to design a new product specification or change an existing product specification for product delivered to a customer. It follows therefore that the requirements of section 4 are not intended to be applied to software, tools, and equipment used for internal purposes. The requirements of element 4 do apply, however, to design testing and verification services.

Design can be as simple as replacing the motor in an existing vehicle with one of a different specification, or as complex as the design of a new automobile or any of its subsystems. Design can be of hardware, software (or a mixture of both).

Before design commences there is either a requirement or simply an idea. Design is a creative process that creates something tangible out of an idea or a requirement. The controls specified in the standard apply to the design process. There are no requirements that will inhibit creativity or innovation. In order to succeed, the process of converting an idea into a design which can be put into production or service has to be controlled. Design is often a process which strives to set new levels of performance, new standards or create new wants and as such can be a journey into the unknown. On such a journey we can encounter obstacles we haven't predicted, which may cause us to change our course but our objective remains constant. Design control is a method of keeping the design on course towards its objectives and as such will comprise all the factors that may prevent the design from achieving its objectives. It controls the process not the designer; i.e. the inputs, the outputs, the selection of components, standards, materials, processes, techniques, and technologies.

The principles outlined in the standard can be applied to any creative activity and while the standard primarily addresses the design of automotive products for onward sale to customers, the principles can be applied to internal systems such as an information technology system, an inventory control system, and even the quality system.

The requirements in element 4.4 are linked with other clauses of the standard even when there is no cross reference. This relationship is illustrated in Figure 4.1.

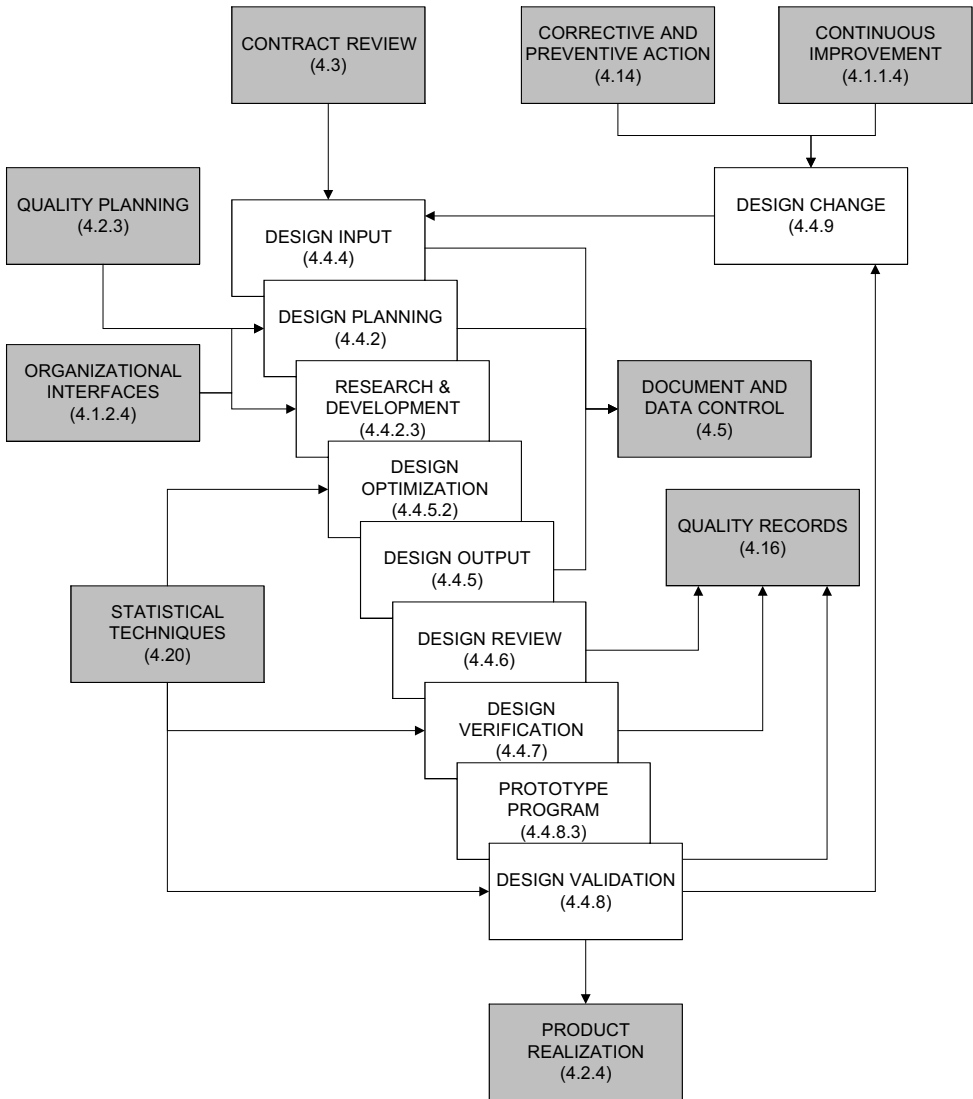


Figure 4.1 *Clause relationships with the design control element*

Design procedures (4.4.1)

Procedures to control the design (4.4.1)

The standard requires the supplier to *establish and maintain documented procedures to control the design of the product in order to ensure that the specified requirements are met.*

To control any design activity there are ten primary steps you need to take in the design process:

- 1 Establish the customer needs.
- 2 Convert the customer needs into a definitive specification of the requirements.
- 3 Conduct a feasibility study to discover whether accomplishment of the requirements is feasible.
- 4 Plan for meeting the requirements.
- 5 Organize resources and materials for meeting the requirements.
- 6 Conduct a project definition study to discover which of the many possible solutions will be the most suitable.
- 7 Develop a specification which details all the features and characteristics of the product or service.
- 8 Produce a prototype or model of the proposed design.
- 9 Conduct extensive trials to discover whether the product or service which has been developed meets the design requirements and customer needs.
- 10 Feed data back into the design and repeat the process until the product or service is proven to be fit for the task.

Procedures need to be produced that address each of these stages. However, control of the design process requires more than procedures. You will need standards and guides or codes of practice, because design is often a process of choosing solutions from available technologies. You may require two types of design control procedures, standards, and guides: those for controlling all designs and those for controlling individual designs. You should either use national and international standards and industry guidelines or develop your own, the latter course being more costly but often the only course if you

are operating at the edge of technology. You may need to develop lists of parts, materials, and processes that have been proven for your application and from which designers can select with confidence.

This general requirement for procedures introduces uncertainty into what particular procedures are actually required. The standard does not require the design control procedures to address each requirement of this clause but were they not to, you would need to demonstrate that the absence of such procedures had no adverse affect on the quality of design.

You need to develop a design strategy that sets out rules for designing your products and services. If your products are grouped into various ranges, you will need standards for each range to ensure that any product added to a particular range is compatible with other products in the range. In other cases you may have modular designs which build designs from existing modules, where the only new design is the “glue” that holds it all together.

Procedures to verify the design (4.4.1)

The standard requires the supplier to *establish and maintain documented procedures to verify the design of the product in order to ensure that the specified requirements are met.*

Design verification in particular should address all the activities identified in clause 4.4.7 of the standard. However, procedures that verify the design should be part of the set of procedures used to control the design. Design verification is not something separate from design control. You cannot control the design without verifying that it meets the requirements. The requirement for procedures to control the design should also be interpreted as including design validation, as it is not specifically stated otherwise.

Design and development planning (4.4.2)

Preparing the plans (4.4.2.1)

The standard requires the supplier to *prepare plans for each design and development activity which describe or reference these activities and define responsibility for their implementation.*

You should prepare a design and development plan for each new design and also for any modification of an existing design that radically changes the performance of the

product or service. For modifications that marginally change performance, control of the changes required may be accomplished through your design change procedures.

Design and development plans need to identify the activities to be performed, who will perform them, and when they should commence and be complete. One good technique is to use a network chart (often called a PERT chart), which links all the activities together. Alternatively a bar chart may be adequate. In addition there does need to be some narrative, as charts rarely convey everything required.

Design and development is not complete until the design has been proven as meeting the design requirements, so in drawing up a design and development plan you will need to cover the planning of design verification and validation activities. As the requirements for this are in clauses 4.4.7 and 4.4.8, this aspect will be dealt with later.

The plans should identify as a minimum:

- The design requirements
- The design and development program showing activities against time
- The work packages and names of those who will execute them (work packages are the parcels of work that are to be handed out either internally or to subcontractors)
- The work breakdown structure showing the relationship between all the parcels of work
- The reviews to be held for authorizing work to proceed from stage to stage
- The resources in terms of finance, manpower, and facilities
- The risks to success and the plans to minimize them
- The controls (quality plan or procedures and standards) that will be exercised to keep the design on course

In drawing up your design and development plans you need to identify the principal activities and a good place to start is with the list of ten steps detailed previously. Any further detail will in all probability be a breakdown of each of these stages, initially for the complete design and subsequently for each element of it. If dealing with a system you should break it down into subsystems, and the subsystems into equipment, and equipment into assemblies, and so on. It is most important that you agree the system hierarchy and associated terminology early on in the development program, otherwise you may well cause both technical and organizational problems at the interfaces. The

ten steps referred to previously can be grouped into four phases, a phase being a stage in the evolution of a product or service:

- Feasibility Phase
- Project Definition Phase
- Development Phase
- Production Phase

Planning for all phases at once can be difficult, as information for subsequent phases will not be available until earlier phases have been completed. So, your design and development plans may consist of four separate documents, one for each phase and each containing some detail of the plans you have made for subsequent phases.

Your design and development plans may also need to be subdivided into plans for special aspects of the design, such as reliability plans, safety plans, electromagnetic compatibility plans, configuration management plans.

With simple designs there may be only one person carrying out the design activities. As the design and development plan needs to identify all design and development activities, even in this situation you will need to identify who carries out the design, who will review the design and who will verify the design. The design and design verification activities may be performed by the same person. However, it is good practice to allocate design verification to another person or organization as it will reveal problems overlooked by the designer. On larger design projects you may need to employ staff of various disciplines, such as mechanical engineers, electronic engineers, reliability engineers, etc. The responsibilities of all these people or groups need to be identified and a useful way of parceling up the work is to use work packages which list all the activities to be performed by a particular group. If you subcontract any of the design activities, the subcontractor's plans need to be integrated with your plans and your plan should identify which activities are the subcontractor's responsibility. While purchasing is dealt with in clause 4.6 of the standard, the requirements apply to the design activities.

The standard requires that the design and development plans describe or reference design and development activities. Hence where you need to produce separate plans they should be referenced in the overall plan so that you remain in control of all the activities.

Assigning design and verification activities (4.4.2.1)

The standard requires that *the design and verification activities be assigned to qualified personnel equipped with adequate resources.*

Once identified, you need to assign the activities and this requires that you identify competent personnel in adequate numbers. Up to this point your plans may only have identified the department or group. You now need to ensure that those carrying out the tasks are competent to do so by virtue of their qualifications and experience. You also need to establish that these groups can provide the staff in adequate numbers to fulfill their responsibilities. Again by using the work package technique you can specify not only what is to be done but estimate the required hours, days, months, or years to do it and then obtain the group's acceptance and hence commitment to the task.

Resources are not limited to human resources, as stated in Part 2 Chapter 1. You need to ensure that the design groups are equipped with the necessary design tools, equipment, and facilities with which to execute the tasks. Once you have asked each group to propose how they are to meet the requirements, you then need to ensure that they have the capability of doing so. This is less of a problem in-house as with subcontractors. Due to their remoteness and the keen competition, they may make claims they cannot fulfill. In controlling the design you need to ensure that adequate resources are deployed by the subcontractors and to do this pre-contract surveys and assessments need to be performed. This is implied in clause 4.6.

You also need to be careful that work is not delegated or subcontracted to parties about whom you have little knowledge. In subcontracts, clauses that prohibit subcontracting without your approval need to be inserted, thereby enabling you to retain control.

Ensuring that plans are updated as the design evolves (4.4.2.1)

The standard requires that *the design and development plans be updated as the design evolves.*

Some design planning needs to be carried out before any design commences, but it is an iterative process and therefore the design plans may be completed progressively as more design detail emerges. It is not unusual for plans to be produced and then as design gets underway, problems are encountered which require a change in direction. When this occurs the original plans should be changed. The assessor will be looking to see that your current design and development activities match those in the approved plans. The design and development plan should be placed under document control after it has been approved. When a change in the plan is necessary you should use the document change request mechanism to change your design and development plan and not implement the change until the request has been approved. In this way you remain in control.

Ensuring the design team is qualified (4.4.2.2)

The standard requires that the supplier *ensures the design team is qualified to achieve design requirements* and identifies a list of appropriate skills.

Quite why this requirements was necessary is a mystery as it duplicates that given in clause 4.18.1. However, in case anyone is in any doubt that the design team has to be qualified, this requirement draws attention to it so that suppliers will need a process in place to ensure unqualified designers are precluded and that auditors will check that designers are qualified.

“Appropriate” in this context means appropriate to the nature of the work to be undertaken to meet the contract requirements. It is not mandatory that the staff of design departments are competent in all these skills. However, there is a customer expectation that if possession of one of these skills in a particular case would lead to a more effective design, the supplier should be employing that skill. Failure to do so requires the supplier to show that it would not be appropriate to the particular design.

While many of these skills may appear relatively new (i.e. the latter part of the last 100 years), geometric tolerancing has been around for some time. Henry Leland, head of Cadillac, was responsible for bringing the techniques of interchangeable parts into automobile manufacturing around 1900, and the technique goes even further back to Eli Whitney in connection with the manufacture of guns.

An explanation of some of the techniques is given in Appendix A.

Access to research and development facilities (4.4.2.3)

The standard requires the supplier to *have access to research and development facilities to ensure innovation of product and processes*.

The supplier does not need to own research and development facilities and may subcontract conceptual or complex design work to design studios. Clearly customers in the automotive sector are seeking new solutions to engineering problems and in order to capture the competitive edge, innovation is paramount.

Design interfaces (4.4.3)

Identifying and documenting organizational interfaces (4.4.3)

The standard requires that *organizational interfaces between different groups which input to the design process be identified and the necessary information documented*.

This may well be covered by your design and development plan. In your design procedures you should identify where work passes from one organization to another and the means you use to convey the requirements, such as work instructions. Often in design work, the product requirements are analyzed to identify further requirements for constituent parts. These may be passed on to other groups as input requirements for them to produce a design solution. In doing so these groups may in fact generate further requirements in the form of development specifications to be passed to other groups and so on. For example, the systems engineer generates the system specification and subsystem specifications and passes the latter to the subsystem engineers. These engineers design the subsystem and generate equipment specifications to pass on to the equipment engineers. To meet the equipment specification new parts may be necessary and so these engineers generate part specifications and pass these to the parts engineers. Some of these transactions may be in-house but many will be subcontracted. Some systems houses only possess systems engineering capabilities and subcontract most of the hardware or the software to specialists. In this way they concentrate on the business they are good at and get the best specialist support through competitive tenders. These situations create organizational interfaces that require contractual arrangements, documented requirements, and careful control.

In documenting the organizational interfaces you will need to:

- Define the customer and the supplier.
- Define the work that the supplier is to carry out in a statement of work or list of tasks.
- Define the requirements that the supplier is to meet in a controlled specification.
- Define the means used to convey the requirements and conditions governing the work, and either use a formal contract if external or a work instruction if internal.
- Define the reporting and review requirements for monitoring the work.
- Define the quality management requirement for assuring the quality of the work.

Identifying and documenting technical interfaces (4.4.3)

The standard requires that *technical interfaces between different groups which input to the design process be identified and the necessary information documented.*

Technical interfaces and organizational interfaces are often inseparable as the detail specification may need to be written around a particular supplier. However, within each development specification the technical interfaces between systems, subsystems, equip-

ments, etc. should be specified so that when all these components are integrated they function properly. In some situations it may be necessary to generate separate interface specifications, defining requirements that are common to all components of the system. In a large complex design, minor details of a component may be extremely important in the design of another component. Instead of providing designers with specifications of all the components, it may be more economical (as well as more controllable) if the features and characteristics at the interface between components are detailed in separate interface specifications.

Transmitting interface information (4.4.3)

The standard requires that *organizational and technical interface information be transmitted*.

Having documented your organizational and technical interfaces you will need to convey it to those who need it. This may seem an obvious and unnecessary requirement; however, many designs have failed because information was not conveyed in the right form at the right time. You need to provide a mechanism for listing all the documentation that the designers require and for making this accessible to them. Some standard interface data can be promulgated in data sheet form, which designers retain in manuals. For other data you may need project-specific listings.

One mechanism of transmitting this design information is to establish and promulgate a set of baseline requirements that are to be used at commencement of design for a particular phase. Any change to these requirements should be processed by a *change control board* and following approval a change to the baseline is made. This baseline listing becomes a source of reference and if managed properly ensures that no designer is without the current design and interface information.

Reviewing interface information (4.4.3)

The standard requires that *organizational and technical interface information be regularly reviewed*.

Interfaces should be reviewed along with other aspects of the design at regular design reviews, scheduled prior to the completion of each phase or more often if warranted.

Where several large organizations are working together to produce a design, an interface control board or similar body may need to be created to review and approve changes to technical interfaces. Interface control is especially difficult with complex projects. Once under way, an organization, like a large ship, gains momentum and takes

some time to stop. The project manager may not know of everything that is happening. Control is largely by information and it can often have a tendency to be historical information by the time it reaches its destination. So it is important to control changes to the interfaces. If one small change goes unreported, it may cause months of delay correcting the error – such as two tracks of a railway or two ends of a tunnel being misaligned.

Design input (4.4.4)

Identifying and documenting design input requirements (4.4.4.1 and 4.4.4.2)

The standard requires that *design input requirements relating to the product be identified and documented and product life, reliability, durability, and maintainability objectives be included in the design inputs.*

This requirement appears low down in the list of requirements and should ideally have been the first requirement that the standard addressed under design control. Until you have a design input you cannot carry out your design and development planning.

Your initial tasks are to establish what the customer requires and what the expectations are, then convert this into a definitive specification or a design brief.

Design input requirements may in fact be detailed in the contract. The customer may have drawn up a specification detailing the features and characteristics product or service needs to exhibit. (See Part 1 Chapter 1 on *Quality characteristics* and Part 2 Chapter 3 under *Ensuring that the requirements are adequately defined and documented.*) Alternatively, the customer needs may be stated in very basic terms; for example:

- * *For the fenders I require a decorative finish that is of the same appearance as the bodywork.*
- * *For interior seating I require a durable fabric that will retain its appearance for the life of the vehicle and is not electrostatic.*
- * *I require an electronic door locking system with remote control and manual override that is impervious to unauthorized personnel.*

From these simple statements of need you need to gather more information and turn the requirement into a definitive specification. Sometimes you can satisfy your customer with an existing product or service, but when this is not possible you need to resort to designing one to meet the customer's particular needs, whether the customer be a specific customer or the market in general.

You should note that these requirements do not require that design input requirements be stated in terms which, if satisfied, will render the product or service fit for purpose – nor does it state when the design input should be documented. Design inputs should reflect the customer needs and be produced or available before any design commences.

To identify design input requirements you need to identify:

- The purpose of the product or service
- The conditions (or environment) under which it will be used, stored, and transported
- The skills and category of those who will use and maintain the product or service
- The countries to which it will be sold and the related regulations governing sale and use of products
- The special features and characteristics which the customer requires the product or service to exhibit, including life, reliability, durability, and maintainability (see Part 1 Chapter 1 for a list of other typical features and characteristics)
- The constraints in terms of time-scale, operating environment, cost, size, weight, or other factors
- The standards with which the product or service needs to comply
- The products or service with which it will directly and indirectly interface, and their features and characteristics
- The documentation required of the design output necessary to manufacture, procure, inspect, test, install, operate, and maintain a product or service

As a supplier you have a responsibility to establish your customer requirements and expectations. If you do not determine conditions that may be detrimental to the product and you supply the product as meeting the customer needs and it subsequently fails, the failure is your liability. If the customer did not provide reasonable opportunity for you to establish the requirements, the failure may be the customer's liability. If you think you may need some extra information in order to design a product that meets the customer needs, you must obtain it or declare your assumptions. A nil response is often taken as acceptance in full.

In addition to customer requirements there may be industry practices, national standards, company standards, and other sources of input to the design input requirements to be taken into account. You should provide design guides or codes of practice that will

assist designers in identifying the design input requirements that are typical of your business.

The design output has to reflect a product which is producible or a service which is deliverable. The design input requirements may have been specified by the customer and hence not have taken into account your production capability. The product of the design may therefore need to be producible within your current production capability using your existing technologies, tooling, production processes, material handling equipment, etc. There is no requirement in the standard for designs to be economically producible and therefore unless such requirements are contained in the design input requirements, producibility will not be verified before product is released into production (see later in this chapter under *Design verification*).

Having identified the design input requirements, you need to document them in a specification that, when approved, is brought under document control. The requirements should not contain any solutions at this stage, so as to provide freedom and flexibility to the designers. If the design is to be subcontracted, it makes for fair competition and removes from you the responsibility for the solution. Where specifications contain solutions, the supplier is being given no choice and if there are delays and problems the supplier may have a legitimate claim against you.

Identifying and documenting statutory and regulatory requirements (4.4.4.1)

The standard requires that *the design input requirements include applicable statutory and regulatory requirements*.

Statutory and regulatory requirements are those which apply in the country to which the product or service is to be supplied. While some customers have the foresight to specify these, they often don't. Just because such requirements are not specified in the contract doesn't mean you don't need to meet them.

Statutory requirements may apply to the prohibition of items from certain countries, power supply ratings, security provisions, markings, and certain notices.

Regulatory requirements may apply to health, safety, environmental emissions, and electromagnetic compatibility and these often require accompanying certification of compliance. In cases where customers require suppliers to be certified to ISO/TS 16949 it imposes a regulatory requirement on the design process.

If you intend exporting the product or service, it would be prudent to determine the regulations that would apply before you complete the design requirement. Failure to meet

some of these requirements can result in no export license being granted as a minimum and imprisonment in certain cases if found to be subsequently noncompliant.

Having established what the applicable statutes and regulations are, you need to plan for meeting them and for verifying that they have been met. The plan should be integrated with the design and development plan or a separate plan should be created. Verification of compliance can be treated in the same way, although if the tests, inspections, and analyses are integrated with other tests etc., it may be more difficult to demonstrate compliance through the records alone. In some cases tests such as pollution tests, safety tests, proof loading tests, electromagnetic compatibility tests, pressure vessel tests, etc. are so significant that separate tests and test specifications are the most effective method.

Reviewing the selection of design input requirements (4.4.4.1)

The standard also requires that *the selection of design input requirements be reviewed by the supplier for adequacy.*

Adequacy in this context means that the design requirements are a true reflection of the customer needs. It is prudent to obtain customer agreement to the design requirements before you commence the design. In this way you will establish whether you have correctly understood and translated customer needs. It is advisable also to hold an internal design review at this stage so that you may benefit from the experience of other staff in the organization. Any meetings, reviews, or other means of determining the adequacy of the requirements should be recorded so as to provide evidence later if there are disputes. Records may also be needed to demonstrate that you have satisfied the requirements of this clause of the standard.

Resolving incomplete, ambiguous, or conflicting requirements (4.4.4.1)

The standard requires that *incomplete, ambiguous, or conflicting requirements be resolved with those responsible for drawing up these requirements.*

The review of the design requirements needs to be a systematic review, not a superficial glance. Design work will commence on the basis of what is written in the requirements or the brief, although you should ensure there is a mechanism in place to change the document should it become necessary later. In fact such a mechanism should be agreed at the same time as agreement to the requirement is reached.

In order to detect incomplete requirements you either need experts on tap or checklists to refer to. It is often easy to comment on what has been included but difficult to imag-

ine what has been excluded. It is also important to remove subjective statements (see Part 2 Chapter 2 on *Clarifying standards of acceptability*).

Ambiguities arise where statements imply one thing but the context implies another. You may also find cross-references to be ambiguous or in conflict. To detect the ambiguities and conflicts you need to read statements and examine diagrams very carefully. Items shown on one diagram may be shown differently in another. There are many other aspects you need to check before being satisfied they are fit for use. Any inconsistencies you find should be documented and conveyed to the appropriate person with a request for action. Any changes to correct the errors should be self-evident so that you do not need to review the complete document again.

Impact of the results of contract reviews on design input (4.4.4.1)

The standard requires that *design input take into consideration the results of any contract review activities*.

In cases where the contract includes a design requirement, then in establishing the adequacy of such requirements during contract review, these requirements may be changed or any conflicting or ambiguous requirements resolved. The results of these negotiations should be reflected in a revision of the contractual documentation, but the customer may be unwilling or unable to amend the documents. In such cases the contract review records become in effect a supplement to the contract. These records should therefore be passed to the designers so they can be taken into account when preparing the design requirement specification or design brief.

Deploying information from previous designs (4.4.4.3)

The standard requires the supplier to *have a process to deploy information gained from previous design projects, competitor analysis, or other sources as appropriate for current and future projects of a similar nature*.

The intent of this requirement is to ensure you *don't* repeat the mistakes of the past and *do* repeat the past successes. The implication of this requirement is that previous design project deploys the information, whereas it cannot do so without a crystal ball that looks into the future. All you can do is to capture such data in a database or library that is accessible to future designers. A rather old way of doing this was for companies to create design manuals containing data sheets, fact sheets, and general information sheets on design topics – a sort of design guide that captured experience. Companies should still be doing this but many will by now have converted to electronic storage medium with the added advantage of the search engine. Information will also be available from

trade associations, libraries, and learned societies. In your model of the design process you need to install a research process that is initiated prior to commencing design of a system, subsystem, equipment, or component. The research process needs to commence with an inquiry such as “Have we done this or used this before? Has anyone done this or used this before?” The questions should initiate a search for information but to make this a structured approach, the database or libraries need to structure the information in a way that enables effective retrieval of information. One advantage of submitting the design to a review by those not involved in the design is that they bring their experience to the review and identify approaches that did not work in the past, or put forward more effective ways of doing such things in the future.

Design optimization (4.4.5.2)

Design occurs between receiving the input requirements and producing the output. In ISO 9001 there are no requirements to govern the very important process of design between the two but ISO/TS 16949 does recognize that certain techniques and activities impact design output. During this process several activities are carried out which can be controlled. These are some concerning product design:

- Selection and use of parts, materials, processes
- Selection and use of standards
- Selection and use of tolerances on dimensions
- Performance predictions and analyses covering reliability, maintainability, and safety
- Trade-off studies
- Computer aided engineering
- Production of laboratory prototypes and qualification models
- Value engineering tasks
- Evaluation of new techniques, components, materials, and processes
- Stress calculations, fault tree analysis, failure modes analysis, and worst case analysis
- Use of field data on similar designs

Should you carry out any of these design activities you should ensure they are under control. Procedures, standards, and guides should be provided, which consolidates the organization's knowledge and ensures that the activities are planned, organized, and conducted against the correct design baseline. If these activities are to be carried out by several design organizations on a given development, it may be to your advantage to establish common standards for these activities so that any analyses, predictions, etc. can be used as a comparison. If every designer used different techniques, you would not be able to compare the various solutions and may need to wait until you can subject the prototype to common tests.

The designers should record the results of their design activities in a log book or other suitable means so that you can confirm their decisions, particularly on the selection of components for use in the design. If any research is carried out you will need confidence in its validity and the supporting evidence, particularly if important decisions are to be taken as a result of the research.

Design output (4.4.5)

Documenting the design output (4.4.5.1)

The standard requires that *the design output be documented and expressed in terms of requirements that can be verified and validated against design-input requirements.*

ISO 9001 does not state when design outputs are to be documented but the additional requirements for product approval in ISO/TS 16949 make it clear that the design is fully documented before the product is launched into production. Some organizations are eager to start producing product before the design is complete, particularly if it is marginally ahead of competitors' designs. However, in meeting the requirements of ISO/TS 16949, you have no choice but to prove the design before commencing the production part approval process.

Expressing the requirements in terms of requirements that can be verified and validated has two meanings. You need to be able to verify that both the design input requirements and user requirements (if different) have been achieved in the product so they need to be expressed in appropriate terms. The vehicle to contain such requirements is usually a product or service specification. You also need to be able to verify that the design output meets the design input and to achieve this you will need to document your calculations and analyses.

An important requirement is missing from ISO 9001, that of expressing the design output in a form suitable to manufacture, procure, inspect, test, install, operate, and

maintain a product or service. This omission is corrected in ISO/TS 16949 by the product approval requirements in clause 4.2.4.11 of the standard. In some industry sectors the design output contains all the specifications needed for these activities. In the automobile, electronics, and aerospace industries, prototyping and pre-production phases are an accepted and required stage through which new designs must pass. For the design output to be expressed in terms that can be verified and validated against design input requirements, the design input requirements need to require documentation of the output necessary in order to manufacture, procure, inspect, test, install, operate, and maintain a product or service.

Product requirements

Expressing the design output in terms that can be verified and validated means that the requirements for the product or service need to be defined and documented. The design input requirements should have been expressed in a way that would allow a number of possible solutions. The design output requirements should therefore be expressed as all the inherent features and characteristics of the design that reflect a product which will satisfy these requirements. Hence it should fulfill the stated or implied needs, i.e. be fit for purpose.

Product specifications should specify requirements for the manufacture, assembly, and installation of the product in a manner that provides acceptance criteria for inspection and test. They may be written specifications, engineering drawings, diagrams, inspection and test specifications, and schematics. With complex products you may need a hierarchy of documents from system drawings showing the system installation to component drawings for piece-part manufacture. Where there are several documents that make up the product specification there should be an overall listing that relates documents to one another.

Service specifications should provide a clear description of the manner in which the service is to be delivered, the criteria for its acceptability, the resources required, including the numbers and skills of the personnel required, the numbers and types of facilities and equipment necessary, and the interfaces with other services and suppliers.

In addition to the documents that serve product manufacture and installation or service delivery, documents may also be required for maintenance and operation. The product descriptions, handbooks, operating manuals, user guides, and other documents which support the product or service in use are as much a part of the design as the other product requirements. Unlike the manufacturing data, the support documents may be published either generally or supplied with the product to the customer. The design of such documentation is critical to the success of the product, as poorly constructed handbooks can be detrimental to sales.

The requirements within the product specification need to be expressed in terms that can be verified. Hence you should avoid subjective terms such as “good quality components”, “high reliability”, “commercial standard parts”, etc. as these requirements are not sufficiently definitive to be verified in a consistent manner. (See the later section on *Design acceptance criteria* and Part 2 Chapter 2 on *Clarifying standards of acceptability*.)

Design calculations

Throughout the design process, calculations will need to be made to size components and determine characteristics and tolerances. These calculations should be recorded and retained together with the other design documentation but may not be issued. In performing design calculations it is important that the status of the design on which the calculations are based is recorded. When there are changes in the design these calculations may need to be repeated. The validity of the calculations should also be examined as part of the design verification activity. One method of recording calculations is in a designer’s log book which may contain all manner of things and so the calculations may not be readily retrievable when needed. Recording the calculations in separate reports or in separate files along with the computer data will improve retrieval.

Design analyses

Analyses are types of calculations but may be comparative studies, predictions, and estimations. Examples are stress analysis, reliability analysis, hazard analysis. Analyses are often performed to detect whether the design has any inherent modes of failure and to predict the probability of occurrence. The analyses assist in design improvement and the prevention of failure, hazard, deterioration, and other adverse conditions. Analyses may need to be conducted as the end-use conditions may not be reproducible in the factory. Assumptions may need to be made about the interfaces, the environment, the actions of users, etc. and analysis of such conditions assists in determining characteristics as well as verifying the inherent characteristics. (See also in Part 2 Chapter 14 under *Detecting design weaknesses*.)

Ensuring that design output meets design input requirements (4.4.5.1a)

The standard requires that *the design output meets the design input requirements*.

The techniques of design verification identified in clause 4.4.7 can be used to verify that the design output meets the design input requirements. However, design verification is often an iterative process. As features are determined, their compliance with the require-

ments should be checked by calculation, analysis, or test on development models. Your development plan should identify the stages at which each requirement will be verified so as to give warning of noncompliance as early as possible.

Defining acceptance criteria (4.4.5.1b)

The standard requires that *the design output contains or makes reference to acceptance criteria*.

Acceptance criteria are the requirements which, if met, will deem the product acceptable. Every requirement should be stated in such a way that it can be verified. Characteristics should be specified in measurable terms with tolerances or min/max limits. These limits should be such that will ensure that all production versions will perform to the product specification and that such limits are well within the limits to which the design has been tested (see also Part 2 Chapter 2 under *Identifying verification requirements*). Where there are common standards for certain features, these may be contained in a standards manual. Where this method is used it is still necessary to reference the standards in the particular specifications to ensure that the producers are always given full instructions. Some organizations omit common standards from their specifications. This makes it difficult to specify different standards or to subcontract the manufacture of the product without handing over proprietary information.

Identifying crucial characteristics (4.4.5.1c)

The standard requires that the supplier *identify those characteristics of the design that are crucial to the safe and proper functioning of the product*.

Certain characteristics will be critical to the safe operation of the product and these need to be identified in the design output documentation, especially in the maintenance and operating instructions. The additional note qualifies these characteristics as “special characteristics”, thereby establishing consistency with other documents and references. Drawings should indicate the warning notices required, where such notices should be placed and how they should be affixed. Red lines on tachometers indicate safe limits for engines, audible warnings on computers, on smoke alarms, low oil warning lights, etc. indicate improper function or potential danger. In some cases it may be necessary to mark dimensions or other characteristics on drawings to indicate that they are critical and employ special procedures for dealing with any variations. In passenger vehicle component design, certain parts are regarded as safety-critical because they carry load or need to behave in a certain manner under stress. Others are not critical because they carry virtually no load, so there can be a greater tolerance on deviations from specification.

The lists of critical items that were described under *Identifying controls* in Part 2 Chapter 2, together with Failure Modes and Effects Analysis and Hazard Analysis, are techniques that aid the identification of characteristics crucial to the safe and proper functioning of the product.

Reviewing design output documents (4.4.5.1)

The standard requires that *the design output documents be reviewed before release*.

As stated in the section on design reviews, design documents should have been through a vetting process prior to presentation for design review. The design output may consist of many documents, each of which fulfills a certain purpose. It is important that these documents are reviewed and verified as being fit for their purpose before release, using the documentation controls developed for meeting section 4.5 of ISO 9001. In the software industry, where documentation provides the only way of inspecting the product prior to installation, document inspections called Fagan Inspections are carried out not only to identify the errors but to collect data on the type of error and the frequency of occurrence. By analyzing this data using statistical techniques the results assist in error removal and prevention.

Design documentation reviews can be made effective by providing data requirements for each type of document as part of the design and development planning process. The data requirement can be used both as an input to the design process and as acceptance criteria for the design output documentation review. The data requirements would specify the input documents and the content and format required for the document in terms of an outline. Contracts with procurement agencies often specify deliverable documents and by invoking formal data requirements in the contract the customer is then assured of the outputs.

Design reviews (4.4.6)

Conducting design reviews (4.4.6)

The standard requires that *formal documented reviews of the design results be conducted*.

A design represents a considerable investment by the organization. There is therefore a need for a formal mechanism for management and the customer (if the customer is sponsoring the design) to evaluate designs at major milestones. The purpose of the review is to determine whether the proposed design solution is compliant with the

design requirement and should continue or should be changed before proceeding to the next phase. It should also determine whether the documentation for the next phase is adequate before further resources are committed. Design review is that part of the design control process which measures design performance, compares it with predefined requirements and provides feedback so that deficiencies may be corrected before the design is released to the next phase.

Although design documents may have been through a vetting process, the purpose of the design review is not to review documents but to subject the design to an independent board of experts for its judgement as to whether the most satisfactory design solution has been chosen. By using a design review methodology, flaws in the design may be revealed before it becomes too costly to correct them. Design reviews also serve to discipline designers by requiring them to document the design logic and the process by which they reached their conclusions, particularly the options chosen and the reasons for rejecting other options.

The standard refers only to *formal design reviews*, implying that any informal design reviews are not governed by the requirements. The formal review has to be recorded. The informal review does not need to be recorded but the act of recording alone does not make an informal review a formal review. The difference between a formal and an informal design review is a difference of purpose. The *formal* design review establishes compliance with requirements and authorizes release of resources for the next phase of development. The *informal* review may result in changes being made to the proposed design solution but occurs between formal reviews and should not result in committing resources to subsequent phases.

ISO 9004-1 contains some guidance on the elements to be considered at design reviews and so rather than reiterate perfectly suitable material only the aspects of the design review procedures which you will need to generate will be addressed in this chapter. A design review is a means of controlling the design; consequently, a design review procedure is required by virtue of the general requirements of clause 4.4.1 of the standard.

Planning design reviews (4.4.6)

The standard requires that *formal documented reviews of the design results be planned at appropriate stages of the design.*

Design review schedules

A schedule of design reviews should be established for each product/service being developed. In some cases there will need to be only one design review after completion of all design verification activities. However, depending on the complexity of the design

and the risks, you may need to review the design at some or all of the following intervals:

- Design Requirement Review – to establish that the design requirements can be met and reflect the needs of the customer before commencement of design
- Conceptual Design Review – to establish that the design concept fulfills the requirements before project definition commences
- Preliminary Design Review – to establish that all risks have been resolved and development specifications produced for each sub-element of the product/service before detail design commences
- Critical Design Review – to establish that the detail design for each sub-element of the product/service complies with its development specification and that product specifications have been produced before manufacture of the prototypes
- Qualification Readiness Review – to establish the configuration of the baseline design and readiness for qualification before commencement of design proving
- Final Design Review – to establish that the design fulfills the requirements of its development specification before preparation for its production

Design review input data

The input data for the review should be distributed and examined by the review team well in advance of the time when a decision on the design has to be made. A design review is not a meeting. However, a meeting will often be necessary to reach a conclusion and to answer questions of the participants. Often analysis may need to be performed on the input data by the participants in order for them to determine whether the design solution is the most practical and cost effective way of meeting the requirements.

Participants at design reviews (4.4.6)

The standard requires that *participants at each design review include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel as required.*

The review team should have a collective competency greater than that of the designer of the design being reviewed. For a design review to be effective it has to be conducted by someone other than the designer. The requirement for participants to include representatives of all functions concerned with the design stage means that it may be difficult to meet this requirement without some members of the review panel being independent.

Design reviews are performed by management or the sponsor rather than the designers, in order to release a design to the next phase of development. A *review* is another look at something. The designer has had one look at the design and when satisfied presents the design to an impartial body of experts so as to seek approval and permission to go ahead with the next phase. Designers are often not the budget holders, or the sponsors. They often work for others. Even in situations where there is no specific customer or sponsor or third party, it is good practice to have someone else look at the design. A designer may become too close to the design to spot errors or omissions and so will be biased towards the standard of his/her own performance. The designer may welcome the opinion of someone else as it may confirm that the right solution has been found or that the requirements can't be achieved with the present state of the art. If a design is inadequate and the inadequacies are not detected before production commences the consequences may well be disastrous. A poor design can lose a customer, a market, or even a business so the advice of independent experts should be valued.

The review team should comprise, as appropriate, representatives of the purchasing, manufacturing, servicing, marketing, inspection, test, reliability, QA authorities, etc. as a means of gathering sufficient practical experience to provide advance warning of potential problems with implementing the design. The number of people attending the design review is unimportant and could be as few as the designer and his/her supervisor, provided that the supervisor is able to impart sufficient practical experience and there are no other personnel involved at that particular design stage. There is no advantage gained in staff attending design reviews who can add no value in terms of their relevant experience, regardless of what positions they hold in the company. The representation at each review stage may well be different – it may be just the designer and his/her supervisor at the conceptual review and representation from manufacturing, servicing, etc. at the final review.

The chairman of the review team should be the authority responsible for placing the development requirement and should make the decision as to whether design should proceed to the next phase based on the evidence substantiated by the review team.

Design review records (4.4.6)

The standard requires *records of design reviews to be maintained*.

The results of the design review should be documented in a report rather than minutes of a meeting, as it represents objective evidence that may be required later to determine product compliance with requirements, investigate design problems, and compare similar designs. The report should have the agreement of the full review team and should include:

- The criteria against which the design has been reviewed
- A list of the documentation that describes the design being reviewed and any evidence presented which purports to demonstrate that the design meets the requirements
- The decision on whether the design is to proceed to the next stage
- The basis on which confidence has been placed in the design
- A record of any outstanding corrective actions from previous reviews
- The recommendations and reasons for corrective action – if any
- The members of the review team and their roles

Design review follow-up

Although not a specific requirement of the standard, the requirements in clause 4.14.2 imply that corrective actions resulting from design reviews should be tracked to ensure they are implemented as agreed and that they resolve the reported problem.

Design verification (4.4.7)

The standard requires that at appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements.

The standard creates a distinction between design verification and design validation. There are two types of verification: those verification activities performed during design and on the component parts to verify conformance to specification and those verification activities performed on the completed design to verify performance; but more on this later.

The standard does not state when design verification is to be performed although “appropriate stages” implies that verification of the design after launch of product into production would not be appropriate.

So what are these appropriate stages? In the note which appends the requirements of clause 4.4.7 of the standard, the reference to design reviews implies that it is a design

verification activity. The other design verification activities referred to in clause 4.4.7 are intended to precede the relevant design review and so provide input data to that review. The appropriate stages of verification will therefore mirror the design review schedule but may include additional stages. Design verification needs to be performed when there is a verifiable output. When designing a system there should be design requirements for each subsystem, each equipment, each unit, and so on down to component and raw material level. Each of these design requirements represents acceptance criteria for verifying the design output of each stage. Verification may take the form of a document review, laboratory tests, alternative calculations, similarity analyses or tests, and demonstrations on representative samples, prototypes, etc. The planning and conduct of these verification activities is treated in the sections which follow.

Recording design verification measures (4.4.7)

The standard requires *design verification measures to be recorded*.

There is no time element in this requirement, therefore it is unclear whether the design verification measures are to be recorded before verification commences or after it is complete. The fact that this requirement is part of section 4.4 implies that design verification is one of the design and development activities which should be planned as required by clause 4.4.2. It would therefore seem sensible to prepare a verification plan as a record of the design verification measures to be undertaken and then produce verification records as evidence that the design output met the design input at the appropriate stages of design.

The design verification plan should be constructed so that every design requirement is verified and the simplest way of confirming this is to produce a verification matrix of requirement against verification methods. You need to cover all the requirements, those that can be verified by test, by inspection, by analysis, by simulation or demonstration, or simply by validation of product records. For those requirements to be verified by test, a test specification will need to be produced. The test specification should specify which characteristics are to be measured in terms of parameters and limits and the conditions under which they are to be measured.

The verification plan needs to cover some or all of the following details as appropriate:

- A definition of the product design standard which is being verified.
- The objectives of the plan. (You may need several plans covering different aspects of the requirements.)

- Definition of the specifications and procedures to be employed for determining that each requirement has been achieved.
- Definition of the stages in the development phase at which verification can most economically be carried out.
- The identity of the various models that will be used to demonstrate achievement of design requirements. (Some models may be simple space models, others laboratory standard or production standard depending on the need.)
- Definition of the verification activities that are to be performed to qualify or validate the design and those which need to be performed on every product in production as a means of ensuring that the qualified design standard has been maintained.
- Definition of the test equipment, support equipment, and facilities needed to carry out the verification activities.
- Definition of the time-scales for the verification activities in the sequence in which the activities are to be carried out.
- Identification of the venue for the verification activities.
- Identification of the organization responsible for conducting each of the verification activities.
- Reference to the controls to be exercised over the verification activities, in terms of the procedures, specifications, and records to be produced, the reviews to be conducted during the program, and the criteria for commencing, suspending, and completing the verification operations. (Provision should also be included for dealing with failures, their remedy, investigation, and action on design modifications.)

As part of the verification plan, you should include an activity plan that lists all the planned activities in the sequence they are to be conducted and use this plan to record completion and conformance progressively. The activity plan should make provision for planned and actual dates for each activity and for recording comments such as recovery plans when the program does not proceed exactly as planned. It is also good practice to conduct test reviews before and after each series of tests so that corrective measures can be taken before continuing with abortive tests (see also under *Design validation*).

The verification plan should be approved by the designers and those performing the verification activities. Following approval the document should be brought under document control. Design verification is often a very costly activity and so any changes in the

plan should be examined for their effect on cost and time-scale. Changes in the specification can put back the program by months while new facilities are acquired, new jigs, cables, etc. procured. However small your design, the planning of its verification is vital to the future of the product. Lack of attention to detail can rebound months (or even years) later during production.

Alternative design calculations

Verification of some characteristics may only be possible by calculation rather than by test, inspection, or demonstration. In such cases the design calculations should be checked either by being repeated by someone else or by performing the calculations by an alternative method. When this form of verification is used the margins of error permitted should be specified in the verification plan.

Comparing similar designs

Design verification can be a costly exercise. One way of avoiding unnecessary costs is to compare the design with a similar one that has been proven to meet the same requirements. This approach is often used in designs that use a modular construction. Modules used in previous designs need not be subject to the range of tests and examinations necessary if their performance has been verified either as part of a proven design or has been subject to such in-service use that will demonstrate achievement of the requirements. Care has to be taken when using this verification method that the requirements are the same and that evidence of compliance is available to demonstrate compliance with the requirements. Marginal differences in the environmental conditions and operating loads can cause the design to fail if it was operating at its design limit when used in the previous design.

Undertaking tests and demonstrations

Development models

Within the clause on verification in ISO/TS 16949 there are no constraints on the standards to be applied to development models used for verifying the design. There are, however, requirements for prototypes under *Design validation* but they only apply when required by the customer.

If design is proven on uncontrolled models, it is likely that there will be little traceability to the production models. Production models may therefore contain features and characteristics which have not been proven. The only inspections and tests which need to be performed on production models are for those features and characteristics that are sub-

ject to change due to the variability in manufacturing, either of raw materials or of assembly processes.

Many different types of models may be produced to aid product development, test theories, experiment with solutions, etc. However, when the design is complete, prototype models representative in all their physical and functional characteristics to the production models may need to be produced. When building prototypes, the same materials, locations, subcontractors, tooling, and processes should be used as will be used in actual production so as to minimize the variation (see also clause 4.4.8.3).

The requirements of clause 4.11 on measuring and test equipment also apply to the design process. Development tests will not yield valid results if obtained using uncontrolled measuring equipment. Within clause 4.11 of the standard is a requirement to identify the measurement to be made and this task is usually carried out during the design process. In fact, design is not complete until the criteria for accepting production versions have been established. Products need to be designed so as to be testable during production using the available production facilities. The proving of production acceptance criteria is therefore very much part of design verification.

Development tests

Where tests are needed to verify conformance with the design specification, development test specifications will be needed to specify the test parameters, limits, and operating conditions. For each development test specification there should be a corresponding development test procedure which defines how the parameters will be measured using particular test equipment and taking into account any uncertainty of measurement (see Part 2 Chapter 11). Test specifications should be prepared for each testable item. While it may be possible to test whole units, equipments, or subsystems you need to consider the procurement and maintenance strategies for the product when deciding which items should be governed by a test specification. Two principal factors to consider are:

- Testable items sold as spare parts
- Testable items the design and/or manufacture of which are subcontracted

If you conduct trials on parts and materials to prove reliability or durability, these can be considered to be verification tests. For example, you may test metals for corrosion resistance or hinges for reliability in the laboratory and then conduct validation tests under actual operating conditions when these items are installed in the final product.

Demonstrations

Tests exercise the functional properties of the product. Demonstrations, on the other hand, serve to exhibit usage characteristics such as access and maintainability, including interchangeability, reparability, and serviceability. Demonstrations can be used to prove safety features such as fire escape provisions in aircraft, ships, and buildings. However, one of the most important characteristics that need to be demonstrated is producibility. Can you actually make the product in the quantities required economically? Does production yield a profit or do you need to produce 50 to yield 10 good ones? The demonstrations should establish whether the design is robust. Designers may be selecting components at the outer limits of their capability. A worst-case analysis should have been performed to verify that under worst-case conditions, i.e. when all the components fitted are at the extreme of their tolerance range, the product will perform to specification. Analysis may be more costly to carry out than a test and by assembling the product with components at their tolerance limits you may be able to demonstrate economically the robustness of the design.

Reviewing design stage documents before release

As design documents are often produced at various stages in the design process they should be reviewed against the input requirements to verify that no requirements have been overlooked and that the requirements have been satisfied.

Design validation (4.4.8)**Performing validation (4.4.8.1)**

The standard requires that *design validation be performed to ensure that product conforms to defined user needs and/or requirements.*

Merely requiring that the design output meets the design input would not produce a quality product or service unless the input requirements were a true reflection of the customer needs. If the input is inadequate the output will be inadequate: “garbage in, garbage out” to use a common software expression. However, the standard does not require user needs or requirements to be specified. Only contract or order requirements are required to be specified in clause 4.3 of the standard. User needs and requirements should be specified also as part of the design input requirements, but if they are, design validation becomes part of design verification!

<p>■ Verification proves the design is right; validation proves it is the right design.</p>
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Design validation is a process of evaluating a design to establish that it fulfills the intended user requirements. It goes further than design verification, in that validation tests and trials may stress the product of such a design beyond operating conditions in order to establish design margins of safety and performance. Design validation can also be performed on mature designs in order to establish whether they will fulfill different user requirements to the original design input requirements. An example is where software designed for one application can be proven fit for use in a different application or where a component designed for one environment can be shown to possess a capability which would enable it to be used in a different environment. Multiple validations may therefore be performed to qualify the design for different applications.

Design validation may take the form of qualification tests which stress the product up to and beyond design limits – beta tests where products are supplied to several typical users on trial in order to gather operational performance data, performance trials, and reliability and maintainability trials where products are put on test for prolonged periods to simulate usage conditions.

In the automobile industry the road trials on test tracks are validation tests as are the customer trials conducted over several weeks or months under actual operating conditions on pre-production models. Sometimes the trials are not successful as was the case of the “Copper Cooled Engine” in General Motors in the early 1920s. Even though the engine seemed to work in the laboratory, it failed in service. Production was commenced before the design had been validated. The engine had pre-ignition problems and showed a loss of compression and power when hot. As a result, many cars with the engine were scrapped. Apart from the technical problems GM experienced with its development, it did prove to be a turning point in GM’s development strategy, probably resulting in what is now their approach to product quality planning.

Other examples are beta tests or public testing conducted on software products where tens or hundreds of products are distributed to designated customer sites for trials under actual operating conditions before product launch. Sometimes, commercial pressures force termination of these trials and products are launched prematurely in order to beat the competition.

The supplementary requirement stipulates that design validation should occur in conjunction with customer programming requirements and ideally design validation of the original design should be complete before product is launched into production. Thereafter, it may be performed at any stage where the design is selected for a different application. However, for the original design the scale of the tests and trials may be such that a sufficiently high degree of confidence has been gained before the end of the trials for pre-production to commence. Some of the trials may take years. The proving of reliability, for instance, may require many operating hours before enough failures have been observed to substantiate the reliability specification. There is no mean time

between failure (MTBF) until you actually have a failure, so you need to keep on testing until you know anything meaningful about the product's reliability.

During the design process many assumptions may have been made and will require proving before commitment of resources to the replication of the design. Some of the requirements, such as reliability and maintainability, will be time-dependent. Others may not be verifiable without stressing the product beyond its design limits. With computer systems, the wide range of possible variables is so great that proving total compliance would take years. It is however necessary to subject a design to a series of tests and examinations in order to verify that all the requirements have been achieved and that features and characteristics will remain stable under actual operating conditions. With some parameters a level of confidence rather than certainty will be acceptable. Such tests are called *qualification tests*. These differ from other tests because they are designed to establish the design margins and prove the capability of the design.

As the cost of testing vast quantities of equipment would be too great and take too long, qualification tests, particularly on hardware, are usually performed on a small sample. The test levels are varied to take account of design assumptions, variations in production processes and the operating environment.

Products may not be put to their design limits for some time after their launch into service, probably far beyond the warranty period. Customer complaints may appear years after the product launch. When investigated this may be traced back to a design fault which was not tested for during the verification program. Such things as corrosion, insulation, resistance to wear, chemicals, climatic conditions, etc. need to be verified as being within the design limits.

Following qualification tests, your customer may require a demonstration of performance in order to accept the design. These tests are called *design acceptance tests*. They usually consist of a series of functional and environmental tests taken from the qualification test specification, supported by the results of the qualification tests. When it has been demonstrated that the design meets all the specified requirements, a Design Certificate can be issued. It is the design standard which is declared on this certificate against which all subsequent changes should be controlled and from which production versions should be produced.

Procedures for controlling qualification tests and demonstrations should provide for:

- Test specifications to be produced which define the features and characteristics that are to be verified for design qualification and acceptance
- Test plans to be produced which define the sequence of tests, the responsibilities for their conduct, the location of the tests, and test procedures to be used

- Test procedures to be produced which describe how the tests specified in the test specification are to be conducted together with the tools and test equipment to be used and the data to be recorded
- All measuring equipment to be within calibration during the tests
- The test sample to have successfully passed all planned in-process and assembly inspections and tests prior to commencing qualification tests
- The configuration of the product in terms of its design standard, deviations, non-conformities, and design changes to be recorded prior to and subsequent to the tests
- Test reviews to be held before tests commence to ensure that the product, facilities, tools, documentation, and personnel are in a state of operational readiness for verification
- Test activities to be conducted in accordance with the prescribed specifications, plans, and procedures
- The results of all tests and the conditions under which they were obtained to be recorded
- Deviations to be recorded, remedial action taken, and the product subject to re-verification prior to continuing with the tests
- Test reviews to be performed following qualification tests to confirm that sufficient objective evidence has been obtained to demonstrate that the product fulfills the requirements of the test specification

Recording results (4.4.8.2)

The standard requires *validation results to be recorded and design failures to be documented in the validation records.*

This requirement was addressed above under *Procedures for controlling qualification tests and demonstrations* and needs no further discussion.

Addressing design failure (4.4.8.2)

The standard requires *the corrective and preventive action procedures to be followed in addressing design failures.*

Preventive action cannot be taken on a failure that has occurred (see ISO 8402) except on other future designs. What is intended is that remedial action is taken to correct the design fault and corrective action taken to prevent the same failure arising again either in the same design or in other designs.

Prototype program (4.4.8.3)

Prototype program standards (4.4.8.3)

The standard requires the supplier to *have a prototype program when required by the customer and to use the same subcontractors, tooling, and processes as will be used in production.*

There will be situations where the customer requires a prototype program but when no such requirement has been stated it does not mean you should not produce prototypes. Prototypes will not normally be required when the design is similar to a previously proven design or standard or the design is so simple that sufficient evidence can be obtained during the production trial run.

Many different types of models may be needed to aid product development, test theories, experiment with solutions, etc. However, when the design is complete, prototype models representative in all their physical and functional characteristics to the production models may need to be produced.

When building prototypes, the same materials, locations, subcontractors, tooling, and processes should be used as will be used in production, so as to minimize the variation.

Tracking performance testing (4.4.8.3)

The standard requires *all performance testing activities to be monitored for timely completion and conformance to requirements.*

As part of the verification plan discussed previously, you should include an activity plan that lists all the planned activities in the sequence they are to be conducted and use this plan to progressively record completion and conformance. The activity plan should make provision for planned and actual dates for each activity and for recording recovery plans when the program does not proceed exactly as planned. It is also good practice to conduct test reviews before and after each series of tests so that corrective measures can be taken before continuing with abortive tests (see also under *Design validation*).

Subcontracting design services (4.4.8.3)

The standard requires the supplier to *provide technical leadership while services are subcontracted*.

Where you do not possess the necessary facilities for building prototypes or conducting design verification and validation, these activities may be subcontracted. However, ISO/TS 16949 requires that you exercise technical leadership in such matters. This means that you need to enter into a formal contract with the subcontractor, apply the controls you established to meet clause 4.6, and manage the test program. You should require the subcontractor to submit test plans and procedures for your approval prior to commencement of the test unless you are providing this information yourself. You need to be confident that the tests will produce valid data so the test set-up, test equipment, test environment, and monitoring methods need to be periodically reviewed. You should have a representative present during test and retain authority for starting and stopping the test.

Design changes and modifications (4.4.9)

This clause covers two different requirements, involving two quite different control processes. Design changes are simply changes to the design and can occur at any stage in the design process from the stage at which the requirement is agreed to the final certification that the design is proven. Modifications are changes made to products to incorporate design changes and occur only after the first prototype is built. During development, design changes that affect the prototype are usually incorporated by rework or rebuild and are not classified as modifications. Following design certification, i.e. when all design verification has been completed and the product launched into production, changes to the product to incorporate design changes are classed as “modifications”.

You need to control design changes to permit desirable changes to be made and to prohibit undesirable changes from being made. Change control during the design process is a good method of controlling costs and time-scales because once the design process has commenced every change will cost time and effort to address. This will cause delays while the necessary changes are implemented and provides an opportunity for additional errors to creep into the design. “If it’s not broke don’t fix it!” is a good maxim to adopt during design. In other words, don’t change the design unless it already fails to meet the requirements. Designers are creative people who love to add the latest devices and the latest technologies, to stretch performance, and to go on enhancing the design regardless of the time-scales or costs. One reason for controlling design changes is to restrain the otherwise limitless creativity of designers in order to keep the design within the budget and time-scale.

The imposition of change control is often a difficult concept for designers to accept. They would prefer change control to commence after they have completed their design rather than before they have started. They may argue that until they have finished there is no design to control. They would be mistaken. Designs proceed through a number of stages (as described previously under *Design reviews*). Once the design requirements have been agreed, any changes in the requirements should be subject to formal procedures. When a particular design solution is complete and has been found to meet the requirements at a design review, it should be brought under *change control*. Between the design reviews the designers should be given complete freedom to derive solutions to the requirements. Between the design reviews there should be no change control on incomplete solutions.

Design changes will result in changes to documentation but not all design documentation changes are design changes. This is why design change control should be treated separately from document control. You may need to correct errors in the design documentation and none of these may materially affect the product. The mechanisms you employ for such changes should be different from those you employ to make changes that do affect the design. By keeping the two types of change separate you avoid bottlenecks in the design change loop and only present the design authorities with changes that require *their* expert judgement.

The sequence of the requirements in this clause is not necessarily the sequence in which the activities will need to be carried out. You may find therefore a little repetition in the following sections.

Identification of design changes (4.4.9.1)

The standard requires *all design changes to be identified before their implementation (including changes to proprietary designs)*.

At each design review a design baseline should be established which identifies the design documentation that has been approved. The baseline should be recorded and change control procedures employed to deal with any changes. These change procedures should provide a means for formally requesting or proposing changes to the design. The most effective method is by use of a *Design Change Form* constructed to collect all the data needed by the approval authorities. For complex designs you may prefer to separate proposals from instructions and have one form for proposing design changes and another form for promulgating design changes after approval. You will need a central registry to collect all proposed changes and provide a means for screening those that are not suitable to go before the review board (either because they duplicate proposals already made or because they may not satisfy certain acceptance criteria which you have prescribed).

On receipt, the *change proposals* should be identified with a unique number that can be used on all related documentation that is subsequently produced. The change proposal needs to:

- Identify the product of which the design is to be changed.
- State the nature of the proposed change.
- Identify the principal requirements, specifications, drawings, or other design documents that are affected by the change.
- State the reasons for the change either directly or by reference to failure reports, nonconformity reports, customer requests, or other sources.
- Provide for the results of the evaluation, review, and decision to be recorded.

Identification of modifications (4.4.9.1)

The standard requires *all design modifications to be identified, before their implementation (including changes to proprietary designs)*.

As *modifications* are changes to products resulting from design changes, the identity of modifications needs to be visible on the product that has been modified. If the issue status of the product specification changes, you will need a means of determining whether the product should also be changed. Not all changes to design documentation are design changes which result in product changes and not all product changes are modifications. (Nonconformities may be accepted which change the product but not the design.) Changes to the drawings or specifications that do not affect the form, fit, or function of the product are usually called “alterations” and those that affect form, fit, or function are “modifications”. Alterations should come under “document control” whereas design changes should come under “configuration control”. You will therefore need a mechanism for relating the modification status of products to the corresponding drawings and specifications. Following commencement of production the first design change to be incorporated into the product will usually be denoted by a number, such as Mod 1, for hardware and by Version or Release number for software. The practices for software differ in that versions can be incremented by points such as 1.1, 1.2, etc., where the second digit denotes a minor change and the first digit a major change. This modification notation relates to the product, whereas issue notation relates to the documentation that describes the product. You will need a modification procedure that describes the notation to be used for hardware and software.

Within the design documentation you will need to provide for the attachment of modification plates on which to denote the modification status of the product.

Documenting design changes (4.4.9.1)

The standard requires *all design changes to be documented before their implementation (including changes to proprietary designs)*

The documentation for design changes should comprise the change proposal, the results of the evaluation, the instructions for change and traceability in the changed documents to the source and nature of the change. You will therefore need:

- A Change Request Form, which contains the reason for change and the results of the evaluation. This was described previously as it is used to initiate the change and obtain approval before being implemented.
- A Change Notice, which provides instructions defining what has to be changed. This is issued following approval of the change as instructions to the owners of the various documents that are affected by the change.
- A Change Record, which describes what has been changed. This usually forms part of the document that has been changed and can be either in the form of a box at the side of the sheet (as with drawings) or in the form of a table on a separate sheet (as with specifications).

Where the evaluation of the change requires further design work and possibly experimentation and testing, the results for such activities should be documented to form part of the change documentation.

Documenting modifications (4.4.9.1)

The standard requires *all design modifications to be documented before their implementation (including changes to proprietary designs)*.

Prior to commencement of production, design changes do not require any modification documentation, the design changes being incorporated in prototypes by rework or rebuild. However, when product is in production, instructions will need to be provided so that the modification can be embodied in the product. These modification instructions should detail:

- Which products are affected, by part number and serial number

- The new parts that are required
- The work to be carried out to remove obsolete items and fit new items or the work to be carried out to salvage existing items and render them suitable for modification
- The markings to be applied to the product and its modification label
- The tests and inspections to be performed to verify that the product is serviceable
- The records to be produced as evidence that the modification has been embodied (see also clause 4.5.2.2 of ISO/TS 16949)

Modification instructions should be produced after approval for the change has been granted and should be submitted to the change control board or design authority for approval before release.

Review and approval of design changes (4.4.9.1 and 4.4.9.2)

The standard requires *all design changes to be reviewed and approved by authorized personnel before their implementation (including changes to proprietary designs)*. The standard also requires the supplier to *address the impact of a design change on the systems in which the product is used, the customer assembly process, and other related products and systems*.

Following the commencement of design you will need to set up a change control board or panel comprising those personnel responsible for funding the design, administering the contract, and accepting the product. All change proposals should be submitted to such a body for evaluation and subsequent approval or disapproval before the changes are implemented. Such a mechanism will give you control of all design changes. By providing a two-tier system you can also submit all design documentation changes through such a body. They can filter the alterations from the modifications, the minor changes from the major changes. Remember that by controlling change you control cost so it is a vital organ of the business and should be run efficiently. The requirement for changes to be approved before their implementation emphasizes the importance of this control mechanism.

The change proposals need to be evaluated:

- To validate the reason for change
- To determine whether the proposed change is feasible

- To judge whether the change is desirable
- To determine the effects on performance, costs, and time-scales
- To determine the impact of the change on other designs with which it interfaces and in which it is used
- To examine the documentation affected by the change and consequently program their revision
- To determine the stage at which the change should be embodied

The evaluation may need to be carried out by a review team, by subcontractors, or by the original proposer; however, regardless of who carries out the evaluation, the results should be presented to the change control board for a decision. During development there are two decisions the board will need to make:

- Whether to accept or reject the change
- When to implement the change in the design documentation

If the board accepts the change, the changes to the design documentation can either be submitted to the change control board or processed through your document control procedures. During development it is a common practice to accumulate design changes for incorporation into the design when design proving has been completed. If there are many of these changes a two or three stage process of incorporation may be desirable. In the event that the development model is deliverable to the customer or, as in the case of one-off systems, the changes need to be incorporated into the design before delivery, acceptance may take place against drawings and specifications extended by change notes. However, unless the change notes accurately reflect the final design configuration, the integrity of any certification of the product against a proven design cannot be assured. There is also a temptation to cut costs by not incorporating latent design changes. This may well avert delayed delivery but will have severe consequences should modifications be necessary later or should the changes affect the integrity of the supporting handbooks and manuals. So, deciding when to incorporate the changes is a very important consideration.

Review and approval of modifications (4.4.9.1)

The standard requires *all design modifications reviewed and approved by authorized personnel before their implementation (including changes to proprietary designs)*.

During production the change control board will need to make four decisions:

- Whether to accept or reject the change
- When to implement the change in the design documentation
- When to implement the modification in new product
- What to do with existing product in production, in store, and in service

The decision to implement the modification will depend on when the design documentation will be changed, when new parts and modification instructions are available. The modification instructions can either be submitted to the change control board or through your document control procedures. The primary concern of the change control board is not so much the detail of the change but its effects, its costs, and the logistics in its embodiment. If the design change has been made for safety or environmental reasons you may need to recall product in order to embody the modification. Your modification procedures need to provide for all such cases.

In some cases the need for a design change may be recognized during production tests or installation and in order to define the changes required you may wish to carry out trial modifications or experiments. Any changes to the product during production should be carried out under controlled conditions, hence the requirement that approval of modifications be given before their implementation. To allow such activities as trial modifications and experiments to proceed you will need a means of controlling these events. If the modification can be removed in a way that will render the production item in no way degraded, you can impose simple controls for the removal of the modification. If the item will be rendered unserviceable by removing the modification, alternative means may need to be determined, otherwise you will sacrifice the product. It is for this reason that organizations provide development models on which to try out modifications.

Task list

This list is not an exhaustive task list for all design activities. It represents a sample of design control tasks that you may need to carry out. Many tasks may not be applicable for simple designs so you should be selective. They reflect one interpretation of the requirements in the standard.

- 1 Identify the types of products and services that the organization designs.
- 2 Determine the processes by which customer requirements or market needs are translated into a set of specifications for a particular product or service.
- 3 Analyze these processes and identify the discrete tasks that are performed.
- 4 Prepare procedures to control these tasks and the interfaces between them.
- 5 Prepare or select guides and standards which assist designers to select proven technologies, parts, materials, methods, etc.
- 6 Qualify your design staff in the appropriate skills.
- 7 Prepare procedures for the conduct of design verification activities.
- 8 Prepare procedures for the preparation and maintenance of design and development plans.
- 9 Determine a methodology for identifying and specifying the documentation requirements for design activities, covering system design, hardware design, software design, service design, etc.
- 10 Determine a methodology for design and development which integrates the major design tasks from the feasibility phase to the production phase.
- 11 Prepare procedures for creating speciality plans covering reliability, safety, environmental engineering, etc.
- 12 Prepare standard requirements for subcontracted design activities which specify the documentation requirements.
- 13 Establish a mechanism of reviewing progress through the design and development process for in-house designs and subcontracted designs.
- 14 Create a procedure for controlling the allocation of work packages to various design groups and to subcontractors.
- 15 Produce procedures and standards governing the specification of development requirements for components of the design.
- 16 Produce procedures and standards governing technical interface specifications, their preparation, promulgation, and maintenance.

- 17 Decide on a mechanism for establishing the design baseline and for controlling changes to the baseline.
- 18 Set up a design change control board to review, evaluate, and approve or reject design changes.
- 19 Set up an interface control board to review and evaluate technical interface data.
- 20 Produce procedures which regulate the specification of design (input) requirements and the documentation of product specifications and drawings.
- 21 Produce procedures that govern the generation, proving, and publication of product/service support documents, such as handbooks, operating instructions, etc.
- 22 Decide on a method of verifying that the design meets each of the requirements.
- 23 Determine how you will establish what regulatory requirements apply in the countries to which you expect your products to be exported.
- 24 Prepare procedures governing the construction of models for use in proving the design.
- 25 Establish standards for preparation of development and production test specifications and procedures.
- 26 Decide on the methods to be employed to make the transition from development to pre-production and from pre-production to production.
- 27 Establish design review procedures that operate at various levels within the design hierarchy, including subcontractors.
- 28 Determine the design controls you intend to impose over the design of test equipment, tools, test rigs, and other articles.
- 29 Produce procedures governing the preparation, review, approval, and distribution of modification instructions.
- 30 Decide on the conventions to be used in identifying the issue status of design documents during development and following design certification.
- 31 Decide on the conventions to be used to identify the modification status of products or services.
- 32 Create and maintain records of the implementation of customer changes in design when applicable.
- 33 Create and maintain records of the embodiment of modifications in production.
- 34 Decide on the criteria for judging when design changes should be incorporated into design documentation.

Design control questionnaire

- 1 How do you control and verify product design?
- 2 Where are your plans in which you have identified the responsibility for each design and development activity?
- 3 How do you ensure that the design and development plans are updated as the design evolves?
- 4 How do you ensure that design and verification activities are planned and assigned to qualified personnel equipped with adequate resources?
- 5 How do you control subcontracted design and design verification activities?
- 6 How do you identify, document, transmit, and regularly review the organizational and technical interfaces between different design groups?
- 7 How do you identify, document, and review design input requirements including applicable statutory and regulatory requirements?
- 8 How do you ensure that the selection of design input requirements is reviewed for adequacy?
- 9 How do you resolve incomplete, ambiguous, or conflicting design input requirements?
- 10 How do you ensure that design inputs take into consideration the results of contract reviews?
- 11 What evidence is there to show that design output requirements can be verified?
- 12 How do you ensure that the design output contains or references acceptance criteria?
- 13 How do you identify those characteristics of the design that are crucial to the safe and proper functioning of the product?
- 14 How do you ensure that design output documents are reviewed before release?
- 15 How are formal design reviews planned, conducted, and documented?
- 16 How are the results of design reviews recorded?
- 17 How do you ensure that design stage output meets design stage input requirements?
- 18 How are the means of design verification documented?
- 19 Under what circumstances would alternative calculations be performed?
- 20 Under what circumstances would design verification by similarity be valid?

- 21 When would tests and demonstrations be an appropriate verification method?
- 22 How do you ensure that design stage documents are reviewed before release?
- 23 How do you ensure that tests performed using prototype models are representative of the results that would be obtained using production models?
- 24 How is the design validated to ensure product conforms to defined user needs?
- 25 How do you identify, document, review, and approve design changes?
- 26 How do you approve modifications?
- 27 How do you ensure that no change is made to the design or modification made to the product without prior approval of authorized personnel?

Do's and don'ts

- ⊗ Don't commence design without a written and agreed requirement.
- ☺ Do commence change control immediately after the design requirement has been agreed and issued.
- ⊗ Don't allow designers to change approved designs without prior approval.
- ☺ Do determine who is to carry out which design task before you start design.
- ☺ Do give all relevant groups in the organization the opportunity to contribute to the design process.
- ☺ Do set standards for design documentation and stick to them.
- ⊗ Don't use unproven material, components, or processes in new designs unless you plan to evaluate and qualify them before production commences.
- ⊗ Don't assume that a proven design will necessarily be suitable for other applications.
- ☺ Do allow for designs to fail design verification in your development plans – never assume designs can be produced right first time.
- ⊗ Don't start pre-production until the design has been functionally proven.
- ⊗ Don't start making prototypes until the interface dimensions have been confirmed.
- ⊗ Don't give designers a wish list – be specific about the purpose of the product/service.
- ⊗ Don't accept changes to requirements from your customer without a change to the contract and always get them in writing.
- ☺ Do involve the specialists as soon as possible, because the later they start the more redesign will result.
- ☺ Do maintain the design requirement document even after you have produced the product specification.
- ☺ Do increase safety factors if verification by analysis is performed in lieu of test.
- ☺ Do record the design documentation status used in the performance of calculations and analyses.
- ☺ Do assess the calculations and analysis when the design changes.
- ☺ Do incorporate all design changes before any product is delivered.

Chapter 5

Document and data control

Scope of requirements

Document and data control is one of the most important aspects of the quality system. Although not the only aspect of the quality system, documentation is the foundation stone. The requirements for document and data control can be confusing because the standard doesn't specify what a document is and whether a record is a document or whether data are documents. As data is information and documents are recorded information perhaps this clause should have been headed *Information control*. There is often confusion also between quality system documents and quality documents and between technical documents and quality documents. There is no doubt that all documents, data, and records should be controlled but the types of control will vary depending on the type of document.

In the world of documents there are two categories: those that are controlled and those that are not controlled. A controlled document is one where requirements have been specified for its development, approval, issue, revision, distribution, maintenance, use, storage, security, obsolescence, or disposal. You do not need to exercise control over each of these elements for a document to be designated a controlled document. Controlling documents may be limited to controlling their revision. On the other hand, you cannot control the revision of national standards but you can control their use, their storage, their obsolescence, etc. Even memoranda can become controlled documents if you impose a security classification upon them.

There are three types of controlled documents, as illustrated in Figure 5.1:

- Policies and practices (these include control procedures, guides, operating procedures, and internal standards)

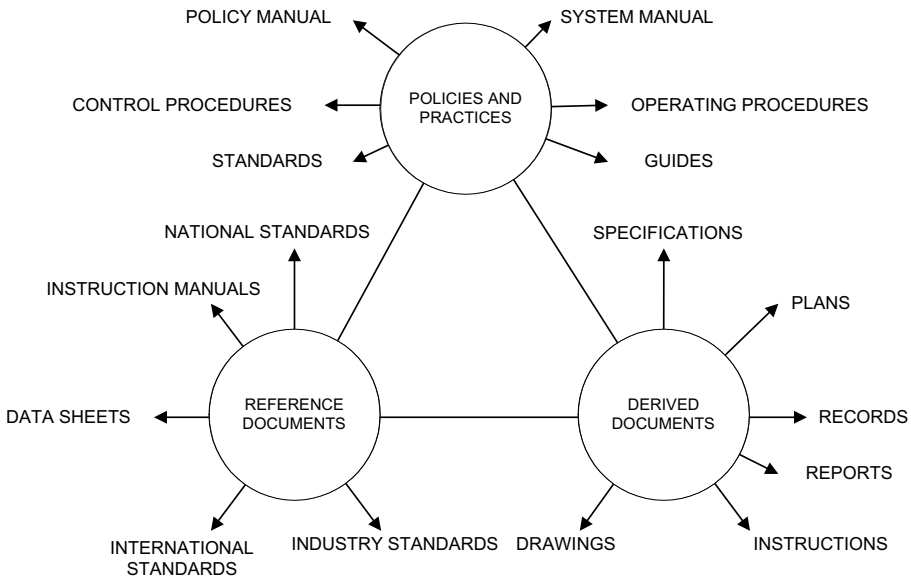


Figure 5.1 Relationship between quality system documents

- Documents derived from these policies and practices, such as drawings, specifications, plans, work instructions, technical procedures, and reports
- External documents referenced in either of the above

Derived documents are those that are derived by implementing policies and procedures; for example, audit reports result from implementing the audit procedure, drawings result from implementing the design procedure, procurement specifications result from implementing the procurement procedure. There are, however, two types of derived document: prescriptive and descriptive documents. *Prescriptive documents* are those that prescribe requirements, instructions, guidance, etc. and may be subject to change. They have issue status and approval signatures, and are implemented in doing work. *Descriptive documents* result from doing work and are not implemented. They may have issue status and approval signatures. Specifications, plans, purchase orders, drawings are all prescriptive whereas audit reports, test reports, inspection records are all descriptive. This distinction is only necessary as the controls required will be different. ISO 8402 defines a record as a *document which furnishes objective evidence of activities performed or results achieved*; therefore records are documents, but what we need to know is whether the requirements of clause 4.5 apply to records. As there is no cross reference to clause 4.16 from clause 4.5 and vice versa, one can safely assume that the requirements of clause 4.5 are not intended to apply to records, even though they are documents. It would have assisted interpretation if this had been made clear in the standard.

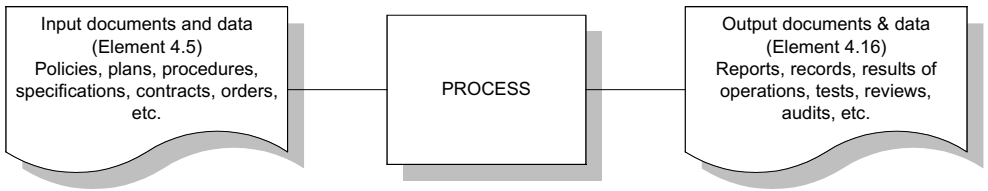


Figure 5.2 Relationship between documents, data, and records

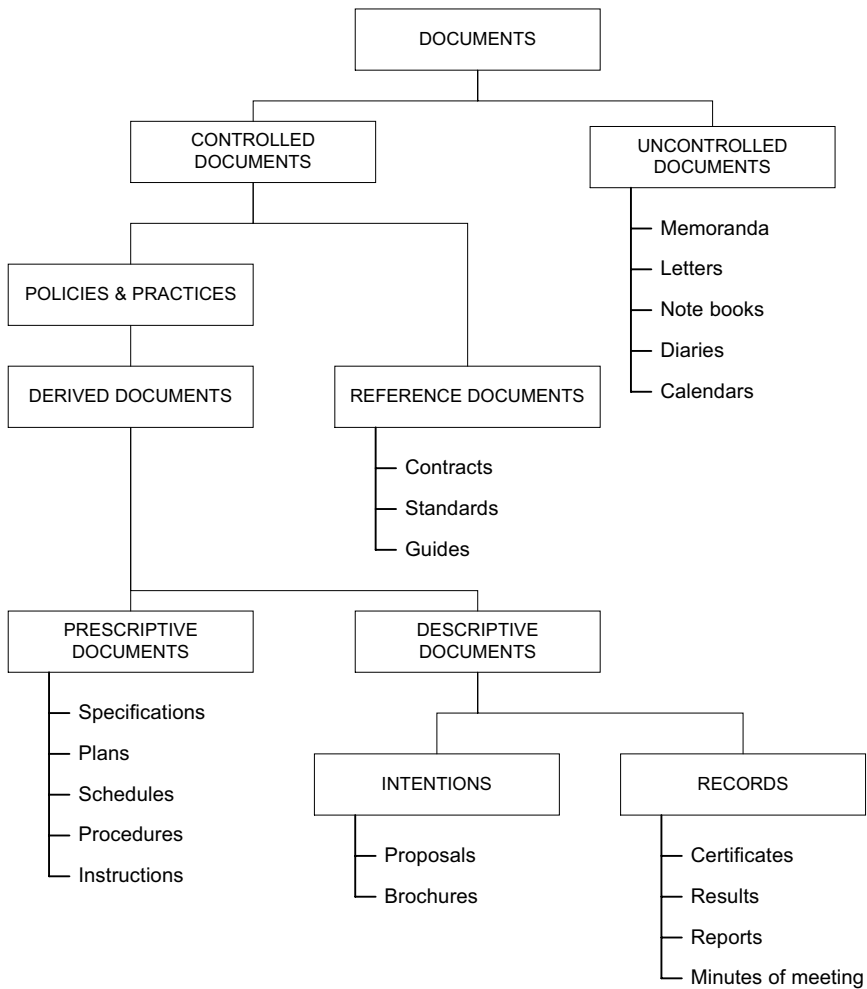


Figure 5.3 Document classification tree

The relationship between elements 4.5 and 4.16 is illustrated in Figure 5.2 above.

Figure 5.3 shows some examples of the different classes of documents and their relationship. All the controlled documents except records are governed by clause 4.5 of the standard. Records are governed by clause 4.16 of the standard.

The requirements of clause 4.5 therefore apply to policies and practices, derived documents, and external documents that are prescriptive but not descriptive. The descriptive documents are covered by clause 4.16 on quality records.

The term *document* should be taken to include data or any information that is recorded and stored either on paper or magnetic media in a database or on disk. It may be

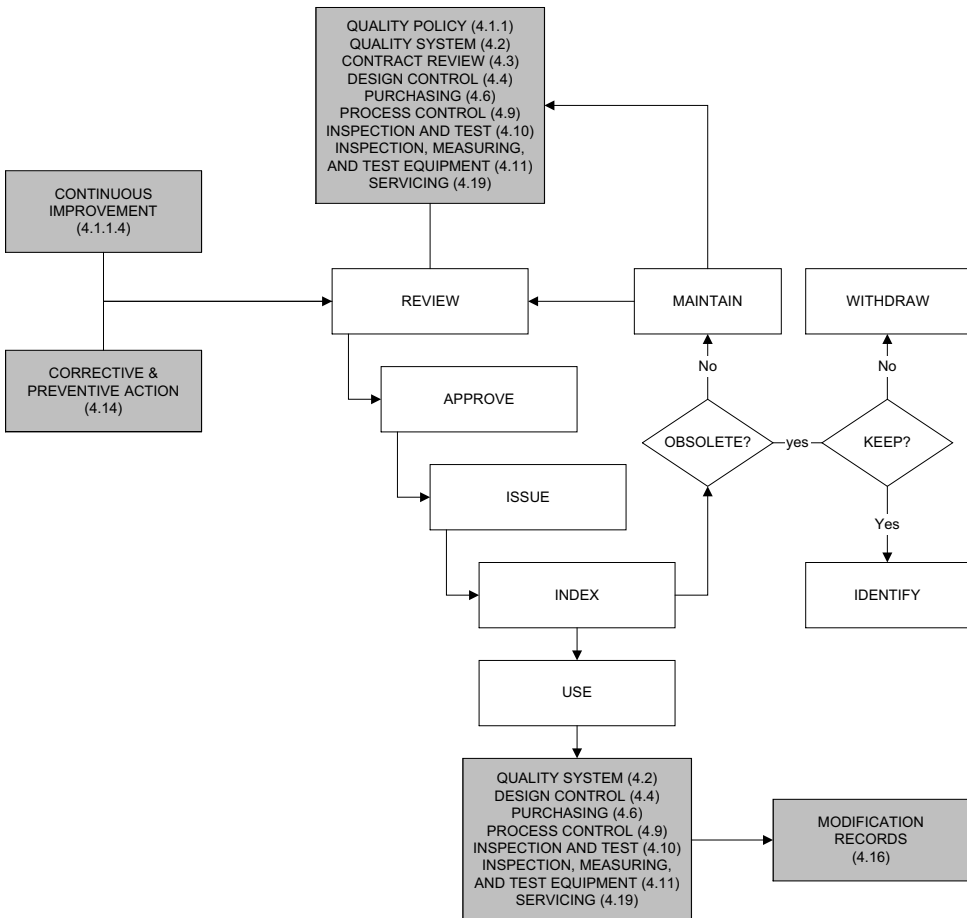


Figure 5.4 Clause relationships with the document control element

both an audio and visual record although the controls that will be applied will vary depending on the media.

The requirements in element 4.5 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 5.4.

Document control procedures (4.5.1)

Documents which relate to the standard

The standard requires that the supplier *establish and maintain documented procedures to control all documents and data that relate to the requirements of the standard.*

Documents and data that relate to the requirements of the standard could be interpreted as including all the documents and data you produce, or be limited to those documents that are essential to the achievement and demonstration of quality. The requirement can be quite onerous because it requires that every document has an associated governing procedure. So if you include memoranda in your system, you will need a procedure to control them. The way out of this maze is to use the quality system to define the documents that need to be controlled.

- Ensure that your documented policies and practices specify all the documents that need to be produced and are used to produce products and service that meet the specified requirements. Any document not referred to in your published policies and procedures is therefore, by definition, not essential to the achievement of quality and not required to be under control.
- Ensure that all documents not traceable to the published policies and procedures are removed or identified as uncontrolled.

The procedures that require the use or preparation of documents should also specify or invoke the procedures for their control. If the controls are unique to the document, they should be specified in the procedure that requires the document. You can produce one or more common procedures which deal with the controls that apply to all documents. Although ISO 9001 does not address all controls under clause 4.5, the provisions of clause 4.16 relating to the identification, access, filing, and storage of quality records are equally appropriate to documents in general and should be applied although it is not mandatory.

Document control process

The principal elements of document control are illustrated in Figure 5.5. This process provides for bringing existing documents under control, for controlling the preparation of new documents and for changing approved and issued documents. Each process could represent a procedure or a form. The processes may differ depending on the type of documents and organizations involved in its preparation, approval, publication, and use. One procedure may cater for all the processes but you may need several.

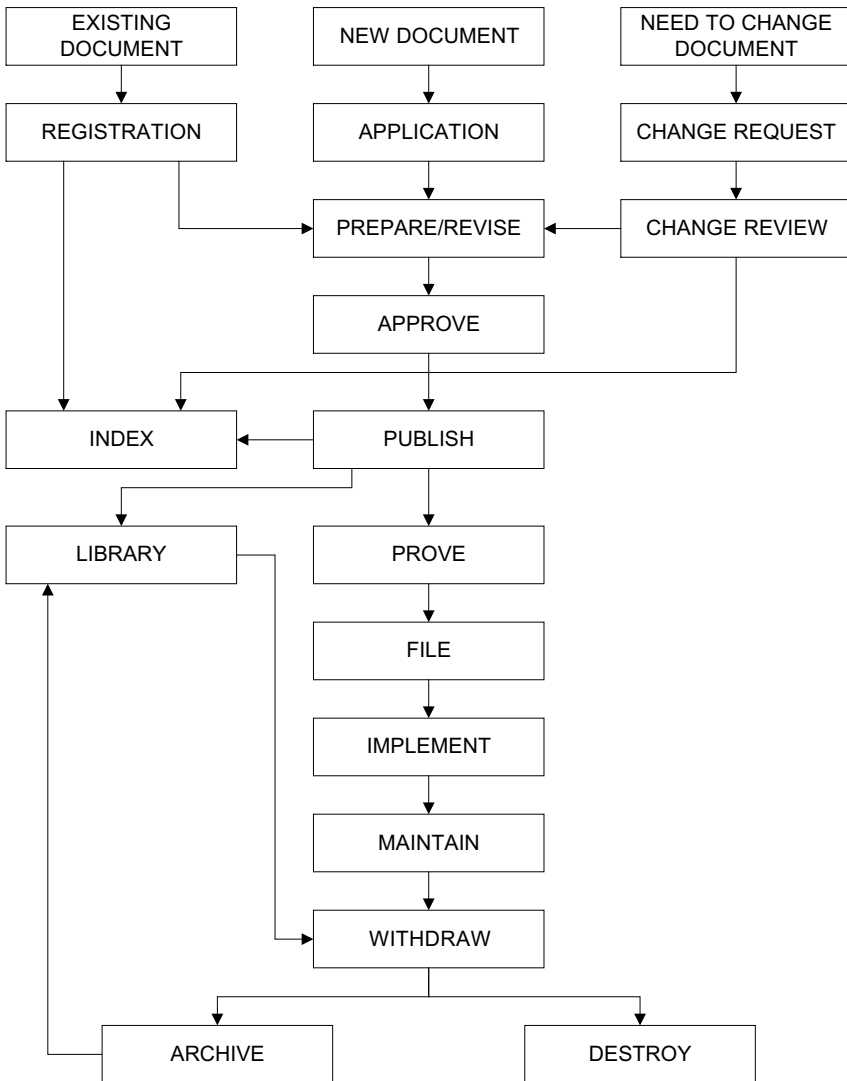


Figure 5.5 Documentation control process

The aspects you should cover in your document control procedures are as follows, some of which are addressed further in this chapter:

- Planning new documents, funding, prior authorization, establishing need, etc.
- Preparation of documents, who prepares, drafting process, text, diagrams, forms, etc.
- Standards for the format and content of documents, forms, and diagrams
- Document identification conventions
- Issue notation, draft issues, post approval issues
- Dating conventions, date of issue, date of approval, or date of distribution
- Document review, who reviews, and what evidence is retained
- Document approval, who approves, and how approval is denoted
- Document proving prior to use
- Printing and publication, who does it, who checks it
- Distribution of documents, who decides, who does it, who checks it
- Use of documents, limitations, unauthorized copying, and marking
- Revision of issued documents, requests for revision, who approves the request, who implements the change
- Denoting changes, revision marks, reissues, sidelining, underlining
- Amending copies of issued documents, amendment instructions, amendment status
- Indexing documents, listing documents by issue status
- Document maintenance, keeping them current, periodic review
- Document accessibility inside and outside normal working hours
- Document security, unauthorized changes, copying, disposal, computer viruses, fire, theft
- Document filing, masters, copies, drafts, custom binders
- Document storage, libraries, and archive, who controls, location, loan arrangements
- Document retention and obsolescence

Control of external documents (4.5.1)

The standard requires the supplier to *establish and maintain documented procedures to control documents of external origin such as standards and customer drawings*.

The control which you exercise over external documents is somewhat limited. You cannot for instance control the revision of such documents; therefore all the requirements concerning document changes will not apply. You can, however, control the use and amendment of external documents. You can control use by specifying which versions of external documents are to be used and you can remove invalid or obsolete external documents from use or identify them in a way that users know that they are invalid or obsolete. You can control the amendment of external documents by controlled distribution of amendment instructions sent to you by the issuing agency.

There are two types of external documents, those in the public domain and those produced by specific customers. In some cases the issues of both types of documents are stated in the contract and therefore it is important to ensure that you possess the correct version before you commence work. Where the customer specifies the issue status of public domain documents that apply you need a means of preventing their withdrawal from use in the event that they are revised during the term of the contract. Where the issue status of public domain documents is not specified you may either have a free choice as to the issue you use or, as is more likely, you may need to use the latest issue in force. Where this is the case you will need a means of being informed when such documents are revised to ensure that you can obtain the latest version. The ISO 9000 series for instance is reviewed every five years, so could well be revised at five-year intervals. With national and international legislation the situation is rather different as these can change at *any* time. You need some means of alerting yourself to changes that affect you and there are several methods from which to choose:

- Subscribing to the issuing agency of a standards updating service
- Subscribing to a general publication that provides news of changes in standards and legislation
- Subscribing to a trade association that provides bulletins to its members on changes in the law and relevant standards
- Subscribing to the publications of the appropriate standards body or agency
- Subscribing to a society or professional institution that updates its members with news of changes in laws and standards

- Consulting the complimentary information you receive as a registered company from government agencies, advising you of changes in legislation
- Joining a business club that keeps its members informed of such matters
- Consulting the bulletins you receive as an ISO 9000 registered company from your registrar on matters affecting registration and subscribing to *ISO 9000 News* to obtain world-wide news of events and changes in the ISO 9000 arena

The method you choose will depend on the number and diversity of external documents you need to maintain and the frequency of usage.

Document and data review and approval (4.5.2.1)

The standard requires that *documents and data be reviewed and approved for adequacy by authorized personnel prior to issue.*

Reviewing internal documents

Users should be the prime participants in the preparation process so that the resultant documents reflect their needs and are fit for the intended purpose – hence the requirement that documents be *reviewed* as well as approved. You will need to be able to demonstrate that your documents have in fact been reviewed prior to issue. The presence of a signature on the front cover is not sufficient evidence. To demonstrate that documents have been reviewed you will need to show that nominated personnel have been issued with drafts for comment and that they have provided comments which have been considered by the approval authorities. A simple method is to employ a standard comment sheet on which reviewers can indicate their comments or signify that they have no comment. During the review process you may undertake several revisions. You may feel it necessary to retain these in case of dispute later, but there is no compulsion for you to do so, providing you have evidence that the review took place. You also need to show that the current issue has been reviewed so your comment sheet needs to indicate document issue status.

Reviewing external documents

The requirements for document review and approval do not distinguish between internal and external documents. However, there is clearly a need to review external documents prior to their internal release in order to establish their impact on the organ-

ization, the product, the process, or the quality system. The external document control procedure should make provision for the review on receipt of new documents and on receipt of amendments to such documents.

Reviewing and approving data

All data should be examined before use, otherwise you may inadvertently introduce errors into your work. The standard does not require that data controls be the same as document controls so you are at liberty to pitch the degree of control appropriate to the consequences of failure.

Regarding approval of data, you will need to define which data needs approval before issue, as some data may well be used as an input to a document which itself is subject to approval. It all depends on how we interpret “approved before issue”. Approval before issue should be taken to mean “issue to someone else”. Therefore, if you use data that you have generated yourself, it does not need review and approval prior to use. If you issue data to someone else, it should be reviewed and approved beforehand such as in a network database. If your job is to run a computer program in order to check out a product, you might use the data resulting from the test run to adjust the computer or the program. You should be authorized to conduct the test, therefore your approval of the data is not required because the data has not in fact been issued to anyone else. The danger hiding in this requirement is that an eagle-eyed auditor may spot data being used without any evidence that it has been approved. As a precaution, ensure you have identified in your procedures those types of data that require formal control and that you know the origin of the data you are using.

Adequacy of documents

While the term *adequacy* is a little vague it should be taken as meaning that the document is fit for its purpose. If the objective is stated in the document, does it fulfill that objective? If it is stated that the document applies to a certain equipment, area, or activity, does it cover that equipment, area, or activity to the depth expected for such a document? One of the difficulties in soliciting comments to documents is that you will gather comments on what you have written but not on what you have omitted. One useful method is to ensure that the procedures requiring the document specify the required content so that the reviewers can check the document against an agreed standard.

Authorized personnel

Authorized personnel are personnel who have been authorized to approve certain documents. In the procedure which requires the document to be produced you should

identify who the approval authorities are by their role or function, preferably not their job title and certainly not their name, as both can change. The procedure need only state that the document shall be approved for example by the Chief Designer and Quality Manager prior to issue. Another method is to assign each document to an owner. The owner is a person who takes responsibility for its contents and to whom all change requests need to be submitted. A separate list of document owners can be maintained and the procedure need only state that the document be approved by the owner.

Denoting approval

The standard doesn't require that documents visibly display approval. Approval can be denoted directly on the document, on a change or issue record, in a register, or on a separate approval record. The presence of a colored header or the stamp of the issuing authority can substitute for actual signatures on documents. Providing signatures and front sheets often adds an extra sheet but no added value. The objective is to employ a reliable means of indicating to users that the document is approved. Some organizations maintain a list of authorized signatories; therefore where you have large numbers of people whose signatures and names may be unknown to users, this may be necessary. If you are dealing with a small group of people who are accessible and whose signatures are known, a list of authorized signatures is probably unnecessary. The quality system will not prevent fraud only inadvertent error. All you need is a means of checking that the person who signed the document was authorized to do so. If below the signature you indicate the position of the person and require his/her name to be printed alongside his/her signature, you have taken adequate precautions.

Issuing documents

The term *issue* in the context of documents means that copies of the document are distributed. You will of course wish to *issue* draft documents for comment but obviously they cannot be reviewed and approved beforehand. The sole purpose of issuing draft documents is to solicit comments. The requirement should be that the documents are reviewed and approved prior to *use*. Some organizations insist that even drafts are approved for issue. Others go further and insist that copies cannot be taken from unapproved documents. This is nonsense and not what is intended by the standard. Your draft documents need to look different from the approved versions either by using letter issue notation (a common convention) or by printing on colored or watermark paper. If the approved document would carry signatures, the absence of any signature indicates that the document is not approved.

Identifying the current revision of documents (4.5.2.1)

The standard requires that *a master list or equivalent document control procedure identifying the current revision status of documents be established and be readily available to preclude the use of invalid and/or obsolete documents*. It is important to note that this requirement only applies to documents and not to data.

As stated previously, staff should have a means of being able to determine the correct revision status of documents they use. You can do this through the work instructions, specification, or planning documents, or by controlling the distribution, if the practice is to work to the latest issue. However, both these means have weaknesses. Documents can get lost, errors can creep into specifications, and the cost of changing documents sometimes prohibits keeping them up-to-date. The issuing authority for each range of documents should maintain a register of documents showing the progression of changes that have been made since the initial issue. With configuration documents (documents which prescribe the features and characteristics of products and services) the relationship between documents of various issue states may be important. For example a design specification at issue 4 may equate with a test specification at issue 3 but not with the test specification at issue 2. This record is sometimes referred to as a Master Record Index or MRI but there is a distinct difference between a list of documents denoting issue state and a list of documents denoting issue compatibility state. The former is a Document Record Index and the latter a Configuration Record Index. You need to be careful not to imply by the title you give the index that there is a relationship between the document issues if there is no relationship.

The index may be issued or, so as to preclude use of obsolete indices, it may be prudent to keep no hard copies. With organizations that operate on several sites using common documentation it may well be sensible to issue the index so that users have a means of determining the current version of documents.

The standard does not require you only to maintain one index. You can have as many as you like. In fact if you have several ranges of documents it may be prudent to create an index for each range.

Ensuring the availability of controlled documents (4.5.2.1a)

The standard requires the supplier to *ensure that the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed*. Note that the requirement does not apply to data.

This requirement contains four separate points:

- a) What are appropriate documents?
- b) What are operations essential to the effective functioning of the quality system?
- c) How do you ensure that documents are available?
- d) What are pertinent issues and how do you recognize them?

Appropriate documents are those which are needed to carry out work and a list of 11 such documents is provided in the standard as examples. However, it may not be appropriate to place the quality manual at all locations if it does not contain any operational policies or procedures. The work instructions should specify the documents that are required for the task so that it is then clear that any not specified are not essential. It should not be left to the individual to determine which documents are essential and which are not.

Operations essential to the effective functioning of the system are operations that contribute to the specification, achievement, control, assurance, or management of quality. Any operation covered by the quality system is an essential operation.

Issue notation

The revision status of a document may be indicated by date, by letter, or by number, or may be a combination of issue and revision state. A pertinent issue is a document of the correct revision state. In fact the term *issue* is not an accurate description of what is required. Documents that reside on magnetic media do not need an issue state because they may not be issued. They are recognized by their revision state. Every change to a document should revise the revision index. Changes may be *major*, causing the document to be reissued or re-released, or they may be *minor*, causing only the affected pages to be revised. You will need to decide on the revision conventions to use. Software documents often use a different convention to other documents, such as Release 1.1 or Version 2.3. Non-software documents use conventions such as Issue 1, Issue 2 Revision 3, Issue 4 Amendment 2. It is safer to be consistent with your revision conventions so as to prevent mistakes and ambiguities.

Pertinent issues

The pertinent issue of documents may not be the latest issue. You may have reason to use different issues of documents such as when building or repairing different versions

of the same product. In such cases you will need a means of indicating which issue of which document is to be used. One method is to specify the pertinent issues of documents in the specifications, drawings, work instructions, or planning documents. This should be avoided if at all possible as it can cause maintenance problems when documents change. It is sometimes better to declare that staff should use the latest issue unless otherwise stated and provide staff with a means of determining what the latest issue is.

A question often asked by assessors is “How do you know you have the correct issue of that document?” One way of ensuring the latest issue is to control the distribution of documents so that each time a document changes, the amendments are issued to the same staff who received the original versions. If you identify authentic copies issued by the issuing authority in some way, by colored header, red stamp, or other means, it will be immediately apparent which copies are authentic and under control and which are uncontrolled. Another way is to stamp uncontrolled documents with an “Uncontrolled Document” stamp. All documents should carry some identification as to the issuing authority so that you can check the current issue if you are in doubt. The onus should always rest with the user regarding the use of documents. It is their responsibility to check that they have the correct issue of a document before commencing work. One way of signifying authenticity is to give documents copy numbers in red ink. The standard doesn't require documents to carry copy numbers but it may be a practical way of retaining control over their distribution. If documents are filed in binders by part or volume, the binder can be given a copy number, but you will need a cross-reference list of who holds which copy.

Availability of documents

In order to make sure that documents are available you should not keep them under lock and key (or password protected), except for those where restricted access is necessary for security purposes. You need to establish who wants which documents and when they need them. If there is a need for access out of normal working hours, access has to be provided. The more copies there are, the greater the chance of documents not being maintained, so minimize the number of copies. A common practice is to issue documents to managers only and not the users. This is particularly true of quality system documents. One finds that only the managers hold copies of the quality manual. In some firms all the managers reside in the same building, even along the same corridor, and it is in such circumstances that one invariably finds that these copies have not been maintained. It is therefore impractical to have all the copies of the quality manual in one place. Distribute the documents by location not named individual. Distribute to libraries or document control centers, so that access is provided to everyone and so that someone has the job of keeping them up-to-date. If using an *intranet*, the problems of

distribution are less difficult but there will always be some groups of people who need access to hard copy¹.

The document availability requirement applies to both internal and external documents alike. Customer documents such as contracts, drawings, specifications, and standards need to be available to those who need them to execute their responsibilities. Often these documents are only held in paper form and therefore distribution lists will be needed to control their location. If documents in the public domain are required, they only need be available when required for use and need not be available from the moment they are specified in a specification or procedure. You should only have to produce such documents when they are needed for the work being undertaken at the time of the audit. However, you would need to demonstrate that you could obtain timely access when needed. If you provide a lending service to users of copyrighted documents, you would need a register indicating to whom they were loaned so that you can retrieve them when needed by others.

Obsolete and invalid documents (4.5.2.1b and 4.5.2.1c)

Ensuring removal of obsolete documents (4.5.2.1b)

The standard requires the supplier to *ensure that invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use*. Again you should note that this requirement does not apply to data.

It is unnecessary to remove invalid or obsolete documents if you provide staff with the means of determining the pertinent issues of documents to use. There are often valid reasons for retaining obsolete documents. What may be obsolete in one situation may not be obsolete in another. In simple terms an obsolete document is one which is no longer required for operational purposes. As stated earlier, there are cases where various issues of the same document may need to be used and in such cases none of the documents is obsolete. One may need to remove copies of previous versions of a document but retain the master for reference purposes. You cannot demonstrate to an assessor that you corrected a deficiency if you don't retain the version that contained the deficiency as well as the subsequent version.

If you do not have a means of readily distinguishing the correct version of a document, amendment instructions should require that the version being replaced is destroyed or returned to the document controller. If you allow uncontrolled copies to be taken, removal of obsolete documents becomes more difficult. However, providing you have a

¹ Further discussion on electronic documentation systems can be found in the *ISO 9000 Quality System Development Handbook* by David Hoyle (Butterworth-Heinemann, 1998).

means of distinguishing controlled and uncontrolled documents you should have no problem. If there is no means of determining current versions, the chances of using the wrong document are significantly increased if several versions are at one time accessible at the same location.

The standard refers to invalid documents as well as obsolete documents. Invalid documents may not be obsolete and may take several forms. They may be:

- Documents of the wrong issue status for a particular task
- Draft documents which have not been destroyed
- Documents which have not been maintained up-to-date with amendments
- Documents which have been altered or changed without authorization
- Copies of documents which have not been authenticated
- Unauthorized documents or documents not traceable through the quality system
- Illegal documents

Identifying invalid and obsolete documents (4.5.2.1c)

The standard requires that *any obsolete document retained for legal and/or knowledge preservation purposes are suitably identified*. Note that this requirement only applies to documents and not data.

One way of identifying obsolete documents is to write SUPERSEDED or OBSOLETE on the front cover, but doing this requires that the custodian is informed. When a version of a document is replaced with a new version, the withdrawal of the obsolete version can be accomplished in the amendment instructions that accompany the revision. When documents become obsolete by total replacement, their withdrawal can also be accomplished with the amendment instruction. However, where a document becomes obsolete and is not replaced there needs to be a Document Withdrawal Notice which informs the custodian of the action to be taken and the reason for withdrawal.

There is no simple way of identifying invalid documents, as the reasons that they are invalid will vary. By printing authentic documents on colored paper or providing paper with a special header one can inject a degree of control. Placing the approval signatures on the front sheet will immediately identify an unapproved document. However, the onus must rest with the user who, if properly trained and motivated, will refrain from using invalid documents.

Control of customer engineering specifications (4.5.2.2)

The standard requires the supplier to *establish a procedure to assure the timely review, distribution, and implementation of all customer engineering standards/specifications and changes.*

Customer engineering standards and specifications are external documents. Therefore your procedure for controlling external documents should also cover these documents. Where ISO/TS 16949 differs from ISO 9001 on this topic is that ISO 9001 does not require external documents to be reviewed or implemented. However, any external document received or procured for the organization should be reviewed for its applicability before it is brought under control, otherwise resources could be wasted on controlling documents that have no practical use in the organization. This requirement could be placed under *Contract review* since any documents issued by customers form part of the contract and should go through contract review before acceptance and implementation.

Timely review means days, not weeks or months – therefore immediately a new customer document is received, it should be routed to a person authorized through procedures to carry out a review. It would be advantageous to set up an interface with your customers so that their documents are always routed to the same position in your company. The review should establish the applicability of the document and its impact on the contract. Any changed documents should be treated as an amendment to the contract and processed accordingly.

As with all controlled documents, a distribution list for customer documents should be maintained so that copies can be withdrawn, replaced, or amended when required.

Maintaining records of change implementation (4.5.2.2)

The standard requires the supplier to *maintain a record of the date on which each change is implemented in production.*

This requirement has been addressed in its general form in Part 2 Chapter 4 under *Documenting modifications* but will be amplified here. There are two types of records that need to be maintained. One deals with changes to documents and the other deals with changes to products resulting from changes to documents. The master document register or list should list all controlled internal and external documents, including customer documents, in terms of their title, date, and revision status. The product modification record should define the design standard of the products to be built. A simplified example is shown in Figure 5.6. What this shows are the batches produced and the revision state of the specifications to which each batch of product has been produced. It also shows the date and batch when changes were embodied. Note that

Specification /ECO	Pre-prod model Serial Numbers		Production model Serial Numbers			
	1001/1010	1011/20	2001/2100	2101/2200	2201/2300	2301/2400
KL7009	1	2	3	3	3	4
KL7500	1	1	1	2	2	2
ECO1001		12/3/95	-	-	-	-
ECO1002			21/9/95	-	-	-
ECO1003					14/11/95	-

Figure 5.6 Modification record

ECO1001 was implemented in the design of KL7009 to raise its status from revision 2 to revision 3 when the next batch of product was built. In addition to this record you will need inspection records that denote the configuration of the build.

Another interesting aspect of this requirement is that *the implementation of changes is to include updates to all appropriate documents*. This means that the impact of a customer change order on your internal documents needs to be evaluated and the corresponding changes made to all affected documents. This should be performed as part of the change review process (see later in this chapter).

Document and data changes (4.5.3)

Review and approval of changes to documents and data (4.5.3)

The standard requires that *changes to documents and data be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise*.

Changes to documents

Meeting this requirement relies on what constitutes a change to a document. If you have a copy of a document and make pencil marks upon it, have you changed it? The answer

is “No!” You have defaced it. But some assessors would argue that you have changed it, especially if you intend to work to the information you have marked on the document. In fact working to unofficial information is often the only practical solution as processing a formal change may take a considerable time. If by the time the product reaches inspection the formal change has been made, the product can be verified against the authorized document. In other cases, working to marked-up documents can be an authorized practice if you provide a legitimate means for doing so, such as a change note.

If you require an urgent change to a document a legitimate means of issuing change instructions is to generate a Document Change Note. The change note should detail the changes to be made and be authorized by the appropriate authorities. On receipt of the change note the recipients make the changes in manuscript or by page replacement, and annotate the changes with the serial number of the change note. You need to state your policy regarding changing documents. Should you allow any markings on documents, you should specify those which have to be supported by change notes and those which do not. Markings that add comment or correct typographical errors may well be acceptable providing instructions are not changed.

In order that a change be reviewed it has to be proposed and the most common method is to employ Document Change Requests. By using a formal change request it allows anyone to request a change to the appropriate authorities. By maintaining a register of such requests you can keep track of who has proposed what, when, and what progress is being made on its approval. You may of course use a memo or phone call to request a change but this form of request becomes more difficult to track and prove you have control. You will need to inform staff where to send their requests. On receipt of the request you need to provide for their review by the same bodies (not the same people necessarily) that reviewed the original document. The change request may be explicit in what should be changed or simply report a problem which a change to the document would resolve. Someone needs to be nominated to draft the new material and present it for review but, before that, the approval authorities need to determine whether they wish the document to be changed at all. There is merit in reviewing requests for change before processing in order to avoid abortive effort. Also you may receive several requests for change that conflict and before processing you will need to decide which change should proceed.

The change does not need to be reviewed and approved by the same individuals who reviewed and approved the original document. The important factor is that the same functions or organizations review and approve the change. The reason is to subject the document to the same scrutiny as the original by personnel as qualified as those who examined the original. Providing your procedures specify the review and approval authorities in terms of functions or positions and not names, the requirement is easily satisfied.

Changes to data

As with the review and approval of data you need to be careful how you control changes to data. Data that has not been issued to anyone does not require approval if changed. Only the data that has been issued to someone other than its producer need be brought under change control. If you are using data provided by someone else, in principle you can't change it without the person's permission. However, there will be many circumstances where formal change control of data is unnecessary and many where it is vital, as with scientific experiments, research, product testing, etc. One way of avoiding seeking approval to change data is to give the changed data a new identity, thereby creating new data from old data. It is perfectly legitimate as you have not changed the original data providing it can still be accessed by others. If you use a common database for any activities you will need to control changes to the input data.

Access to pertinent background information (4.5.3)

The standard requires that *the designated organizations have access to pertinent background information upon which to base their review and approval.*

To provide these authorities with pertinent background information you will need to submit the change request to them. In fact this is another good reason to formalize the change request process. Your change requests need to specify:

- The document title, issue, and date
- The originator of the change request (who is proposing the change, his/her location or department)
- The reason for change (why the change is necessary)
- What needs to be changed (which paragraph, section, etc. is affected and what text should be deleted)
- The changes in text required (the text that is to be inserted or deleted)

The change should be processed in the same way as the original document and submitted to the appropriate authorities for approval. If approval is denoted on the front sheet of your documents, you will need to reissue the front sheet with every change. This is another good reason to use separate approval sheets. They save time and paper.

Issuing changed documents (4.5.3)

Identifying the nature of changes

The standard requires that *where practicable, the nature of the change is to be identified in the document or the appropriate attachments.*

The nature of the change is principally the intrinsic characteristics of the change. You should therefore indicate not only what has changed but also give the reasons for change. The requirement provides a choice as to where you may place this information. To place it in the document you will need to mark the changed material either by sidelining, underlining, boldening, or some other means. You will need to reference the change authority (the change notice, amendment instruction, or other notice) and provide a change record in the document on which you can denote the reason for change. Alternatively, you may provide the reasons for change on the change note or amendment instruction and it is always good practice to instruct staff to retain these instructions so as to provide a source of reference when needed.

If you operate a computerized documentation system, your problems can be eased by the versatility of the computer. Using a database you can provide users with all kinds of information regarding the nature of the change, but be careful. The more you provide the greater the chance of error and the harder and more costly it is to maintain.

Staff should be told the reason for change and you should employ some means of ensuring that where changes to documents require a change in practice, adequate instruction is provided. A system that promulgates change without concern for the consequences is out of control. The changes are not complete until everyone who is affected by them both understands them and is equipped to implement them when necessary.

An aspect not covered by the standard is the effect of one change on other documents. It is important to maintain compatibility between documents. When evaluating the change you should assess the impact of the requested change on other areas and initiate the corresponding changes in the other documents.

Reissue of changed documents

The 1987 version of ISO 9001 required that *documents be reissued after a practical number of changes have been made* but this provision has been removed.

The requirement stems from the days before word processing when changes were promulgated by amendment leaflet or change notes and one had to stick additional paragraphs over ones that were crossed out. In such circumstances there were only so many changes of this nature that you could make before the document became unstable and consequently a potential source of error. If you operate in this fashion, the number of changes may well be a limiting factor but if you use word processors, other factors ought to be taken into account.

However, there are practical reasons even in the IT age when it may not be prudent to reissue a document after each change.

There are several types of changes you may need to consider:

- Changes affecting a whole range of documents
- Changes affecting many pages of a single document
- Changes affecting a few pages of a single document

For the change that affects a whole range of documents you will either need to reissue the complete set of documents or employ a Global Change Notice (GCN). When the cost and time required to process a change that affects many documents is prohibitive, something like a GCN is a useful tool to have in your quality system. With a GCN you can instruct document holders to make changes to certain documents in their possession without having to identify every document. For example, if a component specification changes, a GCN can authorize the new information to be added to any documents which specify that particular component without having to process hundreds of documents. When the document is subsequently revised for other reasons, the GCN can be embodied, so that over a period of time all documents will eventually be brought up-to-date. You will need a means of alerting staff to the issue of a GCN but if you control your distribution lists this should not present a problem.

Where a change affects many pages, the document should be reissued. Even if the substantive change is minor, the knock-on effect in double-sided documents with diagrams etc. can be to change every page. With modern word-processing techniques, even adding a full stop can throw out several pages.

Where a change affects only a few pages, you can issue the changed pages with an amendment instruction informing the recipient which pages to change. Alternatively you can use the Document Change Notice (DCN) to add new pages and amend text at the same time.

If only a few words or figures are affected, the DCN is by far the least expensive and the quickest method.

As an alternative to actually issuing changes, you may wish to process the change requests to the master and hold reissue of the document until a suitable number of changes or a significant proportion of the document has been changed. It is not the number of changes which is significant because a single change could have far greater effect than 20 minor changes. With small documents, say 3 to 6 pages, it is often easier to reissue the whole document for each change.

Task list

- 1 Identify the types of document that you need to control.
- 2 Classify these documents so you can apply controls appropriate to their classification.
- 3 Ensure your quality system procedures identify all the types of document requiring control including external documents.
- 4 Specify appropriate requirements for each of the controlled documents.
- 5 Establish numbering, dating, revision status conventions.
- 6 Identify the issuing authorities for the controlled documents.
- 7 Produce procedures for preparing, reviewing, approving, issuing, and changing controlled documents.
- 8 Determine where each type of document is to be stored.
- 9 Decide how you will indicate the approval status on documents.
- 10 Determine who will review and who will approve the controlled documents.
- 11 Decide who is to receive, distribute, and review customer documents and changes thereto.
- 12 Decide how you will safeguard approved documents from unauthorized change, copying, and removal.
- 13 Create controlled lists of documents which denote the revision status.
- 14 Create distribution lists for controlled documents.
- 15 Produce procedures for tracking embodiment of changes to customer documents.
- 16 Provide document custodians with stamps to mark obsolete documents upon receipt of instructions.
- 17 Create a formal change request mechanism for initiating changes to controlled documents.
- 18 Provide a fast route to change documents.
- 19 Provide an economic means of changing a range of documents affected by a single change.
- 20 Provide a means of withdrawing and disposing of documents when the product, organization, service, or process becomes obsolete.
- 21 Provide a means of evaluating the effects that a change in one document has on other documents.

Document and data control questionnaire

- 1 How do you control documents and data that relate to the requirements of ISO/TS 16949?
- 2 How do you control documents of external origin?
- 3 How do you ensure that documents and data are reviewed for adequacy by authorized personnel prior to issue?
- 4 How do you ensure that customer documents are subjected to timely review and that the documents are distributed to those concerned?
- 5 How do you ensure that documents and data are approved for adequacy by authorized personnel prior to issue?
- 6 How do you ensure that the pertinent issues of appropriate documents including customer documents are available at all locations where operations essential to the effective functioning of the quality system are performed?
- 7 How do you ensure that information on the current revision status of documents is readily available?
- 8 How do you ensure that invalid and/or obsolete documents are assured against inadvertent use?
- 9 What means are used to identify obsolete documents retained for legal and/or knowledge preservation purposes?
- 10 How do you ensure that changes to documents are reviewed by the same functions or organizations that performed the original review?
- 11 How do you ensure that changes to documents are approved by the same functions or organizations that performed the original approval?
- 12 How do you ensure that designated organizations have access to pertinent background information upon which to make their review and approval of changes to documents?
- 13 How do you identify the nature of changes within documents or their attachments?
- 14 How do you indicate the point and date at which changes in customer engineering documents are implemented in production?

Do's and don'ts

- ⊗ Don't state the issue status of reference documents in your procedures and specifications unless absolutely necessary.
- ⊗ Don't put the distribution list on controlled documents – keep it separate.
- ⊗ Don't issue documents to named individuals – use their position titles.
- ⊗ Don't change a controlled document without an approved change notice.
- ⊗ Don't use concessions to change documents – change the document or use a change note.
- ⊗ Don't create a complex change control mechanism – it should represent the easiest way of changing a document.
- ☺ Do provide labeled binders for ranges of documents as they are more easily traced.
- ☺ Do inform staff why changes have been made.
- ⊗ Don't ignore written comments to draft documents.
- ☺ Do give all change requests a unique identity.
- ⊗ Don't purge every office in search of obsolete documents.
- ☺ Do provide for amending the document index before revised documents are issued.
- ⊗ Don't keep all your documents in one place.
- ☺ Do keep “insurance copies” at a remote location.
- ☺ Do protect computer access from unauthorized users.
- ☺ Do use computer virus protection practices.
- ☺ Do limit distribution lists to a “need to know” basis.
- ⊗ Don't impose presentation standards that are costly to meet and maintain.
- ☺ Do secure the masters of documents.
- ☺ Do review controlled documents periodically to determine whether they remain relevant.

Chapter 6

Purchasing

Scope of requirements

Most organizations need to purchase items in order to conduct their business. The purchasing requirements of the standard apply only to items needed to design, manufacture, install, maintain, or operate the products and services which it supplies to its customers. Other items are needed to sustain the business such as stationery, catering supplies, furniture, etc. and may be used in design, manufacture, installation operations, etc. but do not contribute to the quality of the products and services which are supplied to customers. The term *purchasing* involves the payment of money or an equivalent but the requirements still apply if items are obtained without any payment being made, at least by the organization which is to use the item. A more suitable term would be *procurement*, which does not need to involve payment. Although the principles are common sense, the detail requirements of the standard would be too onerous to apply to everything you acquire in connection with your business; so you need a means of classifying purchases so as to apply controls on the basis of their risk to the quality of the products and service supplied to customers.

In addition to products and service which are incorporated or which form part of the products and service supplied to customers, there are tools, test equipment, contract labor, facilities, calibration services, computer services, and many other items which, if not of adequate quality, may adversely affect the quality of the products and service you supply. These items should also be governed by these requirements.

Even though you may not have designed or manufactured the purchased items, you have a responsibility to ensure that such items are fit for their purpose if you sell them on to your customer either directly or as part of another product, because *you* selected them. If your customer selected the products, they should be governed by the requirements on purchaser supplied product (see Part 2 Chapter 7).

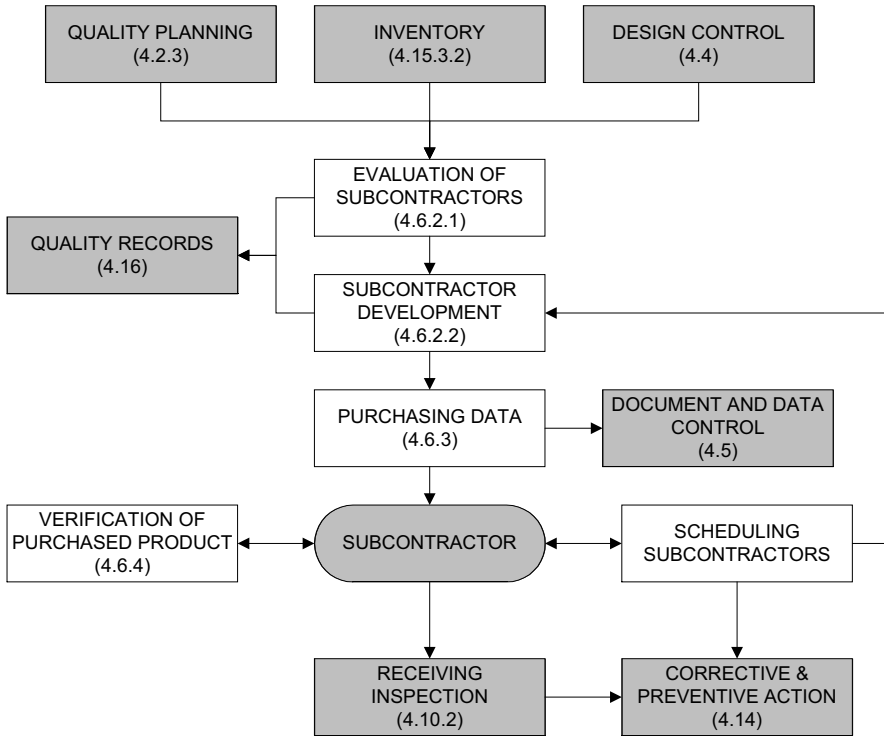


Figure 6.1 Clause relationships with the purchasing element

There are four separate clauses to this part of the standard. The first applies to all purchases, the second only to subcontractors, the third to all purchases, and the fourth when specified in the contract. Subcontractors in the context of ISO 9001 are defined as providers of product, materials, or services. Although a subcontractor is normally an organization that supplies product to your specification and a supplier one who supplies product to their own specification, in the context of ISO/TS 16949 both are classed as subcontractors.

The requirements in element 4.6 are linked with other clauses of the standard even when there is no cross reference. This relationship is illustrated in Figure 6.1.

Ensuring purchased product conforms to specified requirements (4.6.1.1)

The standard requires the supplier to *establish and maintain documented procedures to ensure that purchased product conforms to specified requirements.*

Once the make or buy decision has been made, control of any purchasing activity follows a common series of activities, which are illustrated in Figure 6.2. There are four key processes in the procurement cycle for which you should prepare procedures:

- The specification process, which starts once the need has been identified and ends with a request to purchase. This is covered by clause 4.6.3 of ISO/TS 16949.
- The evaluation process, which starts with the request to purchase and ends with the placement of the order or contract. This is covered by clause 4.6.2 of ISO/TS 16949.
- The surveillance process, which starts with placement of order or contract and ends upon delivery of supplies. This is covered by clauses 4.6.2 and 4.6.4 of ISO/TS 16949.
- The acceptance process, which starts with delivery of supplies and ends with entry of supplies onto the inventory and/or payment of invoice. This is covered by clause 4.10.2 of ISO/TS 16949.

Although the goods inwards or goods receiving function including receipt inspection is considered part of purchasing, as it is the final stage in the purchasing process, the standard covers receipt inspection in clause 4.10. It does not address the receipt of goods activities at all, primarily because this is an accounting or inventory control function and not a function that serves the achievement of quality. Do not separate these processes just to respond to the standard if they are not separate in practice.

Whatever you purchase the processes will be very similar, although there will be variations for purchased services such as subcontract labor, computer maintenance, consultancy services, etc. Where the purchasing process is relatively simple, one procedure may suffice but where the process varies you may need separate procedures so as to avoid *all* purchases, regardless of value and risk, going through the same process. It is likely that you will have one purchasing system for supplies irrespective of whether it is used for deliverable or non-deliverable products. It would therefore make sense to distinguish between the procedures used for deliverable supplies and those for purely internal usage.

The standard does not define what the specified requirements are in this case. Elsewhere in the standard the term seems to relate to customer requirements but when purchasing you may well not be passing on customer requirements to your supplier. In cases other than when truly subcontracting work, you will in all probability be deriving your own requirements.

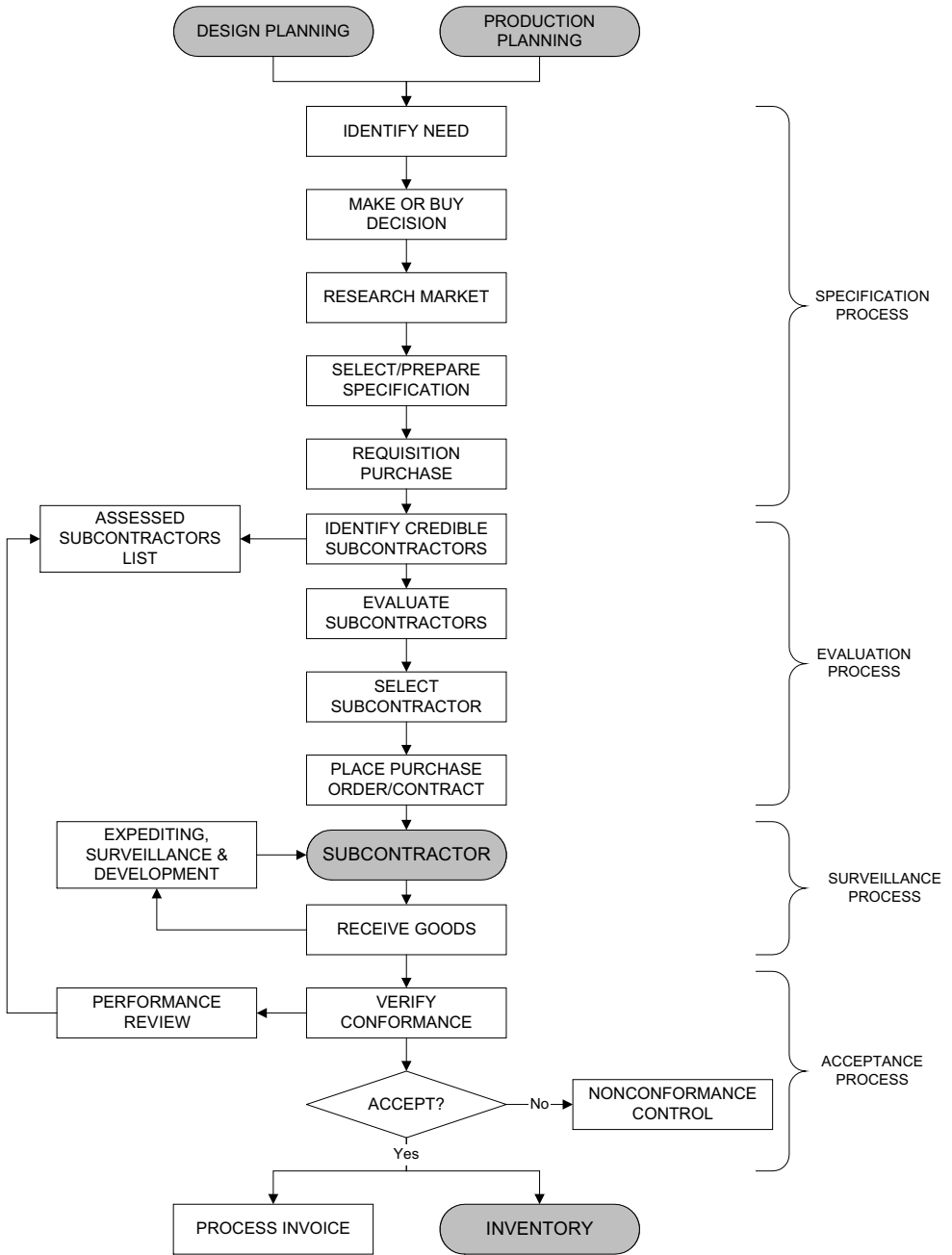


Figure 6.2 The procurement process

Customer-approved subcontractors (4.6.1.2)

The standard requires suppliers to *purchase products, materials, or services from approved subcontractors where specified by the contract.*

Notwithstanding the guidance given below under *Evaluation and selection of subcontractors*, this requirement does not relieve you of the responsibility for ensuring the quality of subcontracted parts, materials, and services. Therefore, it would be unwise to place orders on a customer-specified subcontractor without first going through your evaluation and selection process. You can obviously take some short cuts but don't make assumptions. The customer will not be sympathetic when you are late on delivery or your price escalates. If you find a subcontractor that can meet all your product/service requirements at a lower price you can submit details to your customer for approval.

Satisfying regulatory requirements (4.6.1.3)

The standard requires that *all products or materials used in part manufacture satisfy current regulatory requirements applicable to the country of manufacture and sale.*

The first step in meeting this requirement is to establish a process that will identify all current regulatory requirements pertaining to the part or material. You need to identify the regulations that apply in the country of manufacture and the country of sale. This may result in two different sets of requirements. For example, a part may be manufactured in Mexico and sold in California or made in the UK and sold in Syria. In one case the regulations on recycling materials may be tougher in the country of sale and in the other case there may be restrictions prohibiting the sale of vehicles containing materials from a particular country. It is difficult to keep track of changes in import and export regulations but using the services of a legal department or agency will ease the burden. This illustrates how a quality system can easily involve every department, function, and/or discipline in the company.

In order to ensure compliance with this requirement you need to impose on your subcontractors, through the purchase order, the relevant regulations; and through examination of specifications and products and by on-site assessment, verify that these regulations are being met. It is not sufficient merely to impose the requirement upon your supplier through the purchase order. You can use the certified statements of authorized independent inspectors as proof of compliance instead of conducting the assessment yourself. However, such inspections may not extend to the product being supplied and therefore a thorough examination by your technical staff will be needed. Once deemed compliant, you need to impose change controls in the contract that prohibit the supplier changing the process or the product without your approval. This may

not be possible when dealing with suppliers supplying product to their specification or when using off-shore suppliers where the system of law enforcement cannot be relied upon. In such cases you will need to define accurately the product required and carry out periodic inspections and tests to verify continued compliance.

Evaluation and selection of subcontractors (4.6.2.1a)

The standard requires the supplier to *evaluate and select subcontractors on the basis of their ability to meet subcontract requirements, including the quality system and any specific quality assurance requirements.*

Although the title of this clause refers to *subcontractors*, this term is not used in ISO 9001 in the traditional sense of organizations supplying products or service to customer specifications. It is used in ISO 9001 to refer to any organization that supplies products or services to a customer whether to their own specification or a customer specification. For consistency therefore, the term *subcontractor* in this section has no special meaning.

The process for selection of subcontractors varies depending upon the nature of the products and services to be procured. The more complex the product or service, the more complex the process. You either purchase products and services to your specification (custom) or to the subcontractor's specification (proprietary). For example you would normally procure stationery, fasteners, or materials to the *subcontractor's specification* but procure an oil platform, radar system, or road bridge to *your specification*. There are gray areas where proprietary products can be tailored to suit your needs and custom-made products or services that primarily consist of proprietary products configured to suit your needs. There is no generic model; each industry seems to have developed a process to match its own needs. However we can treat the process as a number of stages, some of which do not apply to simple purchases, as shown in Table 6-1. At each stage the number of potential subcontractors is whittled down to end with the selection of what is hoped to be the most suitable that meets your requirements. With "custom" procurement this procurement cycle may be exercised several times. For instance there may be a competition for each phase of the project: feasibility, project definition, development, and production. Each phase may be funded by the customer. On the other hand, a subcontractor may be invited to tender on the basis of previously demonstrated capability but has to execute project feasibility, project definition, and development of a new version of a product at its own cost. Subcontractor capability will differ in each phase. Some subcontractors have good design capability but lack the capacity for quantity production, others have good research capability but lack development capability.

You need to develop documented procedures that define your subcontractor evaluation and selection process and in certain cases this may result in several closely-related procedures for use when certain conditions apply. Do not try to force every purchase through the same selection process. Having purchasing policies that require three quotations for every purchase regardless of past performance of the current subcontractor is placing price before quality. Provide flexibility so that the policies' and procedures' complexity match the risks anticipated. Going out to tender for a few standard nuts and bolts would seem unwise. Likewise, placing an order for \$1m of equipment based solely on the results of a third party ISO 9000 certification would also seem unwise.

Stage	Purpose	Proprietary	Tailored	Custom
Preliminary subcontractor assessment	To select credible subcontractors	✓	✓	✓
Pre-qualification of subcontractors	To select capable bidders		✓	✓
Qualification of subcontractors	To qualify capable bidders			✓
Request for Quotation (RFQ)	To obtain prices for products/services	✓	✓	
Invitation to Tender (ITT)	To establish what bidders can offer			✓
Tender/quote evaluation	To select a subcontractor	✓	✓	✓
Contract negotiation	To agree terms and conditions	✓	✓	✓

Table 6-1 Subcontractor evaluation and selection stages

Preliminary subcontractor assessment

The purpose of the preliminary subcontractor assessment is to select *credible* subcontractors and not necessarily to select a subcontractor for a specific purchase. There are millions of subcontractors in the world, some of which would be happy to relieve you of your wealth given half a chance, and others that take pride in their service to customers and are a pleasure to have as partners. You need a process for gathering intelligence on potential subcontractors and for eliminating unsuitable subcontractors so that the buyers do not need to go through the whole process from scratch with each purchase. The first step is to establish the type of products and services you require to support your

business, then search for subcontractors that claim to provide such products and services. In making your choice, look at what the subcontractor says it will do and what it has done in the past. Is it the sort of firm that does what it says it does or is it the sort of firm that says what you want to hear and then conducts its business differently? Some of the checks needed to establish the credibility of subcontractors are time consuming and would delay the selection process if undertaken only when you have a specific purchase in mind. You will need to develop your own criteria but, typically, unsuitable subcontractors may be subcontractors that:

- Are unlikely to deliver what you want in the quantities you may require
- Are unable to meet your potential delivery requirements
- Cannot provide after-sales support needed
- Are unethical
- Do not comply with the health and safety standards of your industry
- Do not comply with the relevant environmental regulations
- Do not have a system to assure the quality of supplies
- Are not committed to continuous improvement
- Are financially unstable

You may also discriminate between subcontractors on political grounds, such as a preference for supplies from certain countries or a requirement to exclude supplies from certain countries.

The subcontractor assessment will therefore need to be in several parts:

- Technical assessment

This would check the products, processes, or services to establish they are what the subcontractor claims them to be. Assessment of design and production capability may be carried out at this stage or be held until the pre-qualification stage when specific contracts are being considered.

- Quality system assessment

This would check the certification status of the quality system, verifying that any certification was properly accredited. For non-ISO 9000 registered subcontractors, a quality system assessment may be carried out at this stage either to ISO 9000 or the customer's standards.

- Financial assessment

This would check the credit rating, insurance risk, stability, etc.

- Ethical assessment

This would check probity, conformance with professional standards and codes.

These assessments do not need to be carried out on the subcontractor's premises. Much of the data needed can be accumulated from a subcontractor questionnaire and searches through directories and registers of companies, and you can choose to rely on assessments carried out by accredited third parties to provide the necessary level of confidence. (The Directories of Companies of Assessed Capability that are maintained by the Accreditation Agencies can be a good place to start.) The assessments may yield subcontractors over a wide range and you may find it beneficial to classify subcontractors as follows:

Class A *ISO 9000 certified and demonstrated capability.* This is the class of those certified subcontractors with which you have done business for a long time and gathered historical evidence which proves their capability.

Class B *Demonstrated capability.* This is the class of those subcontractors you have done business with for a long time and warrant continued patronage on the basis that it's better to deal with those subcontractors you know than those you don't. They may not even be contemplating ISO 9000 certification but you get a good product, a good service, and no hassle.

Class C *ISO 9000 certified and no demonstrated capability.* This is the class of those certified subcontractors with which you have done no business. This may appear a contradiction, as ISO 9000 certification is obtained on the basis of demonstrated capability, but you have not established their capability to meet your requirements.

Class D *Capable with additional assurance.* This is the class of first-time subcontractors with which you have not done sufficient business to put in class B and where you may need to impose ISO 9000 requirements or similar to gain the confidence you need.

Class E *Unacceptable performance that can be neutralized.* This is the class of those cases where you may be able to compensate for poor performance if they are sole subcontractors of the product or service.

Class F *No demonstrated capability.* This is the class of those subcontractors you have not used before and therefore have no historical data.

Class G *Demonstrated unacceptable performance.* This is the class of those subcontractors that have clearly demonstrated that their products and services are unacceptable and it is uneconomic to compensate for their deficiencies.

Caution is advised on the name you give to this list of subcontractors. All have been assessed but all may not have been visited or used. Some organizations refer to it as an Approved Subcontractors List (ASL) or Approved Vendor List (AVL), but if you include unacceptable subcontractors you cannot call it an Approved Vendor List. If it is in paper form, two lists may be preferable. Some organizations use colored paper to distinguish between approved and unapproved subcontractors. If the data is stored electronically, the fields can be protected to prevent selection of unacceptable subcontractors.

If your requirements vary from project to project, subcontractors approved for one project may not be approved for others. If your procurement requirements do not vary from product to product, you may well be able to maintain an AVL. Most will meet your minimum criteria for doing business with your company but may not be capable of meeting specific product/service requirements. Others you will include simply because they do supply the type of product/service you require but their credibility is too low at present to warrant preferred status. In the process you have eliminated the “cowboys” or “rogues”. There is no point in adding these to the list as you have established that they won’t change in the foreseeable future.

By linking purchases with the AVL you can indicate usage status: e.g. current, dormant, or unused.

You will need a documented procedure for generating the AVL, adding new subcontractors, changing data, and removing subcontractors that no longer meet your criteria. Whether in paper form or in a computer database, treat it as a controlled document or controlled data and apply the document/data controls developed to meet element 4.5 of ISO 9001.

Pre-qualification of subcontractors

Pre-qualification is a process for selecting contractors for known future work. The design will have proceeded to a stage where an outline specification of the essential parameters has been developed. You know roughly what you want but not in detail. Pre-qualification is undertaken to select those subcontractors that can demonstrate they have the capability to meet your specific requirements on quality, quantity, price, and

delivery. A subcontractor may have the capability to meet quality, quantity, and price requirements but not have the capacity available when you need the product or service. One that has the capacity may not offer the best price and one that meets the other criteria may not be able to supply product in the quantity you require.

A list of potential bidders can be generated from the Assessed Subcontractors List by searching for subcontractors that match given input criteria specific to the particular procurement. However, the evidence you gathered to place subcontractors on your Assessed Subcontractors List may now be obsolete. Their capability may have changed and therefore you need a sorting process for specific purchases. If candidates are selected that have not been assessed, an assessment should be carried out before proceeding any further.

Once the list is generated, a Request for Quotation (RFQ) or Invitation to Tender (ITT) can be issued, depending on what is required. RFQs are normally used where price only is required. This enables you to disqualify bidders offering a price well outside your budget. ITTs are normally used to seek a line-by-line response to technical, commercial, and managerial requirements. At this stage you may select a number of potential contractors requiring each to demonstrate their capability. You know what they do but you need to know if they have the capability of producing a product with specific characteristics and can control its quality.

When choosing a bidder you also need confidence that continuity of supply can be assured. One of the benefits of ISO 9000 certification is that it should demonstrate that the subcontractor has the capability to supply certain types of products and services. However, it is not a guarantee that the subcontractor has the capability to meet *your* specific requirements. Subcontractors who have not gained ISO 9000 registration may be just as good. You may not have a choice if the product or service you require can only be obtained from a non-registered contractor. Using an ISO 9000 registered subcontractor should enable you to reduce your subcontractor controls, so by using a non-ISO 9000 registered subcontractor you will need to compensate by performing more quality assurance activities yourself or employ a third party.

Depending on the nature of the work you may require space models, prototypes, process capability studies, or samples of work as evidence of their capability. You may also make a preliminary visit to each potential bidder but would not send out an evaluation team until the qualification stage.

Qualification of subcontractors

Of those potential bidders that are capable, some may be more capable than others. Qualification is a stage executed to compile a short list of bidders following

pre-qualification. A detail specification is available at this stage and production standard models may be required to qualify the design. Some customers may require a demonstration of process capability to grant production part approval.

During this stage of procurement a series of meetings may be held depending on the nature of the purchase. A pre-bid meeting may be held on the customer's premises to enable the customer to clarify the requirements with the bidders. A mid-bid meeting or pre-award assessment may be held on the subcontractor's premises at which the customer's Subcontractor Evaluation Team carries out a capability assessment on site. This assessment may cover:

- An evaluation of the product
- Audit of design and production plans to establish that, if followed, they will result in compliant product
- Audit of operations to verify that the approved plans are being followed
- Audit of processes to verify their capability
- Inspection and test of product (on or off site) to verify that it meets the specification

The result of subcontractor qualification is a list of capable subcontractors that will be invited to bid for specific work.

ISO 9000 certification was supposed to reduce the amount of subcontractor assessments by customers and it has in certain sectors. However, the ISO 9000 certification, whilst focused on a specific scope of registration, is often not precise enough to give confidence to customers for specific purchases.

The evaluation may qualify two or three subcontractors for a specific purchase. The tendering process will yield only one winner but the other subcontractors are equally suitable and should not be disqualified, as they may be needed if the chosen subcontractor fails to deliver.

Invitation to tender

Once the bidders have been selected, an Invitation to Tender (ITT) needs to be prepared to provide a fixed baseline against which unbiased competitive bids may be made. The technical, commercial, and managerial requirements should be finalized and subject to review and approval prior to release. It is important that all functions with responsibili-

ties in the procurement process review the tender documentation. The ITT will form the basis of any subsequent contract.

The requirements you pass to your bidders need to include as appropriate:

- The tender conditions, date, format, content, etc.
- The terms and conditions of the subsequent contract.
- A specification of the product or service you require which transmits all of the relevant requirements of the main contract (see *Purchasing specifications*).
- A specification of the means by which the requirements are to be demonstrated (see *Purchasing specifications*).
- A statement of work which you require the subcontractor to perform – it might be design, development, management, or verification work and will include a list of required deliverables such as project plans, quality plans, production plans, drawings, test data, etc. You need to be clear as to the interfaces both organizationally and technically (see Part 2 Chapter 4).
- A specification of the requirements which will give you an assurance of quality – this might be a simple reference to the appropriate ISO 9000 standard, but as this standard does not give you any rights you will probably need to amplify the requirements (see *Subcontractor quality system requirements*).

In the tendering phase each of the potential subcontractors are in competition, so observe the basic rule that what you give *one* must be given to *all*. It is at this stage that your subcontractor conducts the tender review defined in clause 4.3.1 of ISO 9001.

Tender/quote evaluation

On the due date when the tenders should have been received, record those that have been submitted and discard any submitted after the deadline. Conduct an evaluation to determine the winner – the subcontractor that can meet all your requirements (including confidence) for the lowest price. The evaluation phase should involve all your staff that were involved with the specification of requirements. You need to develop scoring criteria so that the result is based on objective evidence of compliance.

The standard does not require that you purchase only from “approved subcontractors”. It does require that you maintain records of acceptable subcontractors but does not prohibit you from selecting subcontractors that do not fully meet your purchasing requirements. There will be some subcontractors that fully meet your requirements and

others that provide a product with the right functions but quality, price, and delivery may be less than you require. The requirements of clause 4.6.2(b) provide for the control you exercise over your subcontractors to be dependent upon, amongst other things, the subcontractor's demonstrated capability. If the demonstrated capability is lacking in some respects you can adjust your controls to compensate for the deficiencies.

In some cases your choice may be limited to a single source since no other subcontractor may market what you need. On other occasions you may be spoiled for choice. With some proprietary products you are able to select particular options so as to tailor the product or service to your requirements. It remains a proprietary product, as the subcontractor has not changed anything just for you. The majority of products and services you will purchase from subcontractors, however, is likely to be from catalogs. The designer may have already selected the item and quoted the part number in the specification. Quite often you are buying from a distributor rather than the manufacturer and so need to ensure that both the manufacturer and the distributor will meet your requirements.

Contract negotiation

After selecting a winner you may need to enter contract negotiations in order to draw up a formal subcontract and it is most important that none of the requirements are changed without the subcontractor being informed and given the opportunity to adjust the quotation. It is at this stage that your subcontractor conducts the contract review defined in clause 4.3 of ISO 9001. It is pointless negotiating the price of products and service that do not meet your needs. You will just be buying a heap of trouble! Driving down the price may also result in the subcontractor selling their services to the highest bidder later and leaving you high and dry!

Control of subcontractors (4.6.2.1b)

The standard requires suppliers to *define the type and extent of control exercised by the supplier over subcontractors* and goes on to require that these controls *be dependent upon the type of product, the impact of the product on the quality of the final product, and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors.*

Defining subcontractor controls

Clause 4.6.2.1 requires that you define the extent of subcontractor control but neither this clause nor clause 4.6.4.1 requires you to plan, execute, or record any verification at

subcontractor's premises. The standard also does not indicate where you might define your subcontractor controls as there is no mention of these controls in the clause on purchasing data.

When carrying out subcontractor surveillance you will need a plan which indicates what you intend to do and when you intend to do it. You will also need to agree the plan with your subcontractor. If you intend witnessing certain tests, the subcontractor will need to give you advanced warning of its commencement so that you may attend (see also later in this chapter under *Supplier verification at subcontractor's premises*.)

The quality plan would be a logical place for such controls to be defined but clause 4.2.3 does not specifically refer to subcontractor controls. Any intention that they be defined in the quality plan is hidden in 4.2.3.1(b) where it requires you to give timely consideration to the identification and acquisition of any controls etc. Some companies produce a Quality Assurance Requirement Specification to supplement ISO 9001 and also produce a Subcontractor Surveillance Plan. In most other cases the controls may be defined on the reverse side of the purchase order as standard conditions coded and selected for individual purchases.

Selecting the degree of control

The degree of control you need to exercise over your subcontractors and suppliers depends on the confidence you have in their ability to meet your requirements. In determining the degree of control to be exercised you need to establish whether:

- The quality of the product or service can be verified by you on receipt using your normal inspection and test techniques. (This is the least costly of methods and usually applies where achievement of the requirements is measurable by examination of the end product.)
- The quality of the product can be verified by you on receipt providing you acquire additional equipment or facilities. (More costly than the previous method but may be economic if there is high utilization of the equipment.)
- The quality of the product can be verified by you witnessing the final acceptance tests and inspections on the subcontractor's premises. (If you don't possess the necessary equipment or skill to carry out product verification, this method is an economic compromise and should yield as much confidence in the product as the previous methods. You do, however, need to recognize that your presence on the subcontractor's premises may affect the results. They may omit tests which are problematical or your presence may cause them to be particularly diligent, a stance which may not be maintained when you are not present.)

- The verification of the product could be contracted to a third party. (This can be very costly and is usually only applied with highly complex products and where safety is of paramount importance.)
- The quality of the product can only be verified by the subcontractor during its design and manufacture. (In such cases you need to rely on what the contractor tells you and to gain sufficient confidence you can impose quality system requirements, require certain design, manufacturing, inspection, and test documents to be submitted to you for approval, and carry out periodic audit and surveillance activities. This method is usually applied for one-off systems or small quantities when the stability of a long production run cannot be achieved to resolve problems.)

As a minimum you need some means of verifying that the subcontractor/supplier has met the requirements of your subcontract/order and the more unusual and complex the requirements, the more control will be required. If you have high confidence in a particular subcontractor/supplier you can concentrate on the areas where failure is more likely. If you have no confidence, you will need to exercise rigorous control until you gain sufficient confidence to relax the controls. The fact that a subcontractor/supplier has gained ISO 9000 registration for the products and service you require should increase your confidence, but if you have no previous history of their performance it does not mean they will be any better than the subcontractor/supplier you have used for years who is not registered to ISO 9000. Your subcontractor/supplier control procedures need to provide the criteria for selecting the appropriate degree of control and for selecting the activities you need to perform.

Subcontracts enable you to choose the degree of control exercised over your subcontractors. With suppliers, your choices are often limited as you have no privileges. Control over your suppliers is therefore exercised by the results of receipt inspection or subsequent inspections and tests. If your confidence in a supplier is low, you can increase the level of inspection and if high you can dispense with receipt inspection and rely on in-process controls to alert you to any deterioration in supplier performance.

Records of acceptable subcontractors (4.6.2.1c)

The standard requires that suppliers *establish and maintain records of acceptable subcontractors*.

This requirement does not mean that you need to maintain a list of approved suppliers. You should monitor the performance of all your subcontractors and suppliers and classify each according to prescribed guidelines. It is equally important that you list those

suppliers or subcontractors that should not be used due to previously demonstrated poor performance so that you don't repeat the mistakes of the past.

Assessing subcontractors/suppliers is a costly operation. Having established that a subcontractor/supplier has or hasn't the capability of meeting your requirements you should enter their details on a list but this list is not the quality record of acceptable contractors. There needs to be evidence available that supports the decision to place and keep a subcontractor on an approved list. The quality record is the objective evidence that the subcontractor met the prescribed criteria and continues to do so. It would include the evaluation data, results of assessments, audits, and the performance data that you collect following each shipment. The list should be made available to the purchasing authority, thereby avoiding the necessity of re-assessments each time you wish to subcontract work. The list of assessed subcontractors/suppliers should not only list the name and address of the company but provide details of the products and service that have been assessed. This is important because the assessment will have only covered particular products and services. Other products and services offered by the subcontractor/supplier may not have been acceptable. Some firms operate several production lines, each to different standards. A split between military products and civil products is most common. Just because the military line met your requirement doesn't mean that the civil line will also meet your requirements. Calling it a List of Assessed Subcontractors/Suppliers does not imply that it only lists approved firms – it allows you to include records of all firms with which you have done business and classify them accordingly.

You will need a procedure for controlling the list of assessed subcontractors/suppliers, which covers the entry of organizations onto the list and their removal from the list.

Subcontractor/supplier performance will be evident from audit reports, surveillance visit reports, and receipt inspections carried out by you or the third party if one has been employed. You need to examine these documents for evidence that the subcontractor's quality system is controlling the quality of the products and services supplied. You can determine the effectiveness of these controls by periodic review of the subcontractor's performance: what some firms call "vendor rating". By collecting data on the performance of subcontractors/suppliers over a long period you can measure their effectiveness and rate them on a scale from excellent to poor. In such cases you should measure at least three characteristics: quality, delivery, and service. Quality would be measured by the ratio of defective:conforming products received; delivery would be measured by the number of days early or late; and service would be measured by the responsiveness to actions requested by you on scale of excellent to poor. The output of these reviews should be in the form of updates to the list of assessed subcontractors/suppliers.

Developing subcontractor's quality systems (4.6.2.2)

The standard requires suppliers to *perform subcontractor quality system development with the goal of subcontractor compliance to ISO/TS 16949 or an existing customer quality system requirement.*

The first aspect to note about this clause is that there is no requirement for your subcontractors to gain third party registration to ISO/TS 16949.

To meet the requirements of this clause you would need to invoke ISO/TS 16949 in any orders on your subcontractors. In terms of developing your subcontractors, you may at present find that none are registered to either ISO 9000 or QS-9000. You can pursue a two-stage approach with your subcontractors – encouraging them to seek ISO 9000 registration first and then progress to ISO/TS 16949 registration. Alternatively, you can work with them in building their quality system and perform assessments to ISO/TS 16949 yourself. However, Note 1 to this requirement suggests that to perform this assessment you should be recognized by your customer as having the capability to do so or employ a customer-recognized third party to perform the assessment. In either case the assessment should be carried out against ISO/TS 16949. The advantage of using a third party is that it relieves you of this burden and having to maintain the resources to do it. Any doubts you may have about the efficacy of the assessment may be overcome by your subcontractor employing the same registrar as carries out your assessments.

Subcontractor development should not be limited to the assessment for compliance to ISO/TS 16949 as indicated in Note 1. The standard contains the minimum requirements and, with the requirement for continuous improvement, it may be necessary to work with some of your subcontractors in order to develop their capability to improve process capability and delivery schedules or reduce avoidable costs. You can't develop all your subcontractors and hence Note 2 of the standard indicates that you should prioritize subcontractors for development based upon performance and importance of product or service supplied.

Subcontractor delivery performance (4.6.2.3)

The standard requires the supplier to *require 100% on-time delivery performance from subcontractors.*

A 100% on-time delivery performance means that your subcontractors must deliver supplies within the time window you specify. Unless you so specify, they do not need to operate a just-in-time system but it is obviously less costly to you if they do. It all depends

on the quantities and volume you require and your consumption rate. With a fast consumption rate, you would need the space to store product pending use. The just-in-time system avoids this by allowing shipment directly to the production line.

Providing planning information (4.6.2.3)

The standard requires the supplier to *provide appropriate planning information and purchase commitments to enable subcontractors to meet 100% on-time delivery.*

In order that your subcontractors can achieve 100% on-time delivery, you need to provide the same type of information and make the same commitments as your customer will to enable you to meet 100% on-time delivery to them (see Part 2 Chapter 15). You therefore need to inform your subcontractors of your production schedule and release orders to your subcontractors based on that schedule. If operating under a ship-to-stock system, you will need a means of notifying your subcontractor when stocks drop to the minimum level. Under such arrangements, you do not need a purchase order for every delivery as one order specifying the shipment rate will suffice. A good maxim to work by is:

■ **Don't do unto your suppliers that which you would not wish your customers to do unto you.**

Monitoring delivery performance (4.6.2.3)

The standard requires the supplier to *implement a system to monitor the delivery performance of subcontractors with corrective actions taken as appropriate, including tracking incidents of premium freight.*

Delivery advice notes will be needed to match shipments to inventory and to trace problems should the need arise. A shipment notification system similar to that which you need to have with your customer will also be necessary in order to alert you to any shipment difficulties. A simple database to record planned deliveries against actual deliveries and incidents of premium freight usage may suffice. However, you will need to take account of changes in planned deliveries and therefore you will need to link the notification system with the recording system so that the two are compatible at all times.

Before accepting the subcontractor's quotation you need to establish what provisions have been made for shipping product and it is at that stage that the freight arrangements should be agreed. If you neglect to specify any freight provisions and later discover the freight costs excessive, you may find you have agreed unwittingly to the subcontractor compensating for delays by speedier and more costly transportation. This does need to be monitored.

Purchasing data (4.6.3)

The standard requires that *purchasing documents contain data clearly describing the product ordered.*

If you have managed for years without having to document your purchasing requirements, this clause in the standard will change all that. You need to document purchasing requirements so that you have a record of what you ordered. This can then be used when the goods and the invoice arrive to confirm that you have received what you ordered. The absence of such a record may prevent you from legitimately returning unwanted or unsatisfactory goods. As stated previously, this requirement applies to all purchases that affect the quality of the products and services you provide to your customers but there is no requirement for you to submit your purchasing documents to your vendors. In fact many purchases will be made from catalogs by telephone, quoting reference numbers and quantity required. Providing you have a record and can compare this with the goods received and the invoice, you have met the requirement (see later in this chapter under *Review and approval of purchasing documents*).

Product identification

The standard requires purchasing documents to *include, where applicable, the type, class, style, grade, or other precise identification.*

The product or service identification should be sufficiently precise as to avoid confusion with other similar products or services. The vendor may produce several versions of the same product and denote the difference by suffixes to the main part number. To ensure you receive the product you require you need to consult carefully the literature provided and specify the product in the same manner as specified in the literature.

Purchasing specifications

The standard requires purchasing documents to *include, where applicable, the title or other positive identification, and applicable issue of specification, drawings, process requirements, inspection instructions, and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment, and personnel.*

If you are procuring the services of a subcontractor to design and/or manufacture a product or service, you will need specifications which detail all the features and characteristics that the product or service is to exhibit. The reference number and issue status of the specifications need to be specified in the event that they change after placement of the purchase order. This is also a safeguard against the repetition of problems with

previous supplies. These specifications should also specify the means by which the requirements are to be verified so that you have confidence in any certificates of conformance that are supplied. For characteristics that are achieved using special processes (see Part 2 Chapter 9) you need to ensure that the subcontractor employs qualified personnel and equipment. Products required for particular applications need to be qualified for such applications and so your purchasing documents will need to specify what qualification tests are required.

Subcontract quality system requirements

The standard requires purchasing documents to *include, where applicable, the title, number, and issue of the quality system standard to be applied to the product.*

The inclusion of this requirement in purchasing documents requires the subcontractor/supplier to apply a quality system that meets a particular standard to the design, manufacture, etc. of the product as a means of proving an assurance of compliance with your requirements. This requirement can be invoked in your purchasing documents whether or not your subcontractor/supplier is registered to a quality system standard, but doing so may cause difficulties. If the firm is not registered it may not accept the requirement or may well ignore it, in which case you will need to compensate by invoking surveillance and audit requirements in the subcontract. If your purchasing documents do not reference the appropriate ISO 9000 standard or its equivalent and you have taken alternative measures to assure the quality of the supplies, you are compliant with the requirements of this clause. There is little point in imposing ISO 9000 on non-registered suppliers when ordering from a catalog. It only makes sense when the supplier is prepared to make special arrangements for your particular order – arrangements which may well cost you more for no added value.

Review and approval of purchasing documents

The standard requires the supplier to *review and approve purchasing documents for adequacy of specified requirements prior to release.*

Prior to orders being placed the purchasing documents should be checked to verify that they are fit for their purpose. Again this requirement is appropriate to subcontracts but only if you submit your purchasing documents to your vendors. The extent to which you carry out this activity should be on the basis of risk and if you choose not to review and approve all purchasing documents, your procedures should provide the rationale for your decision. The standard does not require that the review and approval be documented. In some cases orders are produced using a computer and transmitted to the vendor directly without any evidence that the order has been reviewed or approved. The purchase order does not have to be the only purchasing document. If you enter pur-

chasing data onto a database, a simple code used on a purchase order can provide traceability to the approved purchasing documents.

You can control the adequacy of the purchasing data in four ways:

- Provide the criteria for staff to operate under self control.
- Check everything they do.
- Select those orders which need to be checked on a sample basis.
- Classify orders depending on risk and only review and approve those which present a certain risk.

A situation where staff operate under self control is for telephone orders where there is little documentary evidence that a transaction has taken place. There may be an entry on a computer database showing that an order has been placed with a particular supplier. So how would you verify compliance with the requirements of this clause in such circumstances?

- Provide buyers with read-only access to approved purchasing data in the database.
- Provide buyers with read-only access to a list of approved suppliers in the database.
- Provide a computer file containing details of purchasing transactions with read and write access.
- Provide a procedure that defines the activities, responsibilities, and authority of all staff involved in the process.
- Train the buyers in the use of the database.
- Route purchase requisitions only to trained buyers for processing.

This method is suitable for processing routine orders; however, where there are non-standard conditions a more variable process needs to be developed. Providing you define the approach you intend to take in your procedures, you should be able to demonstrate that your methods provide an adequate degree of control.

Supplier verification at subcontractor's premises (4.6.4.1)

The standard requires the supplier to *specify verification arrangements and the method of product release in the purchasing documents where it is proposed that purchased product is verified at the subcontractor's premises.*

It is important that you inform the subcontractor through the contract of how the product or service will be accepted. Will it be as a result of receipt inspection at the specified destination or as a result of acceptance tests witnessed on site by your authorized representative? These details need to be specified at the tendering stage so that the subcontractor can make provision in the quotation to support any of your activities on site. If you have invoked ISO 9001 in the subcontract, you are protected by clause 4.6.4.2. If you have not, you need to specify a similar provision in your subcontract, otherwise you may lose the right to reject the product later. There is no requirement for you to document your proposal to verify product at the subcontractor's premises but such a plan would indeed be a useful section in any quality plan that you produced. (See also *Control of subcontractors* in this chapter.)

Customer verification of subcontracted product (4.6.4.2)

The standard requires that *where specified in the contract the supplier's customer or his/her representative shall be afforded the right to verify at the subcontractor premises and the supplier's premises that subcontracted product conforms to specified requirements.*

The requirements pertain to your customer verifying product purchased by you either at your supplier or on your premises. Verification of purchased product is normally carried out by the supplier before or after receipt as part of the purchasing process but may also be carried out by the customer. However, due to the standard locating most of the inspection and test requirements in clause 4.10, the receipt inspection requirements are displaced.

In cases where your customer requires access to your subcontractors to verify the quality of supplies, you will need to transmit this requirement to your subcontractor in the subcontract and obtain agreement. Where a firm's business is wholly that of contracting to customer requirements, a clause giving their customers certain rights will be written into their standard purchasing conditions. If this is an unusual occurrence, you need to identify the need early in the contract and ensure it is passed on to those responsible for preparing subcontracts. You may also wish to impose on your customer a requirement that you are given advanced notice of any such visits so that you may arrange an escort. Unless you know your customer very well it is unwise to allow unaccompanied visits to your suppliers. You may for instance have changed, for good reasons, the requirements that were imposed on you as the main contractor when you prepared the subcontract and in ignorance your customer could inadvertently state that these altered requirements are unnecessary.

When customers visit your subcontractors or inspect product on receipt, they have the right to reserve judgement on the final acceptance of the product. The product is not under their direct control and they may not be able to carry out all the tests and inspec-

tions that are required to gain sufficient confidence. Customer visits are to gain confidence and not to accept product. The same rules apply to you when you visit your subcontractors. The final decision is the one made on receipt or some time later when the product is integrated with your equipment and you can test it thoroughly in its operating environment or equivalent conditions. This is substantiated by the final clause in this section of the standard which states that *when the purchaser or his/her representative elects to carry out verification at the subcontractor's plant, such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.*

Task list

- 1 Identify the broad categories of products and services which you procure.
- 2 Classify products and services into groups according to their potential effect on end product quality.
- 3 Prepare procedures for purchasing those products and services, the quality of which affects end product quality.
- 4 Provide forms for staff to request the procurement of goods.
- 5 Prepare procedures and standards that govern the specification of items to be purchased.
- 6 Compile a list of preferred suppliers and subcontractors that you regularly use.
- 7 Prepare procedures for assessing your subcontractors and suppliers.
- 8 Decide on the criteria for selecting subcontractors and suppliers.
- 9 Provide for assessment of subcontractors to be carried out before award of contract.
- 10 Provide standard conditions for subcontracts.
- 11 Provide a means for adjusting the standard conditions according to the nature of the work subcontracted.
- 12 Prepare procedures for producing and maintaining subcontract requirements and letting tenders.
- 13 Prepare procedures for evaluating tenders and selecting subcontractors.
- 14 Provide those responsible for the preparation of subcontracts requirements to approve them prior to issue to the subcontractor.
- 15 Provide resources for the control of subcontractors.
- 16 Prepare procedures covering the planning of subcontractor control activities.

- 17 Provide a means for purchasing staff to gain access to current technical data to pass on to suppliers and subcontractors.
- 18 Provide a means of adding and removing subcontractors and suppliers from the list of preferred suppliers and subcontractors.
- 19 Provide a means for changing subcontract requirements during the contract.
- 20 Provide a means for monitoring the subcontractor's progress in meeting the requirements.

Purchasing questionnaire

- 1 How do you ensure that purchased product conforms to specified requirements?
- 2 How do you evaluate and select your subcontractors and suppliers?
- 3 How do you ensure customer approval for use of non-designated subcontractors?
- 4 How do you establish the capability of your subcontractors and suppliers?
- 5 How do you determine the control to be exercised over your subcontractors/suppliers?
- 6 Where are your subcontractor controls defined?
- 7 In what documents do you record those subcontractors/suppliers that are acceptable?
- 8 How do you ensure that purchasing documents clearly describe the product ordered?
- 9 How do you ensure that purchasing documents are reviewed and approved for adequacy of specified requirements prior to release?
- 10 How are your subcontractor verification requirements and methods of product release conveyed to subcontractors?
- 11 How do you enable customers to verify purchased product at source or upon receipt?
- 12 How do you ensure that your subcontractors comply with current regulatory requirements?
- 13 How do you ensure your subcontractors achieve 100% on-time delivery?
- 14 How do you track incidents of premium freight use by your subcontractors?
- 15 To what extent do you steer the development of your subcontractors' quality systems towards ISO/TS 16949 compliance?

Do's and don'ts

- ☺ Do ensure that the requirements placed on subcontractors are compatible with those of the main contract.
- ☺ Do afford the same rights to your subcontractor on contract review as you wish afforded to you by your purchaser.
- ☺ Do provide a means of apportioning the requirements of the main contract to the subcontract.
- ☺ Do perform pre-award surveys of potential subcontractors.
- ☺ Do keep records of both supplier and subcontractor performance whether it be good or bad.
- ☺ Do maintain only one list of assessed suppliers and subcontractors.
- ⊗ Don't constrain yourself to purchase only from approved suppliers unless your customer demands otherwise – compensate for poor performers through subcontractor/supplier controls.
- ☺ Do ensure that purchasing staff and technical staff operate to the same standards and procedures.
- ☺ Do obtain proposals as to how the subcontractor proposes to control the quality of the product or service before acceptance of tender.
- ⊗ Don't change the documents in the tender until after you are in a position to negotiate with the winner.
- ☺ Do obtain documentation of the subcontractor's processes so as to aid problem investigations in-house.
- ⊗ Don't permit subcontractors to subcontract the work further without your approval and assessment of the proposed subcontractors.
- ☺ Do maintain a record of any articles you furnish to your subcontractors.
- ☺ Do establish a means of promptly responding to subcontractor queries and problem reports.
- ☺ Do provide feedback to subcontractors and suppliers of their performance.
- ☺ Do maintain records of all meetings and visits with suppliers and subcontractors.
- ⊗ Don't treat your subcontractors as though they are adversaries; treat them in the way you believe they would wish to be treated.
- ☺ Do attempt to establish "partnerships" with your suppliers so that there are mutual benefits from sharing common objectives.

Chapter 7

Customer supplied product

Scope of requirements

In many cases these requirements will not apply but in some contractual situations the customer may provide products or services for use by the supplier in connection with the contract. This clause of the standard specifies requirements that apply in such situations. The product being supplied may have been produced by a competitor, by the customer, or even by your own firm under a different contract. These requirements apply to any product supplied to you by your customer and not only to what is to be incorporated into supplies. The customer may in fact supply facilities, equipment, software, or documentation for use in conjunction with the contract, which may be provided on loan, to be returned on completion of the contract or to be retained. Customer-owned tooling and returnable packaging also constitutes customer supplied product. If you use the customer's facilities, such use should be governed by the regulations imposed in the contract rather than these requirements. If the customer supplies documentation, unless it is required to be returned, you should assume it is yours to keep. Such documentation is not governed by these requirements although, if the customer requires the documents to be returned, you should assume that these requirements do apply, but apply them with discretion.

The requirements in element 4.7 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 7.1.

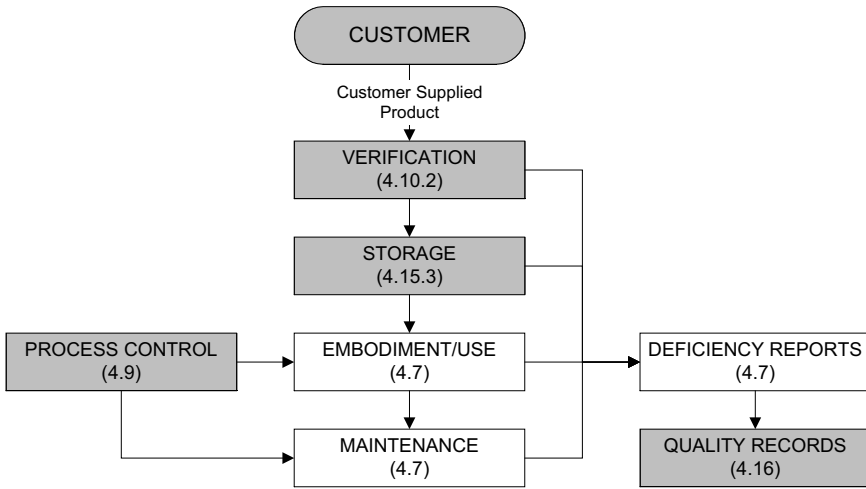


Figure 7.1 Clause relationships with customer supplied product element

Verification of customer supplied product (4.7.1)

The standard requires the supplier to *establish and maintain procedures for verification of customer supplied product provided for incorporation into the supplies or for related activities.*

When product is received from a customer it should be processed in the same way as purchased product so that it is registered and subject to receipt inspection. The inspection you carry out may be limited if you do not possess the necessary equipment or specification, but you should reach an agreement with the customer as to the extent of any receipt inspection before the product arrives. If the product does not bear an identity from which you can readily determine that it is the purchaser's property, you should apply a label and properly identify the item (a provision addressed by clause 4.7.2). Any inspections and tests you carry out should be recorded for two reasons: firstly, to establish the condition of the item on receipt in the event that it is damaged, defective, or incomplete and secondly, to verify that it is fit for the intended purpose before use. If you fail to inspect the product on receipt you may find difficulty in convincing your customer later that the damage was not your fault. You also need to match any delivery note with the product, because the customer may have inadvertently sent you the wrong product. Unless you know what you are doing it is unwise to energize the product without proper instructions from the customer.

Storage of customer supplied product (4.7.1)

The standard requires the supplier to *establish and maintain procedures for storage of customer supplied product provided for incorporation into the supplies or for related activities.*

Customer supplied product, if possible, should be segregated from other products to avoid mixing, inadvertent use, damage, or loss. Depending on the size and quantity of the items and the frequency with which your customer supplies such products you may require a special storage area. The storage areas should be governed by procedures which satisfy clause 4.15.3 of the standard and you may in fact be able to use the same procedures. Wherever the items are stored you should maintain a register of such items, preferably separate from the storage area in, for example, inventory control or the project office. The authorization for releasing product from storage areas may need to be different for inventory control reasons. You also need to ensure that such products are insured. You will not need a corresponding purchase order and hence they may not be registered as stock or capital assets. If you receive customer supplied product very infrequently, you will need a simple system that is only activated when necessary rather than being built into your normal system. Under such circumstances it is easy to lose these products and forget they are someone else's property. You need to alert staff to take extra care especially if they are high value items that cannot readily be replaced.

Maintenance of customer supplied product (4.7.1)

The standard requires the supplier to *establish and maintain procedures for maintenance of customer supplied product provided for incorporation into the supplies or for related activities.*

Customer supplied products that are issued for incorporation into supplies don't often require maintenance; however, items for use in conjunction with the contract may be retained for such a duration that maintenance is necessary. If the products require any maintenance you should be provided with a maintenance specification and the appropriate equipment to do the job. Maintenance may include both preventive and corrective maintenance but you should clarify with your customer which it is. You may have the means for preventive maintenance, such as lubrication and calibration, but not for repairs. Always establish your obligations in the contract regarding customer supplied product, because you could take on commitments for which you are not contractually covered if something should go wrong. You need to establish who will supply the spares and re-certify the equipment following repair.

Reporting problems to the customer (4.7.1)

The standard requires that *any such product that is lost, damaged, or is otherwise unsuitable for use be recorded and reported to the customer* and again advises the supplier that *verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.*

The customer is responsible for the product they supply wherever it came from in the first place. It is therefore very important that you establish the condition of the product before you store it or use it. In the event that you detect that the product is damaged, defective, or incomplete, you should place it in a quarantine area and report the condition to the customer. Even if the product is needed urgently and can still be used, you should obtain the agreement of your customer before using inferior product, otherwise you may be held liable for the consequences.

You could use your own reject note or nonconformity report format to notify the customer of a defective product but these are not appropriate if the product is lost. You also need a customer response to the problem and so a form that combines both a statement of the problem and of the solution would be more appropriate.

You should maintain a register of customer supplied product containing the following details:

- Name of product, part numbers, serial numbers, and other identifying features
- Name of customer and source of product if different
- Delivery note reference, date of delivery
- Receipt inspection requirements
- Condition on receipt including reference to any rejection note
- Storage conditions and place of storage
- Maintenance specification if maintenance is required
- Current location and name of custodian
- Date of return to customer or embodiment into supplies
- Part number and serial number of product embodying the customer supplied product
- Dispatch note reference of assembly containing the product

These details will help you keep track of the customer supplied product whether on embodiment loan or contract loan and will be useful during customer audits or in the event of a problem with the item either before or after dispatch of the associated assembly.

Marking customer-owned tooling (4.7.2)

The standard requires *customer-owned tools and equipment to be permanently marked so that ownership of each item is visually apparent.*

This requirement was addressed above but note that the marking has to be permanent and therefore has to be durable under the anticipated conditions of use. It would be wise to seek guidance from the customer if you are in any doubt as to where to place the marking or how to apply it. Metal identification plates stamped with the customer's identity, date of supply, contract, and limitations of use are durable and permanent.

Task list

- 1 Provide a register of all products supplied by customers and keep it under central control.
- 2 Make provision for customer supplied product to be processed through receipt inspection.
- 3 Prepare procedures for inspecting customer supplied product and notifying the customer of any problems.
- 4 Provide separate storage areas for customer supplied product.
- 5 Provide procedures for the receipt and removal of product from storage areas.
- 6 Make provision in your contract procedures for requiring customers to supply handling, operating, and maintenance instructions as necessary for any product they supply.
- 7 Provide a form for conveying to the customer the results of any defects detected during receipt inspection, maintenance, or operational use.
- 8 Provide a mechanism for gathering change of use and location of customer supplied product.
- 9 Apply permanent markings to all customer-owned tooling and equipment.

Customer supplied product questionnaire

- 1 How do you verify customer supplied product?
- 2 How do you store customer supplied product?
- 3 How do you maintain customer supplied product?
- 4 How do you ensure that any lost or unsuitable customer supplied product is recorded and reported to the customer?

Do's and don'ts

- ⊗ Don't lose track of customer supplied product.
- ☺ Do make sure that users are aware that customer supplied product is not company property.
- ☺ Do give customer supplied product an identity that denotes its source.
- ☺ Do establish the condition of customer supplied product before use.
- ☺ Do report back to the customer any performance variation of customer supplied product following its embodiment in your product.

Chapter 8

Product identification and traceability

Scope of requirements

The requirements for product identification are intended to enable products and services with one set of characteristics to be distinguishable from products or services with another set of characteristics. Product identity is vital in many situations to prevent inadvertent mixing, to enable reordering, to match products with documents that describe them, and to do that basic of all human activities – to communicate. Without codes, numbers, labels, names, and other forms of identification we cannot adequately describe the product or service to anyone else. We use terms such as “thingummybob”, “widget”, “you know what I mean, it’s a ...” The use of names, labels, etc. convey meaning precisely. Traceability on the other hand is a notion of being able to trace something through a process to a point along its course either forwards through the process or backwards through the process. One needs traceability to find the root cause of problems. If records cannot be found which detail what happened to a product, nothing can be done to prevent its recurrence. Traceability is key to corrective action and, although the standard only requires traceability when required by contract, assessors will seek an audit trail to determine compliance with the standard. This trail can only be laid by using the principles of traceability.

The requirements in element 4.8 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 8.1.

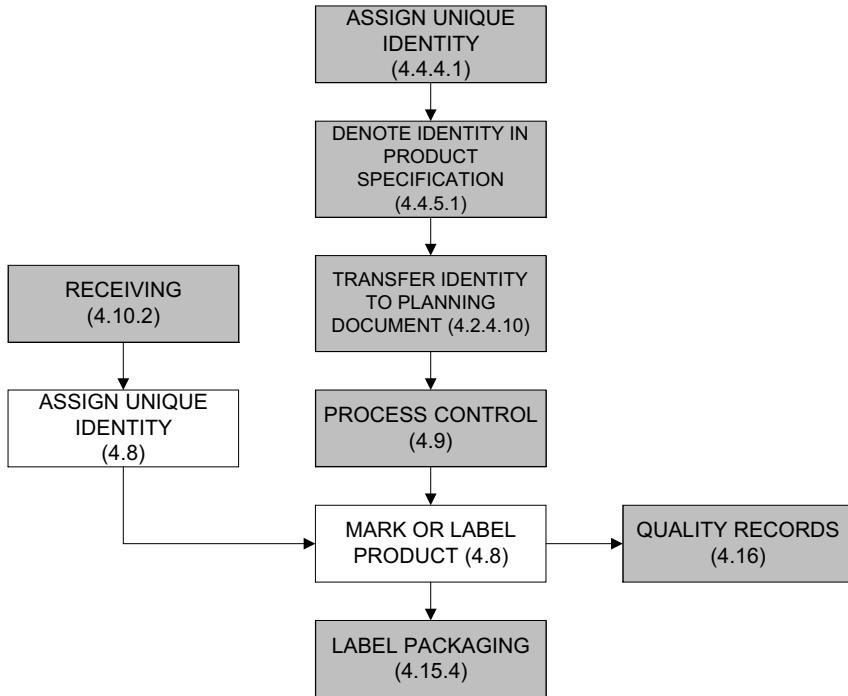


Figure 8.1 *Clause relationships with product identification and traceability element*

Procedures for identifying product

The standard requires the supplier to *establish and maintain documented procedures where appropriate for identifying the product by suitable means from receipt and during all stages of production, delivery, and installation.*

Note that in ISO/TS 16949 documented procedures are needed where the product identity is not inherently obvious – the “where appropriate” condition has been removed. If products are so dissimilar that inadvertent mixing would be unlikely to occur, a means of identifying the products is probably unnecessary. “Inherently obvious” in this context means that the physical differences are large enough to be visible to the untrained eye. Therefore functional differences, no matter how significant – as well as slight differences in physical characteristics, such as color, size, weight, appearance – would constitute an appropriate situation for documented identification procedures.

Procedures for identifying product should start at the design stage when the product is conceived. The design should be given a unique identity, a name, or a number, and that should be used on all related documents. When the product emerges into production,

the product should carry the same number or name but in addition it should carry a serial number or other identification to enable product features to be recorded against specific products. If verification is on a “go no-go” basis, product does not need to be serialized. If measurements are recorded, some means has to be found of identifying the measurements with the product measured. Serial numbers, batch numbers, and date codes are suitable means for achieving this. This identity should be carried on all quality records related to the product.

Apart from the name or number given to a product you need to identify the version and the modification state so that you can relate the issues of the drawing and specifications to the product they represent. Products should either carry a label or markings with this type of information in an accessible position or bear a unique code number that is traceable to such information.

You may not possess any documents that describe the purchased product. The only identity may be marked on the product itself or its container. Where there are no markings, information from the supplier’s invoice or other such documents should be transferred to a label and attached to the product or the container. Documents need to be traceable to the products they represent.

Traceability

The standard requires that where, and to the extent that traceability is a specified requirement, the supplier is to establish and maintain documented procedures for unique identification of individual product or batches and goes on to require this identification to be recorded.

As stated previously, traceability is fundamental to establishing and eliminating the root cause of nonconforming product and therefore it should be mandatory in view of the requirements for Corrective Action. Providing traceability can be an onerous task. Some applications require products to be traced back to the original ingot from which they were produced. In situations of safety or national security it is necessary to identify product in such a manner because if a product is used in a critical application and subsequently found defective, it may be necessary to track down all other products of the same batch and eliminate them before there is a disaster. It happens in product recall situations. It is also very important in the automobile and food industries: in fact, any industry where human life may be at risk due to a defective product being in circulation.

Traceability is also important to control processes. You may need to know which products have been through which processes and on what date, if a problem is found some time later. The same is true of test and measuring equipment. If on being calibrated a

piece of test equipment is found to be out of calibration, it is important to track down all the equipment that has been validated using that piece of measuring equipment. This in fact is a requirement of ISO 9001 clause 4.11 but no requirement for traceability is specified.

Traceability is achieved by coding items and their records such that you can trace an item back to the records at any time in its life. The chain can be easily lost if an item goes outside your control. If, for example, you provide an item on loan to a development organization and it is returned some time later, without a certified record of what was done to it, you have no confidence that the item is in fact the same one, unless it has some distinguishing features; the inspection history is now invalidated because the operations conducted on the item were not certified. Traceability is only helpful when the chain remains unbroken. It can also be costly to maintain. The system of traceability that you maintain should be carefully thought out so that it is economic. There is little point in maintaining an elaborate traceability system for the once in a lifetime event when you need it, unless your very survival, or society's survival, depends upon it.

It may not be practical to document separate procedures to meet this requirement. The conventions you use to identify product and batches need to be specified in the product specifications and the stage at which product is marked specified in the relevant procedures or plans. Often such markings are automatically applied during processing, as is the case with printed circuits, moldings, ceramics, castings, etc. Process setting up procedures should specify how the marking equipment or tools are to be set up.

Task list

- 1 Establish an identification system for products and services.
- 2 Provide registers or other devices for allocating identification numbers to documents that describe products or services.
- 3 Prepare standards or process specifications for applying identification details to products and services.
- 4 Decide on which types of product will be given serial numbers.
- 5 Provide registers for allocating serial numbers to individual products.
- 6 Make provision on all product records for the product identification to be recorded.
- 7 Decide on the convention for denoting modification status.
- 8 Provide specifications for producing and fixing modification plates to product.
- 9 Make provision in product and process records to capture source details of component parts and materials.
- 10 Make provision in inspection and test records to capture details of inspection, test, and measuring equipment used.
- 11 Provide registers for allocating batch numbers, date codes, and other identification data when appropriate.
- 12 Make provision on tags, labels, etc. for recording product identification details.
- 13 Provide data storage systems which enable rapid retrieval of records by product identification.
- 14 Provide for remnant material to retain its identity.
- 15 Decide who will allocate serial numbers, batch numbers, etc.
- 16 Provide for separated lots or batches to be identified to the original lot or batch.
- 17 Decide on the minimum level of traceability which is to be maintained for your products.

Product identification and traceability questionnaire

- 1 How do you enable products to be identified from receipt and during all stages of production, delivery, and installation?
- 2 How do you ensure traceability of product to original material identification, quality status, and the unit responsible for both its supply and verification?
- 3 How do you identify and record individual product and batches?

Do's and don'ts

- ☺ Do centralize the identification system so as to prevent duplication of codes.
- ☺ Do specify the product identification details in the product specification and denote where and with what materials identification is to be applied.
- ⊗ Don't claim a higher level of traceability than is necessary for the type of business.
- ☺ Do make it a routine that identification data is checked at each inspection and test stage.
- ⊗ Don't use product that has lost its identity.
- ⊗ Don't mix product as a safeguard against loss of identity.
- ☺ Do place identification labels where the product user can see them.
- ☺ Do provide a means of tracing the results of verification activities to the characteristics specified in the product specification.

Chapter 9

Process control

Scope of requirements

The process referred to in this section of the standard is the result-producing process, the process of implementing or replicating the design. It is the process which is cycled repeatedly to generate product or to deliver service. It differs from the design process in that it is arranged to reproduce product or service to the same standard each and every time. The design process is a journey into the unknown, whereas the production process is a journey along a proven path with a predictable outcome. The design process requires control to keep it on course towards an objective, the production process requires control to maintain a prescribed standard – the standard that has been approved in the product approval process (see clause 4.2.4.11). Hence, these requirements apply to operations that follow product approval.

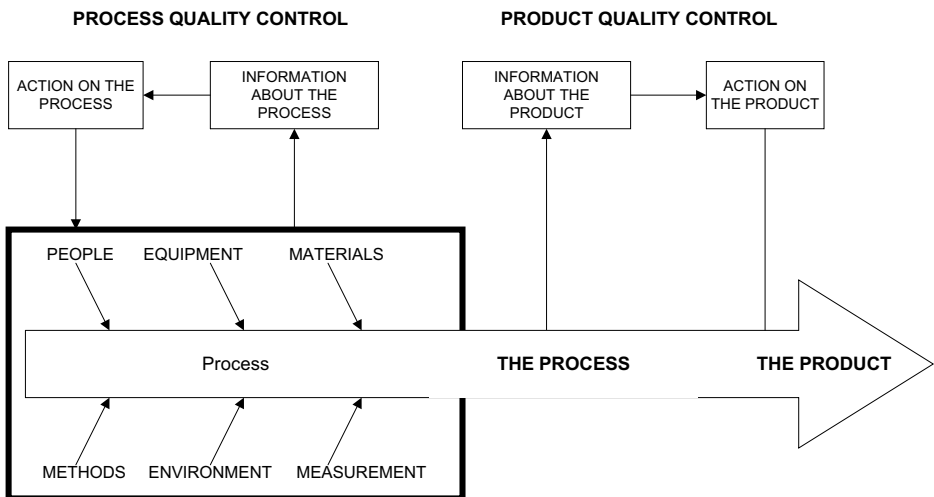


Figure 9.1 Process control model

There are two ways in which product quality can be controlled: by controlling the product which emerges from the producing processes or by controlling the processes through which the product passes. Process control relies upon control of the elements that drive the process, whereas product control relies upon verification of the product as it emerges from the process. In practice it is a combination of these which yields products of consistent quality. Figure 9.1 serves to illustrate this concept. If you concentrate on the process output to the exclusion of all else, you will find there is a high level of rework of

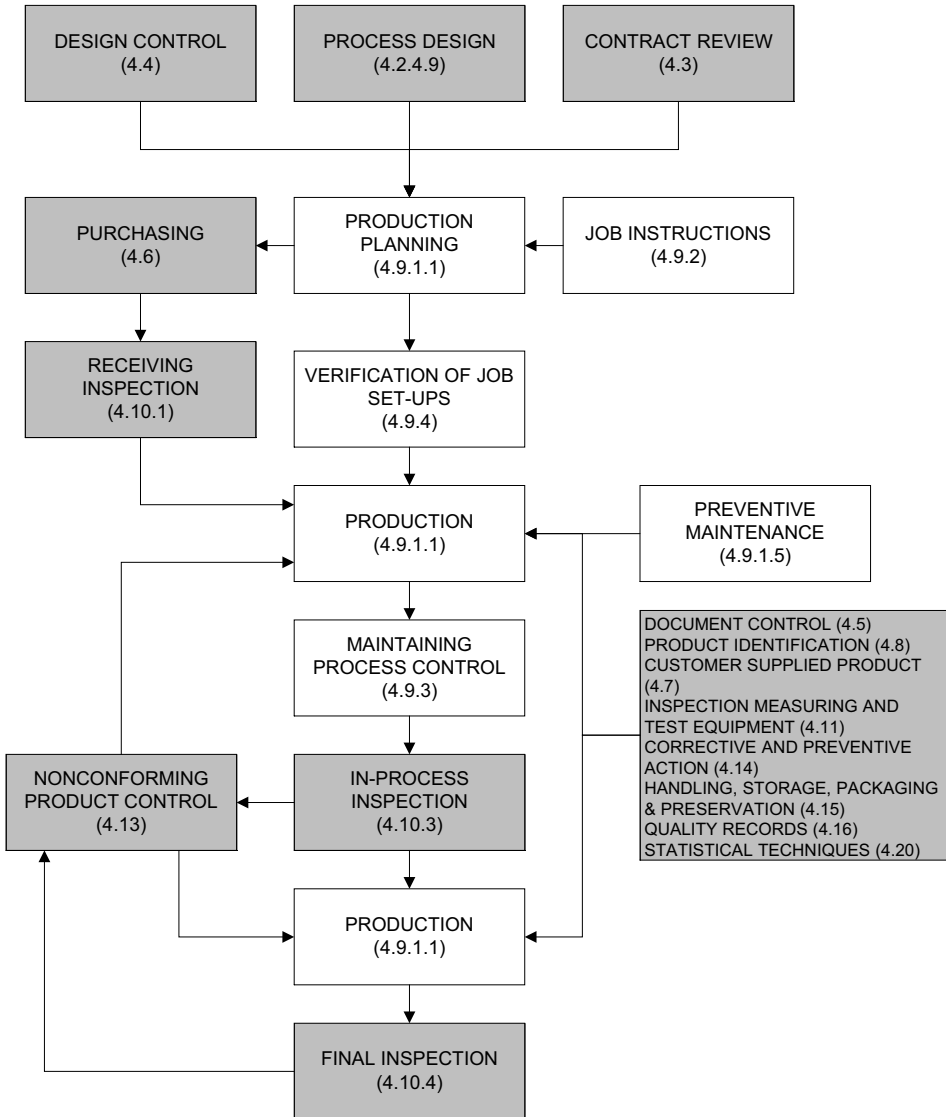


Figure 9.2 *Clause relationships with the process control element*

the end product. If you concentrate on the process using the results of the product verification, you will gradually reduce rework until all output product is of consistent quality. It will therefore be possible to reduce dependence on product inspection and test.

The requirements in element 4.9 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 9.2.

Planning production, installation, and servicing processes (4.9.1.1)

The standard requires that the supplier *identifies and plans the production, installation, and servicing processes which directly affect quality.*

The planning of production, installation, and servicing processes requires three levels:

- Identifying which processes are required to produce, install, and service the product
- Designing, commissioning, and qualifying these processes for operational use
- Routing the product through the appropriate qualified processes

In order to identify the production processes required to produce a particular product you need a production requirement in the form of product specifications which define the features and characteristics of the product that are to be achieved. By studying these specifications you will be able to identify the processes required to turn raw materials and bought-out components into a finished product. With manufactured products the processes may include machining, welding, fabrication, assembly, forming, plating, painting, heat treatment, etc.

The next stage is to design the processes that have been identified. In many cases, existing processes may well satisfy the need but process approval may be required if the tolerance on product characteristics is much less than the currently demonstrated process capability. Process design is a subject outside the scope of ISO 9001 but is covered by clause 4.2.4.9 of ISO/TS 16949 and hence addressed in Part 2 Chapter 2.

The plans that route an item through the various processes from raw material to finished product are often called *route cards*. You may need separate plans for each process and each part, with an overall plan that ensures the product goes through the right processes in the right sequence. The number of plans is usually determined by the manner in which the specifications are drawn up. You may have drawings for each part to be made or one drawing covering several parts.

For installation operations you will need an installation requirement and an installation plan. Similarly for any other process which represents the core for your business, you will need a requirement and a plan to achieve the requirement. The plan should detail the processes you need to implement in order to achieve the requirement.

Unless products, processes, and facilities are developed in parallel, the product will be unlikely to reach the market when required. This requires product and process development to proceed simultaneously with facility development and hence the term “simultaneous engineering” or “concurrent engineering” has emerged to optimize the relationship between design and manufacturing functions. It is not a case of designing only those products for which facilities exist, but designing those products that will give you a competitive edge and laying down facilities that will enable you to fulfill that promise.

Ensuring that work is carried out under controlled conditions (4.9.1.1)

The standard requires that the supplier *ensures that the production, installation, and servicing processes are carried out under controlled conditions.*

To ensure that the processes are carried out under controlled conditions the production plans need to:

- Identify the product in terms of the specification reference and its issue status.
- Define the quantity required.
- Define which section is to perform the work.
- Define each stage of manufacture and assembly.
- Provide for progress through the various processes to be recorded so that you know what stage the product has reached at any one time.
- Define the special tools, processing equipment, jigs, fixtures, and other equipment required to produce the product. (General-purpose tools and equipment need not be specified because your staff should be trained to select the right tool for the job.)
- Define the methods to be used to produce the product either directly or by reference to separate instructions.

- Define the environment to be maintained during production of the product in anything other than ambient conditions.
- Define the process specifications and workmanship standards to be achieved.
- Define the stages at which inspections and tests are to be performed.
- Define any special handling, packaging, and marking requirements to be met.
- Define any precautions to be observed to protect health and safety.

These plans create a basis for ensuring that work is carried out under controlled conditions, but the staff, equipment, materials, processes, and documentation must be up to the task before work commences. A model production process is illustrated in Figure 9.3. The shaded boxes indicate interfaces external to the production process. The variables are too numerous to illustrate the intermediate steps.

Installation plans need to cover similar material but in addition may include:

- Site surveys
- Site preparation
- Transport and delivery of materials and equipment
- Inspection of equipment entering the site
- Storage of equipment awaiting installation
- Storage of spares and consumables
- Installation of equipment
- Commissioning tests
- Acceptance tests
- On-site maintenance before hand-over
- Hand-over to customer
- Return of surplus and defective goods

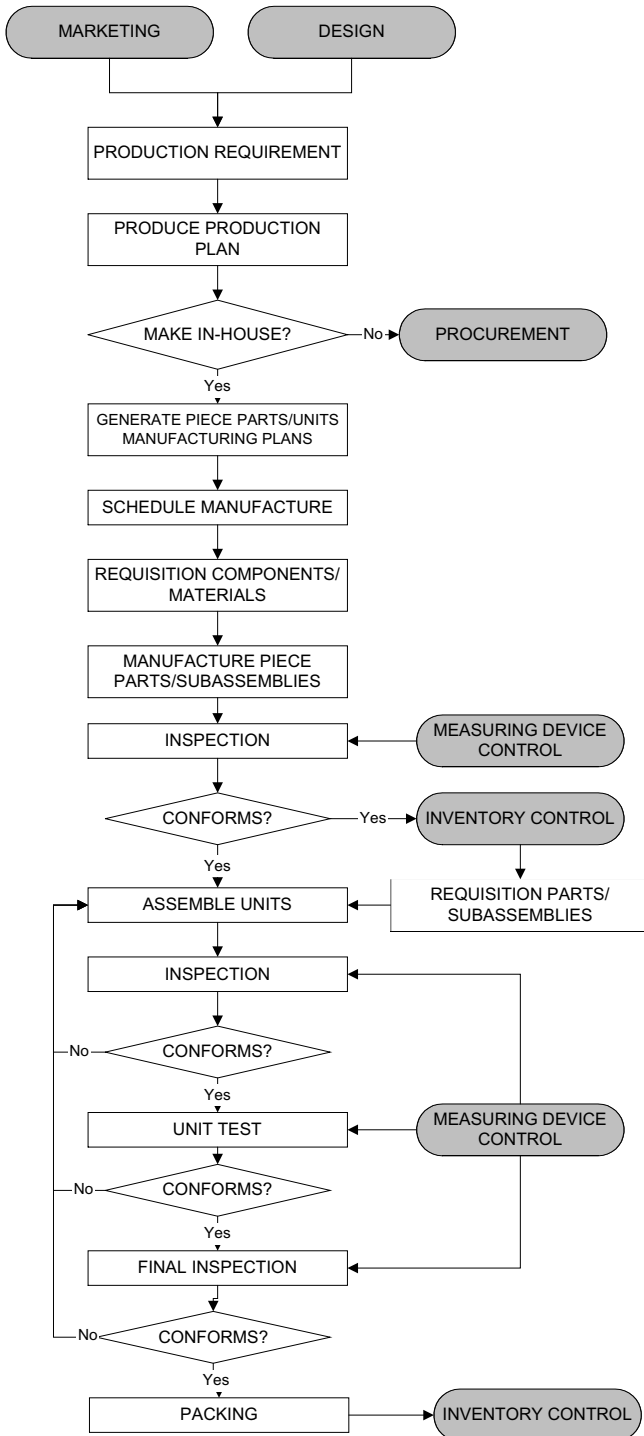


Figure 9.3 Model production process

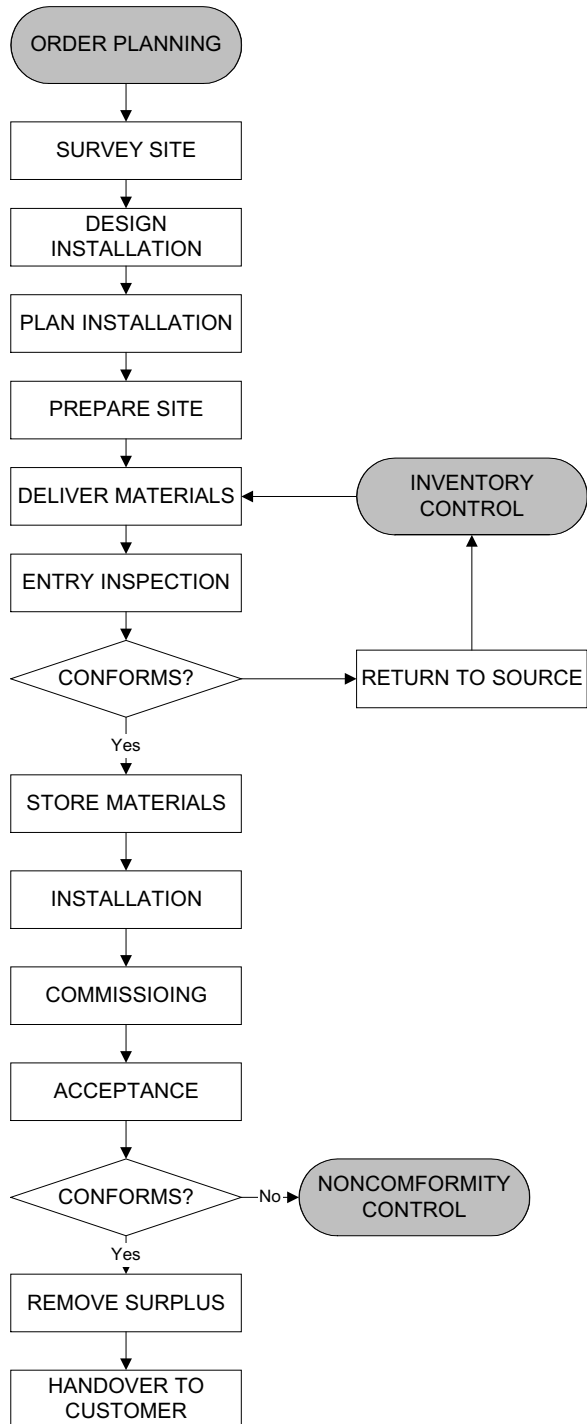


Figure 9.4 Model installation process

A model installation process is illustrated in Figure 9.4 above.

For servicing the plans need to define as appropriate:

- The item to be serviced
- The service to be performed
- The responsibility for performing the work including the inspections and tests
- The activities to be carried out
- The process specifications and workmanship standards to be achieved
- The procedures for disposing of any waste or defective product
- The tools, equipment, and other aids to carry out the service and any inspections and tests
- The manuals and other literature which specify how the tasks need to be performed
- The consumable materials and spares required
- The environment to be maintained if anything other than ambient
- The handling and cleanliness requirements
- The precautions to be observed to protect health and safety
- The checks, inspections, tests, and adjustments to be made

A model servicing process is illustrated in Figure 19.2.

Documented procedures and job instructions (4.9.1.1 and 4.9.2)

The standard requires controlled conditions to *include documented procedures defining the manner of production, installation, and servicing where the absence of such instructions would adversely affect quality*. The supplementary requirements also require *job instructions for all employees having responsibilities for the operation of processes and for these job instructions to be accessible for use at the work station without disruption to the job*.

ISO 9001 permits the absence of procedures where quality will not be adversely affected. However, clause 4.9.2 of ISO/TS 16949 requires job instructions regardless of need. This apparent conflict is resolved by adopting the view that *instructions* command work to be done – *procedures* define the *sequence* of steps to execute the work to be done (see also Part 2 Chapter 2 under *What are the differences between procedures and instructions?*)

The production plan referred to previously is a work instruction, as it instructs those to whom it applies to carry out certain tasks. Control procedures may include assembly procedures, plating procedures, painting procedures, maintenance procedures, etc. and differ from process specifications (see later) in that the process specification defines the results to be achieved in operating a process rather than how to run the process. In addition to the list of contents provided in ISO/TS 16949 clause 4.9.2, the documentation should define:

- The qualifications required for the person carrying out the procedure (if any special qualifications are required)
- The preparatory steps to be taken to prepare the product for processing
- The preparatory steps to be taken to set up any equipment
- The steps to be taken to process the product
- The precautions to observe
- The settings to record

There are instructions for specific activities and instructions for specific individuals. Whether they are contractors or employees is not important – the same requirements apply. As each employee may perform different jobs, they may each have a different set of instructions that direct them to specific documents. Therefore it is unnecessary to combine all instructions into one document, although they could all be placed in the same binder for easy access.

Any operation that relies on skills doesn't need a procedure. However, the operator will not be clairvoyant – you may need to provide procedures for straightforward tasks to convey special safety, handling, packaging, and recording requirements. You need to ensure that you don't make your processes so complex that bottlenecks arise when the slightest variation to plan occurs. The setting up of equipment, other than equipment typical of the industry, should be specified to ensure consistent results (see later in this chapter under *Verification of job set-ups*). In fact any operation that requires tasks to be

carried out in a certain sequence to obtain consistent results should be specified in a procedure.

By imposing formal controls you safeguard against informality which may prevent you from operating consistent, reliable, and predictable processes. The operators and their supervisors may know the tricks and tips for getting the equipment or the process to operate smoothly. You should discourage informal instructions as you cannot rely on them being used when those who know them are absent. If the tip or trick is important, encourage those who know them to bring them to the process owner's attention so that permanent changes can be made to make the process run smoothly all the time.

The standard also requires that the instructions be derived from appropriate sources, such as the quality plan, the control plan, and the product realization process, which means that all instructions should be traceable to one or more of these documents. They should form a set, so that there are no instructions used outside those that have been approved by the planning team. This is to ensure that no unauthorized practices are employed. Another important aspect to consider is the use of informal practices – practices known only to the particular operator. Process capability should be based on formal routines, otherwise repeatability cannot be assured when operators change.

Accessibility of job instructions (4.9.2)

The standard also requires job instructions *to be accessible for use at the work station without disruption to the job.*

If you have a manufacturing process that relies on skill and training then instructions at the work station are unnecessary. For example, if fixing a tool in a tool holder on a lathe is a skill, learnt during basic training, you don't need to provide instructions at each work station where normal tool changes take place. However, if the alignment of the tool is critical and requires knowledge of a setting-up procedure, then obviously documented instructions are necessary. Even for basic skills you can still provide standard machinery data books which are accessible near to the work station, but a failure to do so should not be regarded as a noncompliance. There is merit in not providing basic text books to operators since the information is soon outdated and operators relying on such data instead of consulting the authorized data may inadvertently induce variation into the process.

In interpreting this requirement you need to define what constitutes a "work station". Is it a manufacturing cell where operations of the same type are performed or is it an individual machine? Next you need to define the meaning of "accessible". Does it mean visible by the operator of the machine, in a cupboard near the machine, or on a shelf in the area? If a group of people work in an area equipped with several small machines of

the same type, set up to the same specification, then one set of instructions would probably suffice. Instructions for each machine may be necessary in areas where there are several machines of different types and set-up configuration. If the machines are huge and to access each requires a walk of some distance from your work station, instructions may be needed at each machine, regardless of set-up configuration. Use your common sense. Too many copies of the same document creates the chance that one may get missed when revisions occur. Single-page instructions, encapsulated in plastic to prolong their life, can be fixed on or close to the machine as a source of reference.

■ **Procedures are needed where consistency in results is vital.**

Suitable production, installation, and servicing equipment (4.9.1.1b)

The standard requires controlled conditions to *include the use of suitable production, installation, and servicing equipment.*

The production, installation, and servicing equipment should be selected during the planning process. In selecting such equipment you should determine whether it is capable of producing, maintaining, or handling conforming product in a consistent manner. You need to ensure that the equipment is capable of achieving the specified dimensions within the stated tolerances. Process capability studies can reveal deficiencies with equipment which are not immediately apparent from inspection of the first off (see below under *Process capability and process control*).

Suitable working environments (4.9.1.1b)

The standard requires controlled conditions to *include suitable working environment.*

The working environment may need to be controlled, not for the benefit of the staff but to achieve the required characteristics. To achieve high performance from electronic components, particle and chemical contamination has to be minimized during fabrication and assembly. For these and many other reasons, the production environment may need to be controlled. If these conditions apply you should:

- Document the standards that are to be maintained.
- Prohibit unauthorized personnel from entering the areas.

- Provide training for staff who are to work in such areas.
- Provide alarm systems to warn of malfunctions in the environment.
- Provide procedures for maintaining the equipment to these standards.
- Maintain records of the conditions as a means of demonstrating that the standards are being achieved.

ISO 9001 is not specific on what is meant by “working environment”. ISO 9001 only applies to product and factors that affect the product; therefore “working environment” means the environment in which work on product is carried out. If temperature, cleanliness, humidity, electromagnetic, and other environmental factors need to be controlled to ensure conforming product then their control provides a suitable working environment.

An organization needs to provide safeguards for its people in order to comply with clause 4.1.7 on *Impact on Society*.

Compliance with reference documents (4.9.1.1c)

The standard requires controlled conditions to *include compliance with reference standards/codes, quality plans, and/or documented procedures*.

The product specification should provide all necessary processing requirements that need to be implemented when carrying out particular processes; however, some of the requirements may need to be defined in separate process specifications which are invoked by reference. You may need to develop your own process specifications, but there are many national standards that may suit your needs and they come with the added benefit that they have been proven to work. The quality plan or procedures should not contain any further product requirements but may provide the verification methods to be employed, the precautions to be observed and the recording requirements to be met. You need to identify in your production plans each of these documents at the stage at which they should be applied, otherwise there is the possibility that they may be overlooked.

Controlling process and product characteristics (4.9.1.1d)

The standard requires controlled conditions to *include the monitoring and control of suitable process parameters and product characteristics during production, installation, and servicing.*

Controlled conditions include in-process monitoring and in-process inspection and test. All controls need a verification stage and a feedback loop. You cannot control production processes without performing some kind of verification.

The production of some products can be controlled simply by inspection after the product has been produced. In other cases, as with the continuous production of food and drugs, you may need to monitor certain process parameters to be sure of producing conforming product. By observing the variability of certain parameters using control charts, you can determine whether the process is under control within the specified limits.

Process monitoring can be achieved by observing sensors installed in the production process which measure key process parameters or by taking samples at discrete intervals and taking prescribed measurements. In both cases the measurements should be recorded for subsequent analysis and any decision made to allow the process to continue or to stop should also be recorded together with the reasons for the decision. The data to be recorded should be specified in advance on the forms or computer screens provided at the work station. This will give personnel a clear indication of what to record, when, and where to record it. It also simplifies auditing if data is required in all boxes on a form or computer screen. A blank box indicates an unusual occurrence that should be checked. The forms should also indicate the accept/reject limits so that the operator can easily judge when the process is out of control. The standard does not require inspection to be carried out by full-time inspectors. The term *inspector* is not used but it can apply to anyone performing an inspection.

Operators should be trained to both operate the plant and control the process. As added assurance you should take samples periodically and subject them to a thorough examination. The sampling plan should be defined and documented and operators trained to determine what causes the results they observe. Process control comes about by operators knowing what results to achieve, by knowing what results are being achieved, and by being able to correct performance should the results not be as required. They need to understand what is happening during processing to cause any change in the results as they are being monitored. You will need to define in the process specification the parameters to be observed and recorded and the limits within which the process is to be controlled (see also Part 2 Chapter 20).

■ Understand what causes the dots on the chart to vary.

Approval of processes and equipment (4.9.1.1e)

The standard requires controlled conditions to *include the approval of processes and equipment as appropriate.*

The term *approval* can be taken to mean certification or qualification, the difference being that *certification* is performed each time the equipment is repaired and *qualification* only when the equipment is introduced into service. The standard only refers to the term *qualification* in connection with special processes, but this clause does not distinguish between special and ordinary processes and equipment. However, there are two levels of approval that apply to processes and equipment: initial qualification approval and periodic setting-up approval.

All processes and equipment should be proven capable of performing the task for which they were designed and so should either be subject to qualification tests or process capability tests. There may be documentation available from the supplier of the equipment which adequately demonstrates its capability, otherwise you may need to carry out qualification and capability tests to your own satisfaction. In the process industries the plant is specially designed and so needs to be commissioned and qualified by the user. Your procedures need to provide for such activities and for records of the tests to be maintained.

When equipment or plant is taken out of service, either for maintenance or for repair, it should not be re-introduced into service without being subject to formal acceptance tests that are designed to verify that it meets your declared standard operating conditions. Your procedures need to provide for such activities and for records of the tests to be maintained.

Workmanship criteria (4.9.1.1f)

The standard requires controlled conditions to *include criteria for workmanship which is stipulated in the clearest practical manner.*

The output from many processes depends upon the skill of the producer in manipulating materials, interpreting the requirements, applying knowledge, and the proper use of equipment. The results of some processes cannot be directly measured using gages, tools, test, and measuring equipment and so an alternative means has to be found of determining what is conforming product. The term given to such means is *workmanship criteria*, criteria that will enable producers and inspectors to gain a common understanding of what is acceptable and unacceptable. Situations where this may apply in

manufacturing are soldering, welding, brazing, riveting, deburring, etc. It may also include criteria for finishes, photographs, printing, blemishes, and many others.

Samples indicating the acceptable range of color, grain, and texture may be needed and if not provided by your customer, those that you provide may need customer approval.

The criteria need to be defined by documented standards or by samples and models which clearly and precisely define the distinguishing features that represent both conforming and nonconforming product. In order to provide adequate understanding it may be necessary to show various examples of workmanship from acceptable to unacceptable so that the producer or inspector doesn't strive for perfection or rework product unnecessarily. These standards, like any others, need to be controlled. Documented standards should be governed by the document control provisions. Samples and models need to be governed by the inspection, measuring, and test equipment provisions and be subject to periodic examination to detect deterioration and damage. They should be certified as authentic workmanship samples and measures taken to preserve their integrity. Ideally they should be under the control of the inspection authority or someone other than the person responsible for using them so that there is no opportunity for them to be altered without authorization. The samples represent your company's standards, they do not belong to any individual and, if used by more than one person, you need to ensure consistent interpretation by training the users.

Maintenance of equipment (4.9.1.1g and 4.9.1.5)

The standard requires *suitable maintenance of equipment to ensure continuing process capability and to identify key processes and provide appropriate resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system.*

In a manufacturing environment, this requirement applies to the process plant, machinery, and any other equipment upon which process capability depends. The requirement for documented procedures in 4.9a implies that you will need procedures for maintaining this equipment and this means that you will need:

- A list of the equipment upon which process capability depends
- Defined maintenance requirements specifying maintenance tasks and their frequency
- A maintenance program that schedules each of the maintenance tasks on a calendar

- Procedures defining how specific maintenance tasks are to be conducted
- Procedures governing the decommissioning of plant prior to planned maintenance
- Procedures governing the commissioning of plant following planned maintenance
- Procedures dealing with the actions required in the event of equipment malfunction
- Maintenance logs which record both the preventive and corrective maintenance work carried out

In a service environment if there is any equipment upon which the capability of your service depends, this equipment should be maintained. Maintenance may often be sub-contracted to specialists but nevertheless needs to be under your control. If you are able to maintain process capability by bringing in spare equipment or using other available equipment, your maintenance procedures can be simple. You merely need to ensure you have an operational spare at all times. Where this is not possible you can still rely on the call-out service if you can be assured that the anticipated downtime will not reduce your capability below that which you have been contracted to maintain.

The requirement does not mean that you need to validate all your word-processing software or any other special aids you use. Maintenance means retaining in an operational condition and you can do this by following some simple rules.

The standard refers to *total planned preventive maintenance* for which there is no definition in ISO/TS 16949. There is also a requirement for the system to include predictive maintenance.

- *Planned maintenance* is maintenance carried out with forethought as to what is to be checked, adjusted, replaced, etc.
- *Preventive maintenance* is maintenance carried out at predetermined intervals to reduce the probability of failure or performance degradation. An effective maintenance system should be one that achieves its objectives in minimizing downtime, i.e. the period of time in which the equipment is not in a condition to perform its function.
- *Corrective maintenance* is maintenance carried out after a failure has occurred and is intended to restore an item to a state in which it can perform its required function.
- *Predictive maintenance* is part of planned preventive maintenance. In order to determine the frequency of checks you need to predict when failure may occur. Will failure occur at some future time, after a certain number of operating hours, when

being operated under certain conditions, or some other time? An example of predictive maintenance is vibration analysis. Sensors can be installed to monitor vibration and thus give a signal when normal vibration levels have been exceeded. This can signal tool wear and wear in other parts of the machine in advance of the stage where nonconforming product will be generated.

The manuals provided by the equipment manufacturers should indicate the recommended preventive maintenance tasks and the frequency they should be performed covering such aspects as cleaning, adjustments, lubrication, replacement of filters and seals, inspections for wear, corrosion, leakage, damage, etc.

Another source of data is from your own operations. By monitoring and analyzing tool wear, corrective maintenance, cutting fluids, and incident reports from operators you can obtain a better picture of a machine's performance and predict more accurately the frequency of checks, adjustments, and replacements. For this to be effective you need a reporting mechanism that causes operators to alert maintenance staff to situations where suspect malfunctions are observed. In performing such monitoring you cannot wait until the end of the production run to verify whether the tools are still producing conforming product. If you do you will have no data to show when the tool started producing nonconforming product and will need to inspect the whole batch.

An effective maintenance system depends upon it being adequately resourced. Maintenance resources include people with appropriate skills, replacement parts and materials, access to support from OEMs when needed, and the funds to purchase this material. If the equipment is no longer supported by the OEM, then you may need to cannibalize old machines or manufacture the parts yourself. This can be a problem since you may not have a new part from which to take measurements. At some point you need to decide whether it is more economical to maintain the old equipment than to buy new. Your inventory control system needs to account for equipment spares and to adjust spares holding based on usage.

For the system to be effective there also has to be control of documentation, maintenance operations, equipment, and spare parts. Manuals for the equipment should be brought under document control. Tools and equipment used to maintain the operational equipment should be brought under calibration and verification control. Spare parts should be brought under identity control and the locations for the items brought under storage control. The maintenance operations should be controlled to the extent that maintenance staff should know what to do, know what they are doing, and be able to change their performance should the objectives and requirements not be met. Whilst the focus should be on preventive maintenance, one must not forget corrective maintenance. The maintenance crew should be able to respond to equipment failures promptly and restore equipment to full operational condition in minimum time. The function

needs resourcing to meet both preventive and corrective demands since it is downtime that will have most impact on production schedules.

The exact nature of the controls should be as appropriate to the item concerned, the emphasis being placed upon that which is necessary to minimize operational equipment downtime. It would be far better to produce separate procedures for these tasks rather than force fit the operational procedures to maintenance applications.

Special processes (4.9.1.1)

The standard defines special processes as *processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use.*

Many processes do not present any difficulty in the verification of the output against the input requirements regardless of the tools, personnel, facilities, or other means used to carry out the process. The resultant features and characteristics are relatively easily determined. However, there are some processes where conforming product is totally dependent upon the capability of personnel, equipment, and facilities used, and where conformance cannot be fully verified by examination of the end product at any stage of assembly. If any of these factors is less than adequate, deficiencies may not become apparent until long after the product enters service. Among such processes are welding, soldering, adhesive bonding, casting, forging, forming, heat treatment, protective treatments, and inspection and test techniques such as X-ray examination, ultrasonics, environmental tests, and mechanical stress tests.

In service industries, special processes include correctness of financial or legal documents, software, professional advice, etc. In such cases, these processes are not separated for special treatment, as all processes in the business may fall into this category.

Within your quality system you should produce and maintain a list of special processes that have been qualified and a list of the personnel who are qualified to operate them. In this way you can easily identify an unqualified process or an unauthorized person, or an obsolete list if you have neglected to maintain it.

Ensuring compliance with unverifiable characteristics (4.9.1.1)

The standard requires *special processes to be carried out by qualified operators and/or continuous monitoring and control of process parameters to ensure that the specified requirements are met.*

Where process capability relies upon the competence of personnel, personnel operating such processes need to be appropriately educated and trained and undergo examination of their competency. Where there is less reliance on personnel but more on the consistency of materials, environment, and processing equipment, operations should be monitored continuously by inspection, observation, or other techniques.

Qualification of processes (4.9.1.1)

The standard requires that *the requirements for any qualification of process operations including associated equipment and personnel be specified.*

To limit the potential for deficiencies to escape detection before the product is released, special processes should be documented in the form of procedures and specifications that will ensure the suitability of all equipment, personnel, and facilities, and prevent varying conditions, activities, or operations. Qualification in the context of special processes means that you need to conduct a thorough assessment of the processes to determine their capability to maintain or detect the conditions needed to produce conforming product consistently. The limits of capability need to be determined and the processes only applied within these limits. In qualifying the processes you need to qualify the personnel using them by training and examination as well as the materials, equipment, and facilities employed. It is the combination of personnel, materials, equipment, and facilities which ensure qualified processes.

In production you need to ensure that only those personnel, equipment, materials, and facilities that were qualified are employed in the process, otherwise you will invalidate the qualification and inject uncertainty into the results. If subcontracting special processes you need to ensure that the subcontractor only employs qualified personnel and has qualified process equipment and facilities (see Part 2 Chapters 6 and 18).

Records of qualified processes (4.9.1.1)

The standard requires that *records be maintained for qualified processes, equipment, and personnel, as appropriate.*

The records of qualified personnel using special processes should be governed by the training requirements covered in Part 2 Chapter 18. Regarding the equipment, you will need to identify the equipment and facilities required within the process specifications and maintain records of the equipment in terms of:

- Type designation and serial number
- Manufacturer's name and address
- Date of purchase
- Date of installation
- Date of qualification
- Date of any re-qualification
- Process in which used
- Process specification applicable
- Maintenance schedule
- Record of planned and corrective maintenance
- List of problem reports

This data may be needed to trace the source of any problems with product which was produced using this equipment. To take corrective action you will also need to know the configuration of the process plant at the time of processing the product. If only one piece of equipment is involved, the above records will give you this information but if the process plant consists of many items of equipment which are periodically changed during maintenance, you will need to know which equipment was in use when the fault is likely to have been generated.

Maintaining cleanliness of premises (4.9.1.2)

The standard requires the supplier to *maintain premises in a state of order, cleanliness, and repair appropriate to the product manufactured.*

This requirement should not be necessary, as clause 4.9.1(b) addresses working environment but emphasizes that poor housekeeping and maintenance can affect product quality. For auditors it means that they do not need to find evidence that product has been affected by the working conditions – only prove that the conditions are not appropriate and that product may be affected in due course.

Preparing contingency plans (4.9.1.3)

The standard requires the supplier to *prepare contingency plans to reasonably protect the customer's supply of product in the event of emergency, excluding natural disaster and force majeure.*

Force majeure is an event, circumstances, or an effect that cannot be reasonably anticipated or controlled – often called an act of God, which includes natural disasters caused by weather and land movement. Force majeure also includes war, riots, air crash, labor stoppage, illness, disruption in utility supply by service providers, etc. There is some contradiction in this requirement as you can take effective action to maintain business continuity as a result of certain events that may be classified as force majeure or natural disasters.

Although such events cannot be prevented, their effects can be reduced and in some cases eliminated. Hence contingency plans should cover those events that can be anticipated where the means to minimize the effects are within your control. What may be a force majeure situation for your suppliers does not need to be the same for you.

Start by doing a risk assessment and identify those things on which continuity of business depends: power, water, labor, materials, components, services, etc. Determine what could cause a termination of supply and estimate the probability of occurrence. For those with a relatively high probability (1 in 100) find ways to reduce the probability. For those with lower probability (1 in 10000) determine the action needed to minimize the effect. The FMEA technique works for this as well as for products and processes.

If you are located on or near an airport and a Boeing 747 descends upon your factory, can you claim it to be an event outside your control when you chose to site your plant so close to the airport? You may have chosen to outsource manufacture to a supplier in a poorer country and now depend on them for your supplies. They may ship the product but because it is stopped at customs due to a change in government of the country concerned, it doesn't reach its destination – hence you may need an alternative source of supply.

Designation of special characteristics (4.9.1.4)

The standard requires the supplier to *comply with all customer requirements for designation, documentation, and control of special characteristics and to supply documentation showing compliance with these requirements.*

This clause requires the designation of special characteristics that should have been accomplished during product realization (as required by clause 4.2.4.7). As for the documentation of special characteristics, the symbols should have been applied both when establishing the process controls and preparing the control plan (also clause 4.2.4.7) and associated documentation during the planning phase. Therefore the requirements not previously addressed are for the control of special characteristics and evidence of compliance: i.e. quality records.

As is stated in the standard, all characteristics are important and need to be controlled. However, some need special attention as excessive variation may affect product safety, compliance with government regulations, fit, form, function, appearance, or the quality of subsequent operations. Designating such characteristics with special symbols alerts planners and operators to take particular care. It also alerts those responsible for dispositioning nonconforming product to exercise due care when reaching their decisions.

The control plans should make provision for any specific controls required by the customer and these must be implemented. Evidence is required to show that all the controls specified in the control plan have been implemented and a way of doing this is to make provision for recording verification of conformity against the relevant requirement in the control plan.

Process capability and process control (4.9.1.1g and 4.9.3)

The standard requires *maintenance of equipment to ensure continuing process capability* in clause 4.9.1(g) and in clause 4.9.3 requires the supplier to *maintain or exceed process capability or performance as approved via customer part approval process.*

The object of a process control system is to make economic and sound decisions about the actions affecting the process. Data concerning the variations in process performance are collected and analyzed and decisions taken as to whether action on the process is or is not necessary to maintain production of conforming product (see Figure 9.1). However, process control and process capability are not one and the same, as illustrated in Figure 9.5.

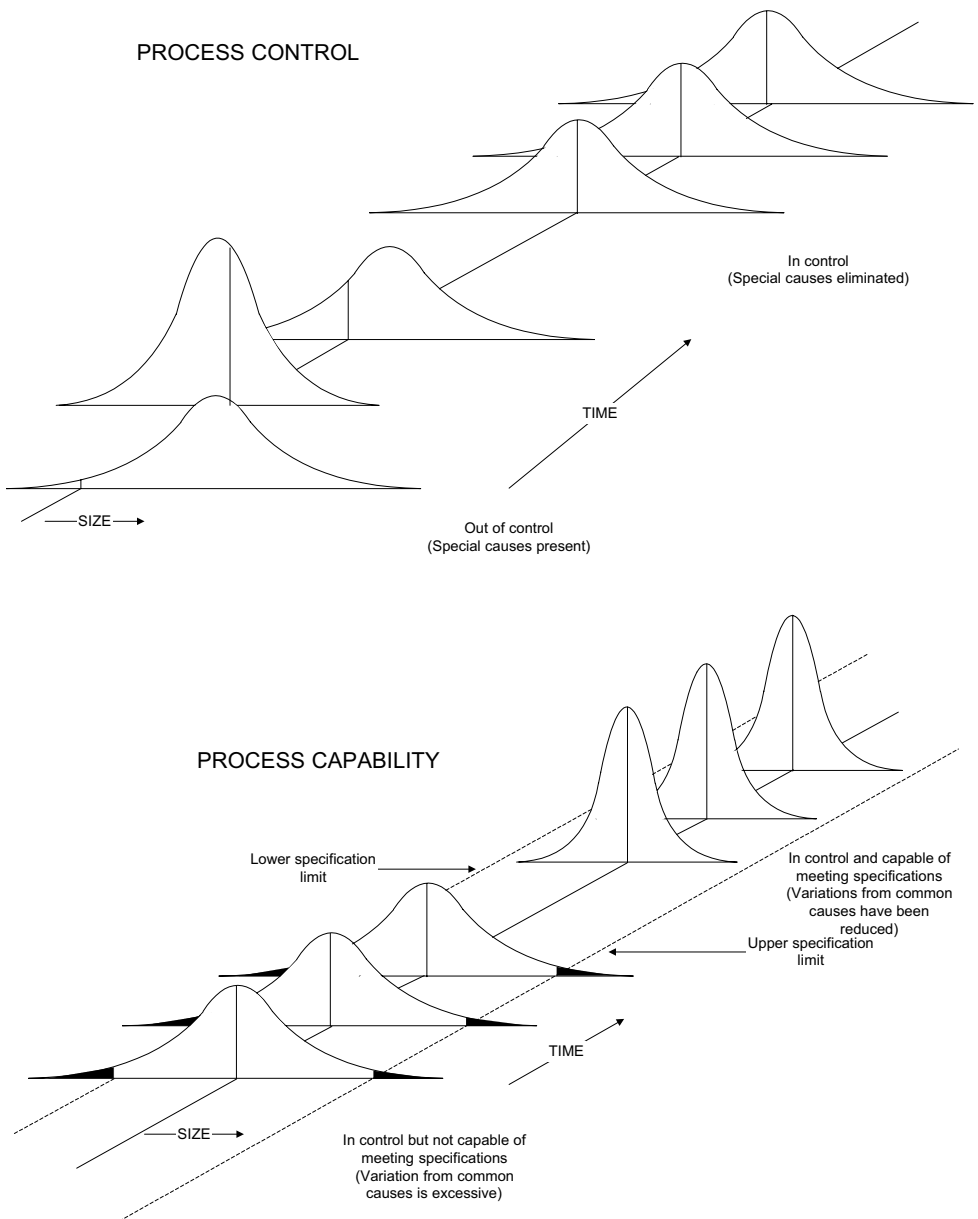


Figure 9.5 *Process control and process capability*

A process is in control when the average spread of variation coincides with the nominal specification for a parameter. The range of variation may extend outside the upper and lower limits but the proportion of parts within the limits can be predicted. This situation will remain as long as the process remains in statistical control. A process is in statistical

control when the source of inherent variation is from common causes only: i.e. a source of variation that affects all the individual values of the process output and appears random. Common cause variation results in a stable and repeatable distribution of results over time. When the source of variation causes the location, spread, and shape of the distribution to change, the process is not in statistical control. These sources of variation are due to special or assignable causes and must be eliminated before commencing with process capability studies. It is only when the performance of a process is predictable that its capability to meet customer expectations can be assessed.

Process capability studies are studies conducted to obtain information about the inherent variation present in processes that are under statistical control, in order to reduce the spread of variation to less than the tolerances specified in the product specification.

■ A capable process will produce all parts within the specified limits.

Preliminary process capability studies are those based on measurements collected from one operating run to establish that the process is in statistical control and hence no special causes are present. Studies of unpredictable processes and the determination of associated capability indices have little value. Preliminary studies should show acceptable results for special characteristics before production approval can be given. These studies and associated indices only apply to the measurement of variables and not to attributes (see below).

Several measures of process capability have evolved and are presented as indices C_p , C_{pk} , and P_{pk} . These are defined in Appendix A.

Acceptable processes are those with a P_{pk} value greater than 1.67. Those with P_{pk} between 1.33 and 1.67 may not meet customer requirements but approval may be granted. If the P_{pk} is less than 1.33, the process is not acceptable.

The object of the studies is to compute the indices and then take action to reduce common cause variation by preventive maintenance, mistake-proofing, operator training, revision to procedures and instructions, etc.

The inherent limitations of attribute data prevent their use for preliminary statistical studies since specification values are not measured. Attribute data have only two values (conforming/nonconforming, pass/fail, go/no-go, present/absent) but they can be counted, analyzed, and the results plotted to show variation. Measurement can be based on the fraction defective, such as parts per million (PPM). While variables data follows a distribution curve, attribute data varies in steps since you can't count a fraction. There will either be zero errors or a finite number of errors.

Following production launch, process capability and performance should be measured continually in order to demonstrate that your processes remain capable and the capability index continues to rise. Appropriate action should be taken on characteristics that are either unstable or non-capable. Action plans should be implemented to contain process output and continually improve performance.

Verification of job set-ups (4.9.4)

The standard requires that *job set-ups be verified whenever a set-up is performed and that job instructions be available for set-up personnel.*

In setting up a job prior to commencing a production run, you need to verify that all the requirements for the part are being met. You will therefore need job set-up instructions so as to ensure each time the production of a particular part commences that the process is set up against the same criteria. In addition, process parameters may change whenever there is material changeover, a job change, or if significant time periods elapse between production runs.

Documentation verifying job set-ups should include documentation to perform the set-up and records that demonstrate that the set-up has been performed as required. This requires that you record the parameters set and the sample size and retain the control charts used which indicate performance to be within the central third of the control limits. These records should be retained as indicated in clause 4.16 of the standard.

Using statistical techniques during job set-up (4.9.4)

The standard requires the supplier to *use statistical methods of verification during job set-up.*

You will need to produce more than one part to verify that the process is stable. You need to form a sample large enough to take statistical measurement. If the measurements taken on the product fall within the central third of the control limits then the set-up can be approved – if not, then adjustments should be made and further samples produced until this condition is achieved. The Note in clause 4.9.4 indicates that regardless of the number of parts in the sample, it is the comparisons made on the last part that establish the conditions for commencement of production.

Appearance items (4.9.5)

The standard requires suppliers to *provide appropriate lighting, product masters, maintenance control, and qualified personnel should they be manufacturing parts designated by the customer as “appearance items”*.

Appearance items are those with surface finish characteristics that are visible to the end user. These items will be designated by your customer so you don't need to guess which items they are. Appearance is a subjective characteristic so means need to be provided to reduce the subjectivity and make judgement more objective.

Samples indicating the acceptable range of color, gloss, metallic brilliance, grain and texture, and distinctness of image may be needed and, if not provided by your customer, those that you provide will need customer approval.

It is also important when selecting personnel for making appearance decisions to ensure that they have the requisite physical attributes. Eye sight and color blindness tests should be conducted when appropriate. Lighting conditions should be appropriate for the evaluations performed, avoiding shadows, glare, and other adverse factors. The tests need to be conducted periodically as a safeguard against deterioration in the relevant physical attributes.

Task list

- 1 Identify the result-producing processes.
- 2 Provide for the production requirement to be documented and made available to the production planners.
- 3 Prepare procedures for planning production of product lines, batched and single products.
- 4 Prepare procedures for providing instructions governing production activities where necessary.
- 5 Prepare procedures for provisioning tools, equipment, and facilities needed for production.
- 6 Establish standards of workmanship where appropriate and provide means for their control.
- 7 Provide suitable environments for the conduct of production operations.
- 8 Provide libraries or other areas where staff can gain access to the documentation needed to produce the product.
- 9 Install controls to enable operators to monitor production processes.
- 10 Provide travelers or route cards to route product through the production process into storage areas.
- 11 Carry out pre-production runs on new designs to prove the production set-up and debug the design.
- 12 Qualify all new process plant and equipment prior to use in production.
- 13 Train and qualify operators working with special processes.
- 14 Prepare and maintain a list of special processes and records of these processes.
- 15 Provide designated work-in-progress areas for holding product waiting further processing.

- 16 Provide designated areas or bins for product waiting inspection.
- 17 Provide equipment and containers for the safe transportation of product between operations.
- 18 Provide separate areas for reworking, repairing, or modifying product.
- 19 Provide a means of distributing parts from storage areas to assembly stations.
- 20 Provide security and protection for workmanship standards.
- 21 Identify any equipment that is vital to your operation and make provision for its maintenance or replacement in the event of failure.
- 22 Carry out a risk assessment on your utilities, labor force, and suppliers and prepare contingency plans to minimize effect on business continuity.

Process control questionnaire

- 1 How do you ensure that production processes which directly affect quality are identified, planned, and carried out under controlled conditions?
- 2 How do you ensure that installation processes which directly affect quality are identified, planned, and carried out under controlled conditions?
- 3 How do you ensure that servicing processes which directly affect quality are identified, planned, and carried out under controlled conditions?
- 4 In which documents do you define the manner of production?
- 5 In which documents do you define the manner of installation?
- 6 In which documents do you define the manner of servicing?
- 7 In which documents do you define the production equipment?
- 8 In which documents do you define the installation equipment?

- 9 In which documents do you define the servicing equipment?
- 10 In which documents do you define the production working environments?
- 11 In which documents do you define the installation working environments?
- 12 In which documents do you define the servicing working environments?
- 13 In which documents do you define the reference standards, codes of practice, quality plans, and procedures to be complied with during production?
- 14 In which documents do you define the reference standards, codes of practice, quality plans, and procedures to be complied with during installation?
- 15 In which documents do you define the reference standards, codes of practice, quality plans, and procedures to be complied with during servicing?
- 16 How do you monitor and control process and product characteristics during production?
- 17 How do you monitor and control process and product characteristics during installation?
- 18 How do you monitor and control process and product characteristics during servicing?
- 19 How do you approve processes and equipment?
- 20 How do you define criteria for workmanship?
- 21 How do you ensure continued process capability?
- 22 In which documents do you define how process equipment is maintained?
- 23 In which documents do you identify the processes which produce results that cannot be fully verified by subsequent inspection and testing of product?
- 24 How do you ensure that the results of these processes comply with specified requirements?
- 25 How are the requirements for process qualification specified?
- 26 In what documents do you record those processes, personnel, and equipment that have been qualified?

Do's and don'ts

- ☺ Do record the issue status of documents used to fabricate product.
- ⊗ Don't destroy labels attached to product when removed for assembly or installation – transfer data to assembly records before destroying the labels.
- ⊗ Don't permit product to exit from the production process without having a plan for the operations to be carried out until its return.
- ⊗ Don't inspect product until it reaches the planned inspection stage.
- ⊗ Don't work to instructions unless provided in the quality system procedures, product specification, production plan or in approved change notices or remedial action instructions or by the nonconformity review board.
- ⊗ Don't countenance informalities, work-around plans, or unwritten tips as they create problems when those who know them are absent.
- ⊗ Don't work to marked-up specifications unless covered by an approved change note.
- ⊗ Don't use parts that have lost their identity.
- ⊗ Don't skip operations without considering the effects and obtaining planning approval.
- ☺ Do gain set-up approval before commencing long production runs.
- ☺ Do delegate as much control to the operator as possible but provide the means for enabling self control.
- ⊗ Don't put dots on charts without knowing what causes the results.
- ☺ Do monitor the effects of adjusting the process.
- ⊗ Don't conduct experiments on the production line.
- ⊗ Don't give control of the process to inspection.
- ☺ Do display process flowcharts in strategic areas to remind staff of the relationships.

Chapter 10

Inspection and testing

Scope of requirements

Inspection and test are methods of verifying that product complies with the specified requirements. A more suitable term for this section of the standard would be “Product/service verification”, as used in ISO 9004, because inspection and test are only two methods of verification. Others are demonstration, analysis, and validation of records or a combination of such methods. Product verification is not limited to production, installation, and servicing. The inspections, tests, demonstrations, and other forms of verification that are used in product and service development should also be governed by these requirements as a means of ensuring that the product upon which design verification is carried out conforms with the prescribed requirements. If the product is noncompliant it may invalidate the results of design verification. Inspection and test also apply to any inspection, measuring, and test equipment that you design and manufacture to ensure that it is capable of verifying the acceptability of product, as required by clause 4.11 of the standard. Product verification is part of process control and not something separate from it, although the way the requirements are structured may imply otherwise.

It should also not be assumed that these requirements are only intended for implementation by a department with the title Inspection or Test. Whenever a product is supplied, produced, or repaired, rebuilt, modified, or otherwise changed, it should be subject to verification that it conforms with the prescribed requirements and any deficiencies corrected before being released for use. That is what control means. Control is not just the *inspection* part of the process and hence “quality control”, which for years was the name given to inspection departments, was misunderstood. Inspection and test don’t *control* quality. Inspection and test merely measure the quality achieved and pass the results to the producer for remedial action.

The requirements in element 4.10 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 10.1.

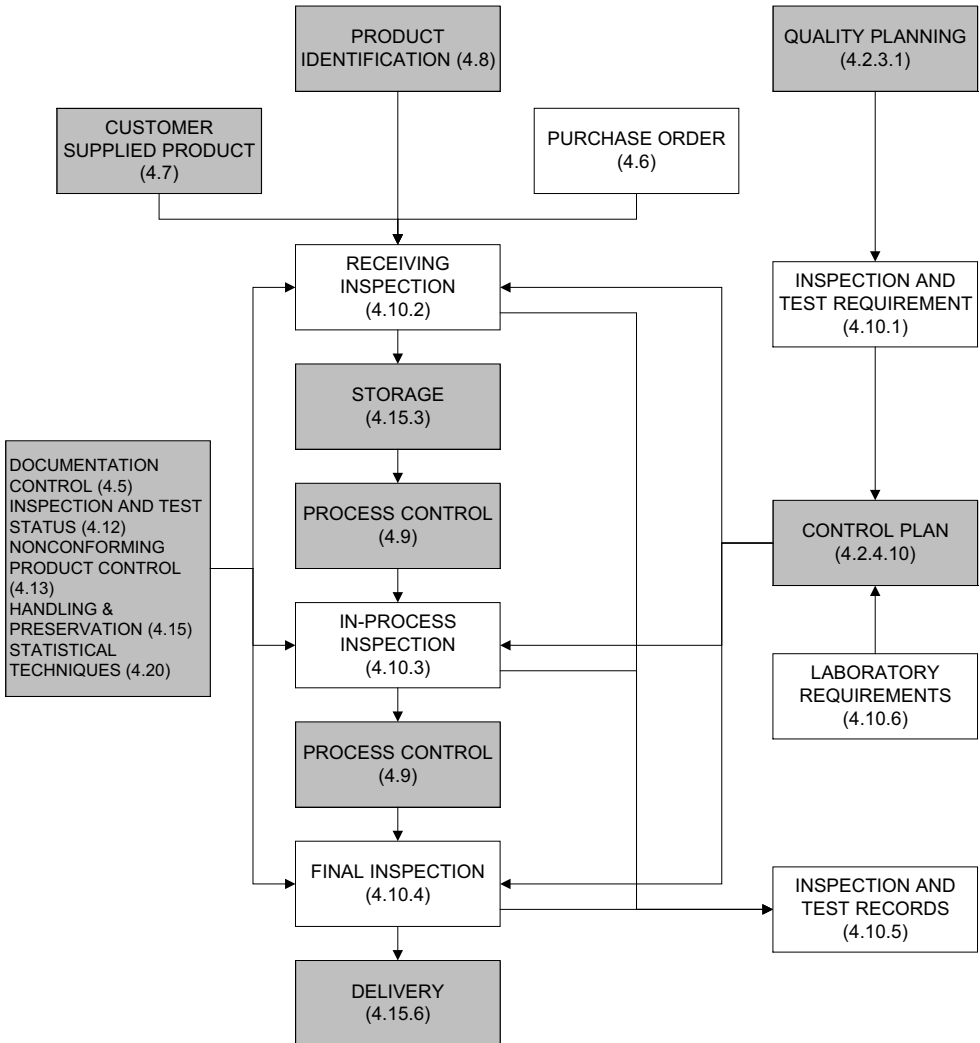


Figure 10.1 Clause relationships with the inspection and testing element

Inspection and test planning (4.10.1)

Documenting inspection and test procedures (4.10.1.1)

The standard requires suppliers to *establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for product are met.*

The way the requirement is worded implies that the purpose of the procedures is to verify that specified requirements are met rather than this be the purpose of carrying out the inspection and test. Whether the procedures verify that specified requirements have been met or whether the inspections and tests achieve this purpose is immaterial, as you need to verify that you have met the specified requirement and have records which demonstrate this.

To meet this requirement for documented procedures you will need two types of procedure: procedures which provide for the necessary inspections and tests to be planned and carried out at the appropriate stage of the process and procedures for carrying out the specific inspections and tests. However, this is not to say that you need to document how you conduct every type of inspection or test. You only need procedures which define how inspections and tests are to be performed when the lack of them will adversely affect the result. Where the inspection and test methods are no more than using the tools of the trade, no procedures will be necessary providing the acceptance criteria are specified in a specification, drawing, or other such document.

The requirement only relates to the specified requirements (i.e. the requirements specified by the customer) but clearly you will need to verify that the product meets the requirements which you have prescribed in the product or process specification.

Documenting inspections and tests (4.10.1.1)

The standard requires that *the required inspecting and testing and the records to be established be detailed in the quality plan or documented procedures.*

The standard provides a choice as to whether you define the inspections and tests required in a quality plan or in documented procedures. You may of course need to do both. As the quality system is often designed to accommodate all products and services you supply, it may not specify inspections and tests which are needed for particular products. This is one of the roles of the quality plan. Within such a plan you should identify the verification stages during product development, production, installation, and servicing as applicable. These stages will vary depending on the product, so your quality plan will be product, contract, or project specific (see Part 2 Chapter 2). There may

well be many routine inspections and tests that are needed which are carried out by type of product regardless of contract or project and these can be specified in your documented procedures, which need to be invoked within the quality plan. If the degree of special planning needed for the product, contract, or project is limited to these inspections and tests, the plan may be termed an Inspection and Test Plan. These plans may of course be integrated with your production, installation, or servicing plans as covered in Part 2 Chapter 9. This clause could have been made more consistent with those in sections 4.2 and 4.9 if the term “inspection and test planning” had been used to describe the requirements.

In defining your inspection and test requirements it is necessary not only to specify what inspections and tests are required and when, but also to define the acceptance criteria and the frequency of inspection and test. Are the acceptance criteria those defined in the product specification or are the limits to be closed to gain better control over the process? Is every product to be inspected or are the quantities so large that it would be economically unviable? If sampling is to be performed what are the acceptance criteria? Answers to these and other questions need to be provided by your documented inspection and testing requirements.

The second part of the requirement deals with inspection and test records, which are also covered in clause 4.10.5. The difference between these requirements is that clause 4.10.1 requires you to document the records to be established (in other words “define”) in the quality plan or procedures and clause 4.10.5 requires you to produce the records defined in the quality plan or procedures. Your inspection and test procedures therefore need to specify or contain the forms on which you intend to record the results of the inspections and tests performed. The details are covered later in this chapter, but there are two types of record to be considered: the record that shows which inspections and tests have been performed and the record that shows the results of these inspections and tests. One may be a route card, shop traveler, or document which acts as both a plan of what to do and a record of the progress made and the other may be a table of results with specified parameters and accept/reject criteria.

Acceptance criteria for attribute data (4.10.1.2)

The standard requires *the acceptance criteria for attribute data sampling plans to be zero defects.*

With attribute data the product either has or has not the ascribed attribute – it can therefore either pass or fail the test. There are no gray areas. Attributes are measured on a go or no-go basis. With variables, the product can be evaluated on a scale of measurement. However, with inspection by attributes we sometimes use an acceptable quality level (AQL) that allows us to ship a certain percent defective in a large batch of product –

probably no more than 10 in 1,000 – but to the automobile industry that is not good enough. The standard imposes a strict requirement on characteristics that are measured by attributes. There shall be no AQL, there shall be zero percent defective in the sample selected for inspection, otherwise the batch shall be rejected. This is what it implies, as your customer does not want to be supplied any defective products.

For inspection by variables the acceptance criteria have to be specified and the place to specify it is the control plan, which is submitted to your customer for approval.

Receiving inspection and testing (4.10.2)

The standard requires that the supplier *ensures that incoming product is not used or processed (except in the circumstances described in 4.10.1.2) until it has been inspected or otherwise verified as conforming to specified requirements* and requires that *verification be in accordance with the quality plan or documented procedures*.

When we purchase items as individuals it is a natural act to inspect what has been purchased before using it. To neglect to do this may result in us forfeiting our rights to return it later if found defective or nonconforming. When we purchase items on behalf of our employers we may not be as tenacious. We don't get the same pleasure out of it and are not necessarily eager to see what the product can do for us. So the company has to enforce its own receipt inspection policy as a way of protecting itself from the mistakes of its suppliers. Another reason for inspecting product on receipt is that it is often the case that characteristics are not accessible for inspection or test after subsequent processing. Characteristics that have not been verified on receipt may never be verified. This is the main purpose behind the requirement rather than of forfeiting your rights.

The key phrase in this clause is “or otherwise verified” as it allows you to receive product into your company and straight onto the production line if you have verified that it conforms to the specified requirements before it arrives. An example of this is where you have performed acceptance tests or witnessed tests on the supplier's premises. You may also have obtained sufficient confidence in your supplier that you can operate a “Just-in-time” arrangement but you must be able to show that you have a continuous monitoring program which informs you of the supplier's performance.

Regarding purchases made by the supplier, there are three parties: the ultimate customer, the supplier, and the supplier's supplier (the subcontractor). The standard has overlooked the fact that items are often inspected on receipt for conformance with the supplier's purchase order and not against requirements placed by the supplier's customer. Product may be nonconforming with the supplier's requirements but not the

supplier's customer's requirements, because ISO 9001 only requires positive recall if nonconforming with the customer's requirements.

The standard requires that you ensure that incoming product is not used or processed until verified as conforming, but how do you do this? The only way to make certain of this is to install a "gate" through which only conforming items may pass. You need to register the receipt of items and then pass them to an inspection station equipped to determine conformance with your purchasing requirements. If items would normally pass into storage areas following inspection, as a safeguard you should also make provision for the storeperson to check that all items received have been through inspection, rejecting any that have not. By use of labels attached to items you can make this a painless routine (see Part 2 Chapter 12). If some items are routed directly to the user, you need a means of obtaining written confirmation that the items conform to the prescribed requirements so that at receipt inspection you can provide evidence that:

- Nothing comes into the company without being passed through inspection.
- Nothing can come out of inspection without it being verified as conforming.

If the user is unable to verify that requirements have been met, you will need to provide evidence either that it has passed your receipt inspection or that it has been certified by the vendor.

This requirement poses something of a dilemma when purchasing subcontract labor because it cannot be treated the same as product. You still need to ensure, however, that the labor conforms with your requirements before use. Such checks will include verification that the personnel provided have the requisite qualifications, skills, and knowledge and they are who they say they are. These checks can be made on the documentary evidence provided, such as certificates, but you will probably wish to monitor their performance because it is the effort you have purchased, not the people. You will not be able to verify whether they are entirely suitable until you have evaluated their performance. Subcontract labor could be classified as product released prior to verification being performed and so you need to keep records of the personnel and their performance during the tenure of the contract.

Receipt inspection doesn't need to be a department, a section, a separate room, a full time job for someone, or a particular person. It is a process through which all product must pass, even those received on a "Just-in-time" basis. Someone should verify that products can pass uninspected. At a customs post some people are stopped, others are waved through; all are inspected to some degree – it all depends on the confidence gained by observation.

The verification carried out, however, has to be in accordance with some plan. The standard requires firstly that you verify conformance and secondly that you should do it in accordance with some plan or other. Your plans, therefore, need to prescribe the acceptance criteria for carrying out such verification. If the standard required that you verify conformance in accordance with the quality plan, as it does in clause 4.10.3, it would give you the option of not specifying any measures at all in your quality plan for verifying conformance, but this has been covered by the requirements of 4.10.1 as already explained.

So what should you put into your quality plan or documented procedures on receipt inspection? The main aspects to cover are as follows:

- Define how the receipt inspection personnel obtain current purchasing requirements.
- Categorize all items that you purchase so that you can assign levels of receipt inspection based on given criteria (see later in this chapter under *Determining the amount and nature of receiving inspection*).
- For each level of inspection, define the checks that are to be carried out and the acceptance criteria to be applied.
- Where dimensional and functional checks are necessary, define how the receipt inspection personnel obtain the acceptance criteria and how they are to conduct the inspections and tests.
- Define the action to be taken when the product, the packaging, or the documentation is found to be acceptable.
- Define the action to be taken when the product, the packaging, or the documentation is found to be unacceptable.
- Define the records to be maintained.

As stated previously everything should be passed through a receipt inspection. However, in order to relate the degree of inspection to the importance of the item, you should categorize purchases, an example of which is as follows:

- If the subsequent discovery of a nonconformity will *not* cause design, production, installation, or operational problems of any nature, a simple identity, carton quantity, and damage check may suffice. An example of this would be stationery.

- If the subsequent discovery of a nonconformity will cause *minor* design, production, installation, or operational problems, you should examine the features and characteristics of the item on a sampling basis. An example of this would be electrical, electronic, or mechanical components.
- If the subsequent discovery of a nonconformity will cause *major* design, production, installation, or operational problems, you should subject the item to a complete test to verify compliance with all prescribed requirements. An example of this would be an electronic unit.

These criteria would need to be varied depending on whether the items being supplied were in batches or separate. However, these are the kind of decisions you need to make in order to apply practical receipt inspection procedures.

Determining the amount and nature of receiving inspection (4.10.2.2 and 4.10.2.4)

The standard requires that *in determining the amount and nature of receiving inspection, consideration should be given to the control exercised at the subcontractor's premises and recorded evidence of conformance provided.* The supplementary requirements require the supplier to *use one or more of four prescribed methods unless waived by the customer.*

Audits on subcontractor's premises

Within your procedures you need to provide a means of identifying which items have been subject to inspection at the subcontractor's premises and the receipt inspection action to be taken depending on the level of that inspection. In one case, the product may have been accepted by your representative on the subcontractor's premises. In another case, a product from the same batch may have been accepted by your representative but not the one that has been delivered. Alternatively your representative may have only performed a quality audit to gain a level of confidence. You need to specify the inspection to be carried out in all such cases. The standard emphasizes that consideration should also be given to the recorded evidence provided. Even if someone has performed inspection at the subcontractor's premises, if there is no evidence of conformance the inspections are of little value. The fact that an inspection was carried out is insufficient. There has to be a statement of what was checked and what results were obtained and a decision as to whether conformance has been achieved. Without such evidence you may need to repeat some of the inspections carried out on the subcontractor's premises.

Evaluation of supplier's statistical data

If the subcontractor supplies statistical data from the manufacturing process that indicates that quality is being controlled, then an analysis of this data based on assurances you have obtained through site evaluation can provide sufficient confidence in part quality to permit release into the organization.

Where you have required your subcontractors to send a certificate of conformity (C of C) testifying the consignment's conformity with the order, you cannot omit all receiving checks. Once supplier capability has been verified, the C of C allows you to reduce the frequency of incoming checks but not to eliminate them. The C of C should be supported with test results. Therefore you need to impose this requirement in your purchasing documents. However, take care to specify exactly what test results you require and in what format you require them presented, as you could be provided with attribute data when you really want variables data.

Sampling inspection and test

Sampling inspection should be used when statistical data is unavailable to you or you don't have the confidence for permitting ship to line.

Second or third party assessment

Assessments by second or third parties can be an acceptable alternative but it depends on the standards used for the assessments. An ISO 9000 assessment alone would not give sufficient confidence to remove all receiving inspection for deliveries from that particular supplier. You need to examine product as well as the system until you have gained the confidence to reduce inspection and eventually remove it. Subsequently continual assessment of the subcontractor should be carried out.

Part evaluation by accredited laboratories

Part evaluation by accredited contractors or test laboratory provides independent verification which can substitute for your own receiving inspection, providing you maintain control over the contractor.

Premature release of product (4.10.2.3)

The standard requires that *where incoming product is released for urgent production purposes, prior to verification, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.*

If you do release a batch of product prior to verification being performed and one out of the batch is subsequently found to be nonconforming, you will need to retrieve all others from the same batch. This may not be as simple as it seems. In order to retrieve a component that has subsequently been assembled into a printed circuit board, which has itself been fitted into a unit along with several other assemblies, not only would you need a good traceability system but also one that is constantly in operation. You never can tell when product is going to be needed for urgent production purposes.

It would be considered prudent to prohibit the premature release of product if you did not have an adequate traceability system in place. If in fact any nonconformities in a component will be detected by the end product tests, it may be worth allowing production to commence without the receipt tests being available, in which case the tests will only be confidence checks and not verification checks. If only one product is received and released prior to verification one would think that, as the requirement applies prior to verification, there is no need to positively identify the product to permit recall because you would know where it was if you found it to be nonconforming. However, the nonconformity may have been reported to you by the supplier after delivery. The standard does not stipulate when and by whom the nonconformity may have been detected. If you lose the means of determining conformity by premature release, don't release the product until you have verified it is acceptable.

In-process inspection and testing (4.10.3a)

The standard requires the supplier to *inspect, test, and identify product as required by the quality plan or documented procedures.*

In-process inspection is carried out in order to verify those features and characteristics that would not be accessible to verification by further processing or assembly. When producing a product that consists of several parts, sub-assemblies, assemblies, units, equipment, and subsystems, each part, sub-assembly, etc. needs to be subject to final inspection but may also require in-process inspection for the reasons given above. Your quality plan, or better still the control plan (see Part 2 Chapter 9), should define all the in-process inspection and test stages that are required for each part, sub-assembly, assembly, etc. In establishing where to carry out the inspections, a flow diagram may help. The inspections and tests need to occur after a specified feature has been produced and before it becomes inaccessible to measurement. This doesn't mean that you should check features as soon as they are achieved. There may be natural breaks in the process where the product passes from one stage to another or stages at which several features can be verified at once. If product passes from the responsibility of one person to another, there should be a stage inspection at the interface to protect the producer even if the features achieved are accessible later. Your inspection and test plans should:

- Identify the product to be inspected and tested.
- Define the specification and acceptance criteria to be used and the issue status that applies.
- Define what is to be inspected at each stage. Is it all work between stages or only certain operations? The parameters to be verified should include those that are known to be varied by the manufacturing processes. Those which remain constant from product to product need verifying only once, usually during design proving.
- Define the inspection aids and test equipment to be used. There may be jigs, fixtures, gages, and other aids needed for inspection. Standard measuring equipment would not need to be specified as your inspectors and testers should be trained to select the right tools for the job. Any special test equipment should be identified.
- Define the environment for the measurements to be made if critical to measurement accuracy (see Part 2 Chapter 11 under *Ensuring that environmental conditions are suitable*).
- Identify the organization that is to perform the inspections and tests.
- Make provision for the results of the inspections and test to be recorded.

Held product (4.10.3b)

The standard requires the supplier to *hold product until the required inspection and tests have been completed or necessary reports have been received and verified except when product is released under positive recall procedures. Release under positive recall procedures shall not preclude the activities outlined in 4.10.3(a).*

In continuous production, product is inspected by taking samples from the line which are then examined while the line continues producing product. In such cases you will need a means of holding product produced between sampling points until the results of the tests and inspections are available. You will also need a means of releasing product when the results indicate that the product is acceptable. So a Product Release Procedure or Held Product Procedure may be necessary. The standard implies, however, that if you have released product under positive recall procedures you do not need to hold product while in-process inspection and tests are performed. The reference to clause 4.10.3(a) is also ambiguous because the inspections and tests carried out in accordance with the quality plan or documented procedures may not cover those necessary to verify product on receipt into the plant. It would be wise to hold any product until you have

completed your inspections and tests regardless of positive recall procedures being in force.

Final inspection and testing (4.10.4.1)

Final inspection is in fact the last inspection of the product that you will perform before dispatch but it may not be the last inspection before delivery if your contract includes installation. The term *final inspection* has three meanings:

- The inspection carried out on completion of the product – afterwards the product may be routed to storage areas rather than to a customer.
- The last inspection carried out before dispatch – afterwards you may install the product and carry out further work.
- The last inspection that you as a supplier carry out on the product before ownership passes to your customer – this is the final inspection of all inspections.

In place of the term *final inspection*, the term *product acceptance* is more appropriate and tends to convey the purpose of the inspection rather than the stage of the inspection.

Completing the evidence of conformance (4.10.4.1)

The standard requires that the supplier *carries out final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.*

To accomplish this, you need to specify either in the quality plan or the documented procedures, the inspections and tests you intend to carry out to verify that the product meets specified requirements. In Part 2 Chapter 4 there is a description of a Design Verification Plan and this includes a specification of the tests and inspections to be performed on each production item as a means of ensuring that the qualified design standard is being maintained. This requires that you produce something like an Acceptance Test Plan which contains, as appropriate, some or all of the following:

- Identity of the product to be inspected and tested.
- Definition of the specification and acceptance criteria to be used and the issue status which applies.

- Definition of the inspection aids and test equipment to be used (see above).
- Definition of the environment for the measurements to be made (see Part 2 Chapter 11).
- Provision for the results of the inspections and test to be recorded – these need to be presented in a form that correlates with the specified requirements.

Having carried out these inspections and tests it should be possible for you to declare that the product has been inspected and tested and objective evidence produced that will demonstrate that it meets the specified requirements. Any concessions given against requirements should also be identified. If you can't make such a declaration, you haven't done enough verification. Whether or not your customer requires a certificate from you testifying that you have met the requirements, you should be in a position to produce one. The requirement for a certificate of conformance should not alter your processes, your quality controls, or your procedures. One advantage of ISO 9000 is that it will enable you to build a quality system that will give you the kind of evidence you need to assure your customers that your product meets their requirements without having to do anything special.

Ensuring all inspections and test have been carried out (4.10.4.1)

The standard requires *the quality plan or documented procedures for final inspection and testing to require that all the specified inspections and tests, including those specified either on receipt of product or in-process, have been carried out and that the data meets specified requirements.*

There are two aspects to final inspection. One is checking what has gone before and the other is accepting the product.

Final inspection and test checks should detect whether:

- All previous inspections and checks have been performed.
- The product bears the correct identification, part numbers, serial numbers, modification status, etc.
- The as-built configuration is the same as the issue status of all the parts, sub-assemblies, assemblies, etc. specified by the design standard.
- All recorded nonconformities have been resolved and remedial action taken and verified.

- All concession applications have been approved.
- All inspection and test results have been collected.
- Any result outside the stated limits is subject to an approved concession, an approved specification change, or a retest which shows conformance with the requirements.
- All documentation to be delivered with the product has been produced and conforms to the prescribed standards.

Where the standard requires data to meet specified requirements this could be interpreted in two ways. If the specified requirements included data requirements, clearly you will have to satisfy them. But if the specified requirements do not define what you have to record, whatever you record you will meet the specified requirements. Alternatively, the standard could be interpreted, and this is more likely, as implying that the results you achieve are within the limits defined by the specified requirements. The next clause requires you to complete the evidence. You may have some difficulty with this as the specified requirements may not define the same parameters as you are measuring and some analysis may be necessary to correlate the results. This analysis is all part of inspection even though it may be performed by another group of people.

Ensuring no incomplete product is dispatched (4.10.4.1)

The standard requires that *no product be dispatched until all the activities specified in the quality plan or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.*

This requirement can impose unnecessary constraints if you take it literally. Many activities in quality plans and procedures are performed to give early warning of nonconformities. This is in order to avoid the losses that can be incurred if failure occurs in later tests and inspections. The earlier you confirm conformance the less costly any rework will be.

■ **The later the inspection the more costly the rework.**

Therefore you should not hold shipment if later activities will verify the same parameters whether or not earlier activities have been performed. It is uneconomic for you to omit the earlier activities, but if you do, and the later activities confirm that the end product meets the requirements, and that this can be demonstrated, it is also uneconomic to

go back and perform those activities that have not been completed. Your quality plan could cover installation and maintenance activities which are carried out after dispatch and so it would be unreasonable to insist that these activities were completed before dispatch or to insist on separate quality plans just to sanitize a point. A less ambiguous way of saying the same thing is to require no product to be dispatched until objective evidence has been produced to demonstrate that it meets the specified or contracted requirements and authorization for its release has been given.

You need four things before you can release product whether it be to a storage area, to the customer, to the site for installation, or anywhere else:

- Sight of the product
- Sight of the requirement with which the product is to conform
- Sight of the objective evidence which purports to demonstrate that the particular product meets the requirement
- Sight of an authorized signatory or the stamp of an approved stamp holder who has checked that the particular product, the evidence, and the requirement are in complete accord

Layout inspection and functional testing (4.10.4.2)

The standard requires *a layout inspection and a functional verification to applicable customer engineering material and performance standards to be performed for all products at a frequency specified in the control plan.*

When a product undergoes design verification and validation, the tests are conducted on a small sample of product that is representative of the production standard. The variation in materials, environment, and characteristics that is possible over long production runs cannot be fully predicted and, therefore, periodic tests are necessary to verify that the product in current production is of the same standard as the product that gained production approval. In some industries these checks are called “verification of qualification” (VOQ). In the automobile industry they are called “layout inspection and functional verification”. A *layout inspection* is the complete measurement of all part dimensions shown on the design record and a *functional verification* is testing to ensure that the part conforms to all customer engineering material performance standards and hence fully satisfies the approved design requirements.

The frequency of such checks and the sample size will be specified by the customer and could be annually or more or less often, depending on quantities produced and other considerations.

The tests and inspections carried out need to be to the same specifications and procedures as those used for the original production part approval and as amended by subsequent approved engineering changes. The results of the tests should be recorded in the same format as the original tests, unless otherwise required by the customer.

Inspection and test records (4.10.5)

The standard requires that the supplier *establishes and maintains records which provide evidence that the product has been inspected and/or tested.*

Types of inspection and test records

Your inspection and test records or verification records should be of two forms: one which indicates what inspections and tests have been carried out and the other which indicates the results of such inspections and test. They may be merged into one record but when parameters need to be recorded it is often cleaner to separate the progress record from the technical record. Your procedures, quality plan, or product specifications should also indicate what measurements have to be recorded.

Content of inspection and test records (4.10.5)

The standard requires that *the inspection and test records show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria.*

Don't assume that because a parameter is shown in a specification that an inspector or tester will record the result. A result can be a figure, a pass/fail, or just a tick. Be specific in what you want recorded as you may get a surprise when gathering the data for analysis. If you use computers, you won't have the same problems but beware, too much data is probably worse than too little! In choosing the method of recording measurements, you also need to consider whether you will have sufficient data to minimize recovery action in the event of the measuring device subsequently being found to be out of calibration. As a general rule, only gather that data you need to determine whether the product meets the requirements or whether the process is capable of producing a product that meets the requirements. You need to be selective so that you can spot the

out-of-tolerance condition. All inspection and test records should define the acceptance criteria, the limits between which the product is acceptable and beyond which the product is unacceptable and therefore nonconforming.

Action required on failed product (4.10.5)

The standard requires *the procedures for control of nonconforming product to apply to any product which fails to pass any inspection and/or test.*

The standard emphasizes that a nonconforming product is one which has failed a planned inspection and/or test. Up to that stage the product is neither conforming nor nonconforming – it is merely in-process. Hence the requirements of section 4.13 only apply after product or service has been inspected or tested and are clearly not intended to be applied at any other stage.

Identifying the inspection authority (4.10.5)

The standard requires that *records identify the inspection authority responsible for the release of conforming product.*

The inspection authority is the organization that decides whether the product is conforming or nonconforming.

It may be an individual or an organization. Within an organization you may wish to identify the individual responsible so that you can go back to him/her and ask questions. This is more likely in the case of a reject decision as opposed to an acceptance decision. As products emerge from the organization there is less need to identify individuals and more of a need to identify which organization made the decision but it can be either. It is also important to protect your staff from prying users or customers or those with a grudge against the person who released the defective product. The use of numbered inspection stamps avoids putting the name of an individual on a product.

The inspection authority for a document is the person who approved it. There may be other personnel in the chain such as the issuing authority or the publishing authority, but the person who verified the content is normally the approval authority. With documents that carry signatures you have less protection from prying users and so here is a good reason for excluding the name of the author or approver from the finished document if it is to be used externally. Separate document development records can be used to trace authors and approvers to specific documents.

Some organizations maintain a list of authorized signatures as a means of being able to trace signatures to names of people who carry certain authority. If you have a large number of people signing documents and records and there is a possibility that the wrong person may sign a document, the list is a good tool for checking that there has been no abuse of authority. Otherwise, the name of the individual and his or her position below or alongside the signature should be adequate. The quality system is a tool for achieving quality not for detecting criminals. If people want to commit fraud they will and the only system that comes close to preventing such incidents is a real-time computerized quality system – but even that is not immune to the determined hackers.

Laboratory requirements (4.10.6)

Use of supplier's laboratories (4.10.6)

The standard requires that *where inspection, testing, and calibration services are conducted by a supplier's laboratory facility, the laboratory shall comply with ISO/IEC 17025 including use of a laboratory scope.*

ISO/IEC 17025 replaces ISO/IEC Guide 25 and defines the internationally-accepted criteria for the technical evaluation of laboratories in the future.

There are two sources of confusion with this requirement. First is the issue of accreditation and second is the difference between ISO/TS 16949 and ISO/IEC 17025.

Accreditation and certification

Laboratory accreditation is defined by ISO as formal recognition that a laboratory is competent to carry out specific tests or specific types of tests. The key words in this definition are “competent” and “specific tests”. Each accreditation recognizes a laboratory's technical capability (or competence) to do specific tests, measurements, or calibrations. In that sense, it should be recognized as a standalone form of very specialized technical certification, as distinct from a purely quality system certification as provided by ISO 9000. An accredited organization is authorized to issue certificates of conformity to national or international standards. ISO 9000 certification does not authorize an organization to issue such certificates. Accreditation is awarded for a specific scope of service or range of products, as is certification, except that for laboratory accreditation they are accredited for very specific tests or measurements – usually within specified ranges of measurement – with associated information on uncertainty of measurement and for particular product and test specifications. An ISO 9000 certificate for a laboratory does not accurately specify the performance characteristics of the product that the organization is capable of supplying.

ISO/TS 16949 vs ISO/IEC 17025

ISO/TS 16949 states that *accreditation of supplier facilities to ISO/IEC 17025 or national equivalent is neither required nor does it satisfy all requirements in ISO/TS 16949*. It can also be said that ISO/TS 16949 does not satisfy all the requirements of ISO/IEC 17025. Hence, ISO/IEC 17025 is the equivalent of ISO/TS 16949 for the calibration sector.

The intent is that wherever the calibration is performed, the same standards apply. Calibrating equipment in-house should not absolve you from complying with the same requirements that you would need to impose on an external test house.

As ISO/IEC 17025 does not cover some of the system elements, your laboratory should therefore be subject to audit against the relevant requirements of ISO/TS 16949.

Use of independent laboratories (4.10.6)

The standard requires that *where inspection, testing, and calibration services are conducted by a commercial/independent laboratory facility, the laboratory shall be accredited to ISO/IEC 17025 or national equivalent*.

Currently laboratories seek accreditation to ISO/IEC Guide 25 but this is being replaced by ISO/IEC 17025 in 2000.

ISO/IEC Guide 25 states in its introduction that: "Laboratories meeting the requirements of this Guide comply, for calibration and testing activities, with the relevant requirements of the ISO 9000 series of standards, including those of the model described in ISO 9002, when they are acting as suppliers producing calibration and test results." However, laboratories meeting the minimum requirements of ISO 9002 would not meet the requirements or the intent of Guide 25 and will therefore not meet the requirements of ISO/IEC 17025.

Task list

- 1 Establish a receipt inspection area for processing incoming goods.
- 2 Prepare procedures for inspecting and testing incoming goods.
- 3 Classify goods so as to apply inspection and test according to the need.
- 4 Define the criteria for acceptance of goods into the organization.
- 5 Appoint an authority for releasing incoming product to storage areas or for use.
- 6 Establish means of dealing with nonconforming product.
- 7 Provide measuring facilities and equipment for use in the receipt inspection area and measures for their control.
- 8 Provide a quarantine area to place nonconforming product pending disposition.
- 9 Establish a means of tracing product back to its inspection on receipt.
- 10 Produce procedures for in-process and final inspection and test.
- 11 Provide for inspection and test plans to be produced for verifying product through the various stages of production.
- 12 Provide a means for progressing the inspections and tests and for identifying those responsible for carrying them out.
- 13 Provide inspection stations in-process to which product is passed for inspection.
- 14 Provide inspection aids, tools, and measuring equipment appropriate for the task.
- 15 Provide environmental controls for inspection and test areas where measurement accuracy requires them.
- 16 Provide facilities for inspectors to obtain current versions of all relevant product specifications, drawings, and process specifications.
- 17 Provide a means of recording inspection and test results so that any omissions can be checked at subsequent inspections.
- 18 Provide secure areas for storing inspection and test records.
- 19 Provide areas for held product pending results of final inspection.
- 20 Provide for products to re-enter the inspection flow following rework, repair, or modification.
- 21 Assess your internal laboratories against ISO/IEC 17025 and act on the differences.
- 22 Check that your external laboratories are accredited to ISO/IEC Guide 25 as a minimum.
- 23 Perform layout inspection and functional testing at a frequency defined by the customer.

Inspection and testing questionnaire

- 1 How do you establish the inspections and tests required to verify that the specified requirements for product are met?
- 2 In which procedures are the inspection and test activities documented?
- 3 In which documents are the inspecting and testing requirements defined?
- 4 In which document do you specify the inspection and test records to be established?
- 5 How do you ensure that product is not used until verified as conforming with specified requirements?
- 6 How do you ensure that product is not processed until verified as conforming with specified requirements?
- 7 How do you ensure that product is not dispatched until verified as conforming with specified requirements?
- 8 How is the amount and nature of receipt inspection determined?
- 9 When you need to release incoming product for urgent processing, how do you enable immediate recall and replacement in the event of nonconformities being revealed?
- 10 How do you ensure that incoming product released for urgent production purposes is identified and recorded?
- 11 How do you ensure that product is inspected, tested, and identified as required by the quality plan or documented procedures?
- 12 How do you ensure product is held until the required inspections and tests or necessary reports have been received and verified?
- 13 In which documents do you define the inspections and tests required to complete the evidence of conformance with specified requirements?
- 14 How do you ensure that no product is dispatched until all the inspections and tests specified have been satisfactorily completed?
- 15 Which documents record the evidence that product has been inspected and tested and passed or failed defined acceptance criteria?
- 16 How do you ensure that records identify the inspection authority responsible for the release of product?

Do's and don'ts

- ☺ Do attach labels to products on receipt to indicate their inspection status.
- ⊗ Don't mix inspected product with uninspected product.
- ⊗ Don't permit the release of incoming product until it has either passed inspection or a sample has been taken for inspection.
- ☺ Do ensure current purchasing data is available at the place of receipt inspection.
- ⊗ Don't place product back in the receipt inspection area once it has been released.
- ☺ Do keep a register of the articles placed in quarantine.
- ⊗ Don't permit articles to be removed from quarantine without authorization, a record of why they have been removed, and who has removed them.
- ⊗ Don't permit product to skip planned inspections and tests without the prior authorization of the planners.
- ☺ Do re-plan inspection and test in the event of rework, repair, or modification action.
- ⊗ Don't accept product back into the inspection flow without verification that previous inspection stages have not been invalidated.
- ⊗ Don't delegate inspection and test operations to others without confirming that they meet the criteria for trained inspectors and testers.
- ⊗ Don't permit designers to tinker with deliverable product.
- ☺ Do re-validate processes that have been stopped for remedial action before running product.
- ⊗ Don't use gages or other tools for inspection and test purposes unless verified as accurate.
- ⊗ Don't release nonconforming product until remedial action has been authorized and carried out.
- ⊗ Don't permit inspectors to rework product unless they produced it.
- ☺ Do train operators to inspect and test their own work.
- ☺ Do monitor inspection errors, classify them, and act on those which are under your control.
- ☺ Do protect product after inspection operations.
- ☺ Do keep a check on the criteria your inspectors are using to accept product.
- ⊗ Don't assume that a laboratory that is registered to ISO 9002 – whether internal or external – can meet the requirements of ISO/IEC 17025.
- ⊗ Don't apply AQLs to attribute data – set the standard as zero defects.

Chapter 11

Inspection, measuring, and test equipment

Scope of requirements

The integrity of products depends upon the quality of the devices used to create and measure their characteristics. This part of the standard specifies requirements for ensuring the quality of such devices. If the devices you use to create and measure characteristics are inaccurate, unstable, damaged, or in any way defective, the product will not possess the required characteristics and furthermore you will not know it. You know nothing about an object until you can measure it, but you must measure it accurately and precisely. Hence the devices you use need to be controlled.

However, these requirements go further than merely controlling the devices used for measurement. They address the measurements themselves, the selection of the devices for measurement and also apply to devices which create product features, if they are used for product verification purposes. If you rely on jigs, tools, fixtures, templates, patterns, etc. to form shapes or other characteristics and have no other means of verifying the shape achieved, these devices become a means of verification. If you use software to control equipment, simulate the environment or operational conditions, or carry out tests and you rely on that software doing what it is supposed to do, without any separate means of checking the result, the quality of such software becomes critical to product verification. In fact the requirements apply to metrology as a whole rather than being limited to the equipment that is used to obtain the measurement and therefore a more appropriate title of the section would be “Control of measurements”.

Devices that you use for product verification at all stages in the quality loop need to be controlled and this includes devices used for inspection and test on receipt of product, in-process, and final acceptance before release to the customer. It also includes devices used during design and development for determining product characteristics and for design verification. Some characteristics cannot be determined by calculation and need to be derived by experiment. In such cases the accuracy of devices you use must be con-

trolled, otherwise the parameters stated in the resultant product specification may not be achievable when the product reaches production.

Should you not use measuring devices in your organization, these requirements will not apply. If your means of verification are limited to visual inspection or professional judgement, as is the case with organizations that deal only with documentation, you will have no devices to control. However, you may use tools or computer software to assist you to determine conformance and these will need to be proven capable of producing a reliable result.

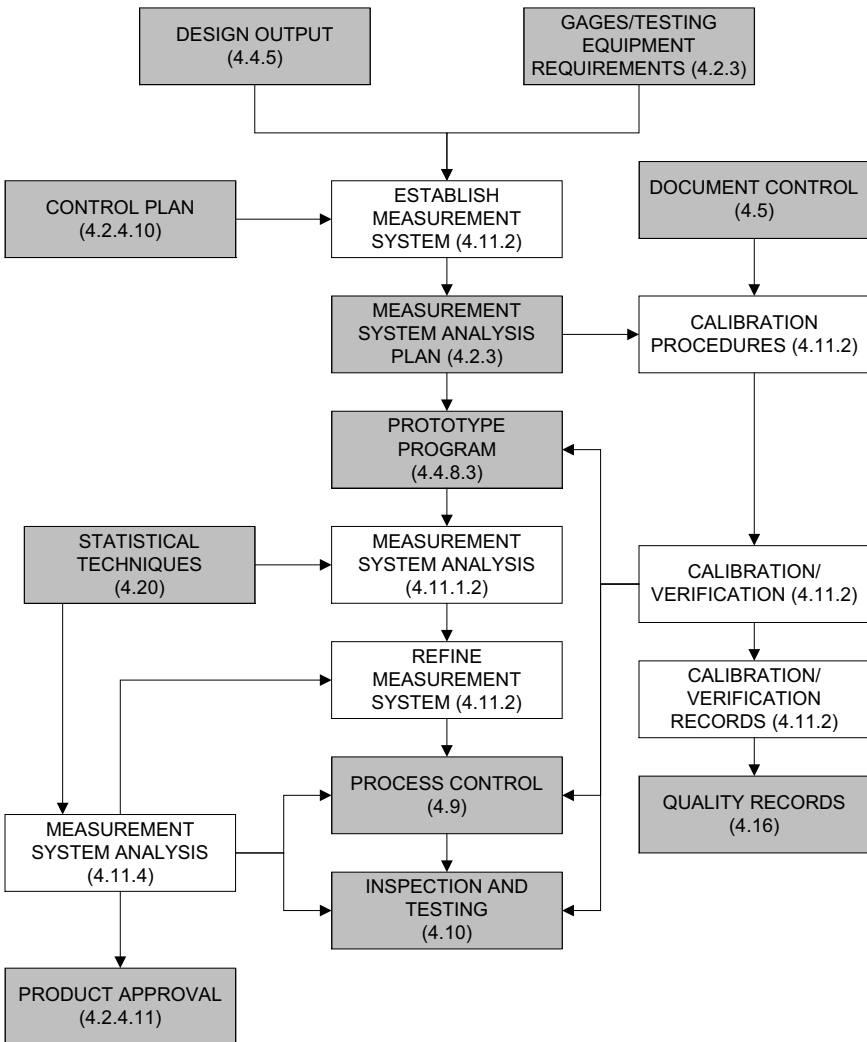


Figure 11.1 Clause relationships with the inspection, measuring, and test equipment element

The standard refers you to ISO 10012 for guidance in meeting these requirements and indeed this standard should be consulted when setting up your measurement system. ISO 10012, however, does not cover all the aspects of element 4.11 of ISO 9001.

The requirements in element 4.11 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 11.1.

Although the concept of a measurement system is not specifically addressed in ISO 9001, the requirements in element 4.11 serve to establish and maintain a measurement system, hence the reason for its inclusion in the model in Figure 11.1.

Inspection, measuring, and test equipment procedures (4.11.1.1)

The standard requires the supplier to *establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring, and test equipment including test software*.

Procedures are required for the control and maintenance of inspection, measuring, and test equipment and to cover test software, not only for calibration. This section of the standard is often referred to as the calibration requirement but it goes far beyond mere calibration. In assessing compliance with section 4.11, there are at least 30 requirements to check (see the questionnaire at the end of this chapter) and calibration is only one of them. Figure 11.2 shows the processes needed to control, calibrate, and maintain inspection, measuring, and test equipment. The shaded boxes indicate interfaces with other processes.

The requirement for procedures does not stipulate that they need to address all 30 requirements of this section of the standard. Procedures are required only for the control, calibration, and maintenance of these devices. The requirements in clause 4.11(a), for instance, requiring you to determine the measurements to be made and the accuracy required, are not requirements concerning the control, calibration, and maintenance of these devices. They are requirements concerning measurement. The procedure requirement only addresses the devices used for measurement and therefore does not apply to software other than software used for measurement.

Whether you have one procedure or twenty to address this requirement you need to cover all types of equipment as well as test software if you use it. Some of the requirements of this section may need to be addressed in procedures developed for other purposes, such as the requirement for determination of measurements.

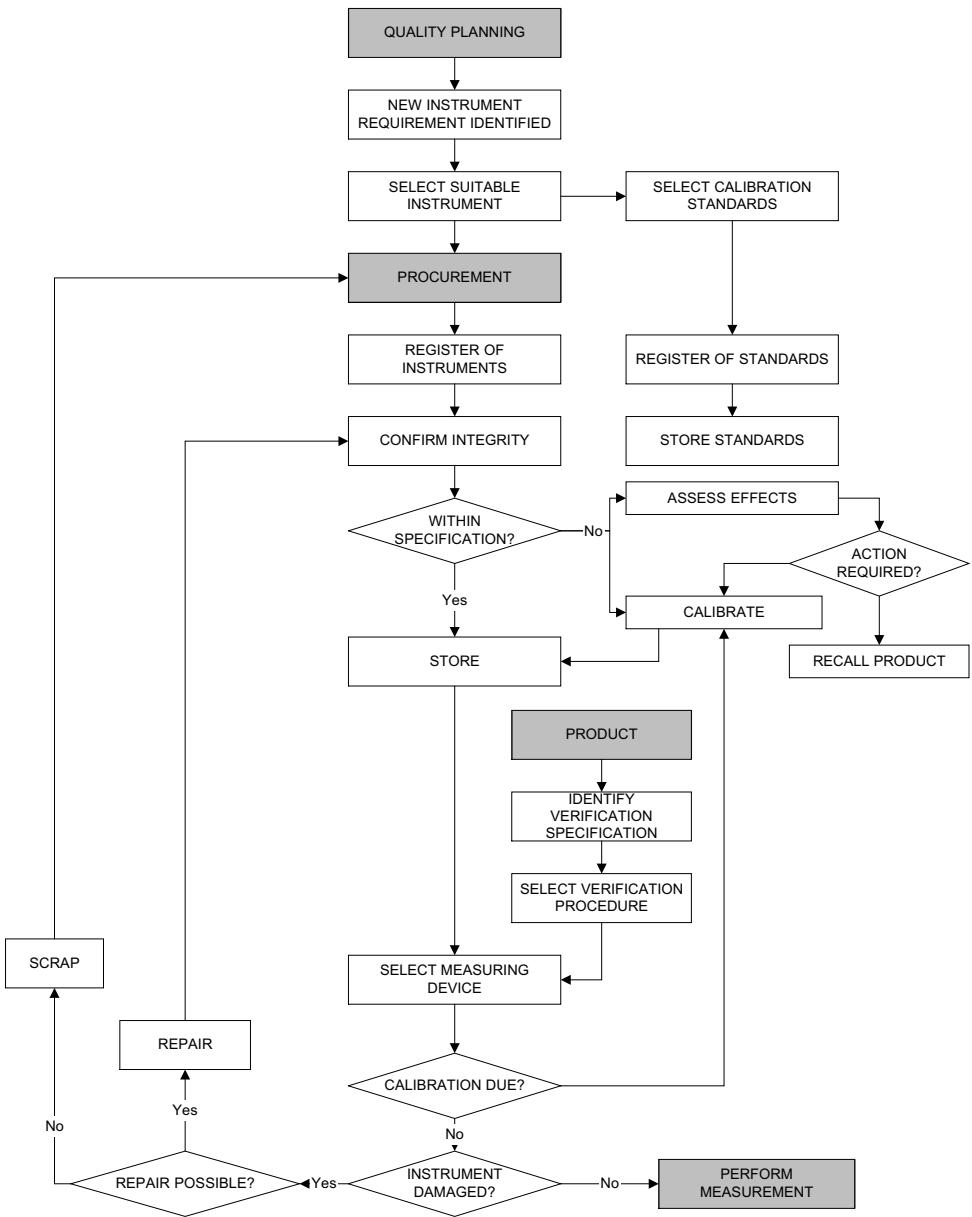


Figure 11.2 Measuring device control process

Procedures for the control, calibration, and maintenance of measuring devices will need to cover the various types of devices you employ for measurement purposes, such as:

- Electronic measuring equipment
- Mechanical measuring devices
- Test software
- Forming tools and equipment

The procedures needed to specifically calibrate and maintain these devices will vary but the procedures you employ to control the use of these devices may be common.

Control of inspection, measuring, and test equipment (4.11.1.1)

The standard requires the supplier to *control inspection, measuring, and test equipment used to demonstrate the conformance of product to the specified requirements.*

Control in this instance can mean several things:

- Knowing what devices are used for product verification purposes so that you can distinguish between controlled and uncontrolled devices – you will need to maintain a list of devices for this purpose.
- Knowing where the equipment is located so that you can recall it for calibration and maintenance – you will need a Recall Notice for this purpose.
- Knowing who the current custodian is so that you have a name to contact.
- Knowing what condition the equipment is in so that you can prohibit its use if the condition is unsatisfactory – you will need a Defect Report for this purpose.
- Knowing when the instrument's accuracy was last checked so that you can have confidence in its results – calibration records and labels fulfill this need.
- Knowing what checks have been made using the instrument since it was last checked, so that you can repeat them should the instrument be subsequently found out of calibration – this is only necessary for instruments whose accuracy drifts over time, i.e. electronic equipment. (It is not normally necessary for mechanical devices. You will need a traceability system for this purpose.)

- Knowing that the measurements made using the instrument are accurate so that you can rely on the results – a valid calibration status label will fulfill this purpose.
- Knowing that the instrument is only being used for measuring the parameters for which it was designed, so that results are reliable and equipment is not abused – the abuse of measuring devices needs to be regulated primarily to protect the device but also, if high pressures and voltages are involved, to protect the person. Specifying the devices to be used for making measurements in your work instructions will serve this purpose.

You may not need to know all these things about every device used for product verification but you should know most of them. This knowledge can be gained by controlling:

- The selection of measuring devices
- The use of measuring devices
- The calibration of measuring devices

You may know where each device is supposed to be, but what do you do if a device is not returned for calibration when due? Your procedures should track returns and make provision for tracking down any maverick devices, since they could be being used on product acceptance.

Calibration of inspection, measuring, and test equipment (4.11.1.1)

The standard requires the supplier to *calibrate inspection, measuring, and test equipment used to demonstrate the conformance of product to the specified requirements.*

Calibration is concerned with determining the values of the errors of a measuring instrument and often involves its adjustment or scale graduation to the required accuracy. You should not assume that just because a device was once accurate it will remain so forever. Some devices, if well treated and retained in a controlled environment, will retain their accuracy for very long periods. Others, if poorly treated and subjected to environmental extremes, will lose their accuracy very quickly. Ideally you should calibrate measuring devices before use in order to prevent an inaccurate device being used in the first place and afterwards to confirm that no changes have occurred during use. However, this is often not practical and so intervals of calibration are established which are set at such periods as will detect any adverse deterioration. These intervals should be varied with the nature of the device, the conditions of use, and the seriousness of the consequences should it produce incorrect results.

It is not necessary to calibrate all test and measuring equipment. Some equipment may be used solely as an indicator, such as a thermometer, a clock, or a tachometer; other equipment may be used for diagnostic purposes, to indicate if a fault exists. If such devices are not used for determining the acceptability of products and services or process parameters, their calibration is not essential. However, you should identify such devices as for “Indication Purposes Only” if their use for measurement is possible. You don’t need to identify all clocks and thermometers fixed to walls unless they are used for measurement. Having observed that you record the time when observations were made, a zealous assessor may suggest that the clock be calibrated. If the time is not critical to product or process acceptability, calibration is unnecessary.

There are two systems used for maintaining the accuracy and integrity of measuring devices: a calibration system and a verification system. The calibration system determines the accuracy of measurement and the verification system determines the integrity of the device. If accuracy is important then the device should be included in the calibration system. If accuracy is not an issue but the device’s form, properties, or function is important then it should be included in the verification system. You need to decide the system in which your devices are to be placed under control and identify them accordingly.

There are two types of devices subject to calibration: those that are adjustable and those that are not. An adjustable device is one where the scale or the mechanism is capable of adjustment (e.g. micrometer, voltmeter, load cell). For non-adjustable devices a record of the errors observed against a known standard can be produced which can be taken into account when using the device (e.g. slip gage, plug gage, surface table, thermometer).

Comparative references are not subject to calibration. They are, however, subject to verification. Such devices are those which have form or function where the criteria is either pass or fail (i.e. there is no room for error) or where the magnitude of the errors does not need to be taken into account during usage. Such devices include software, steel rules/tapes, templates, forming and molding tools. Devices in this category need carry no indication of calibration due date. The devices should carry a reference number and verification records should be maintained showing when the device was last checked. Verification of such devices include checks for damage, loss of components, function, etc. (See later in this chapter.)

Some electronic equipment has self-calibration routines built in to the start-up sequence. This should be taken as an indication of serviceability and not of absolute calibration. The device should still be subject to independent calibration at a defined frequency.

■ Use – not function – determines need for calibration.

Maintenance of inspection, measuring, and test equipment (4.11.1.1)

The standard requires the supplier to *maintain inspection, measuring, and test equipment used to demonstrate the conformance of product to the specified requirements.*

In addition to calibrating the devices, you will need to carry out preventive and corrective maintenance in order to keep them in good condition. Preventive maintenance is maintenance to reduce the probability of failure, such as cleaning, testing, inspecting, replenishment of consumables, etc. Corrective maintenance is concerned with restoring a device (after a failure has occurred) to a condition in which it can perform its required function. These activities may cover a wide range of skills and disciplines depending on the nature of the measuring devices you use. The skills will include software development skills if you use test software, for instance, or electronic engineering if you use electronic equipment. You can of course subcontract the complete task to a specialist who will not only maintain the equipment but, on request, carry out calibration. Take care to confirm that the subcontractor is qualified to perform the calibrations to national standards and to provide a valid certificate of calibration.

Control, calibration, and maintenance of test software (4.11.1.1)

The standard requires the supplier to *control, calibrate, and maintain test software used to demonstrate the conformance of product to the specified requirements.*

This requirement is similar to that stated in clause 4.11.2 of the standard and addressed later in this chapter. The checks and rechecks required to prove that the software is capable of verifying the acceptability of product are a means of calibrating test software. However, test software does not wear or drift with age or use and so cannot be calibrated against a standard traceable to national standards. To control test software you need to consider what it is that you need to control. As a minimum you should control its use, modification, location (in terms of where it is installed), replication, and disposal. Requirements for other controls are covered in clause 4.11.2 of the standard, where they can be applied to test software.

Use is controlled by specifying the software by type designation and version in the development and production test procedures or a register which relates products to the test software which has to be used to verify its acceptability. You should also provide procedures for running the software on the host computer or automatic test equipment. They may of course be menu driven from a display screen and keyboard rather than paper procedures.

Modifications should be controlled in a manner that complies with the requirements of clauses 4.4.9 and 4.5 of the standard (see Part 2 Chapter 4).

The location could be controlled by index, register, inventory, or other such means which enables you to identify on what machines particular versions of the software are installed, where copies and the master tapes or disks are stored.

Replication and disposal could be controlled by secure storage and prior authorization routines where replication and disposal is carried out only by authorized personnel or organizations.

Ensuring measurement uncertainty is known (4.11.1.1)

The standard requires the supplier to *use equipment in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.*

There is uncertainty in all measurement processes. There are uncertainties attributable to the measuring device being used, the person carrying out the measurements and the environment in which the measurements are carried out. When repeated measurements are taken with the same device on the same dimension of the same product and the results vary, this is measurement uncertainty (see also under *Precision and accuracy*). When you make a measurement with a calibrated instrument you need to know the specified limits of permissible error (how close to the true value the measurement is). If you are operating under stable conditions, you can assume that any calibrated device will not exceed the limit of permissible error. Stable conditions exist when all variation is under statistical control. This means that all variation is due to common causes only and none due to special causes. In other cases you will need to estimate the amount of error and take this into account when making your measurements. Test specifications and drawings etc. should specify characteristics in true values, i.e. values that do not take into account any inherent errors. Your test and inspection procedures, however, should specify the characteristics to be measured, taking into account all the errors and uncertainties that are attributable to the equipment, the personnel, and the environment when the measurement system is in statistical control. This can be achieved by tightening the tolerances in order to be confident that the actual dimensions are within the specified limits. This brings us back to the concept of a measurement system, discussed briefly at the beginning of this chapter.

Proving test hardware, comparative references, and test software (4.11.1.1)

Where test software or comparative references such as test hardware are used as suitable forms of inspection, the standard requires that *they be checked to prove that they are capable of verifying the acceptability of product prior to release for use during production, installation, and servicing and shall be rechecked at prescribed intervals*. The standard also requires the supplier to *establish the extent and frequency of such checks and to maintain records as evidence of control*.

Test hardware and software

The requirements for control of test software and hardware and other verification devices should apply not only to production, installation, and servicing but to design, development, and operations. The integrity of these devices is critical to the resultant product, whether it be a deliverable product to a customer or a product being developed or in use. The design of test software and test hardware should be governed by the requirements of clause 4.4 although this is not mandated by the standard; indeed, if these requirements are applied, the design verification requirements should adequately prove that the devices are capable of verifying the acceptability of product. However, the design control requirements may be impractical for many minor verification devices. The hardware which provides the environment for the test software should also be controlled and, while it may not measure any parameters, its malfunction could result in nonconforming product being accepted. Complex hardware of this nature should be governed by the design controls of clause 4.4 if designed in-house as it ensures product quality. If bought out, you should obtain all the necessary manuals for its operation and maintenance and it should be periodically checked to verify it is fully operational.

Jigs, tools, and fixtures

Drawings should be provided for jigs, fixtures, templates, and other hardware devices and they should be verified as conforming to these drawings prior to use. They should also be proven to control the dimensions required by checking the first off to be produced from such devices. Once these devices have been proven they need checking periodically to detect signs of wear or deterioration. The frequency of such checks should be dependent on usage and the environment in which they are used. Tools that form characteristics, such as crimping tools, punches, press tools, etc., should be checked prior to first use to confirm they produce the correct characteristics and then periodically to detect wear and deterioration. Tools that need to maintain certain temperatures, pressures, loads, etc. in order to produce the correct characteristics in materials should be checked to verify that they will operate within the required limits.

Steel rules, tapes, and other indicators of length should be checked periodically for wear and damage and although accuracy of greater than 1mm is not normally expected, the loss of material from the end of a rule may result in inaccuracies that affect product quality.

While you may not rely entirely on these tools to accept product, the periodic calibration or verification of these tools may help prevent unnecessary costs and production delays. While usage and environment may assist in determining the frequency of verification hardware checks, these factors do not affect software. Any bugs in software have always been there or were introduced when it was last modified. Software therefore needs to be checked prior to use and after any modifications have been carried out, so you cannot predetermine the interval of such checks.

Reference materials

Comparative references are devices which are used to verify that an item has the same properties as the reference. They may take the form of materials such as chemicals which are used in spectrographic analyzers or those used in tests for the presence of certain compounds in a mixture or they could be materials with certain finishes, textures, etc. Certificates should be produced and retained for such reference materials so that their validity is known to those who will use them. Materials that degrade over time should be dated and given a “use by” date. Care should be taken to avoid cross contamination and any degradation due to sunlight. A specification for each reference material should be prepared so that its properties can be verified.

Measurement design data

Where and to the extent that the availability of technical data pertaining to the measurement devices is a specified requirement, the standard requires *such data to be made available, when required by the customer or customer’s representative, for verification that it is functionally adequate.*

Where you devise original solutions to the measurement of characteristics the theory and development of the method should be documented and retained as evidence of the validity of the measurement method. Any new measurement methods should be proven by rigorous experiment to detect the measurement uncertainty and cumulative effect of the errors in each measurement process. The samples used for proving the method should also be retained so as to provide a means of repeating the measurements should it prove necessary.

Measurement systems analysis (4.11.1.2)

Conducting statistical studies

The standard requires appropriate statistical studies *to be conducted to analyze the variation present in the results of each type of measuring and test equipment system.*

In ISO 9001 the terms *accuracy* and *precision* are used and these were explained previously. ISO/TS 16949 takes the study of measurement further and divides variation into five classes. Although, ISO/TS 16949 has not deleted the requirement on *measurement uncertainty*, compliance with the measurement systems analysis requirement achieves the same purpose.

A measurement system consists of the *operations* (i.e. the measurement tasks and the environment in which they are carried out), *procedures* (i.e. how the tasks are performed), *devices* (i.e. gages, instruments, software, etc. used to make the measurements), and the *personnel* used to assign a quantity to the characteristics being measured.

Measurement systems must be in statistical control so that all variation is due to common cause and not special cause. ISO/TS 16949 therefore requires that you devise a measurement system for all measurements specified in the control plan in which all variation is in statistical control.

It is often assumed that the measurements taken with a calibrated device are accurate, and indeed they are if we take account of the variation that is present in every measuring system and bring the system under statistical control. Variation in measurement systems arises due to bias, repeatability, reproducibility, stability, and linearity.

- *Bias* is the difference between the observed average of the measurements and the reference value.
- *Repeatability* is the variation in measurements obtained by one appraiser using one measuring device to measure an identical characteristic on the same part.
- *Reproducibility* is the variation in the average of the measurements made by different appraisers using the same measuring instrument when measuring an identical characteristic on the same part.
- *Stability* is the total variation in the measurements obtained with a measurement system on the same part when measuring a single characteristic over a period of time.
- *Linearity* is the difference in the bias values through the expected operating range of the measuring device.

It is only possible to supply parts with identical characteristics if the measurement system as well as the production processes are under statistical control. In an environment in which daily production quantities are in the range of 1,000 to 10,000 units, inaccuracies in the measurement system that go undetected can have a disastrous impact on customer satisfaction and hence profits.

Gage and test equipment requirements are required to be formulated during product design and development and this forms the input data to the process design and development phase. During this phase a measurement system analysis plan is required to accomplish the required analysis. During the product and process validation phase, measurement system evaluation is required to be carried out during or prior to the production trial run and during full production continuous improvement is required to reduce measurement system variation.

Customer reference manuals for MSA

The standard requires *the analytical methods and acceptance criteria used to conform to those in the customer reference manuals.*

In the bibliography to ISO/TS 16949 there is only one customer reference manual mentioned: the *QS-9000 Measurement Systems Analysis Manual*. This provides excellent guidelines for selecting procedures to assess the quality of a measurement system. It includes an introduction to measurement systems, explains the factors that cause variation in a measurement system, has guidance for preparing for a measurement system study, and includes step-by-step procedures for determining the degree of each type of variation present in a measurement system.

For those suppliers not conforming to Ford, General Motors, and Daimler Chrysler requirements, other analytical methods and acceptance criteria may be used if approved by the customer. If you lack any documented methods, the *MSA Reference Manual* is recommended.

Identifying measurements to be made and accuracy required (4.11.2a)

The standard requires the supplier to *determine the measurements to be made and the accuracy required.*

These are the measurements required to carry out product verification rather than the measurements to calibrate a measuring device. The measurements to be made should

be identified in test specifications, process specifications and drawings, etc. but often these documents will not define how to take the measurements. The method of measurement should be defined in test and inspection procedures which, as stated previously, take into account the measurement uncertainty, the devices used to perform the measurements and the environment. The reason for requiring measurements to be identified is so that you have a means of relating the parameter to be measured to the device employed to make the measurement and hence determine whether the device is capable of the required accuracy. There should be a tolerance on all dimensions so as to determine the accuracy required. You may use general tolerances to cover most dimensions and only apply specific tolerances where this is warranted by the application. Although this requirement appears in the standard under *Inspection, measuring, and test equipment*, it is a design process requirement or a quality planning requirement and should be addressed as part of product and process design and preparation for production.

■ **Specifications define which characteristics to measure – procedures define how the characteristics should be measured.**

Selecting appropriate inspection, measuring, and test equipment (4.11.2a)

The standard requires the supplier to *select the appropriate inspection, measuring, and test equipment that is capable of the accuracy and precision necessary.*

There are two categories of equipment which determine the selection of equipment: *general-purpose* and *special-to-type* equipment. It should not be necessary to specify all the general-purpose equipment needed to perform basic measurements, which would be expected to be known by appropriately trained personnel. You should not need to tell an inspector or tester which micrometer, vernier caliper, voltmeter, or oscilloscope to use. These are the tools of the trade and they should select the tool which is capable of measuring the particular parameters with the accuracy and precision required. However, you will need to tell them which device to use if the measurement requires unusual equipment or the environmental conditions prevailing require that only equipment be selected that will operate in such an environment. In such cases the particular devices to be used should be specified in the test or inspection procedures. In order to demonstrate that you selected the appropriate device at some later date, you should consider recording the actual device used in the record of results. With mechanical devices this is not normally necessary because wear should be detected well in advance of there being a problem by periodic calibration.

With electronic devices subject to drift with time or handling, a record of the device used will enable you to identify suspect results in the event of the device being found to be outside the limits at the next calibration. A way of reducing the effect is to select devices that are several orders of magnitude more accurate than needed. (See later under *Action on equipment found out of calibration.*)

Accuracy and precision

Turning now to the requirement for *accuracy and precision*. These are often perceived as synonyms but are quite different concepts. *Accuracy* is the difference between the average of a series of measurements and the true value. *Precision* is the amount of variation around the average. You can have a measuring device which, with repeated measurements, gives a large variation around the true value but where the average is the true value (see Figure 11.3). Alternatively you could have a device which gives small variation with repeated measurements around a value which is wide of the true value. The aim is to obtain both accuracy and precision. The difference in accuracy and precision can cause expensive errors. You should not assume that the result you have obtained is both accurate and precise unless the device has been calibrated immediately prior to use and the results of its accuracy and precision provided. In many cases you can rely on the calibration certificate informing you that the device has been calibrated but sometimes you will need the results of the calibration in order to compensate for the inherent errors.

On occasions you may require a measurement capability that exceeds the known state of the art, such accuracy and precision that no available device can achieve. If under contract to a customer you should inform your customer of this situation so that you can negotiate the measures needed to develop the technology required. (See Part 2 Chapter 2 on *Identifying new measurement capabilities.*)

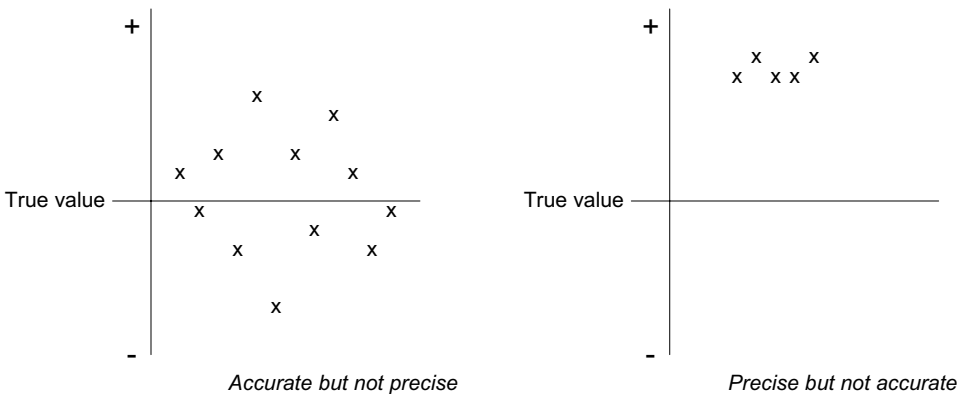


Figure 11.3 Dispersion of measurements relative to the true value

Identifying devices that can affect product quality (4.11.2b)

The standard requires the supplier to *identify all inspection, measuring, and test equipment including measurement devices that can affect product quality.*

Devices that can affect product quality are those which are used:

- To measure product characteristics, such as devices which measure mass, length, or time, or derivatives of these parameters
- To form product characteristics, such as jigs, tools, and fixtures
- To control processes that create product characteristics (such as sensors that indicate temperature, pressure, volume, etc.)

In order to meet this requirement you will either need a register or listing of all devices that can affect product quality or label each device so that those that affect product quality are distinguishable from those that do not. This is not the same as a calibration label, as some devices that affect quality may not require calibration. The means you use should enable anyone to determine whether or not the characteristics of the device should be controlled.

The register or listing should include the following details as appropriate:

- Name of device, type designation, and serial number (in order to distinguish it from others)
- Specification or drawing defining the device (together with its date and issue status as a record of the acceptance criteria)
- Date of manufacture or purchase (to determine its age and origin)
- Name of custodian and the location of the device (in order to trace and resolve problems)
- Date when proven against specification and first off (in order to determine when it was first deemed serviceable)
- Date when re-verification is required
- Details of any modifications and repairs
- Details of any limitations of use
- Details of application if restricted to particular processes, products, ranges, etc.

Calibration operations

Calibrating and adjusting devices against certified equipment (4.11.2b)

The standard requires the supplier to *calibrate and adjust all inspection, measuring, and test equipment including measurement devices at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards.*

Calibration against certified equipment

Calibration has been addressed previously; however, all calibrations should be traceable through an unbroken chain to a national or international measurement standard. If you calibrate your own devices you will need (in addition to the “working standards” that you use for measurement) calibration standards for checking the calibration of the working standards. The calibration standards should also be calibrated periodically against national standards held by your national measurement laboratory. This unbroken chain ensures that there is compatibility between measurements made in different locations using different measuring devices. By maintaining traceability you can rely on obtaining the same result (within the stated limits of accuracy) wherever and whenever you perform the measurement, providing the dimensions you are measuring remain stable. If you calibrate your own standards you should comply with ISO 10012.

The relationship between the various standards is illustrated in Figure 11.4.

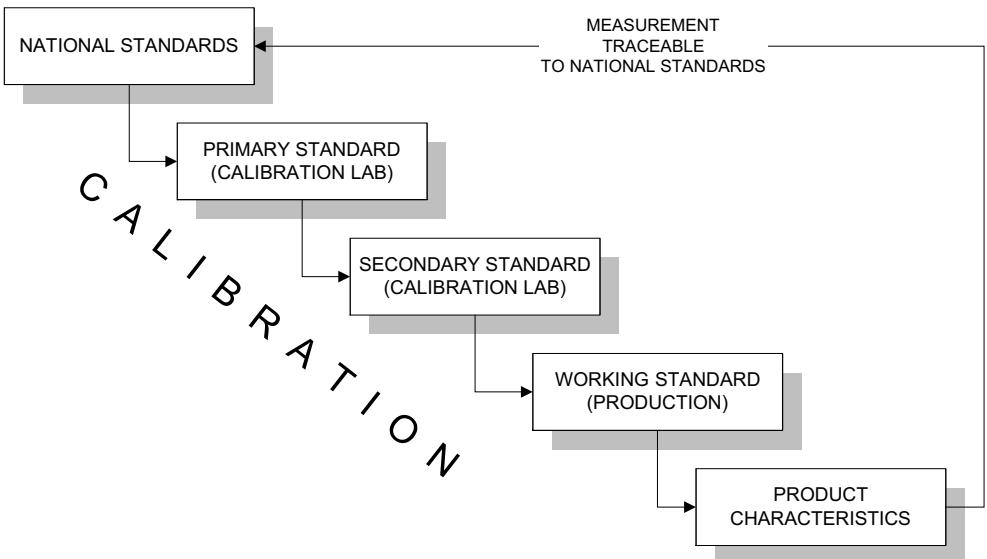


Figure 11.4 Traceability of standards

Adjustment of devices

Regarding the adjustment of measuring devices, adjustment is only possible with devices that have been designed to be adjustable. Mechanical devices are normally adjusted to the null position on calibration. Electronic devices should only be adjusted if found to be outside the limits. If you adjust the device at each calibration you will not be able to observe drift. Adjustments, if made very frequently, may also degrade the instrument. It is best to observe the adage:

■ **If it is well within specification, leave well alone!**

If the observed drift is such that the device may well be outside the specified limits by the next calibration, adjustment will be necessary.

Documenting the basis for calibration (4.11.2b)

The standard requires the supplier to *document the basis used for calibration where no nationally recognized standards exist.*

In some situations there may be no national standard against which to calibrate your devices. Colors and textures are two examples. If you face this situation, you should gather together a group of experts within your company or trade association and establish by investigation, experimentation, and debate what constitutes the standard. Having done this you should document the basis of your decisions and produce a device or number of devices which can be used to compare the product with the standard using visual, quantitative, or other means.

Defining the calibration process (4.11.2c)

The standard requires the supplier to *define the process employed for the calibration of inspection, measuring, and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory.*

The standard requires you to define the calibration process rather than the calibration procedures. Calibration procedures will define how you control all calibration activities. The calibration process required only applies to the process of calibrating a particular device. This does not mean that you need to define the process of calibrating every device. The process of calibration may be:

- Detailed in the device manufacturer's manuals and handbooks
- Detailed in published standards or reference books
- So simple that one would expect it to be known by calibration personnel

Whichever method applies you should define it within your quality system. You should maintain lists of all the devices that require calibration and indicate in these lists:

- The device type, identification number, and serial number
- The calibration method to be used, cross referring to the manuals or individual procedures as appropriate
- The frequency of calibration
- The location of the device

A calibration process may consist of no more than a single data sheet but may also consist of several pages for very complex equipment. Even if you possess all the manufacturers' manuals and these cover calibration, it is still good practice to generate your own data sheet as a means of tailoring the method to your own needs. You may wish to limit adjustments, add checks, provide clearer instructions, or generate your own records and as part of the process the pro forma should be included.

The documents that define the calibration process themselves are "derived" documents and therefore will be governed by your control procedure. They do not need to be listed along with all your other control and operating procedures in the index of quality system documents. A separate index of calibration methods should be maintained. Calibration methods are like test and inspection procedures, they are product specific.

Determining calibration frequency (4.11.2c)

The standard requires *the frequency of checks to be defined* and the supplementary requirements advise that *wear and frequency of use should be taken into account*.

ISO 10012 requires that the integrity of measuring equipment be confirmed at appropriate intervals established on the basis of stability, purpose, and usage. With new equipment it is customary to set the frequency at 12-month intervals unless recommended otherwise by the manufacturer. Often this frequency remains despite evidence during calibration that accuracy and precision is no longer stable. Such action indicates that the calibration staff have not been properly trained or that cost rather than quality

is driving calibration services. Calibrations should be performed prior to any significant change in accuracy that can be anticipated. The results of previous calibrations will indicate the amount of drift; if drift is detected, the intervals of confirmation should be shortened. Conversely, if drift is not detected, the intervals may be lengthened if two previous confirmations indicate such action would not adversely affect confidence in the accuracy of the device. Environment, handling, frequency of use, and wear are factors that can affect the stability of devices; therefore regardless of the calibration results, both previous and future conditions need to be taken into account. In order to demonstrate you have reviewed the results and determined the appropriate calibration frequency, provision should be made on the calibration records for the frequency to be decided at each calibration. Specifying a date is insufficient if the calibration instructions specify a frequency, as it is unreasonable to expect the person subsequently performing calibration to detect whether any change has been made.

Indicating calibration status (4.11.2d)

The standard requires the supplier to *identify inspection, measuring, and test equipment with a suitable indicator or approved identification record to show the calibration status.*

All devices subject to calibration should display an identification label which, either directly or through traceable records, indicates the authority responsible for calibrating the device and the date when the calibration is due. Don't state the actual calibration date because this would be dependent on users having knowledge of the calibration frequency. The standard requires that measuring equipment show its calibration status to any potential user. Measuring instruments too small for calibration status labels showing the due date may be given other types of approved identification. It is not mandatory that users identify the due date solely from the instrument itself but they must be able to determine that the instrument has been calibrated. Serial numbers alone do not do this unless placed within a specially designed label that indicates that the item has been calibrated or you can fix special labels that show a circular calendar marked to show the due date. If you do use serial numbers on special labels then they need to be traceable to calibration records that indicate the calibration due date.

Devices used only for indication purposes or for diagnostic purposes should also display an identity that clearly distinguishes them as not being subject to calibration. If devices are taken out of use for prolonged periods, it may be more practical to cease calibration and provide a means of preventing inadvertent use with labels indicating that the calibration is not being maintained. You may wish to use devices that do not fulfill their specification either because part of the device is unserviceable or because you were unable to perform a full calibration. In such cases, you should provide clear indication to the user of the limitation of such devices.

Maintaining calibration records (4.11.2e and 4.11.3)

The standard requires the supplier to *maintain calibration records for inspection, measuring, and test equipment* and the supplementary requirements specify the content of these records.

Calibration records are records of the calibration activities that have taken place. Records should be maintained not only for proprietary devices but also for devices you have produced and devices owned by customers and employees.

These records should include where appropriate:

- The precise identity of the device being calibrated (type, name, serial number, configuration if it provides for various optional features)
- The name and location of the owner or custodian
- The date calibration was performed
- Reference to the calibration procedure, its number, and issue status
- The condition of the device on receipt
- The results of the calibration in terms of readings before adjustment and readings after adjustment for each designated parameter
- The date fixed for the next calibration
- The permissible limits of error
- The serial numbers of the standards used to calibrate the device
- The environmental conditions prevailing at the time of calibration
- A statement of measurement uncertainty (accuracy and precision)
- Details of any adjustments, servicing, repairs, and modifications carried out
- The name of the person performing the calibration
- Details of any limitation on its use

It is important to record the as received condition in order to determine whether the device was outside the prescribed limits when last used. It also permits trends to be monitored and the degree of drift to be predicted.

The records required are only for formal calibrations and verification and not for instances of self-calibration or zeroing using null adjustment mechanisms. While calibration usually involves some adjustment to the device, non-adjustable devices are often verified rather than calibrated. However, as was discussed previously, it is not strictly correct to regard all calibration as involving some adjustment. Slip gages and surface tables are calibrated but not adjusted. An error record is produced to enable users to determine the uncertainty of measurement in a particular range or location and compensate for the inaccuracies when recording the results.

Calibration records are also required to include notification to the customer if suspect product or material has been shipped.

Action on equipment found out of calibration (4.11.2f)

The standard requires the supplier to *assess and document the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration.*

This is perhaps the most difficult of requirements to meet for some organizations. The standard does not allow any relaxations but clearly it is not always possible or practical to be able to trace product to the particular devices used to determine its acceptability. The requirements apply not only to your working standards but also to your calibration standards. When you send calibration standards away for calibration and they are subsequently found to be inaccurate, you will need a method of tracing the devices they were used to calibrate. If you have a small number of measuring devices and only one or two of each type, it may not be too difficult to determine which products were accepted using a particular device. In large organizations that own many pieces of equipment that are constantly being used in a variety of situations, meeting the requirements can be very difficult. One way is to record the type and serial number of the devices used to conduct a series of inspections and tests but you will also need to record the actual measurements made. Some results may be made in the form of ticks or pass/fail and not by recording actual readings. In these cases you have a problem in determining whether the amount by which the equipment is out of specification would be sufficient to reject the product. In extreme circumstances, if the product is no longer in the factory, this situation could result in your having to recall the product from your customer or distributor.

In order to reduce the effect, you can select measuring devices that are several orders of magnitude more accurate than your needs so that when the devices drift outside the tol-

erances, they are still well within the accuracy you require. There still remains a risk that the device may be wildly inaccurate due to damage or malfunction. In such cases you need to adopt the discipline of re-calibrating devices that have been dropped or are otherwise suspect before further use.

You need to carefully determine your policy in this area paying particular attention to what you are claiming to achieve. You will need a procedure for informing the custodians of unserviceable measuring devices and one for enabling the custodians to track down the products verified using the unserviceable device and assess the magnitude of the problem. You will need a means of ranking problems in order of severity so that you can resolve the minor problems at the working level and ensure that significant problems are brought to the attention of the management for resolution. It would be irresponsible for a junior technician to recall six months' production from customers and distributors based on a report from the calibration laboratory. You need to assess what would have happened if you had used serviceable equipment to carry out the measurements. Would the product have been reworked, repaired, scrapped, or the requirement merely waived. If you suspect previously shipped product to be nonconforming and now you have discovered that the measurements upon which their acceptance was based were inaccurate, you certainly need to notify your customer. In your report to your customer, state the precise amount by which the product is outside specification so that the customer can decide whether to return the product. Remember the product specification is but an interpretation of what constitutes fitness for use. Out of "spec" doesn't mean unsafe, unusable, unsaleable, etc.

Protection of measuring equipment

Ensuring that environmental conditions are suitable (4.11.2g)

The standard requires the supplier to *ensure that the environmental conditions are suitable for the calibration, inspections, measurements, and tests being carried out.*

This requirement hides an important provision. It not only applies to inspection, measuring, and test equipment but to the measurements that are performed with that equipment. Anywhere you intend performing product verification or monitoring processes you need to ensure that the environmental conditions are suitable. By *environmental conditions* is meant the temperature, pressure, humidity, vibration, lighting, cleanliness, dust, acoustic noise, etc. of the area in which such measurements are carried out. To avoid having to specify the conditions each time, you need to establish the ambient conditions and write this into your procedures. If anything other than ambient conditions prevail, you may need to assess whether the measuring devices will perform adequately in these conditions. If you need to discriminate between types of equipment, the ones most suitable should be specified in the verification procedures.

If you cannot select suitable equipment for your current environment, you may need to control the environment in order to carry out the measurements. In such areas the environmental factors important to maintaining stable measurement should be monitored and the monitoring equipment calibrated. Chart recorders enable you to monitor conditions without having to be in constant attendance. The environment should be controlled in areas where calibration is carried out in order to provide stable conditions in which accurate and precise measurement can be taken. However, some modern equipment is so stable that environmental controls are unnecessary except in special circumstances.

Ensuring that accuracy and fitness for use is maintained (4.11.2h)

The standard requires the supplier to *ensure that the handling, preservation, and storage of inspection, measuring, and test equipment is such that the accuracy and fitness for use is maintained.*

When not in use, measuring devices should always be stored in the special containers provided by the manufacturer. Handling instructions should be provided with the storage case where instruments may be fragile or prone to inadvertent damage by careless handling. Instruments prone to surface deterioration during use and exposure to the atmosphere should be protected and moisture-absorbent or resistant materials used. When transporting measuring equipment you should provide adequate protection. Should you employ itinerant service engineers, ensure that the instruments that they carry with them are adequately protected as well as being calibrated (see Part 2 Chapter 5 for further details on handling, storage, and preservation).

Safeguarding inspection, measuring, and test equipment (4.11.2i)

The standard requires the supplier to *safeguard inspection, measuring, and test facilities including both test hardware and test software from adjustments which would invalidate the calibration setting.*

The purpose of this requirement is to ensure that the integrity of the measurements is maintained by precluding errors that can occur if measuring equipment is tampered with.

Unlike the other requirements, which only referred to inspection, test, and measuring equipment, this clause adds test facilities. Facilities include the equipment and the area or room in which it is kept or used. Test facilities are any room, area, or complex in which tests are carried out. Inspection, measuring, and test facilities include functional and environmental test laboratories, test and inspection chambers, calibration rooms,

clean rooms, computer rooms, and any area where tests are being conducted either with staff in attendance, remotely, or with staff paying monitoring visits. To safeguard against deliberate or inadvertent adjustments, these areas should be restricted to authorized personnel. They should be locked when no one is in attendance and the key in the custody of an authorized person or in a secure safe. You will also need some form of security to prevent calibration standards being inadvertently used as working standards.

To safeguard against any deliberate or inadvertent adjustment to measuring devices, seals should be applied to the adjustable parts or, where appropriate, to the fixings securing the container. The seals should be designed so that tampering will destroy them. Such safeguards may not be necessary for all devices. Certain devices are designed to be adjusted by the user without needing external reference standards, for example zero adjustments on micrometers. If the container can be sealed, you don't need to protect all the adjustable parts inside.

Your procedures need to specify:

- Which verification areas have restricted access and how you control access
- The methods used for applying integrity seals to equipment
- Who is authorized to apply and break the seals
- The action to be taken if the seals are found to be broken either during use or during calibration

Task list

- 1 Produce and maintain a list of the devices that will be used for measuring product and process characteristics.
- 2 Produce and maintain a list of all tools, jigs, fixtures, etc. that will be used as a means of inspection.
- 3 Produce a list of the software that will be used to verify product or process characteristics and to control equipment that is used to verify product and process characteristics.
- 4 Provide recall notices to recall devices requiring calibration.
- 5 Provide defect reports for reporting details of unserviceable equipment.

- 6 Provide labels for fixing to devices in order to denote their calibration status.
- 7 Provide facilities for the storage of calibration records.
- 8 Prepare procedures for controlling the use of measuring devices.
- 9 Prepare procedures for controlling the calibration of measuring devices.
- 10 Prepare procedures controlling the development and maintenance of software used in measurement systems.
- 11 Provide a calibration laboratory or select an approved laboratory to calibrate your measurement devices.
- 12 Arrange for the calibration of your calibration standards.
- 13 Prepare calibration procedures or data sheets for each measuring device.
- 14 Process all measuring devices through your established calibration system.
- 15 Ensure your test and inspection procedures identify the measurements to be made and the accuracy required.
- 16 Provide containers for transportation of measuring devices.
- 17 Provide procedures for tracing product verified with equipment and standards found out of calibration.
- 18 Validate software used for measurement purposes or for driving measuring equipment.
- 19 Make provision for recording the identity of devices used in product/process verification.
- 20 Provide specification and drawings for all jigs, tools, gages, etc. used for measurement purposes.
- 21 Establish a register of all reference materials used to judge characteristics of samples.
- 22 Provide specifications and validation certificates for reference materials.
- 23 Provide secure storage for reference materials and avoid cross contamination and degradation.
- 24 Perform measurement system studies on each measurement system and bring the system under statistical control.

Inspection, measuring, and test equipment questionnaire

- 1 How do you control devices used to demonstrate conformance of product with specified requirements?
- 2 How do you calibrate devices used to demonstrate conformance of product with specified requirements?
- 3 How do you maintain devices used to demonstrate conformance of product with specified requirements?
- 4 What documented procedures have you established to control, calibrate, and maintain inspection, measuring, and test equipment?
- 5 What documented procedures have you established to control and maintain comparative references?
- 6 What documented procedures have you established to control, validate, and maintain test software?
- 7 How do you ensure that measurement uncertainty is known and consistent with the required measurement capability?
- 8 How do you ensure that devices used as suitable forms of inspection are proven capable of verifying the acceptability of product prior to their use for production, installation, or servicing?
- 9 How do you ensure that such devices remain capable of verifying the acceptability of product?
- 10 What records are kept to demonstrate you have control over test software?
- 11 What records are kept to demonstrate you have control over comparative references?
- 12 In which documents do you define your measurement design data?
- 13 How do you determine the measurements to be made and the accuracy required to demonstrate conformance of product to specified requirements?
- 14 How do you ensure that appropriate inspection, measuring, and test equipment is selected?
- 15 How do you ensure that inspection, measuring, and test equipment is capable of the accuracy and precision necessary?

- 16 How do you ensure all calibrated inspection, measuring, and test equipment has a known valid relationship to nationally recognized standards?
- 17 How do you identify whether an item of inspection, measuring, and test equipment can affect product quality?
- 18 How do you ensure that all inspection, measuring, and test equipment that can affect product quality is calibrated at prescribed intervals or prior to use?
- 19 How do you ensure that devices are adjusted when they have drifted outside the specified limits?
- 20 In what documents is the process employed for the calibration of inspection, measuring, and test equipment defined?
- 21 In what documents do you record the basis used for calibration where no nationally recognized standards exist?
- 22 What action is taken with previous verification results when devices are found to be out of calibration?
- 23 What means do you use to identify the calibration status of inspection, measuring, and test equipment?
- 24 What documents record the calibration of inspection, measuring, and test equipment?
- 25 How do you ensure that environmental conditions are suitable for the calibrations being carried out?
- 26 How do you ensure that environmental conditions are suitable for the inspections, measurements, and tests being carried out?
- 27 How do you maintain the accuracy and fitness for use of inspection, measuring, and test equipment during handling and storage?
- 28 How do you safeguard inspection, measuring, and test equipment from adjustments that would invalidate the calibration setting?
- 29 How do you safeguard test facilities from adjustments that would invalidate the calibration setting?
- 30 How do you safeguard test software from adjustments that would invalidate the calibration setting?

Do's and don'ts

- ⊗ Don't bring devices under control of the measurement system if they are not used in performing measurements.
- ☺ Do fix labels to all devices that have been designed for inspection purposes and indicate their calibration status.
- ☺ Do calibrate personal tools if they are to be used for making acceptance decisions.
- ☺ Do take account of measurement uncertainty in determining the acceptability of product.
- ☺ Do vary the intervals of calibration with the proven stability of the device.
- ☺ Do require external calibration laboratories to provide calibration certificates and results.
- ⊗ Don't use calibration labels that will not retain their markings in the equipment's operating environment.
- ☺ Do provide set-up instructions and diagrams for making special measurements.
- ☺ Do calibrate working standards against calibration standards that have at least an order of accuracy greater than the working standards.
- ⊗ Don't continue using measuring equipment that has sustained damage even if it appears to have had no effect.
- ☺ Do verify that your subcontractors have an adequate calibration system.
- ⊗ Don't calibrate test devices in the same environment as they will be used unless you compensate for the environmental effects on measurement accuracy.
- ☺ Do retain calibration records for periods that match the period from manufacture to end of warranty or longer.
- ☺ Do keep calibration records in secure areas.
- ☺ Do display notices in calibration rooms and test laboratories etc. to warn of prohibited access to unauthorized persons.
- ⊗ Don't leave the doors of calibration and test rooms open when vacated.
- ⊗ Don't purchase any second-hand measuring equipment without the original manual.
- ⊗ Don't permit measuring equipment to collect on the floor while waiting calibration.

Chapter 12

Inspection and test status

Scope of requirements

The requirements for inspection and test status are identification requirements that enable conforming product to be distinguishable from nonconforming product. Another term would be *verification status* because means other than inspection and test may be used to determine whether an item conforms with a requirement. The requirements mainly apply to manufactured product but can equally apply to software and to deliverable documentation. They also apply to services which involve a product such as maintenance, transport, computing, etc. but it is difficult to apply the requirements to services such as teaching, consultancy, accounting, etc. Conforming services can only be combined with nonconforming services if they remain accessible to the user. If services are found nonconforming they are usually stopped and measures put in place to prevent their use until corrected.

The requirements in element 4.12 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 12.1.

Identifying inspection and test status

The standard requires the supplier to *identify the inspection and test status of product by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed.*

Inspection and test status is either “reject” or “accept”. There are no gray areas. If not fully conforming the product should be rejected and identified as such. If conforming the product should be accepted and identified as such. If a nonconforming product is later deemed acceptable, the identification should be changed but this can lead to problems.

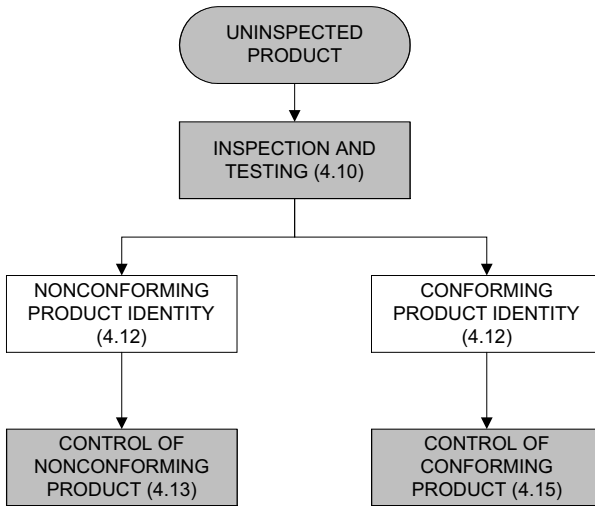


Figure 12.1 *Clause relationships with the inspection and test status element*

If the rejection was for cosmetic reasons, there is no problem but if the rejection was an out-of-tolerance condition the product should either be reworked, repaired, or regraded because the original decision may not be acceptable to all customers. If you do not do these things, the internal concessions should be carried through to the final inspection label, so that if a customer requires products to a particular specification you can check whether the out-of-tolerance condition will be acceptable.

You are only required to indicate whether product conforms to the inspections and tests performed. This is not the same as indicating whether the product conforms to the customer requirements. It may well pass the prescribed inspections and tests but these inspections and tests may not be sufficiently comprehensive to verify conformance to all the customer's requirements. However, the only indication you can give is the product's conformance or nonconformance with some verification requirement. It follows therefore that you should not go around putting reject labels on products, or acceptance labels for that matter, if you have not performed a specific inspection to determine conformance. There are only three conditions: "uninspected", "inspected and found conforming", and "inspected and found nonconforming". If you have a policy of only applying labels after inspection, anything without a label is therefore deemed uninspected, unless it has been installed and the label removed.

Identifying inspection and test status is not just a matter of tying a label on a product. The status should be denoted by an authorized signature, stamp, mark, or other identity which is applied by the person making the accept/reject decision and which is secure

from misuse. Signatures are acceptable as a means of denoting verification status on paper records but are not suitable for computerized records. Secure passwords and “write-only” protection has to be provided to specific individuals. Signatures in a workshop environment are susceptible to deterioration and illegibility, which is why numbered inspection stamps with unique markings have evolved. The ink used has to survive the environment and if the labels are to be attached to the product for life, it is more usual to apply an imprint stamp on soft metal or a bar code.

The method of identification depends upon the type, size, quantity, or fragility of the product. You can mark the product directly (provided the item is not an “appearance item”) or tie a label to it or the container in which it is placed. You can also use records remote from the product providing they bear a unique identity that is traceable to the product.

Marking products has its limitations as it may damage the product, be removed, or deteriorate during subsequent processing. If applied directly to the product, the location and nature of identification should be specified in the product drawings or referenced process specifications. If applied to labels which themselves are permanently secured to the product, the identification needs to be visible when the product is installed so as to facilitate checks without its removal.

Small and fragile products should be held in containers and the container sealed and marked with the inspection status. Large products should either carry a label or have a related inspection record.

In some situations the location of a product can constitute adequate identification of inspection status. However, these locations need to be designated as “Awaiting Inspection”, “Accepted Product”, or “Reject Product” or other such labels as appropriate to avoid the inadvertent placement of items in the wrong location. The location of product in the normal production flow is not a suitable designation unless an automated transfer route is provided.

When a service is out of service, tell your customers. Services which rely on products should carry a label or a notice when accessed. A bank cash machine is one example where a notice is displayed when the machine is out of service. In some cases customers may need to be informed by letter or telephone.

With software the verification status can be denoted in the software as a comment or on records testifying its conformance with requirements.

With documentation you can denote verification status either by an approval signature on the document or by a reference number, date, and issue status which is traceable to records containing the approval signatures.

Maintaining inspection and test status

The standard requires the supplier to *maintain the identification of inspection and test status of the product, as defined in the quality plan and/or documented procedures throughout production, installation, and servicing to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used, or installed.*

Maintaining inspection and test status means retaining the status markings once they have been affixed or recorded until your responsibility for the product ceases. Labels should be attached in a way that prevents their detachment during handling. If labels need to be removed during further processing, the details should be transferred to inspection records so that at a later date the status of the components in an assembly can be checked through the records. At dispatch, the inspection status of product should be visible. Any product without inspection status identification should be quarantined until re-inspected and found conforming.

It should be possible when walking through a machine shop, for example, to identify which products are awaiting inspection, which have been inspected and found conforming, and which have been rejected. If, by chance, some product were to become separated from its parent batch, it should still be possible to return the product to the location from whence it came. A machine shop is where this type of identification is essential – it is where mix-ups can occur. In other places, where mix-ups are unlikely, inspection and test identification does not need to be so explicit.

Not all product intended for delivery may in fact have passed the required inspections and tests as the customer may have waived some of the requirements for that particular delivery. Hence the reference to release under an authorized concession. Identifying product correctly will help preclude any unidentified or nonconforming product from being delivered, used, or installed. However, the only way to make certain is to remove them from areas where they may be inadvertently dispatched, used, or installed.

Inspection and test status procedures

The standard doesn't require a procedure covering inspection and test status; however, as clause 4.2 requires a documented quality system, you will need to document the methods employed to denote inspection and test status. If you use stamps you will need a register to allocate stamps to particular individuals and to indicate which stamps have been withdrawn. When a person hands in a stamp it is good practice to avoid using the same number for 12 months or so to prevent mistaken identity in any subsequent investigations.

Task list

- 1 Document the methods you employ to denote inspection and test status for hardware, software, documents, and services.
- 2 Specify the status identification methods to be used in product drawings and specifications.
- 3 Provide separate designated areas for holding product awaiting inspection, passed inspection, and failed inspection.
- 4 Label these areas to prevent inadvertent misplacement of product.
- 5 Maintain registers of inspection stamp holders.

Inspection and test status questionnaire

- 1 How do you identify product in a way that indicates its conformance or nonconformance with regard to inspections and tests performed?
- 2 How do you ensure the identification of inspection and test status is maintained throughout production and installation?

Do's and don'ts

- ⊗ Don't re-assign inspection stamps to another individual until a reasonable period of time has elapsed.
- ☺ Do secure stamps from unauthorized use.
- ⊗ Don't leave stamps unattended.
- ⊗ Don't lend your stamp to another person.
- ⊗ Don't stamp anything unless you have personally inspected the item.
- ⊗ Don't stamp any document unless there is a proper location to place the stamp because it could mean anything – a stamp has to indicate that the specified requirements have been met.

Chapter 13

Control of nonconforming product

Scope of requirements

The definition of nonconformity in ISO 8402 states that it is the nonfulfillment of specified requirements; therefore a nonconforming product is one that does not conform to the specified requirements. Specified requirements are either requirements prescribed by the customer and agreed by the supplier in a contract for products or services, or are requirements prescribed by the supplier which are perceived as satisfying a market need. This limits the term *nonconformity* to situations where you have failed to meet customer requirements. However, ISO 8402:1987 suggests that nonconformity also applies to the absence of one or more quality system elements, but clearly the requirements of clause 4.13 cannot be applied to nonconformity with *quality system requirements*. Both ISO 9001 and ISO 9004 only address nonconformity in the context of products, processes, and services and when addressing quality system elements the term *deficiencies* is used. Some auditors use the term *nonconformity* to describe a departure from the requirements of ISO 9001 but it would be preferable if they chose the term *noncompliance* to avoid any confusion. The requirements of clause 4.13 therefore only apply to products, processes, and services and not to activities, quality system elements, or procedures.

The standard does not make it clear whether these requirements apply to nonconformities detected while the supplier is responsible for the product or after the supplier's responsibility ceases, as is the case with nonconformity reports received from customers. Reports of nonconformities are also addressed under Corrective Action in clause 4.14 but it is assumed that in this case the standard is concerned with external reports of nonconformities.

There will also be cases where you fully satisfy the specified requirements but the product is unfit for use because of omissions in the specified requirements. ISO 8402 states that the nonfulfillment of intended usage requirement is a defect. ISO 9000 does not address the subject of defects because it assumes that a product which meets the speci-

fied requirements must meet intended usage requirements. However, a product may fail to meet the specified requirements and still be fit for use. The definition of quality complicates the issue even more. ISO 9000 requires that you meet specified requirements, it does not require that you produce products which satisfy stated or implied needs, or satisfy intended usage requirements or meet customer expectation. In practice, however, you should produce products and services which:

- Satisfy the specified requirements
- Satisfy intended usage requirements
- Satisfy stated or implied needs
- Satisfy your own requirements
- Satisfy customer expectations

All these may be in harmony but there may be occasions when there is conflict. To avoid any confusion you should classify all failures to meet these four requirements as non-conformities and then assign classification so as to treat each according to its merits.

The requirements in element 4.13 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 13.1.

The standard indicates that these requirements are to apply to product that is suspected of being nonconforming – which might be the case with a batch of product that has failed the sampling inspection. Only the samples checked are definitely nonconforming – the others in the batch are only suspected as being nonconforming. You should therefore look further than the product that has been found to be nonconforming and seek out other products which may possess the same characteristics as those found to be nonconforming. These other products may have already been released to customers. This latter situation can arise if you discover the measuring or processing equipment to be inaccurate or malfunctioning. Any product that has passed through that process since it was last confirmed as serviceable is now suspect. This aspect is also covered in clause 4.11.2(f). Seeking suspect product should also be a factor to be considered when determining corrective action (see Part 2 Chapter 14).

Another example of suspect product is when product is mishandled but shows no obvious signs of damage. This may arise when product is dropped or not handled in the stipulated clean conditions or in accordance with electrostatic safe-handling procedures.

Suspect product should be treated in the same manner as nonconforming product and quarantined until dispositioned. However, until a nonconformity can be proven, the documentation of the nonconformity merely reveals the reason for the product being suspect.

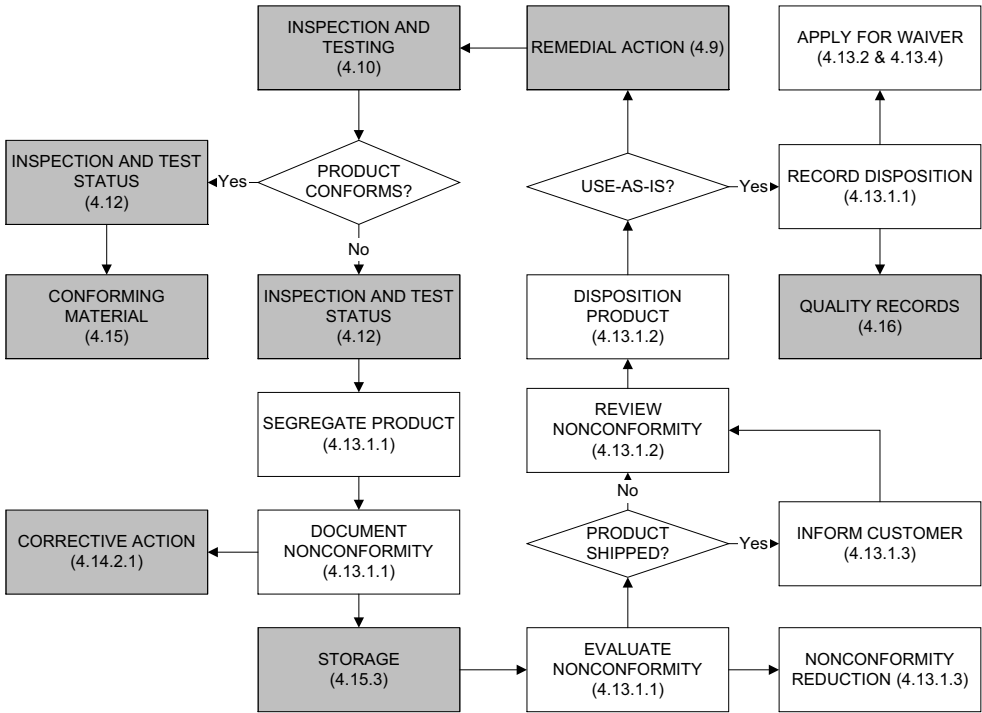


Figure 13.1 Clause relationships with the control of nonconforming product element

Classifying nonconformities

Although the standard does not recognize any classification of nonconformities, the practical application of nonconformity controls requires controls to be balanced with the severity of the nonconformity. It is not necessary to seek concessions from a customer against requirements that have not been specified, or seek design authority approval for workmanship imperfections. The definition of the term *defect* in ISO 8402, and the fact that there are many requirements other than those specified in a contract or needed to satisfy market needs, demands that it is sensible to classify nonconformities into three categories:

- **Critical Nonconformity:** a departure from the specified requirements which renders the product or service unfit for use
- **Major Nonconformity:** a departure from the specified requirements included in the contract or market specification
- **Minor Nonconformity:** a departure from the supplier's requirements not included in the contract or market specification

Note that these are not the same as the nonconformity classifications used in assessing quality systems; see Part 1 Chapter 5.

Ensuring that nonconforming product is not used (4.13.1.1)

The standard requires the supplier to *establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from inadvertent use or installation.*

A nonconformity exists only when product has been inspected against an acceptance standard and found not to comply. Prior to this the product is either serviceable or unserviceable. Unserviceable products are not necessarily nonconforming – they may simply lack lubrication or calibration. A piece of test equipment, the calibration date of which has expired, is not nonconforming – it is merely unserviceable. When checked against a standard it may be found to be out of calibration and it is then nonconforming, but it could be found to be within the specified calibration *limits*.

The only sure way of preventing inadvertent use of nonconforming product is to destroy it, but that may be a little drastic in some cases. It may be possible to eliminate the nonconformity by repair, completion of processing, or rework. A more practical way of preventing the inadvertent use or installation of nonconforming or unserviceable products is to identify the product as *nonconforming* or *unserviceable* and place in an area where access to it is controlled. These two aspects are covered further below.

Identifying nonconforming product (4.13.1.1 and 4.13.1.2)

The standard requires the supplier to *provide for the identification of nonconforming product* and that *this identification be visual.*

The most common method is to apply labels to the product that are distinguishable from other labels. It is preferable to use red labels for nonconforming and unserviceable items and green labels for conforming and serviceable items. In this way you can determine product status at a distance and reduce the chance of confusion. You can use segregation as a means of identifying nonconforming product but if there is the possibility of mixing or confusion, this means alone should not be used.

On the labels themselves you should identify the product by name and reference number, specification and issue status if necessary and either a statement of the nonconformity or a reference to the service or nonconformity report containing full

details of its condition. Finally the person or organization testifying the nonconformity should be identified either by name or inspection stamp.

Unlike products, nonconforming services are usually rendered unavailable for use by notices such as “Out of Order” or by announcements such as “Normal service will be resumed as soon as possible”. Products are often capable of operation with nonconformities whereas services tend to be withdrawn once the nonconformity has been detected, however trivial the fault.

Documenting nonconforming product (4.13.1.1)

The standard requires the supplier to *provide for the documentation of nonconforming product*.

There are several ways in which you can document the presence of a nonconformity. You can record the condition:

- On a label attached to the item
- On a form unique to the item, such as a nonconformity report
- Of functional failures on a failure report and physical errors on a defect report
- In a log book for the item, such as an inspection history record or snag sheet
- In a log book for the workshop or area, such as a process log

The detail you record depends upon the severity of the nonconformity and to whom it needs to be communicated. In some cases a patrol inspector or quality engineer can deal with minor snags on a daily basis, as can an itinerant designer. Where the problem is severe and remedial action complicated, a panel of experts may need to meet. Rather than gather around the nonconforming item, it may be more practical to document the remedial action on a form. In some cases the details may need to be conveyed to the customer off-site and in such cases a log book or label would be inappropriate. It is important when documenting the nonconformity that you record as many details as you can because they may be valuable to any subsequent investigation in order to prevent its recurrence. In addition to the product name, reference number, serial number, and specification issue, you may need to record the operating conditions, temperature, humidity, time of day, identification of inspection and test equipment used, and any other details that may help diagnose the cause.

Evaluation of nonconforming product (4.13.1.1)

The standard requires the supplier to *provide for the evaluation of nonconforming product*.

Evaluating nonconforming product is a process of determining the effects of the nonconformity, classifying it as to its severity, and providing information of use to those who will decide what to do about it. Establishing the cause of the nonconformity so as to avoid making further nonconforming product is dealt with under *Corrective action*; however, with new products the remedial action may well take the form of a redesign which will not only eliminate the nonconformity but prevent it from recurring with that particular product. Of course, it may not prevent it from recurring with other designs; that is the purpose of preventive action (see Part 2 Chapter 14).

Segregation of nonconforming product (4.13.1.1 and 4.13.1.2)

The standard requires the supplier to *provide for the segregation (when practical) of nonconforming product* and that *quarantine areas have visual identification*.

Segregating a nonconforming product (or separating good from bad) places it in an area with restricted access. Such areas are called *quarantine areas*. Products should remain in quarantine until disposal instructions have been issued. The area should be clearly marked and a register maintained of all items that enter and exit the area. Without a register you won't be able to account for the items in the area, check whether any are missing, or track their movements. The quarantine store may be contained within another area, providing there is adequate separation that prevents mixing of conforming and nonconforming articles. Where items are too large to be moved into a quarantine area, measures should be taken to signal to others that the item is not available for use and this can be achieved by cordons or floor markings. With services the simplest method is to render the service unavailable or inaccessible.

Disposition of nonconforming product (4.13.1.1)

The standard requires the supplier to *provide for the disposition of nonconforming product and for notification to the functions concerned*.

Disposition means to dispose of or decide what to do with the nonconforming item: whether to use it, repair it, scrap it, etc. The options available are discussed later. By providing for the disposition of product you need to determine the action to take and notify

those who are to carry it out. You cannot merely accumulate nonconforming items in a quarantine area. Apart from anything else they occupy valuable space and could present a hazard as they deteriorate. To implement this requirement you will need a form or other such document in which to record the decision and to assign the responsibility for the remedial action.

Nonconformity reduction plan

The standard requires suppliers to *quantify, analyze, and reduce all nonconforming product by establishing a corrective action plan and tracking progress.*

Element 4.13 of ISO 9001 deals with specific nonconformities and element 4.14 deals with the action to eliminate their cause and prevent their recurrence. This additional ISO/TS 16949 requirement does seem to duplicate what is covered in clause 4.14.2. However, it does add a significant aspect – a reduction plan. One could be complying with elements 4.13 and 4.14 of ISO 9001 but have no reduction plan, since element 4.14 does not impose any time constraints on corrective action or require the incidence of nonconformity to be reduced. It is quite possible to take corrective action continuously and still not reduce the number of nonconformities. The requirement may be in the wrong place (i.e. in 4.13 rather than 4.14) but it is a useful addition nonetheless.

The nonconformity data should be collected and quantified using one of the seven quality tools (see Part 2 Chapter 14), preferably the Pareto analysis. You can then devise a plan to reduce the 20% of causes that account for 80% of the nonconformities. However, take care not to degrade other processes by your actions (see *Theory of constraints* in Part 2 Chapter 2). The plan should detail the action to be taken to eliminate the cause and the date by which a specified reduction is to be achieved. You should also monitor the reduction. The appropriate data collection measures therefore need to be in place to gather the data at a rate commensurate with the production schedule. Monthly analysis may be too infrequent; analysis by shift may be more appropriate.

Defining disposition responsibility (4.13.2)

The standard requires the supplier to *define the responsibility for review and authority for the disposition of nonconforming product.*

The decision on product acceptance is a relatively simple one because there is a specification against which to judge conformance. When product is found to be nonconforming there are three decisions you need to make based on the following questions:

- Can the product be made to conform?
- If the product cannot be made to conform, is it fit for use?
- If the product is not fit for use, can it be made fit for use?

The authority for making these decisions will vary depending on the answer to the first question. If, regardless of the severity of the nonconformity, the product can be made to conform simply by rework or completing operations, these decisions can be taken by operators or inspectors, providing rework is economical. Decisions on scrap, rework, and completion would be made by the fund-providing authority rather than the design authority. If the product cannot be made to conform by using existing specifications, decisions requiring a change or a waiver of a specification should be made by the authority responsible for drawing up or selecting the specification.

It may be sensible to engage investigators or quality engineers to review the options to be considered and propose remedial actions for the authorities to consider. In your procedures or the quality plan you should identify the various bodies that need to be consulted for each type of specification. Departures from customer requirements will require customer approval; departures from design requirements will require design approval; departures from process requirements will require process engineering approval, etc. The key lies in identifying who devised or selected the requirement in the first place. All specifications are but a substitute for knowledge of fitness for use – any departure from such specification must be referred back to the specification authors for a judgement.

Review of nonconforming product (4.13.2, 4.13.3, and 4.15.3.2)

The standard requires the supplier to *review nonconforming product in accordance with documented procedures* and advises that *it may be:*

- a) Reworked to meet the specified requirements, or*
- b) Accepted with or without repair by concession, or*
- c) Regraded for alternative applications, or*
- d) Rejected or scrapped.*

There is also a supplementary requirement in clause 4.15.3.2 that requires obsolete product to be controlled in a similar manner to nonconforming product. This requires

that you identify obsolete product and pass it through your nonconforming product process for appropriate disposition.

Several terms here may need explanation as they are unusual outside manufacturing industry.

Rework means the continuation of processing that will make an item conform to specification. Rework requires only normal operations to complete the item and does not require any additional instructions. Rework when applied to documents means correcting errors without changing the original requirement.

If you choose to accept a nonconforming item as is without rework, repair, etc., you are in effect granting a *concession* or waiving the requirement *only* for that particular item. If the requirements cannot be achieved at all, this is not a situation for a concession but a case for a change in requirement. If you know in advance of producing the product or service that it will not conform with the requirements, you can then request a deviation from the requirements. This is often referred to as a *production permit*. Concessions apply *after* the product has been produced, production permits apply *before* it has been produced and both are requests that should be made to the acceptance authority for the product.

In some cases products and services are offered in several models, types, or other designations but are basically of the same design. Those which meet the higher specification are graded as such and those which fail may meet a lower specification and can be *regraded*. The grading should be reflected in the product identity so that there is no confusion.

The inclusion of the term *rejected* is not a disposition because all nonconforming items are initially rejected. Items may be rejected and then returned to their supplier for action but all other rejections should be subject to one of the other dispositions.

Scrapping an item should not be taken lightly – it could be an item of high value. Scrapping may be an economical decision with low cost items, whereas the scrapping of high value items may require prior authorization as salvage action may provide a possibility of yielding spares for alternative applications.

The list in the standard omits two other possibilities, those of modification and completion. A product that is nonconforming may be so due to errors in the specification and can be eliminated by a modification to the design. The product may meet the specified requirement but be unfit for use, in which case this is a major modification.

Alternatively, the product may meet the supplier's specifications but not meet the customer or market specified requirements; this calls for a minor modification. Some

modifications may be necessary only for certain batches due to variations in material or component tolerances. Modifications may be necessary to overcome component obsolescence or changes in bought-in parts that were not covered by the procurement specification.

Completion of product is different to rework as “rework” implies that something was carried out incorrectly whereas “returning product for completion” implies that something was not done at all. This minor distinction can be a useful classification in subsequent analyses.

To meet this requirement your documented procedures should specify the authorities who make the disposition, where it is to be recorded, and what information should be provided in order that it can be implemented and verified as having been implemented.

In order to implement these requirements your nonconformity control procedures should include the following actions:

- Specify how product should be scrapped or recycled, the forms to be used, the authorizations to be obtained.
- Specify the various repair procedures, how they should be produced, selected, and implemented.
- Specify how modifications should be defined, identified, and implemented.
- Specify how production permits (deviations) and concessions (waivers) should be requested, evaluated, and approved or rejected.
- Specify how product should be returned to its supplier, the forms to be completed, and any identification requirements in order that you can detect product on its return.
- Specify how regrading product is to be carried out, the product markings, prior authorization, and acceptance criteria.

When making the disposition your remedial action needs to address:

- Action on the nonconforming item to remove the nonconformity
- A search for other similar items which may be nonconforming (i.e. suspect product)
- Action to recall product containing suspect nonconforming product

If you need to recall product that is suspected as being defective you will need to devise a *recall plan*, specify responsibilities and time-scales, and put the plan into effect. Product recall is a *remedial action* not a *corrective action*, as it does not prevent a recurrence of the initial problem.

An auditor would expect to find staff consulting the rework instructions when carrying out rework. However, information in documents can be memorized or become habit through familiarity with the process. Rework instructions are often unique to the non-conformity and therefore personnel cannot rely on prior knowledge. This is addressed as a supplementary requirement in clause 4.14.3.

When deciding on repair or rework action, you may need to consider whether the result will be visible to the customer on the exterior of the product. Rework or repairs that may not be visible when a part is fitted into the final assembly might be visible when these same parts are sold as service spares. To prevent on-the-spot decisions being at variance each time, you could:

- a) Identify in the drawings, plans, etc. those products which are supplied for service applications: i.e. for servicing, maintenance, and repair.
- b) Provide the means for making rework invisible where there are cost savings over scrapping the item.
- c) Stipulate on the drawings etc. the approved rework techniques.

Use of nonconforming product (4.13.2 and 4.13.1.3)

The standard requires that *where required by the contract, the proposed use or repair of product which does not conform to specified requirements shall be reported for concession to the customer or customer's representative*. The supplementary requirement requires *customers to be informed promptly in the event that nonconforming product is shipped*.

The original ISO 9001 requirements and the additional ISO/TS 16949 requirement define two situations: one where you know in advance that the product is nonconforming and you want permission for its shipment, the other where at the time of shipment you did not know it was nonconforming and only found out subsequently.

The only cases where you need to request concession from your customer are when you have deviated from one of the customer requirements and cannot make the product conform. Even when you repair a product, providing it meets all of the customer

requirements, there is generally no need to seek a concession from your customer. While it is generally believed that nonconformities indicate an out-of-control situation, providing you detect and rectify them before release of the product, you have quality under control, and have no need to report nonconformities to your customer.

In informing your customer when nonconforming product has been shipped you obviously need to do this immediately you are certain that there is a nonconformity. If you are investigating a suspect nonconformity it only becomes a matter for reporting to your customer when the nonconformity remains suspect after you have concluded your investigations. Alerting your customer every time you think there is a problem will destroy confidence in your organization. Customers appreciate zeal but not paranoid personnel!

Deviating from approved processes (4.13.4)

The standard requires prior written customer authorization whenever the product or process is different from that currently approved.

This may seem a very onerous requirement since it stops you changing almost anything without customer approval. In the context of nonconforming product, it applies to any action you take to eliminate the nonconformity other than scrapping and regrading the item, if permitted. Any rework and repair procedure has to be approved in the product approval submission. Obviously to improve performance continuously you must change something, but not the product's physical and functional characteristics, the key process parameters, or the dimensions and tolerances of the tools and gages used. The requirement also applies to your subcontractors. Therefore you will need a product approval submission from each of your subcontractors and will need to put in place procedures to regulate deviations from the approved standard. An example where this may be quite common is where specified materials become unobtainable and alternatives need to be selected, or where there is a slight change in the material specification. ISO/TS 16949 allows for such a situation but you must seek prior authorization. It means that before you deviate from approved specifications for production items you must obtain authorization to apply the procedure. You will need a procedure for conveying the information to the customer, obtaining approval, and keeping records of the expiration date or quantity authorized. Concessions or waivers are issued only on specific quantities or for a specific duration, therefore cannot be open-ended.

You also need a system of identifying the conceded product up to shipment in order that the shipping staff can apply the same identity to the shipping containers. One way of doing this is to tag the parts with a special label that is neither red nor green (signifying *reject* or *pass*) in order that the identity of conceded product will not be overlooked.

Recording the actual condition of nonconforming product (4.13.2)

The standard requires the supplier to *record the description of nonconformity that has been accepted, and of repairs, to denote the actual condition.*

The original nonconformity report should indicate the nature of the nonconformity but after rework, or completion of operations, the nonconformity will have been eliminated. Where the nonconformity was accepted as is without rework, repair, or changing the specification then the actual condition is the original condition and this can be specified by the original nonconformity report. If the product has to be repaired or modified, the actual condition can be specified by the repair, salvage, or modification scheme, which is usually a separate document and can either be detailed on the nonconformity report or cross referenced to it. A lot of time can be saved if this information is readily accessible when problems arise later.

Re-inspection of repaired and reworked product (4.13.2)

The standard requires the supplier to *re-inspect repaired and reworked product in accordance with the quality plan and/or documented procedures.*

Any product that has had work done to it should be re-inspected prior to it being released to ensure the work has been carried out as planned and has not affected features that were previously found conforming. There may be cases where the amount of re-inspection is limited and this should be stated as part of the remedial action plan. However, after rework or repair the re-inspection should verify that the product meets the original requirement, otherwise it is not the same product and must be identified differently.

The inspection and test records should indicate the original rejection, the disposition, and the results of the re-inspection in order that there is traceability of the decisions that were made.

Task list

- 1 Decide what constitutes a nonconformity.
- 2 Decide what products and processes will be governed by the nonconformity control procedures.
- 3 Develop a means of classifying nonconformities.
- 4 Decide who the acceptance authority is to be for each product, project, or contract for each class of nonconformity.
- 5 Provide forms or logs for recording details of nonconformities.
- 6 Provide reject labels for identifying nonconforming articles.
- 7 Provide serviceable and unserviceable labels for identifying operational equipment.
- 8 Provide a register of nonconformity reports.
- 9 Decide on who is to evaluate nonconformities.
- 10 Prepare procedures for the processing of nonconforming articles.
- 11 Provide quarantine areas in which to place articles pending disposition action.
- 12 Prepare procedures for controlling these quarantine areas.
- 13 Set up a review board to disposition nonconformities and allocate responsibilities.
- 14 Set up a file for storing records of nonconformity dispositions.
- 15 Provide for product to re-enter the process for rework, repair, or modification action.
- 16 Provide procedures for product recall.
- 17 Provide a means of controlling the return of reject articles to suppliers.
- 18 Provide a means for scrapping unusable articles under controlled conditions.
- 19 Provide forms for requesting deviations and waivers from your customer when appropriate.
- 20 Provide a means for tracking remedial actions on nonconforming articles.

Control of nonconforming product questionnaire

- 1 How do you ensure that product which does not conform to specified requirements is prevented from inadvertent use or installation?
- 2 How do you ensure nonconforming product is identified?
- 3 How do you ensure nonconforming product is documented?
- 4 How do you ensure nonconforming product is evaluated?
- 5 How do you ensure nonconforming product is segregated?
- 6 How do you ensure nonconforming product is dispositioned and concerned functions notified?
- 7 In which documents do you define the responsibility for the review and the authority for the disposition of nonconforming product?
- 8 How do you ensure that dispositions on nonconforming product are implemented as specified?
- 9 How do you seek permission for the purchaser to use or repair product that does not conform to specified requirements?
- 10 In which document do you record the description of nonconformity or repairs that has been accepted?
- 11 How do you ensure that repairs and reworked product is re-inspected in accordance with documented procedures?

Do's and don'ts

- ⊗ Don't apply the nonconformity controls of the standard to anything other than products and services.
- ☺ Do specify the requirement as well as the actual condition on nonconformity reports.
- ☺ Do schedule verification activities so as to detect nonconformities as early as possible.
- ☺ Do consider the cost of replacement against the cost of rework or repair.
- ☺ Do check other articles if the nonconformity appears to be symptomatic of the producing process.
- ⊗ Don't change the design by means of a nonconformity report or concession.
- ☺ Do make nonconformity data available at final inspection.
- ☺ Do confirm the nonconformity before advocating remedial action.
- ⊗ Don't identify nonconformities in a manner that will leave a permanent mark on the article.
- ☺ Do remove nonconforming articles from the process as soon as the nonconformity has been confirmed.
- ☺ Do provide limited access to quarantine areas.
- ☺ Do investigate the history of the nonconformity before specifying remedial action – the previous remedial action may not have been successful.
- ☺ Do record the remedial action required and the nature of re-verification.
- ☺ Do obtain agreement to any repair instructions prior to being implemented.
- ☺ Do file nonconformity data where operators and inspectors can review it.
- ⊗ Don't limit the nonconformity review board to members of the quality department.
- ☺ Do subject reported subcontractor nonconformities to equal treatment.
- ☺ Do achieve unanimous agreement on the disposition of all nonconformities.
- ☺ Do keep the records of the nature of nonconformity, the disposition, and the result of post-remedial action verification together.

Chapter 14

Corrective and preventive action

Scope of requirements

Corrective action is the pattern of activities which traces the symptoms of a problem to its cause, produces solutions for preventing the recurrence of the problem, implements the changes, and monitors that the changes have been successful. Corrective action provides a feedback loop in the control cycle. Inspection detects nonconformity, nonconformity control identifies, segregates, and rectifies the nonconforming item, and corrective action serves to prevent the nonconformity from recurring. While the notion of correction implies that it could be as concerned with the nonconforming item as with the cause of nonconformity, correcting the nonconforming item is a remedial action. It doesn't stop it recurring. Preventing the recurrence of a nonconformity is a corrective action. A problem has to exist for you to take corrective action. When actual problems don't exist but there is a possibility of failure, the action of preventing the occurrence of a nonconformity, or any problem for that matter, is a preventive action. So we have *remedial action*, *corrective action*, and *preventive action*, each with a different meaning. Remedial action is covered by clause 4.13 and corrective and preventive action by clause 4.14 of the standard. Further details of preventive action can be found in ISO 9004-4.

Let us take a medical analogy. You have a head cold so you go to the doctor for advice. The doctor prescribes a remedy: "Take two pills three times a day and the cold symptoms should subside". You do as the doctor advises and indeed the cold symptoms subside. This is *remedial action*. You then return to the doctor year after year with the same problem and ask the doctor to prescribe a means of preventing the cold symptoms from recurring each year. The doctor prescribes a course of injections that will prevent the symptoms occurring. You take the course of injections and behold, you do not feel cold symptoms ever again! This is *corrective action*. You observe over the years that the course of injections work providing you continue with the regime. You have a daughter who has never had a head cold and, mindful of the treatment you are given, wish to

preserve your daughter from the suffering you have had over the years. You seek the doctor's advice, which is that you enter your daughter on to a course of injections to safeguard against the risk of attracting the cold virus. Your daughter undertakes the prescribed course of treatment and never experiences a head cold. This is *preventive action*.

Returning to the standard, this clause also only addresses the correction and prevention of nonconformities, i.e. departures from the specified requirements. It does not address the correction of defects, of inconsistencies, of errors, or in fact any deviations from your internal specifications or requirements. As explained in Part 2 Chapter 13, if we apply the definition of nonconformity literally, a departure from a requirement that is not included in the "Specified Requirements" is not a nonconformity and hence the standard is not requiring corrective action for such deviations. Clearly this was not the intention of the requirement because preventing the recurrence of any problem is a sensible course of action to take, providing it is economical. Economics is, however, the crux of the matter. If you include every requirement in the "Specified Requirements", you not only overcomplicate the nonconformity controls but the corrective and preventive action controls as well.

In element 4.13 of ISO 9001, the requirements are intended to be limited to product and service nonconformities. However, in element 4.14 of ISO 9001, the requirements are intended to be applied to process and system nonconformities as well as product and service nonconformities.

The corrective action requirements fail to stipulate when corrective action should be taken except to say that they shall be to a degree appropriate to the risks encountered. There is no compulsion for the supplier to correct nonconformities before repeat production or shipment of subsequent product. However, immediate correction is not always practical. You should base the timing of your corrective action on the severity of the nonconformities. All nonconformities are costly to the business, but correction also adds to the cost and should be matched to the benefits it will accrue (see later under *Risks*). Any action taken to eliminate a nonconformity before the customer receives the product or service could be considered a preventive action. By this definition, final inspection is a preventive action because it should prevent the supply of nonconforming product to the customer. However, an error becomes a nonconformity when detected at any acceptance stage in the process, as indicated in clause 4.12 of the standard. Therefore an action taken to eliminate a potential nonconformity prior to an acceptance stage is a preventive action. This rules out any inspection stages as being preventive action measures – they are detection measures only.

The requirements in element 4.14 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 14.1.

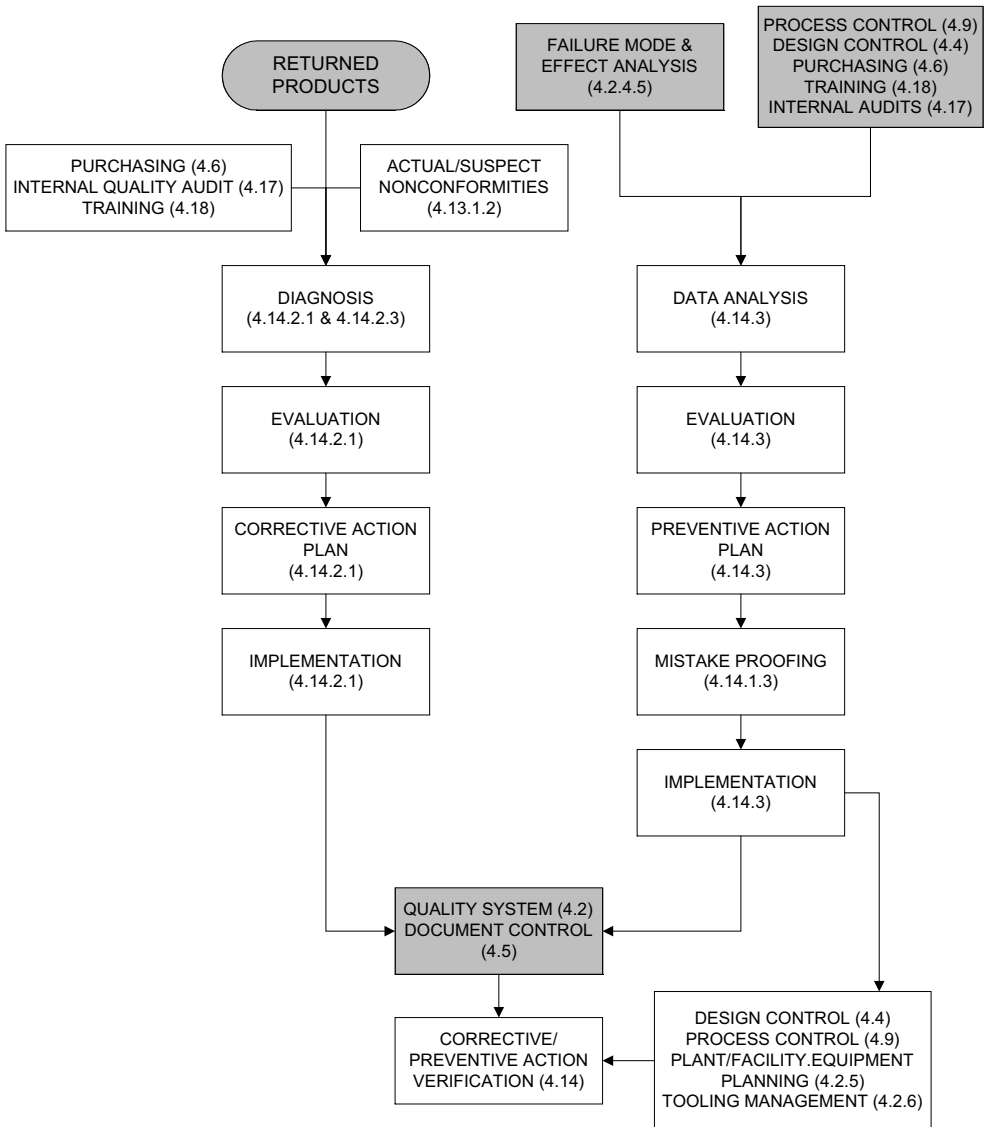


Figure 14.1 Clause relationships with the corrective and preventive action element

Corrective and preventive action procedures (4.14.1.1)

The standard requires the supplier to *establish, document, and maintain documented procedures for implementing corrective and preventive action.*

As the source of nonconformities are so varied it may not be practical to have a single corrective or preventive action procedure. It may be more practical to embody corrective action provisions in the following procedures:

- Failure investigation procedure
- Nonconforming material review procedure
- Customer complaints procedure
- Quality system document change procedure
- Specification change procedure
- Maintenance procedures

Preventive action provisions on the other hand may be embodied in the following procedures:

- Performance analysis procedure
- Design review procedure
- Design analysis procedures (reliability, safety, maintainability, etc.)
- Supplier/subcontractor performance review procedure
- Management review procedure
- Continuous improvement procedure

The standard only requires a procedure for implementing corrective and preventive action and not for determining it, although the requirements of clauses 4.14.2 and 4.14.3 do require the actions to be determined – presumably before being implemented!

Assessing the degree of corrective and preventive action necessary (4.14.1.1)

The standard requires that *any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities is to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.*

The standard does not require you to take corrective action on every nonconformity or prevent every potential nonconformity. Here it is suggested that the decision to act should be based on the magnitude of the problem and the risks encountered. It is therefore implying that you only need act on the vital few. In fact this is good practice anyway, but to find that vital few you need to collect and analyze *most* of the data in the first place. Having made your proposals you should then conduct a risk analysis as part of the solution. Before managers will take action, they need to know:

- What is the problem or potential problem?
- Has the problem been confirmed?
- What are the consequences of doing nothing, i.e. what effect is it having?
- What is the preferred solution?
- How much will the solution cost?
- How much will the solution save?
- What are the alternatives and their relative costs?
- If I need to act, how long have I got before the effects damage the business?

Whatever you do, don't act on suspicion, always confirm that a problem exists or that there is a certain chance that a problem will exist if the current trend continues.

■ Validate causes before proclaiming action!

Implementing and recording changes in procedures (4.14.1.1)

The standard requires the supplier to *implement and record changes in the documented procedures resulting from corrective and preventive action.*

To do this you need a link between your corrective and preventive action procedures and your change control procedures. If your Corrective Action Report (e.g. CAR023) indicated that procedure XYZ requires a change, a reference to the Document Change Request (e.g. DCR134) initiating a change to procedure XYZ will provide the necessary link. The Change Request can indicate as the reason for change the Corrective Action Report. If you don't use formal change requests, the Amendment Instructions can cross-reference the Corrective Action Report. Alternatively, if your procedures carry a change record, the reason for change can be added. There are several methods to choose from, but whatever the method you will need some means of tracking the implementation of corrective actions. This use of forms illustrates one of the many advantages of form serial numbers.

There is only a requirement for a record of changes in procedures and not changes in plans, specifications, and drawings, which are clearly not procedures, but whether it be procedures, work instructions, or other types of instructions, you will need to be able to demonstrate that you have a system for preventing the recurrence of nonconformities.

Corrective action (4.14.2)

Effective handling of customer complaints (4.14.2.1a)

The standard requires *the corrective action procedures to include the effective handling of customer complaints.*

You can only handle effectively those customer complaints that you receive and record. Customers may complain about your products and services but not go the extent of writing a formal complaint. Complaints may arise in conversation between the customer and your sales and service staff and this is where you need to instill discipline and ensure the complaints are recorded. Your customer complaints procedure should cover the following aspects to be effective:

- A definition of when a message from a customer can be classified as a complaint
- The method of capturing the customer complaints from all interface channels with the customer
- The registration of complaints in order that you can account for them and monitor progress
- A form on which to record details of the complaint, the date, customer name, etc.
- A process for acknowledging the complaint in order that the customer knows you care

- A process for investigating the nature of the complaint
- A process for replacing product, for repeating the service, or for compensating the customer

There is also merit in preparing a customer feedback procedure rather than limiting the procedure to complaints. Your staff should be informed of the compliments made by customers as well as the complaints, because it improves morale.

Customer complaints are addressed under the heading of corrective action; however, you should not limit your action to eliminating the cause and preventing recurrence. You also need to take remedial action to deal with the particular complaint – hence the requirements of element 4.13 also apply to the handling of customer complaints.

Effective handling of reports of nonconformities (4.14.2.1a)

The standard requires *the corrective action procedures to include the effective handling of reports of product nonconformities.*

The reports of nonconformities could be internal or external reports of nonconformities although the standard does not make this clear. Internal reports of nonconformities should be covered by the requirements of clause 4.13. The next requirement concerning the investigation of nonconformities does relate to both internal and external reports. An external nonconformity report is not necessarily a customer complaint. The customer may have merely returned the product claiming it to be defective. When the customer has done this several times a complaint may well follow.

Another area where there may be some overlap is with the servicing requirements of section 4.19. The servicing arrangements may include provision for responding to requests from the customer for assistance. On investigation it may be found that the problem is caused by a nonconforming product that you have supplied, so in effect the customer is reporting a nonconformity. Should you address the arrangement for dealing with service calls under Servicing or under Corrective Action? The simple answer is under Servicing, because that is where your staff will expect to find the policies and practices defined. If you have written your quality manual around the standard, you should address this situation under Corrective Action.

The standard does not address *product recall* other than in the context of releasing product for urgent production purposes in clause 4.10.2.3. The reported nonconformities from your customers may be so severe that you need to recall product, not just one or two but a whole batch or several batches between two dates or serial numbers. Product recall can be considered to fall within the scope of handling reported nonconformities;

therefore your corrective action procedures need to address product recall – in fact it would probably make sense to establish a separate product recall procedure.

Assuming that the standard is only referring to external reports of nonconformities, your procedures should cover very similar processes to those for handling customer complaints. The procedures should cover:

- The method of receiving and identifying returned product
- The method of logging reports of nonconformities from customers
- The process of responding to customer requests for assistance
- The process of dispatching service personnel to the customer's premises
- A form on which to record details of the nonconformity, the date, customer name, etc.
- A process for acknowledging the report in order that the customer knows you care
- A process for investigating the nature of the nonconformity
- A process for replacing or repairing nonconforming product and restoring customer equipment into service
- A process for assessing all product in service that is nonconforming, determining and implementing recall action if necessary

Investigating the cause of nonconformities (4.14.2.1b and 4.14.1.2)

The standard requires the supplier to *investigate the cause of nonconformities relating to product, process, and quality system and record the results of the investigation*. The supplementary requirements require the supplier to *use problem-solving methods when an internal or external nonconformity occurs*.

All nonconformities are caused, all causes within your control can be avoided – all that is needed is concerted action to prevent recurrence. There are three types of corrective action: product-related, process-related, and system-related. Product-related nonconformities can be either internal or external, as addressed previously, and you will have nonconformity reports to analyze. Process-related nonconformities may arise out of a product nonconformity but if you expect something less than 100% yield from the process, the reject items may not be considered nonconformities. They may be regarded as scrap. By analyzing the process you can find the cause of low yield and improve

performance of the process. Product and process nonconformities may be detected at planned inspection and test stages and may also be detected during product and process audits. System-related nonconformities can arise out of system audits and clause 4.17 on internal audits requires timely corrective actions for all types of audits. Clause 4.17 does not cover external audits but this is covered by the above requirement. So how would you respond to these requirements?

Your corrective action procedures need to cover the collection and analysis of product nonconformity reports and the collection and analysis of process data to reveal process nonconformities. The corrective action provisions of your internal audit procedure need to address the causes of the nonconformities and you will need an additional procedure to deal with external audits, investigating the cause of any nonconformities and recording the results. The procedure also needs to cover the investigation of customer complaints as the previous requirement only deals with the handling of complaints.

You need to record the results of the investigations but not the corrective action you need to take. Even in clause 4.17 on internal quality audits, the requirement for the agreed corrective action to be recorded has been omitted. The results of the audit, the action taken, and its effectiveness need to be recorded but not the agreed corrective action. ISO 10011-1 does not require agreed corrective actions to be recorded either.

Some nonconformities appear random but often have a common cause. In order to detect these causes, statistical analysis may need to be carried out. The causes of such nonconformities are generally due to noncompliance with (or inadequate) working methods and standards. Other nonconformities have a clearly defined special or unique cause which has to be corrected before the process can continue. Special cause problems generally require the changing of unsatisfactory designs or working methods. They may well be significant or even catastrophic. These rapidly result in unsatisfied customers and loss of profits. In order to investigate the cause of nonconformities you will need to:

- Identify the requirements that have not been achieved.
- Collect data on nonconforming items, the quantity, frequency, and distribution.
- Identify when, where, and under what conditions the nonconformities occurred.
- Identify what operations were being carried out at the time and by whom.

Many organizations use a Nonconformity Report to deal with the remedial action and a Corrective Action Report or Request (CAR) to prevent the recurrence of one or more nonconformities. In this way you are not committed to taking action on every incident but on a group of incidents when the action and its cost can be more easily justified.

Having collected the data you will need to sort it and manipulate it so as to reveal the significance of the nonconformities and theorize about the possible causes. There may be several causes, in which case there will be some that dominate the others. Your job is to discover the dominant cause of the nonconformity and test the theories to find the actual cause, using problem-solving methods (see below).

There are many tools you can use to help you determine the root cause of problems. These are known as *disciplined problem solving methods*.

Disciplined methods are those proven methods that employ fundamental principles to reveal information. There are two different approaches to problem solving. The first is used when data is available, as is the case when dealing with nonconformities. The second approach is when not all the data needed is available.

The seven quality tools in common use are as follows:

- 1 Pareto diagrams – used to classify problems according to cause and phenomenon
- 2 Cause and effect diagrams – used to analyze the characteristics of a process or situation
- 3 Histograms – used to reveal the variation of characteristics or frequency distribution obtained from measurement
- 4 Control charts – used to detect abnormal trends around control limits
- 5 Scatter diagrams – used to illustrate the association between two pieces of corresponding data
- 6 Graphs – used to display data for comparative purposes
- 7 Check-sheets – used to tabulate results through routine checks of a situation

The further seven quality tools for use when not all data is available are:

- 1 Relations diagram – used to clarify interrelations in a complex situation
- 2 Affinity diagram – used to pull ideas from a group of people and group them into natural relationships
- 3 Tree diagram – used to show the interrelations among goals and measures

- 4 Matrix diagram – used to clarify the relations between two different factors (e.g. QFD)
- 5 Matrix data-analysis diagram – used when the matrix chart does not provide information in sufficient detail
- 6 Process decision program chart – used in operations research
- 7 Arrow diagram – used to show steps necessary to implement a plan (e.g. PERT)

There are other techniques such as force field analysis and the simple “Why? Why?” technique which very quickly often reveals the root cause of a problem.

The source of causes is not unlimited. Nonconformities are caused by one or more of the following:

- Deficiencies in communication
- Deficiencies in documentation
- Deficiencies in personnel training and motivation
- Deficiencies in materials
- Deficiencies in tools and equipment
- Deficiencies in the operating environment

Each of these is probably caused by deficiencies in management, its planning, organization, or control.

Once you have identified the root cause of the nonconformity you can propose corrective action to prevent its recurrence. Eliminating the cause of nonconformity and preventing the recurrence of nonconformity are essentially the same thing. The key to successful diagnosis of causes is to keep asking the question: why? When you encounter a “don’t know” then continue the investigation to find an answer.

Determining corrective actions (4.14.2.1c)

The standard requires *corrective action procedures to include determining the corrective action needed to eliminate the cause of nonconformities.*

You will need a means of recording both the cause and the proposed solutions. You can either incorporate the information within the Nonconformity Report or provide a separate Corrective Action Report.

The report should also make provision for the proposed solution to be approved or rejected. Remember that anyone may investigate nonconformities and propose corrective actions but the responsibility for taking the corrective action rests with those responsible for the process (see Part 2 Chapter 1 under *Personnel who initiate action to prevent nonconformity*).

To prevent a nonconformity from recurring you may need to take action on product which is in service. Some products may not have failed because they may not have been used in the manner needed to cause failure. Nevertheless there is a nonconformity if some product has failed and it is discovered that it is a common-cause nonconformity and all product is affected. You then need to decide whether to recall *all* product which has the defect and devise and implement a recall plan.

Your corrective action plan should therefore address as appropriate:

- Immediate action to prevent recurrence such as warning notices, alerts, etc.
- Longer term action to prevent recurrence such as changes to plans, procedures, specifications, training, etc.

Ensuring that corrective actions are effective (4.14.2.1d)

The standard requires the supplier to *apply controls to ensure that corrective actions are taken and that they are effective*.

This contains two separate requirements: one for verifying that the prescribed action has been taken and the other for verifying that the action has been effective in eliminating the original nonconformity. The Corrective Action report should define the corrective action to be taken, the actionee, and the date by which it is to be completed. The actionee should report when the action has been completed in order that it may be verified. The effectiveness of some actions can be verified at the same time but quite often the effectiveness can only be checked after a considerable lapse of time. Remember it took an analysis to detect the nonconformity; therefore it may take further analysis to detect that the nonconformity has been eliminated. In such cases the report should indicate when the checks for effectiveness are to be carried out and provision made for indicating that the corrective action has or has not been effective.

Some corrective actions may be multidimensional in that they may require training, changes to procedures, changes to specifications, changes in the organization, changes to equipment and processes – in fact so many changes that the corrective action becomes more like an improvement program. When corrective actions require interdepartmental action, it may be necessary to set up a corrective action team to introduce the changes. Each target area should be assigned to a person with responsibility in that area reporting to a team leader. In this way the task becomes a project with a project manager equipped with the authority to make the changes through the department representatives. Checking the effectiveness becomes a test of the system carried out over many months. Removing the old controls and committing yourselves to an untested solution may be disastrous; therefore it is often prudent to leave the existing controls in place until your solution has been proven to be effective.

Your quality system therefore needs to accommodate various corrective action strategies, from simple intradepartmental analysis with solutions that affect only one area, procedure, process, or product to projects that involve many departments, occasionally including suppliers and customers. Your corrective action procedures need to address these situations in order that when the time comes you are adequately equipped to respond promptly.

Corrective action impact (4.14.2.2)

The standard requires the supplier to *apply corrective actions taken and controls implemented to eliminate the cause of a nonconformity to other similar processes and products.*

This requirement was addressed in Chapter 13 under *Review of nonconforming product*. It is at the time you review a nonconforming product that you should consider whether other similar products could be affected. Some regard this as remedial action because it is searching for like items. Others regard it as corrective action because it is preventing a recurrence of a problem in the same and similar products. There are also some people who regard it as preventive action because although the nonconformity has occurred in a specific product or process it is only a potential nonconformity for other products or processes.

Returned product analysis (4.14.2.3)

The standard requires the supplier to *analyze parts returned from customer's manufacturing plants, engineering facilities, and dealerships and minimize the cycle time of this process.*

ISO 9001 partially covers this requirement in clause 4.14.2(b) and this is addressed in the next section in this chapter. However, the parts returned from dealers, customer manufacturing plants, etc. may not be nonconforming. They may be obsolete, surplus to requirements, have suffered damage in handling, or have been used in trials, etc. Whatever the reason for return, you are required to log each return and perform an analysis to reveal opportunities for corrective action when appropriate. You should process these items as indicated previously but prior to expending effort on investigations, you should establish your liability and then investigate the cause of any nonconformities for which you are liable. In analyzing the cycle time the standard advises that it should be consistent with the determination of root cause, as this will vary depending upon the reason for return or the nature of nonconformity.

Preventive action (4.14.3)

Detecting and eliminating potential causes of nonconforming product (4.14.3a)

The standard requires the supplier to *use appropriate sources of information to detect and eliminate potential causes of nonconforming product.*

The purpose behind such a requirements is twofold:

- a) To provide a means of detecting any deterioration in standards.
- b) To provide a means for detecting any inherent design weakness in products and processes

Detecting deterioration in standards

What may appear trivial on a case-by-case basis may well be significant when taken over a longer period or a larger population. This detective work is another form of inspection although this time it focuses on processes and not on specific products. Managers have a habit of reacting to events particularly if they are serious nonconformities in the form of a customer complaint. What we are all poor at is perceiving the underlying trends that occur daily and gradually eat away at our profits. We therefore need a means of alerting management to these trends in order that they may consider the corrective action to take.

The steps you need to take to detect specific problems will vary depending on the nature of the problem. The part that can be proceduralized is the discovery process for detecting problems and isolating their cause. A typical process may be as follows:

- Establish a means of collecting relevant data and transmitting it to personnel for analysis
- Analyze the data and search for trends and conditions that signal a deterioration in standards.
- Establish the concentration of the variance.
- Establish if the variance is significant both statistically and economically.
- Determine the effects if the trends continue.
- Gain agreement on the problem (expending further effort may be uneconomic if no one agrees with your prognosis).
- Investigate the cause of the deterioration.
- Isolate the dominant cause.

To analyze *anything* you need data. If you have no data on processes, work operations, concessions, service reports, and customer complaints, this clause requires that you create some. Without data you cannot know if your processes are under control, if your customers are satisfied, if your service personnel carried out the planned service, etc. It is not sufficient to claim that you have had no concessions or customer complaints. You need to have a system for capturing such matters should they occur. Introducing ISO 9000 does generate a lot of paper but it should all serve a specific purpose. Plan the data requirements carefully so that you:

- Only collect data on events that you intend to analyze.
- Only analyze data with the intention of discovering problems.
- Only provide solutions to real problems.
- Only implement solutions that will improve performance.

You also need to take care and avoid the “garbage in, garbage out” syndrome. Your analysis will only be as good as the data you are provided with. If you want to determine certain facts, you need to ensure that the means exist for the necessary information to be obtained. To do this you may need to change the input forms or provide new forms on which to collect the data. The data needed for corrective action is rarely of use to those providing it; therefore design your forms with care. Reject any incomplete forms as a sign that you are serious about needing the data. A sure sign that forms have

become obsolete is the number of blank boxes. Also it is better to devise unique forms for specific uses rather than rely on general multipurpose forms because they degrade the reliability of the data.

The requirement contains some terms that need explaining.

- *Processes* in this context means those series of related activities that turn inputs into outputs of added value. They include design, procurement, manufacture, packing, delivery, installation, maintenance, operations, disposal as well as the processes which serve these primary processes such as calibration, training, inspection, test, document control, etc.
- *Work operations* are operations which form part of the above processes but include manual work, knowledge work, and management work associated with these processes.
- *Concessions* are any relaxations granted by the customer, design authority, inspection authority, or other body authorized to accept nonconforming product.
- *Quality records* are those records identified in Chapter 16. This is a bit of a catch-all as concessions, service reports, customer complaints, and data from processes and work operations are all quality records. However, the standard does not cross refer to clause 4.16 at every mention of records or similar document and therefore the requirements of 4.16 only apply in those cases where it is referenced. Service reports, for instance, do not need to comply with the requirements of clause 4.16.
- *Service reports* are reports from service or maintenance personnel identifying the nature of faults, the components replaced, and time taken. They are required in clause 4.19.
- *Customer complaints* are any reports of dissatisfaction from the customer whether written by the customer or recorded from a telephone conversation.

A potential cause of nonconforming product is a situation either where a deterioration exists which will result in nonconformity if allowed to continue or the conditions are such that a failure is possible even though there is no evidence that occurrence could be imminent.

Regarding processes and work operations you will need to establish performance indicators as a means of determining whether the potential for generating nonconformities is present. Establish standards for each of the processes and collect data on how well the standards are being achieved. Such factors as quantity processed, process yield, time

through process, quantity of waste, and process downtime are useful measures of performance and indicators of quality.

Regarding concessions you will need to register all requests for concessions to product requirements and carry out a periodic analysis to detect trends. Is it always the same product, the same requirement, the same person or are there other variables that indicate that the requirements are unachievable and in need of change? Under ideal conditions there should be no need for requesting concessions. The process should be fully capable for producing the goods. But if it happens frequently, there may be some underlying cause that has been overlooked.

Regarding quality records, you will need to be selective and choose for analysis those which will yield some useful data. Don't embark upon a progressive analysis without good reason as it can be a fruitless exercise.

Regarding service reports, these should be collected from the servicing or maintenance personnel and analyzed for repetitive problems. The data can also be used to compute the actual reliability, maintainability, and many other characteristics of the products.

Detecting design weaknesses (4.14.3a and 4.2.4.5)

Several techniques have evolved to identify potential sources of failure in designs and process. These techniques serve to prevent nonconformity and hence are preventive action measures. One such technique is Failure Mode and Effects Analysis (FMEA).

A failure modes and effects analysis is a systematic analytical technique for identifying potential failures in a design or a process, assessing the probability of occurrence and likely effect, and determining the measures needed to eliminate, contain, or control the effects. Action taken on the basis of an FMEA will improve safety, performance, reliability, maintainability and reduce costs. The outputs are essential to balanced and effective quality plans for both development and production as it will help focus the controls upon those products, processes, and characteristics that are at risk. It is not the intention here to give a full appreciation of the FMEA technique and readers are advised to consult other texts.

The FMEA is presented as a table or spreadsheet and contains the following information:

- Function of the item or process
- Potential failure mode (the manner in which the item or process could potentially fail to meet the design intent)
- Potential effects of failure in terms of what the customer might notice or experience

- Severity in the range 1 to 10, 10 being hazardous without warning and 1 having no effect
- Classification in terms of critical, key, major, significant
- Potential cause(s)/mechanism(s) of failure
- Occurrence (the likelihood that a specific cause/mechanism will occur in the range 1 to 10, with 10 being almost inevitable and 1 being unlikely)
- Current design/process controls in terms of the prevention, verification, or other activities to assure design/process adequacy
- Detection in the range 1 to 10, with 10 meaning that the control will not detect the potential failure and 1 meaning that the control will almost certainly detect the potential cause of failure.
- Risk priority number: this is the product of the severity, occurrence, and detection factors
- Recommended actions, prioritizing action on the highest ranked concerns
- Responsibility for actions
- Actions taken
- Resulting severity, occurrence, detection ranking, and risk priority number

Dealing with problems requiring preventive action (4.14.3b)

The standard requires that *the preventive action procedures include the determination of steps needed to deal with any problems requiring preventive action.*

This is probably one of the most powerful requirements in the standard, much under-used in ISO 9000 quality systems. If you examine the words closely you will find that it can be applied to any situation where measures can be taken to prevent problems. A common weakness in many organizations is the absence of planning. Planning is a preventive action. We plan to achieve an objective which we would fail to meet if we didn't make adequate provision for the resources and activities needed to meet our objective. Therefore, although the standard does not require plans for every activity, if preparation is necessary before an activity can take place and such preparation has not been accom-

plished then you *have not determined the steps needed to deal with any problems requiring preventive action* and are therefore noncompliant with ISO 9001.

The action taken during process monitoring (see Part 2 Chapter 9) can be considered preventive action when corrections are made to the process ahead of occurring non-conformities. Hence Statistical Process Control is a technique which serves nonconformity prevention as well as detection.

The steps you need to take to deal with specific problems will vary depending on the nature of the problem. The part that can be proceduralized is the planning process for determining the preventive action needed. A typical process may be as follows:

- Devise a strategy for eliminating the cause together with alternative strategies, their limitations and consequences.
- Gain agreement on the strategy.
- Prepare an improvement plan which if implemented would eliminate the potential problem and not cause any others.
- Prepare a timetable and estimate resources for implementing the plan.
- Gain agreement of the improvement plan, timetable, and resources before going ahead.

The procedure would need to define the authority and responsibilities of those involved, the methods used to analyze the data, and the recommended format of any improvement plan in order that plans submitted to management gain their agreement. Some plans may be very simple and require no more than an instruction to implement an existing procedure. Others may be more involved and require additional resources. The improvement plan should be seen as defining a quality objective and hence if a major change in performance is necessary, should be part of your Improvement Plan, which was addressed in Part 2 Chapter 1. In this way you are seen to operate a coherent and coordinated improvement strategy rather than a random and unguided strategy. While those on the firing line are best equipped to notice the trends any preventive action should be coordinated in order that the company's resources are targeted at the problems which are most significant.

Mistake-proofing (4.14.3b and 4.14.1.3)

The standard requires the supplier to *use mistake-proofing in corrective and preventive action process*.

Mistake-proofing is a means to prevent the manufacture or assembly of nonconforming product. All people make mistakes. Mistakes are inadvertent errors and arise through human fallibility. We all occasionally forget things and we can either make actions mistake-proof in order that they can only be performed one way or we can provide signals to remind us of what we should be doing. The terms *fool-proofing* and *Poka-Yoke* (coined by Shigeo Shinto) are also used to describe the same concepts.

Mistake-proofing can be accomplished by product design features in order that the possibility of incorrect assembly, operation, or handling is avoided. In such cases the requirements for mistake-proofing need to form part of the design input requirements for the part.

Mistake-proofing can also be accomplished by process design features such as sensors to check the set-up before processing, audible signals to remind operators to do various things. However, signals to operators are not exactly mistake-proof; only mechanisms that prevent operations commencing until the right conditions have been set are proof against mistakes. In cases where computer data-entry routines are used, mistake-proofing can be built into the software such that the operator is prompted to make decisions before irreversible actions are undertaken.

In both cases the Design FMEA and Process FMEA should be analyzed to reveal features that present a certain risk which can be contained by redesign with mistake-proofing features.

Initiating preventive action (4.14.3c)

The standard requires that *the preventive action procedures include the initiation of preventive action and application of controls to ensure that it is effective.*

This requirement addresses the implementation of the improvement plan prepared to deal with problems requiring preventive action. The improvement plan should have defined who is to take the preventive action and also the extent of the action to be taken: that is, only in the area where the trend was detected or over a much wider area. In initiating the action (see also Part 2 Chapter 1 under *Personnel with organizational freedom*) you need to carry it out in an organized manner, as follows:

- Notify those who will be affected by the change.
- Take the action in accordance with the prescribed control procedures.
- Monitor the effects of the action and collect the data.

- Analyze the data to determine whether the potential problem has been averted.
- Audit the implementation of the preventive action to verify that the agreed plans have been followed and conditions stabilized.

Ensuring that information is submitted for management review (4.14.3d)

The standard requires that *the preventive action procedures confirm that the relevant information on actions taken including changes to procedures is submitted for management review.*

To ensure that information on your preventive actions is considered by the management review of the quality system, you should document the problem, the plan to solve it, the action actually taken, and the result. However, this section of the standard does not require you to produce any records of preventive action because no cross reference is made to clause 4.16. You could therefore meet the requirement by ensuring that those with intimate knowledge of the preventive actions taken attend a management review meeting and give a verbal report. The changes to procedures, if any, will have been documented because it is required by clause 4.14.1 and as you need to maintain records of management reviews, you will capture the information on preventive actions, and thus meet the requirement. If you operate a more complex quality system, verbal reports may not be reliable. You will therefore need to maintain records of preventive actions, as stated previously. Your management review procedure, if you have one (see Part 2 Chapter 1), should therefore make provision for collecting preventive action data.

Task list

- 1 Provide a means of collecting data from all verification operations.
- 2 Set up a procedure for recording customer complaints.
- 3 Provide a means for collecting design change and document change requests.
- 4 Provide (in the relevant procedures) requirements for recording and transmitting data pertinent to any subsequent corrective action analysis.
- 5 Provide, where relevant, a means of recording continuous processes to detect deviation from the agreed standard.
- 6 Establish performance indicators for each significant process.
- 7 Establish a method of recording the baseline performance for each of these processes.
- 8 Decide on who is to collect and analyze the data for determination of both corrective and preventive actions.
- 9 Decide on who is to investigate and propose corrective actions and preventive actions.
- 10 Prepare procedures for the analysis, investigation, and determination of the causes of potential and actual deviation including the formation of diagnostic teams where necessary.
- 11 Provide tools and techniques to help investigators discover the causes of potential and actual deviation and determine their significance.
- 12 Provide for solutions to prevent the occurrence and recurrence of deviations to be proposed and agreed.
- 13 Provide forms for recording the agreed corrective and preventive action and target dates for completion.
- 14 Prepare procedures for reporting the results of the analyses to management.
- 15 Provide links between the corrective and preventive action reports and document, product, process, and organization changes.
- 16 Devise nonconformity reduction plans for common cause nonconformities.
- 17 Provide an escalation procedure for use when corrective and preventive action target dates have been exceeded or where detected problems require management action.
- 18 Provide procedures for managing corrective and preventive action programs where corrective action is required.
- 19 Provide visual evidence of required performance against actual performance at work locations.
- 20 Provide procedures for verifying that corrective and preventive actions achieve their objectives.

Corrective and preventive action questionnaire

- 1 In what documents have you defined your corrective action and preventive action procedures?
- 2 How do you ensure that the corrective or preventive action taken is to a degree appropriate to the magnitude of the problem and commensurate to the risks encountered?
- 3 How do you implement and record changes resulting from corrective and preventive action?
- 4 How do you handle customer complaints?
- 5 How do you handle reports of product nonconformities?
- 6 How do you ensure that the cause of nonconforming product is investigated?
- 7 How do you eliminate the cause of nonconformities?
- 8 How do you ensure that corrective actions are taken and are effective?
- 9 What sources of information are used to detect, analyze, and eliminate potential causes of nonconformity?
- 10 How are problems requiring preventive action dealt with?
- 11 How is preventive action initiated?
- 12 What controls ensure the effectiveness of preventive actions?
- 13 How do you ensure that information on preventive action is submitted for management review?

Do's and don'ts

- ☺ Do clarify the differences between remedial action, corrective action, and preventive action and apply them in a manner consistent with the definitions in ISO 8402.
- ⊗ Don't take action before you have confirmed the presence of a problem.
- ⊗ Don't announce you have confirmed that a problem exists before you have assessed its significance.
- ☺ Do check that the agreed corrective actions are being taken.
- ⊗ Don't wait until the due date for the completion of the action to check if work has started.
- ☺ Do accept legitimate reasons for inaction and agree on new target dates.
- ⊗ Don't display performance data unless those affected agree to it being displayed.
- ☺ Do look for potential causes of deviation – don't wait until the alarm bells ring.
- ☺ Do concentrate on the *vital* few problems.
- ☺ Do monitor the trivial problems to detect a systematic deterioration in standards.
- ☺ Do enlist the support of the organization responsible for the problem to investigate the cause.
- ⊗ Don't impose corrective actions on other organizations.
- ⊗ Don't collect data for the sake of it – always have a purpose.
- ☺ Do classify the problems into groups that have a common cause and special cause.
- ☺ Do attract management's attention to special cause problems and obtain commitment to action.
- ☺ Do train your investigators in diagnostic techniques.
- ⊗ Don't persist with proposals for corrective action if management tells you they are not economic – find more economic solutions.
- ☺ Do capture your organization's recovery plans into the corrective action system.
- ☺ Do impress on management that corrective action procedures exist to save resources.
- ☺ Do tell your complaining customers the action you have taken to resolve their problem.
- ⊗ Don't limit your corrective action system to products – apply it to all operations including management decision making.

Chapter 15

Handling, storage, packaging, preservation, and delivery

Scope of requirements

These requirements are concerned with conformance control; that is, ensuring that products remain conforming once they have been certified as conforming. A more apt heading might have been *Control of conforming product*. While handling, storage, preservation, and packaging appear in the quality loop (see ISO 9004) after inspection and test, they are by no means only applicable at this stage. They should appear in the quality loop at several stages because handling, storage, preservation, and packing can be carried out following receipt of items from suppliers up to dispatch of end product to customers.

They mainly apply to products as most of them are concerned with protecting the product from damage and deterioration. They apply to the end product and any items that either form part of the product or are used to produce the product, including any tools, test equipment, and processing materials. Although it is possible for some types of services to deteriorate, this use of the term *preservation* is covered by the process control and auditing requirements. The only requirements that do apply to services are those for identification, unless product is used in the delivery of a service. If the servicing is done to a product, whether or not the product is owned by the supplier, protection of that product is important.

The requirements in element 4.15 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 15.1.

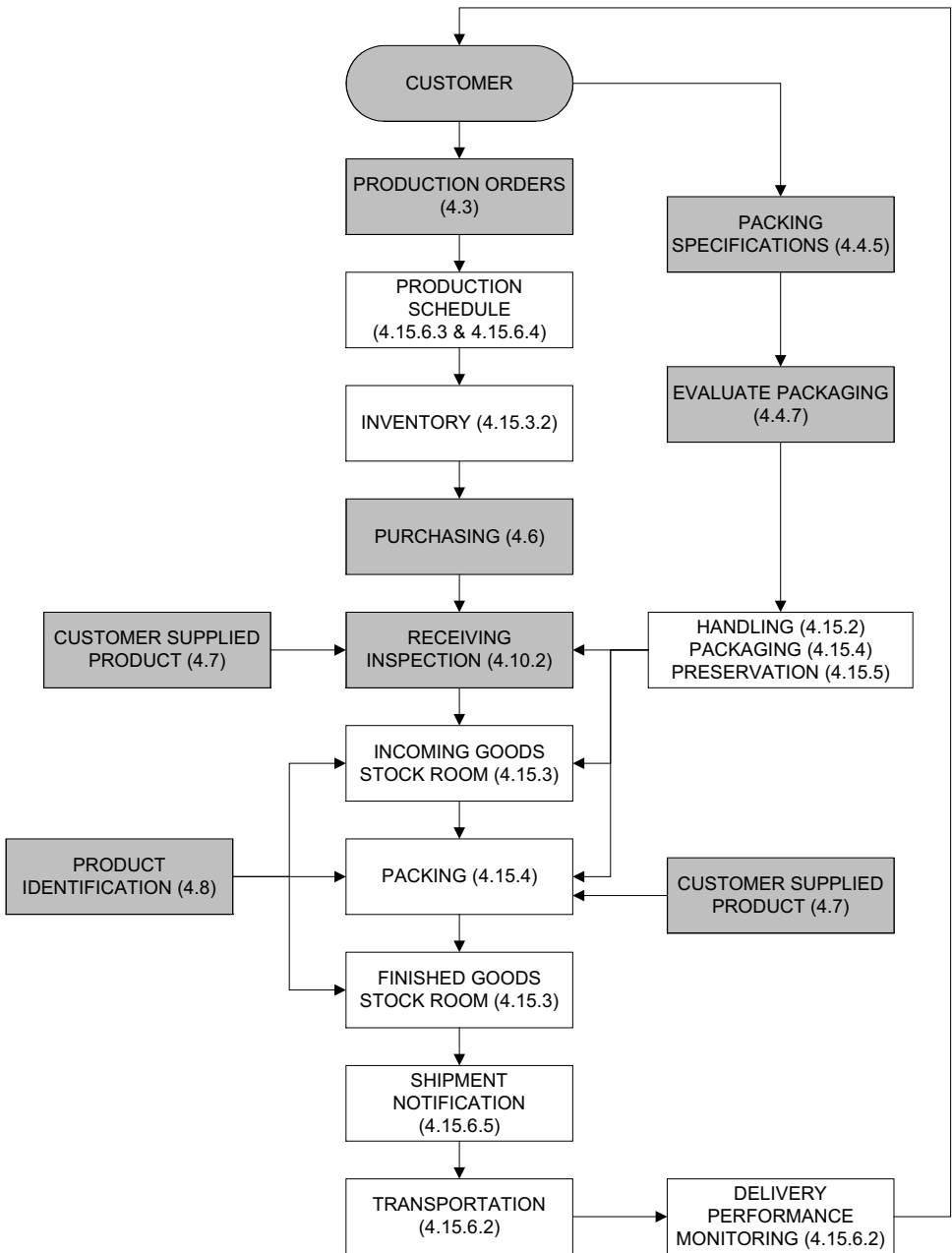


Figure 15.1 Clause relationships with the handling, storage, packaging, preservation, and delivery element

Handling, storage, packaging, preservation, and delivery procedures (4.15.1)

The standard requires the supplier to *establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of product.*

It is likely that you will need two types of procedure to cover these requirements, one general and the other specific.

You will need a means of identifying when handling, storage, packaging, preservation, and delivery procedures will be required and a method of preparing, identifying, publishing, selecting, and controlling specific procedures covering these subjects. These aspects should be covered by a general procedure.

The identification of special handling, storage, packaging, preservation, and delivery provisions usually occurs in the design stage or the manufacturing or service planning phase, by assessing the risks to product quality during its manufacture, storage, movement, transportation, and installation. Having identified that there is a risk to product quality you may need to prepare instructions for the handling, storage, packing, preservation, and delivery of particular items.

In addition to issuing the procedures you will need to reference them in the appropriate work instructions in order that they are implemented when necessary. In some cases it may be more appropriate to include these provisions as an integral part of other procedures rather than have separate procedures. Whatever the method, you will need traceability from the identification of need to implementation of the provisions and from there to the records of achievement.

Handling (4.15.2)

The standard requires the supplier to *provide methods and means of handling that prevent damage or deterioration.*

Handling provisions serve two purposes, both related to safety: protection of the product from the individual and protection of the individual handling the product. By referring back to clause 4.15.1 it would appear that element 4.15 of the standard is only concerned with safety of the product and not the individual; however, the two cannot and should not be separated and handling procedures should address both aspects.

Handling product can take various forms, depending on the hazard you are trying to prevent from happening. In some cases notices on the product will suffice, such as “LIFT

HERE”, “THIS WAY UP”, or the notices on batteries warning of acid. In other cases you will need to provide special containers or equipment. There follows a short list of handling provisions which your procedures may need to address:

- Lifting equipment
- Pallets and containers
- Conveyors and stackers
- Design features for enabling handling of product
- Handling of electrostatic-sensitive devices
- Handling hazardous materials
- Handling fragile materials

Storage (4.15.3)

Use of designated storage areas (4.15.3.1)

The standard requires the supplier to *use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery.*

In order to preserve the quality of items that have passed receipt inspection they should be transferred to stock rooms in which they are secure from damage and deterioration. You need secure storage areas for several reasons:

- For preventing personnel from entering the stock rooms and removing items without authorization.
- For preventing items from losing their identity – once the identity is lost it is often difficult, if not impossible, to restore complete identification without testing material or other properties.
- For preventing vermin damaging the stock.
- For preventing climatic elements causing stock to deteriorate.

While loss of product may not be considered a quality matter, it is if the product is customer property or if it prevents you from meeting your customer requirements. Delivery

on time is a quality characteristic of the service you provide to your customer and therefore secure storage is essential.

To address these requirements you will need to identify and specify the storage areas that have been established to protect product pending use or delivery. Although it need be only a brief specification, the requirements to be maintained by each storage area should be specified, based on the type of product, the conditions required to preserve its quality, its location, and its environment. Products that require storage at certain temperatures should be stored in areas that maintain such temperatures. If the environment in the area in which the room is located is either uncontrolled or at a significantly higher or lower temperature, an environmentally controlled storage area will be required.

All items have a limit beyond which deterioration may occur and therefore temperature, humidity, pressure, air quality, radiation, vibration, etc. may need to be controlled. At some stage, usually during design or manufacturing or service planning, the storage conditions need to be defined and displayed. In many cases dry conditions at room temperature are all that is necessary but problems may occur when items requiring non-standard conditions are acquired. You will need a means of ensuring that such items are afforded the necessary protection and your storage procedures need to address this aspect. It is for this reason that it is wiser to store items in their original packaging until required for use. If packets need to be opened, they should be sealed again before return into storage.

The standard requires you to designate storage areas. This means that any area where product is stored should have been designated for that purpose in order that the necessary controls can be employed. If you store product in undesignated areas then there is a chance that the necessary controls will not be applied.

■ The quality system should make the right things happen by design and not by chance.

You can identify the areas you have designated for storage of different types of product in your quality manual or in a general storage control procedure. You can then place notices and markers around the area, if necessary, to indicate the boundaries where the controls apply.

Receipt and dispatch from storage areas (4.15.3.1)

The standard requires the supplier to *stipulate appropriate methods for authorizing receipt and the dispatch to and from storage areas.*

The content of storage areas should be known at all times in order that you can be confident that only that which is in storage areas is of a known condition. Storage areas containing conforming items should be separate from those containing nonconforming items (see later under *Preserving and segregating product*). It follows therefore that when an item is taken from a storage area the person taking it should be able to rely on it conforming unless otherwise stated on the label. If free access is given to add and remove items in such areas, this confidence is lost. If at any time the controls are relaxed, the whole stock becomes suspect.

There is often a need to supply items as free issue, as the loss of small value items is less than the cost of the controls to prevent such loss. This practice can be adopted only if the quality of the items can be determined wholly by visual inspection by the person using them.

There are, however, issues other than quality which will govern the control of items in stock. Inventory control is a vital part of any business. Stock ties up capital, so the less stock that is held the more capital the firm has available to apply to producing output.

A common solution, which satisfies both the inventory control and quality control, is to institute a stock requisition system. Authorization of requisitions may be given by a person's supervisor or can be provided via a work order. If someone has been authorized to carry out a particular job, this should authorize the person to requisition the items needed. Again for inventory control reasons, you may wish to impose a limit on such authority requiring the person to seek higher authority for items above a certain value.

The standard does not require stock records or inventory lists; however, without such a system you cannot demonstrate you have control over the receipt and dispatch of items from storage areas. The standard also does not require you to identify the location of items in stock, although without some reliable method of retrieving and accounting for items you cannot demonstrate whether or not unauthorized items have entered the storage area.

Stock condition assessments (4.15.3.1)

The standard requires the supplier to *assess the condition of product in stock at appropriate intervals in order to detect deterioration.*

Each time the storage controller retrieves an item for issue, there is an opportunity to check the condition of stock and this requirement should be written into the stock control procedures. However, some items may have a slow turnover in some storage areas, particularly maintenance storage areas where spares are held pending use. There is also a need to check periodically the overall condition of the stock for damage to the fabric

of the building or room. Rainwater may be leaking onto packaging and go undetected until that item is removed for use.

Some items, such as electrolytic capacitors and two-part adhesives, may deteriorate when dormant. Others, such as rubber, adhesive tape, and chemicals, deteriorate with the passage of time regardless of use. These are often referred to as “Shelf Life Items” or “Limited Life Items”. Dormant electronic assemblies can deteriorate in storage and provision should be made to retest equipment periodically or prior to release if in storage for more than one year.

The assessment interval should depend on the type of building, the stock turnover, the environment in which the stock is located, and the number of people allowed access, and a period fixed and stated in your procedures. The interval may vary from storage area to storage area and should be reviewed and adjusted as appropriate following the results of the assessment.

Inventory (4.15.3.2)

The standard requires use of an inventory management system to optimize inventory turns over time and assure stock rotation.

To enable you to achieve delivery requirements you may need adequate stocks of parts and materials to make the ordered products in the quantities required. In typical commercial situations, predicting the demand for your products is not easy – organizations tend to carry more inventory than needed to cope with unexpected demand. The possibility of an unexpected increase in demand leads to larger inventories as an out-of-stock situation may result in lost customer orders. Most companies have to rely on forecasts and estimates. Some customers may protect you to some extent from fluctuations in demand by giving you advanced notification of their production and service requirements in order that your production schedule can be “order driven”. Should an increase in demand be necessary you should be given adequate warning in order that you can increase your inventory in advance of the need. If adequate warning cannot be given, you need suitable clauses in your contract to protect you against any unexpected fluctuations in demand that may cause you to fail to meet the delivery requirement.

Inventory management is concerned with maintaining economic order quantities so that you order neither too much stock nor too little to meet your commitments. The stock level is dependent upon what it costs both in capital and in space needed to maintain such levels. Even if you employ a “ship-to-line” principle, you still need to determine the economic order quantities. Some items have a higher value than others, thereby requiring a higher degree of control. Use of the Pareto principle will probably reveal that 20%

of inventory requires a higher degree of control to enable you to control 80% of the inventory costs.

It is not my purpose here to elaborate on inventory management as this is a management function in its own right. From the quality management viewpoint, however, there are some factors that need to be considered.

An inventory management system should be established – meaning set up on a permanent basis to meet defined inventory policies and objectives approved by executive management. It should be documented – meaning that there should be a description of the system, how it works, the assignment of responsibilities, the codification of best practice, procedures, and instructions. The system should be planned, organized, and controlled in order that it achieves its purpose. A person should therefore be appointed with responsibility for the inventory management system and the responsibilities of those who work the system should be defined and documented. Records should be created and maintained that show how order quantities have been calculated in order that the calculations can be verified and repeated if necessary with new data. The records should also provide adequate data for continual improvement initiatives to be effective.

Whether or not 100% on-time delivery is a requirement of your customers, you won't retain customers for long if you continually fail to meet their delivery requirements, regardless of the quality of the products you supply. It is only in a niche market that you can retain customers with a long waiting list for your products. In competitive markets you need to exceed delivery expectations as well as product quality expectations to retain your market position.

In addition to establishing a documented inventory management system, you should optimize turnover time – meaning that the time a part goes through the system from receipt to use should be an optimum. (The phrase “turns over time” equates to “turnover time”.) To achieve optimum turnover you will need metrics for receiving and storage times. You should also assure stock rotation – meaning that parts and materials are used on a first-in-first-out (FIFO) basis. The picking system will need to be date sensitive to operate FIFO.

Controlling packing, packaging, and marking processes (4.15.4.1)

The standard requires the supplier to *control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.*

Packing is an activity and packaging a material in this context. A Packing Specification defines how an item should be packed, whereas a Packaging Specification details the nature of the package.

Control means setting standards, verifying conformance, and taking action on the difference. The control of packaging and marking processes therefore means that you have to set packaging and marking standards or requirements, verify that these requirements are being met by inspection, test, or analysis, and then remedy any deficiencies found.

Packing, packaging, and marking processes need to be controlled in order that product remains in its original condition until required for use. Packing processes should be designed to protect the product from damage and deterioration under the conditions that can be expected during storage and transportation.

Control of packing and marking processes commences during the design phase or the manufacturing or service planning phase. Packaging design should be governed by the requirements of clause 4.4, although if you only select existing designs of packaging these requirements would not be applicable.

You will need a means of identifying the packaging and marking requirements for particular products and of identifying procedures for the design of suitable packaging including the preservation and marking requirements. Depending on your business you may need to devise packages for various storage and transportation conditions, preservation methods for various types of product, and marking requirements for types of product associated with their destination. Packages for export may require different markings than those for the home market. Those for certain countries may need to comply with particular laws.

Systems for packaging (4.15.4.2)

Where applicable, preservation processes should require that the product be cleaned before being packed and preservative applied. In other cases the product may need to be stored in sealed containers in order to retard decay, corrosion, and/or contamination.

Unless your customer has specified packaging requirements, there are several national standards that can be used to select the appropriate packaging, marking, and preservation requirements for your products. Your procedures should make provision for the selection to be made by qualified personnel at the planning stage and for the requirements thus selected to be specified in the packing instructions to ensure their implementation.

Packing can be classed as a special process since once the units are placed in the containers and the containers sealed, the only way to subsequently verify the right units are in the right containers is to break the seal and inspect the contents. Your packing controls should therefore give you sufficient confidence concerning the contents of containers without having to break the seals.

Packing instructions should not only provide for protecting the product but also for including any accompanying documentation, such as:

- Assembly and installation instructions
- License and copyright notices
- Certificates of conformity
- Packing lists identifying the contents of the container
- Export documents
- Warranty cards

The packing instructions are likely to be one of the last instructions you provide and probably the last operation you will perform for a particular consignment. This also presents the last opportunity for you to make mistakes! They may be your *last* mistakes but they will be the *first* your customer sees. The error you made on component assembly probably won't be found, but the slightest error in the packaging, the marking, or the enclosures will almost certainly be found; therefore this process needs careful control. It may not be considered so skilled a process but all the same it is vital to your image.

Systems for labeling (4.15.4.3)

The standard requires the supplier *to have a system to ensure that all materials shipped are labeled according to customer requirements.*

Unless your customer has specified labeling requirements, markings should be applied both to primary and secondary packaging as well as to the product itself. Markings should also be made with materials that will survive the conditions of storage and transportation. Protection can be given to the markings while in storage and in transit but this cannot be guaranteed while products are in use. Markings applied to the product therefore need to be resistant to cleaning processes both in the factory and in use.

Preserving and segregating product (4.15.5)

The standard requires the supplier to *apply appropriate methods for preservation and segregation of product when such product is under the supplier's control.*

Preserving product while the product is under your control may be addressed by your handling and packaging provisions, but in-process preservation may also be necessary to protect finishes from deterioration during further processing. Such measures need to be specified in the work instructions for particular products. For products that start to deteriorate when the packaging seal is broken, the supplier's responsibility extends beyond delivery to the point of use. In such cases markings need to be applied to the containers to warn the consumers of the risks.

The preservation processes should be designed to prolong the life of the product by inhibiting the effect of natural elements. While the conditions in the factory can be measured, those outside the factory can only be predicted. Markings on packaging are therefore essential to warn handlers of any dangers or precautions they must observe.

Limited life items should be identified so as to indicate their useful shelf life. The expiry date should be visible on the container and provisions should be made for such items to be removed from stock when their indicated life has expired.

Segregation is another important requirement and not only for nonconforming product as specified in clause 4.13. Segregation is vital in many industries where products can only be positively identified by their containers. It is also important to prevent possible mixing or exposure to adverse conditions or cross-contamination. Examples where segregation makes sense are:

- Toxic materials
- Flammable materials
- Limited life items
- Explosives

Segregation is not only limited to the product but also to the containers and tools used with the product. Particles left in containers and on tools, no matter how small, can cause blemishes in paint and other finishes, as well as violate health and safety regulations. If these are such risks in your manufacturing process, procedures need to be put in place that will prevent product mixing.

Segregation may also be necessary in the packaging of products not only to prevent visible damage but electrical damage, as with electrostatic-sensitive devices. Segregation may be the only way of providing adequate product identity, as is the case with fasteners. While a well-equipped laboratory can determine the difference between products and materials the consumer needs a simple practical method of identification and labeled packets are often a reliable and economic alternative.

Delivery (4.15.6)

Protection of product after final inspection (4.15.6.1)

The standard requires the supplier to *arrange for the protection of the quality of product after final inspection and test and, where contractually specified, this protection shall extend to include delivery to destination.*

The ISO 9001 requirements do not add anything that isn't covered in clause 4.15.4 although the heading signals a quite different requirement. The requirement that the supplier arrange for protection of the product is different from the requirement in clause 4.15.4 for the supplier to preserve the product but the main purpose of the packaging requirements is to afford protection to the product. Packaging does have another purpose – that of easing handling and distribution. These are economic and marketing considerations rather than quality considerations.

It is quite common for companies to document their delivery practices covering preparation for delivery, packaging, preservation, documentation checks, delivery documentation including, where applicable, export documents, transportation practices, etc. ISO/TS 16949 supplements ISO 9001 in clause 4.15.6.2 by requiring all product or material to be shipped in conformance with customer-specified requirements including mode of transportation, routings, and containers. It is therefore important that these details be identified in the contract and, if they have been omitted, that you inform the customer of the arrangement you intend taking and seek customer approval. The final inspection requirements require you to complete the evidence of compliance with the specified requirements, but only with respect to the finished product. These requirements also require you to complete all activities stated in the procedures or quality plan before product is dispatched and (through the supplementary requirement) for no product to be dispatched until all the relevant specified requirements have been complied with.

Sometimes delivery is made electronically using a modem and telephone line. The product may be a software package, a document stored in electronic form, or a facsimile. Protection of the product is still required but takes a different form. You need to protect the product against loss and corruption during transmission.

After implementing all the requirements of ISO 9001 you should be able to certify with each delivery that the products supplied have been designed and produced under conditions that meet ISO 9001 and tests and inspections carried out to confirm their conformance with the contractual requirements. The standard does not require such a certificate of conformance and while not essential it is a good way of giving your customers confidence. You may have many product lines, some of which may not be registered to ISO/TS 16949. A certificate provides the appropriate objective evidence that the products supplied have been processed through the line registered to ISO/TS 16949. Although many certificates are indeed worthless, by suitable regulation their quality can be assured.

Establishing delivery systems (4.15.6.2)

The standard requires *systems to be established to support 100% on-time deliveries to meet customer production and service requirements.*

To guarantee shipment on time, you either need to maintain an adequate inventory of finished goods for shipment on demand or utilize only predictable processes and obtain sufficient advanced order information from your customer. When you examine some of the requirements in ISO/TS 16949, you may be tempted to question how you can continually improve performance, reduce costs, and minimize space, material travel, equipment downtime, process variation, etc. and meet 100% on-time shipments. You can't, unless you have a partnership with your customer in which there is mutual assistance to meet common objectives. Without sufficient lead time on orders you will be unlikely to meet the target. However, the standard does acknowledge that you may not always be successful. There will be matters outside your control and matters over which you need complete control. It is the latter that you can do something about and take corrective action should the target not be achieved.

Firstly, you need to estimate the production cycle time during the production trial runs in the product and process validation phase. An assessment of the PFMEA should enable you to identify the risk areas and build in appropriate contingencies. An assessment of your subcontractor's previous delivery performance will also enable you to predict their future performance. There are, however, many factors not featured in the technical assessment that may jeopardize shipment and this is where the quality system is most beneficial. Internal audits and management reviews will highlight activities that present unacceptable risk to achieving shipment targets. However, the primary source of information will arise in the regular meetings of the cross-functional teams and by addressing potential problems preventive action can be taken to minimize delivery problems.

Monitoring lead-time requirements (4.15.6.2)

The standard requires suppliers to *monitor adherence to established lead-time requirements*.

One of the factors requiring improvement is service and this can be construed to include timing. This can relate not only to delivery timing but also reduction in lead time. When new processes become stabilized over long periods and the frequency of improvement reduces as more and more problems are resolved, you will be able to reduce lead time.

Monitoring performance to customer delivery requirements (4.15.6.2)

The standard requires suppliers to *monitor performance to the customer delivery requirements with corrective actions taken as appropriate*.

Your planning and delivery procedures need to record estimated and actual delivery dates and the data collected and analyzed through a delivery performance monitoring procedure. When targets are not met you should investigate the cause under the corrective action procedures and formulate corrective action plans. Where the cause is found to be a failure of the customer to supply some vital information or equipment, it would be prudent not to wait for the periodic analysis but to react promptly.

Records of premium freight (4.15.6.2)

The standard requires *records of supplier responsible premium freight to be maintained*.

Premium freight was addressed briefly in Part 2 Chapter 3 under *Contract review*, as it is at the contract negotiation stage that the criteria will be established as to what is premium freight. If you fail to make delivery by the planned means (the means agreed in the contract) you may have no alternative but to choose a faster way of getting the shipment to its intended destination. This may result in additional cost. It is this cost that the customer wishes you to monitor and record.

Production scheduling (4.15.6.3)

The standard requires *appropriate scheduling to meet customer requirements that is supported by an information system that permits access to production information at the key stages of the process and is order driven*.

This requirement makes it very clear that customers in the automotive industry do not expect you to make for stock. You therefore need to have forecasts of orders expected or to have received the actual orders before scheduling production. The difference between production planning and production scheduling is that planning is concerned with preparation, whereas scheduling initiates production after all preparation has been completed. Throughout production you need a means of tracking progress in order that from the start delivery time can be predicted.

A problem you may find is that the customer changes the order quantity or the delivery date after you have scheduled production and the only way you can meet the prescribed schedule is to pay a premium for shipment. Providing you notify the customer in advance and obtain authorization to alter the mode of transportation there should not be a problem. However, you need a process in place to ensure this happens.

Electronic communication (4.15.6.4)

The standard requires the supplier to *have a computerized system for receipt of customer planning information and shipping schedules unless another method is agreed with the customer.*

The reason for this requirement is so that data from the customer can be transmitted quickly and reliably. The customer may need to change quantities and delivery dates due to variations in production. This does not mean the changes will always be to shorten delivery times but on occasions the delivery times may need to be extended owing to problems on the assembly line or as a result of problems with other suppliers. The customer may not have made provision to store your product so urgently needs to be able to inform you to hold or advance deliveries.

Advanced shipment notification system

The standard requires a *computerized system for on-line transmittal of advanced shipment notification and a method of backup in the event of failure.*

The customer will advise on the format of the advanced shipment notification (ASN). A computerized system will give you flexibility such that you are able to transmit the information immediately the shipment is loaded. You could use a fax machine as your backup since transmission is nearly as fast but this is likely to present the customer with data-handling problems. A computerized transmission feeds the data directly onto the customer database, by-passing the manual data-entry stage. Your backup system should do the same in order that your customer perceives no noticeable change in the information.

Documentation checks are vital at this stage since you are being judged on your on-time shipment performance. A delay caused by an error in the ASN will jeopardize all your hard work to meet the shipment date. The system that prints the container labels should therefore use the same data that is entered onto the ASN in order to avoid error. Eliminate human transcription errors and you are halfway there. The only other action is making sure that what's in the box is what it says on the label.

Task list

- 1 Produce procedures for developing storage, handling, and packing instructions.
- 2 Identify handling requirements for bulky, fragile, sensitive, and hazardous items.
- 3 Identify storage conditions for hazardous and environmentally sensitive items.
- 4 Identify packaging and preservation requirements for all types of items.
- 5 Identify marking requirements for product, as well as secondary and primary packaging.
- 6 Provide storage areas or rooms for items pending use.
- 7 Provide separate storage areas or rooms for items awaiting disposal, remedial action, or further processing.
- 8 Periodically assess conditions of stock and storage areas, rooms, and buildings.
- 9 Specify segregation rules for keeping items and materials apart.
- 10 Provide procedures for controlling limited life items.
- 11 Establish retest conditions for items which may deteriorate when dormant.
- 12 Provide packing instructions for packing certain types of product.
- 13 Set up electronic communication systems to receive and transmit data to and from customers.
- 14 Arrange for backup systems in the event that the computerized system breaks down.
- 15 Establish an inventory management system that enables FIFO and just-in-time deliveries and shipments.

Handling, storage, packaging, preservation, and delivery questionnaire

- 1 How are procedures for handling, storage, packaging, preservation, and delivery established, documented, and maintained?
- 2 How do you prevent damage or deterioration of product during handling?
- 3 How do you prevent damage or deterioration of product during storage?
- 4 How do you prevent damage or deterioration of product during delivery?
- 5 Which areas have you designated for the storage of product pending use or delivery?
- 6 How do you authorize receipt into storage areas or stock rooms?
- 7 How do you authorize dispatch from storage areas or stock rooms?
- 8 How do you detect deterioration in the condition of product in stock?
- 9 How do you control packing and packaging processes including the materials used?
- 10 How do you control preservation processes including the materials used?
- 11 How do you control marking processes including the materials used?
- 12 How do you preserve product when such product is under your control?
- 13 How do you segregate product when such product is under your control?
- 14 How do you ensure that the quality of product after final inspection and test is protected up to its destination?
- 15 How do you ensure your production schedules are order driven?
- 16 How do you ensure 100% on-time delivery?

Do's and don'ts

- ⊗ Don't allow items into storage areas without being subject to satisfactory inspection.
- ⊗ Don't allow unauthorized access to storage areas.
- ⊗ Don't store items that have lost their identity with items that haven't.
- ☺ Do segregate serviceable items from unserviceable items.
- ☺ Do segregate limited life items.
- ☺ Do identify items with special handling, storage, or packaging requirements.
- ☺ Do identify remnant material.
- ⊗ Don't allow packaging seals to be broken other than by authorized personnel.
- ☺ Do identify contents on the outside of containers.
- ☺ Do remove life-expired items from the serviceable items storage areas.
- ☺ Do instruct stock keepers on the effects of lost identity, mixing product, handling and packaging methods.
- ☺ Do maintain good housekeeping practices in storage and packaging areas.
- ☺ Do provide checklists for packaging operations.
- ☺ Do issue articles on a first in first out basis.
- ⊗ Don't permit unauthorized disposal of items suspected of being damaged.
- ☺ Do inspect items for identity, damage, and deterioration prior to issue.
- ⊗ Don't replenish stock other than with articles of the same specification.

Chapter 16

Control of quality records

Scope of requirements

Throughout the standard, various clauses reference the clause on quality records. To avoid repetition, the common requirements for quality records are assembled under one heading. The requirements, however, are not limited to those clauses in which this requirement is referenced as many other clauses refer to records. However, as all clauses will generate some documentary evidence it should not be assumed that all such documents are quality records. The requirements, however, apply only to original records and not to any copies other than those taken for security reasons or copies of subcontractor records. There are several types of document used in a quality system and only some are classified as quality records. As quality records are documents it might be assumed that the requirements of clause 4.5 on document and data control apply to quality records. As clause 4.16 is not cross referenced in clause 4.5 (except for clause 4.5.2.2), there is clearly no requirement for you to apply the requirements for document control to quality records. (See also Part 2 Chapter 5.) Figure 5.2 illustrates the difference between quality records and documents.

The requirements in element 4.16 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 16.1.

Types of quality records

The standard requires that *quality records be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.*

But what are quality records, you may ask? If we put all the references to clause 4.16 together we get a list of 20 quality records:

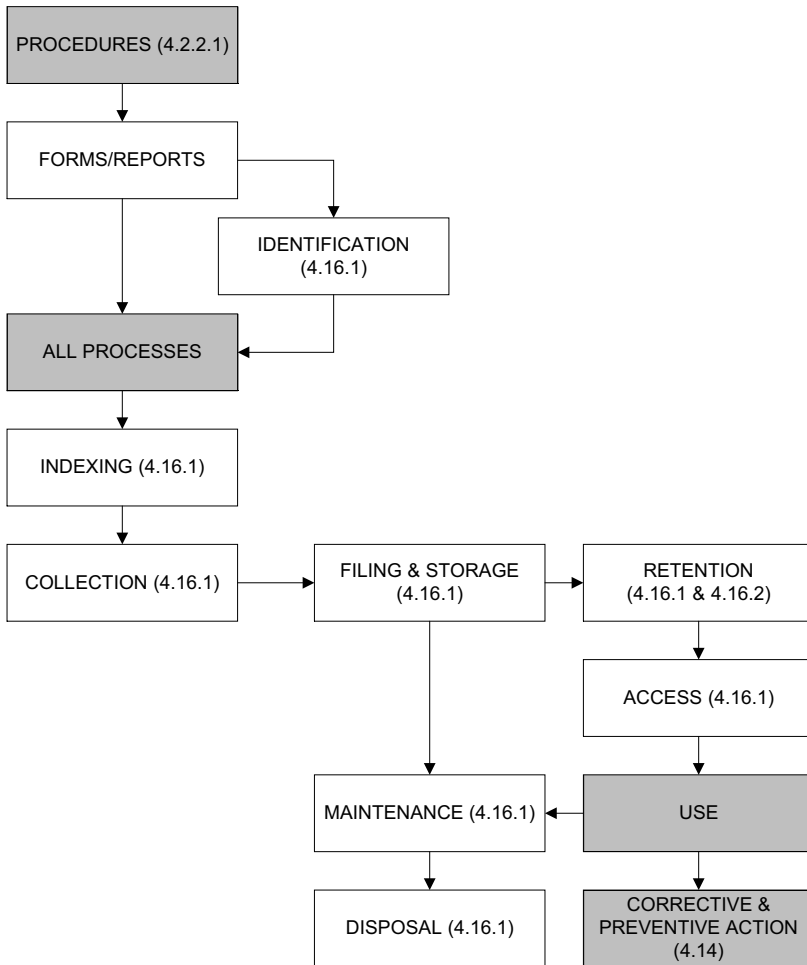


Figure 16.1 Clause relationships with the quality records element

- Management review records (clause 4.1.3)
- Process verification records (clause 4.2.4.9.4)
- Contract review records (clause 4.3.4)
- Design review records (clause 4.4.6)
- Design verification measures (clause 4.4.7)
- Design validation records (clause 4.4.8.2)

- Change implementation records (clause 4.5.2.2)
- Records of acceptable subcontractors (clause 4.6.2.1)
- Records of unsuitable customer supplied products (clause 4.7.1)
- Product identification records (clause 4.8)
- Qualified process records (clause 4.9.1.1)
- Qualified equipment records (clause 4.9.1.1)
- Qualified personnel records (clause 4.9.1.1)
- Control charts (clause 4.9.3)
- Positive recall records (clause 4.10.2.3)
- Inspection and test records (clause 4.10.5)
- Verification records for test hardware and test software (clause 4.11.1.1)
- Calibration records (clauses 4.11.2 and 4.11.3)
- Nonconformance records (clause 4.13.2)
- Nonconformance investigation records (clause 4.14.2.1)
- Subcontract quality records (clause 4.16.1)
- Internal audit result records (clause 4.17.1)
- Follow-up audit records (clause 4.17.1)
- Training records (clause 4.18.1)

These are the minimum number of records to be created and maintained. There are a further three records which a scan of the standard will reveal, although there is no cross reference to clause 4.16:

- Calibration status identification records (clause 4.11.2)
- Procedure change records (clause 4.14.1.1) – *these are not quality records (see below)*
- Subcontractor surveillance records (clause 4.6.2.1)

Although records are mentioned in clause 4.1.2.1 this clause deals with responsibilities and authority and contains no requirements to generate any records.

These lists tell us something about the nature of quality records, especially by what is not included. Absent from the lists are policies, procedures, instructions, plans, specifications, and any other prescriptive documents. The records all have one thing in common: they describe the results of some activity – the results of inspections, tests, reviews, audits, assessments, calculations, etc. However, these lists are dominated by records relating to product quality rather than to the operations of the quality system. In addition to audit records, the following records may need to be maintained to demonstrate the effectiveness of the quality system:

- Customer complaints
- Warranty claims
- Failure analysis reports
- Process capability studies
- Service reports
- Concessions
- Change requests
- Subcontractor assessments
- Performance analysis
- Deviations and waivers
- Contract change records
- Quality cost data
- External Quality Audit records

It is advisable to identify all your quality records within your procedures. This will avoid arguments on what is or is not a quality record, because once you have chosen to identify a record as a quality record you have invoked all the requirements that are addressed in this chapter. Any document which describes the achieved features and characteristics of a product or service are quality records. Those records which will demonstrate that work has been planned, organized, resourced, monitored, verified, and corrected when found deficient are also quality records. The note following the requirement acknowledges that quality records can be in hard copy or held on a computer disk or magnetic tape. Should both forms be held, you will need to declare which are the masters and provide the appropriate security to prevent inadvertent loss or damage (see below).

Some auditors believe that any document generated or used by the quality system is a quality record and will attempt to apply the requirements of clause 4.16. Whilst it can be argued that any documented output is a record of an activity, the reader is referred to ISO 8402 for a definition of records in the context of the quality system. ISO 8402 states that a record is *a document which furnishes objective evidence of activities performed or results achieved. A quality record provides objective evidence of the fulfillment of the requirements for quality (e.g. product quality record) or the effectiveness of the operation of a quality system element (e.g. quality system record).*

If a quality record was intended to be any document generated or used by the quality system, the definition would surely have indicated this. If we decompose the definition further, *requirements for quality* are defined in ISO 8402 as the *expression of the needs or their translation into a set of quantitatively stated requirements for the characteristics of an entity to enable its realization and examination*. Clearly, such a requirement would be a contract, product specification, design requirement, etc. This implies that any product verification records are quality records, but it rules out any recorded information as being a quality record.

Regarding the effectiveness of the quality system, the very existence of a document is not evidence of effectiveness but it can be regarded as a record. To be a quality record, the document would need to contain results of an examination into the effectiveness of the system.

Identification of quality records

The standard requires the supplier to *establish and maintain documented procedures for the identification of quality records*.

Whatever the records, they should carry some identification in order that you can determine what they are, what kind of information they record, and what they relate to. A simple way of doing this is to give each record a reference number and a name or title.

Records can take various forms: reports containing narrative, computer data, forms containing data in boxes, graphs, tables, lists, and many others. Where forms are used to collect data, they should carry a form number and name as their identification. When completed they should carry a serial number to give each a separate identity. Records should also be traceable to the product or service they represent and this can be achieved either within the reference number or separately, providing the chance of mistaken identity is eliminated. The standard does not require records to be identifiable to the product involved but unless you do make such provision you will not be able to access the pertinent records or demonstrate conformance to specified requirements.

Collection of quality records

The standard requires the supplier to *establish and maintain documented procedures for the collection of quality records*.

In order to demonstrate the achievement of quality and the effectiveness of the quality system, records will need to be gathered in from the locations where they were produced. This is more than a convenience because you will be unable to analyze all the data efficiently unless you need it in front of you. If you are lucky enough to operate a computer network and all the data is available on the network, data collection is a simple affair. However, many organizations still rely on paper records and therefore you will need a means of enabling such records to be either submitted to the analysis points or collected from source. To facilitate the collection of records you will need to insert submission or collection instructions in the relevant procedures which specify the records.

Indexing of quality records

The standard requires the supplier to *establish and maintain procedures for the indexing of quality records*.

This is a similar requirement to that concerned with the identification of quality records but it serves a different purpose. You will need a means of ensuring that you have all the records that have been produced and that none are missing or, if they are, you know the reason. A simple means of indexing quality records is to create and maintain registers listing the records in numerical order as reference or serial numbers are allocated. The records could be filed in sequence so that you can easily detect if any are missing, or you can file the records elsewhere, providing your registers or your procedures identify the location.

Access to quality records

The standard requires the supplier to *establish and maintain procedures for the access of quality records*.

This requirement supplements that for records to be readily retrievable but in addition implies a further requirement for security of records. After addressing the filing and storage requirements, you need to ensure that the records are accessible to those who will need to use them. This applies not only to current records but to those in the archive and any “insurance copies” you may have stored away. A balance has to be attained

between security of the records and their accessibility. You may need to consider those who work outside normal working hours and those rare occasions when the trouble shooters are working late, perhaps away from base with their only contact via a computer link. As implied above, access has two meanings, one allowing access and the other prohibiting access. If your records are held on a computer database, then password protection may be necessary. If they are held in a locked room or filing cabinet then you need to nominate certain persons as key holders and ensure that these people can be contacted in an emergency. Your procedures should define how you provide and prohibit access to the records.

Filing quality records

The standard requires the supplier to *establish and maintain documented procedures for the filing of quality records*.

The requirement for filing quality records is linked to the indexing requirement. You should know where to find your quality records in order that you can retrieve them when needed. They will be needed to demonstrate compliance with the standard to an assessor or to a customer and they will be needed to carry out the corrective action and management review requirements. One method is to create a filing system that allocates file locations to certain types of documents. Remember, these records are not personal property or the property of a particular department; they belong to the organization and are a record of the organization's performance. Such records should not be stored in personal files. The filing system you create should therefore be integrated with the organization's main filing system and the file location should either be specified in the procedure which defines the record or in a general filing procedure. However, don't state the room number, otherwise your procedures will become difficult to maintain if you move offices often.

If you operate a computerized record system, filing will be somewhat different although the principles are the same as for paper records. Computerized records need to be located in named directories for ease of retrieval and the locations identified in the procedures.

Storage of quality records

The standard requires the supplier to *establish and maintain documented procedures for the storage of quality records* and in addition requires *quality records to be stored in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss*.

Linked to the filing and indexing requirement, this requirement addresses the conditions of storage and also provides the reasons: i.e. to prevent loss. On the subject of loss, you will need to consider loss by fire, theft, and unauthorized removal. If using computers you will also need to consider loss through computer viruses and unauthorized access, deletion, or the corruption of files. A booking in/out system should be used for completed records when they are in storage, in order to prevent unauthorized removal.

Records soon grow into a mass of paper and occupy valuable floor space. To overcome this problem you may choose to microfilm the records but keep them in the same location or archive them in some remote location. In both cases you need to control the process and the conditions of storage. With paper archives you will need to maintain records of what is where, and if the archive is under the control of another group inside or outside the organization, you will need adequate controls to prevent loss of identity and inadvertent destruction.

It is always risky to keep only one copy of a document. If computer generated, you can easily make another copy provided you always save it, but if manually generated, its loss can be very costly. It is therefore prudent to produce additional copies of critical records as an insurance against inadvertent loss. These “insurance copies” should be stored in a remote location under the control of the same authority that controls the original records. Insurance copies of computer disks should also be kept in case of problems with the hard disk or file server, if you use one.

Maintenance of quality records

The standard requires the supplier to *establish and maintain procedures for the maintenance of quality records*. In addition it requires *records to be retained in such a way that they are readily retrievable and legible*.

There are three types of maintenance regarding quality records:

- Keeping records up to date
- Keeping the information in the records up to date
- Keeping the records in good condition

Some records are designed to collect data as they pass through the process and need to be promptly updated with current information. Remember:

■ **The job isn't done until the paperwork is complete.**

The filing provisions you have made should enable your records to be readily retrievable; however, you need to maintain your files if the stored information is to be of any use. In practice, records will collect at the place they are created and unless promptly removed to secure files may be mislaid, lost, or inadvertently destroyed. Once complete, quality records should not be changed. If they are subsequently found to be inaccurate, new records should be created. Alterations to records should be prohibited as they bring into doubt the validity of any certification or authentication as no one will know whether the alteration was made before or after the records were authenticated. In the event that alterations are unavoidable due to time or economic reasons, errors should be struck through in order that the original wording can still be read, and the new data added and endorsed by the certifying authority.

Records, especially those used in workshop environments, can become soiled and therefore provisions should be made to protect them against attack by lubricants, dust, oil, and other materials that may render them unusable. Plastic wallets can provide adequate protection while records remain in use.

Disposition of quality records

The standard requires the supplier to *establish and maintain documented procedures for the disposition of quality records*.

Disposition in this context means the disposal of records once their useful life has ended. The requirement should not be confused with that on the retention of records. Retention times are one thing and disposal procedures quite another.

As said previously, records are the property of the organization and not personal property so their destruction should be controlled. The controls should ensure that records are not destroyed without prior authorization and, depending on the medium on which data is recorded and the security classification of the data, you may also need to specify the method of disposal. The management would not be pleased to read details in the national press of the organization's performance, collected from a waste disposal site by a zealous newspaper reporter!

Demonstrating conformance to specified requirements

The standard requires that *quality records be maintained to demonstrate conformance to specified requirements*.

The impact of this requirement depends upon what constitutes the specified requirements. The standard does not require you to demonstrate conformance with every requirement of ISO 9001. However, if your customer has invoked ISO 9001 in the contract, this clause requires that you maintain sufficient records to demonstrate compliance. As stated elsewhere in this book, there is no definition clarifying what specified requirements are. If “specified requirements” are *all* the requirements that you have specified in your quality system, your plans, procedures, specifications, etc., this requirement may well be viewed as the most onerous in the standard. A pragmatic approach to take is to declare in your quality manual that the “specified requirements” are “specified customer requirements”.

Demonstrating the effective operation of the quality system

The standard requires that *quality records be maintained to demonstrate the effective operation of the quality system.*

One can demonstrate the effective operation of the quality system in several ways:

- By examination of customer feedback
- By examination of quality system audit results
- By examination of the management review records
- By examination of quality cost data

Showing records that every requirement of the standard has been met will not, however, demonstrate that the system is effective. You may have met the requirement but not carried out the right tasks or made the right decisions. The effectiveness of the quality system should be judged by how well it fulfills its purpose (see Part 1 Chapters 1 & 4 and Part 2 Chapters 2 & 17). There is in fact no requirement for you to do this and while it may seem that this is the purpose of the requirement, if this was the case it would be clearly stated as such. Some assessors may quote this requirement when finding that you have not recorded a particular activity that is addressed in the standard. They are not only mistaken but attempting to impose an unnecessary burden on companies, which will be perceived as bureaucratic nonsense. One can demonstrate the effectiveness of the system simply by producing and examining one or more of the above records.

Pertinent subcontractor quality records

The standard requires that *pertinent subcontractor quality records be an element of these data*.

The subcontractor records that are delivered to you should form part of your records. However, the controls you can exercise over your subcontractor's quality records are somewhat limited. You have a right to the records you have paid for but no more unless you invoke the requirements of this clause of the standard in your subcontract. Your rights will probably only extend to your subcontractor's records being made available for your inspection on their premises; therefore you will not be able to take away copies. It is also likely that any subcontractor records you do receive are *copies* and not originals. Before placing the contract you will need to assess what records you will require to be delivered and what records the contractor should produce and retain.

Retention of quality records

The standard requires *the retention times of quality records to be established and recorded*. The supplementary requirements extend the records retention requirements to *quality system related documents and records to satisfy regulatory and customer requirements as a minimum*.

It is important that records are not destroyed before their useful life is over. There are several factors to consider when determining the retention time for quality records:

- *The duration of the contract* – some records are only of value while the contract is in force.
- *The life of the product* – access to the records will probably not be needed for some considerable time, possibly long after the contract has closed. On defense contracts the contractor has to keep records for up to 20 years and for product liability purposes, in the worst case situation (taking account of appeals), you could be asked to produce records up to 17 years after you made the product.
- *The period between quality system assessments* – assessors may wish to see evidence that corrective actions from the last assessment were taken. If the period of assessment is three years and you dispose of the evidence after two years, you will have some difficulty in convincing the assessor that you corrected the deficiency.

You will also need to take account of the subcontractor records and ensure adequate retention times are invoked in the contract.

Where the retention time is actually specified can present a problem. If you specify it in a general procedure you are likely to want to prescribe a single figure, say five years for all records. However, this may cause storage problems – it may be more appropriate, therefore, to specify the retention times in the procedures that describe the records. In this way you can be selective.

You will also need a means of determining when the retention time has expired so that if necessary you can dispose of the records. The retention time doesn't mean that you must dispose of the records when the time expires – only that you must retain the records for at least that stated period. Records will need to be dated, the files that contain the records dated, and, if stored in an archive, the shelves or drawers dated. It is for this reason that all documents should carry a date of origin and this requirement needs to be specified in the procedures that describe the records. If you can rely on the selection process, a simple method is to store the records in bins or on computer disks that carry the date of disposal.

While the ISO 9001 requirement applies only to quality records, ISO/TS 16949 extends retention times for many other documents because you cannot demonstrate you have or had operations under control without specifications, plans, procedures, etc. You may also need to retain tools, jigs, fixtures, test software – in fact anything that is needed to repair or reproduce equipment in order to honor your long-term commitments.

Availability of quality records

The standard requires *quality records to be made available for evaluation by the customer or his representative for an agreed period, where agreed contractually.*

Providing you adopt the methods previously described, any records required by your customer will be available, easily retrievable, and in good condition. Should the customer specify a retention period greater than what you prescribe in your procedures, special provisions will need to be made and this is a potential area of risk. Customers may choose not to specify a particular time and require you to seek approval before destruction. Any contract which requires you to do something different creates a problem in conveying the requirements to those who are to carry them out. The simple solution is to persuade your customer to accept your policy. You may not want to change your procedures for one contract. If you can't change the contract, the only alternative is to issue special instructions. You may be better off storing the records in a special contract store away from the normal storage area or alternatively attach special labels to the files to alert the people looking after the archives.

Quality records procedures

The standard requires that the supplier *establish and maintain procedures covering quality records* and from the previous explanation it should be clear what they need to address.

You may only need one procedure that covers all the requirements but this is not always practical. The provisions you make for specific quality records should be included in the procedures for controlling the activity being recorded. For example, provisions for inspection records should be included in the inspection procedures, provisions for design review records should be included in the design review procedure. Within such procedures you should provide the forms (or content requirements for the records), the identification, collection/submission provisions, the indexing and filing provisions. It may be more practical to cover the storage, disposal, and retention provisions in separate procedures because they may not be type-dependent. Where each department retains its own records, these provisions may vary and therefore warrant separate procedures.

Authentication of records

Apart from inspection and test records (clause 4.10.5), the standard does not require records to be authenticated, certified, or validated. A set of results without being endorsed with the signature of the person who captured them lacks credibility. Facts that have been obtained by whatever means should be certified for four reasons:

- They provide a means of tracing the result to the originator in the event of problems.
- They indicate that the provider believes them to be correct.
- They enable you to verify whether the originator was appropriately qualified.
- They give the results credibility.

If the records are generated by computer and retained in computerized form, a means needs to be provided for the results to be authenticated.

Task list

- 1 Identify all the records that demonstrate the achievement of quality.
- 2 Identify all the records that demonstrate the effectiveness of the quality system.
- 3 Give each record a name and a reference number, and each completed form a serial number.
- 4 Create and maintain registers for allocation of reference numbers and serial numbers.
- 5 Quote the product/service identification number on all related records.
- 6 Include record collection or submission provisions in your procedures.
- 7 Introduce file references for containing records.
- 8 Take “insurance copies” of all important records.
- 9 Introduce computer virus controls.
- 10 Provide secure means by which authorized staff can access records outside normal working hours.
- 11 Restrict access to records held on computer disk or tape.
- 12 Introduce a booking in and out system for files and records in storage.
- 13 Control storage conditions of paper, microfilm, and computerized records.
- 14 Introduce filing disciplines, clean desk policies, etc.
- 15 Provide plastic wallets for records that may become soiled in use.
- 16 Introduce a disposal procedure for documentation.
- 17 Introduce standard clauses on quality records for insertion into subcontracts.
- 18 Specify retention times for quality records and quality system related documents in the related procedures.
- 19 Store records by disposal date.
- 20 Provide a means of varying the retention times to accommodate specific customer requirements.

Quality records questionnaire

- 1 In which document do you identify the records which demonstrate conformance to specified requirements?
- 2 In which documents do you identify the records which demonstrate the effective operation of the quality system?
- 3 How do you identify your quality records?
- 4 How do you collect your quality records?
- 5 How do you index your quality records?
- 6 How do you provide and prevent access to quality records?
- 7 How do you file your quality records?
- 8 How do you store your quality records?
- 9 How do you maintain your quality records?
- 10 How do you dispose of your quality records?
- 11 How do you ensure that pertinent subcontractor quality records are maintained?
- 12 How do you ensure that all quality records remain legible?
- 13 How do you ensure that quality records are readily retrievable?
- 14 How do you ensure that quality records are stored in facilities that provide a suitable environment that minimizes deterioration and damage and that prevents loss?
- 15 In which documents do you record the retention times of quality records and quality system documents?

Do's and don'ts

- ⊗ Don't retain boxes of forms that serve no purpose.
- ⊗ Don't permit unauthorized deletions on certified records.
- ⊗ Don't permit the unauthorized design of record blanks.
- ⊗ Don't change record blanks without authorized changes to the related procedure.
- ⊗ Don't leave records lying around.
- ⊗ Don't archive uncompleted records.
- ⊗ Don't lose track of where records are stored.
- ⊗ Don't forget to transfer records to their new owners.
- ☺ Do ensure someone is made responsible for maintaining each type of record.
- ☺ Do record all product and process acceptance decisions.
- ☺ Do record all changes to the quality system.
- ☺ Do record all changes to design, products, processes, and measuring devices.
- ☺ Do ensure all records are dated.
- ☺ Do record the date on which new documents and changes become effective.
- ☺ Do test new records for their fitness for use before general release.
- ☺ Do denote the issue status on record blanks.

Chapter 17

Internal quality audits

Scope of requirements

The requirements for internal audits apply to audits of the quality system, including the policies, practices, products, and services to which the quality system relates. They are not limited to audits of procedures. In order to determine whether the quality system is effective in maintaining control, you need to check that the resultant products and services meet the specified requirements and that prescribed quality objectives are being achieved. If the products and services are not meeting the specified requirements, or the prescribed objectives are not being achieved, something is clearly amiss with the quality system. The requirements do not apply to audits of suppliers or subcontractors as they are covered in clause 4.6 of the standard.

The purpose of quality audits is to establish, by an unbiased means, factual information on quality performance. Quality audits are the measurement component of the quality system. Having established a quality system it is necessary to install measures that will inform management whether the system is being effective. Installing any system without some means of being able to verify whether it is doing its intended job is a waste of time and effort – hence the importance of the internal audit requirement. Audits gather facts, they should not change the performance of what is being measured and should always be performed by someone who has no responsibility for what is being measured. Audits should not be performed to find faults, to apportion blame, or to investigate problems; other techniques should be used for these purposes. Further guidance is provided in the *ISO 9000 Quality System Assessment Handbook* and in ISO 10011.

The requirements in element 4.17 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 17.1.

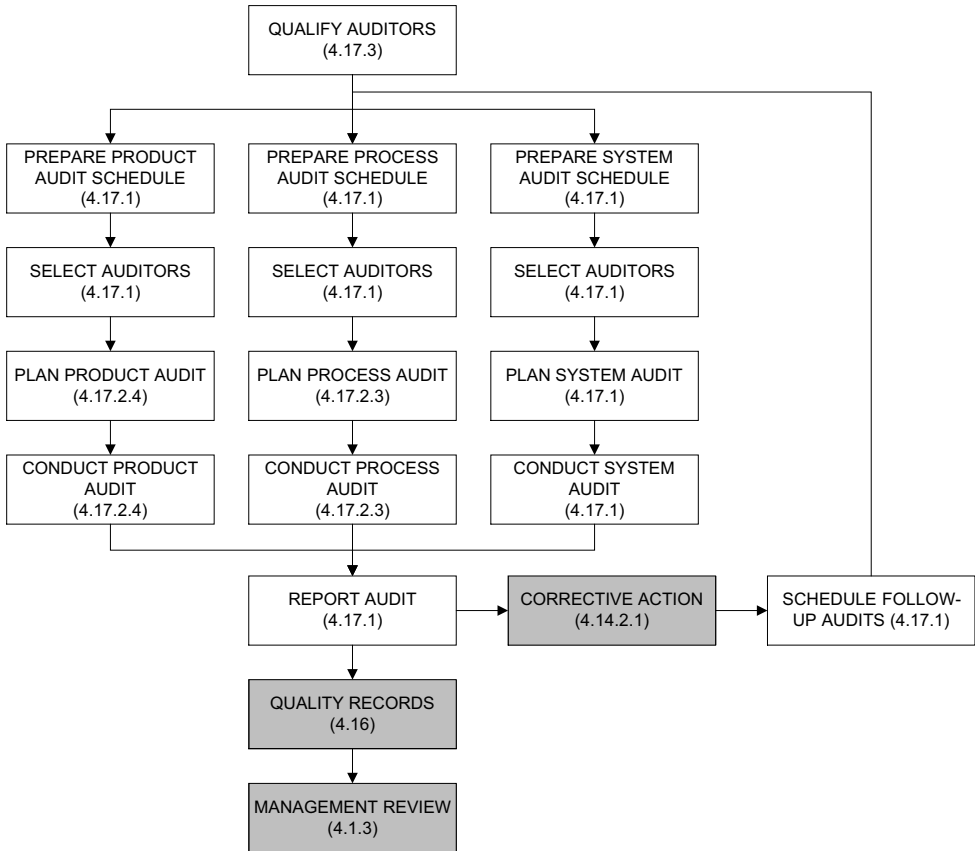


Figure 17.1 Clause relationships with the internal quality audit element

Audit procedures (4.17.1)

The standard requires the supplier to *establish and maintain documented procedures for planning and implementing internal quality audits.*

The standard requires procedures for both planning and implementing audits and these should cover the following:

- Preparing the annual audit program
- The selection of auditors and team leader if necessary
- Planning audits of each type
- Conducting the audit

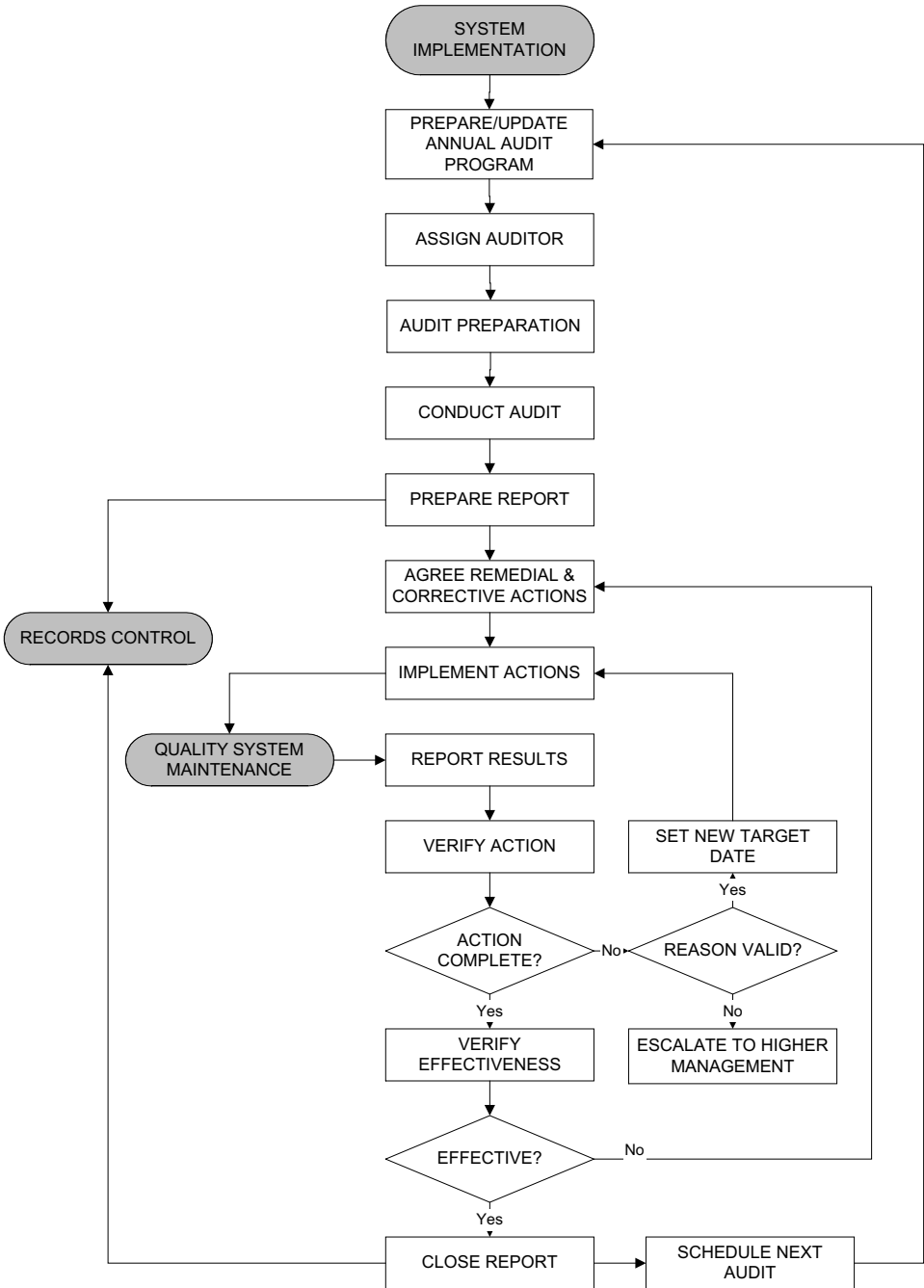


Figure 17.2 Internal quality system audit process

- Recording observations
- Determining corrective actions
- Reporting audit findings
- Implementing corrective actions
- Confirming the effectiveness of corrective actions
- The forms on which you plan the audit
- The forms on which you record the observations and corrective actions
- Any warning notices you send out of impending audits, overdue corrective actions, escalation actions

The system audit process is shown in Figure 17.2. Certain activities such as the opening and closing meeting have been omitted for clarity because they are not always needed for internal audits. The product audit process would be somewhat different but the principles would be the same. Further guidance on the conduct of audits can be found in Appendix C.

The audit program (4.17.1)

The standard requires audits to be planned but does not specify whether it is the system that should be planned or whether it is individual audits that should be planned. The overall plan is in fact a *program* because this should have dates on which the audits are to be conducted. There is no requirement for audits to be comprehensive; however, planned audits may not be comprehensive and comprehensive audits may not be planned, so there is a need to ensure that the audit program covers all aspects of the quality system in all areas where it is to be employed. The coverage of the audit program should be designed so that it obtains sufficient confidence in operations to be able to declare that the system is effective. There may be a need for different types of audit programs depending on whether the audits are of the quality system, processes, products, or services. The audit program should be presented as a calendar chart showing where and when the audits will take place.

All audits should be conducted against a standard for the performance being measured. Examinations without such a standard are surveys, not audits. Audits can also be conducted against contracts, project plans, specifications – in fact any document with which the organization has declared it will comply. The standard now requires system audits to be conducted to verify compliance with ISO/TS 16949 and any other system requirements.

An audit of one procedure or requirement of the standard in one area only will not be conclusive evidence of compliance if the same procedures and requirements are also applicable to other areas. Where operations are under different managers but performing similar functions you cannot rely on the evidence from only one area – management styles, commitment, and priorities will differ. In order to ensure that your audit program is comprehensive you will need to draw up a matrix showing what policies, procedures, standards, etc. apply to which areas of the organization. The program also has to include shift working so your auditors need to be very flexible. One audit per year covering 10% of the quality system in 10% of the organization is hardly comprehensive. However, there are cases where such an approach is valid. If sufficient confidence has been acquired after conducting a comprehensive series of audits over some time, the audit program can be adjusted so that it targets only those areas where change is most likely, auditing more stable areas less frequently.

Procedures will contain many provisions, not all of which may be susceptible to verification at the time of the audit. This may be due either to time constraints or to work for which the provisions apply not being scheduled. It is therefore necessary to record which aspects have or have not been audited and engineer the program so that over a one to three year cycle all procedures and all requirements are audited in all areas at least once.

Planning quality audits

The detail plan for each audit may include dates if it is to cover several days but the main substance of the plan will be what is to be audited, against what requirements, and by whom. At the detail level, the specific requirements to be checked should be identified based upon risks, past performance, and when it was last checked. Overall plans are best presented as program charts and detail plans as checklists. Audit planning should not be taken lightly. Audits require effort from auditees as well as the auditor so a well-planned audit designed to discover pertinent facts quickly is far better than a rambling audit which jumps from area to area looking at this or that without any obvious direction.

Although checklists may be considered a plan, in the context of an audit they should be considered only as an aid to allow the auditor to follow trails that may lead to the discovery of pertinent facts. However, there is little point in drawing up a checklist then putting it aside. The checklist should represent the minimum aspects to be checked so that following the audit you have evidence indicating:

- Which activities were compliant
- Which activities did not comply
- Which activities were not checked

Verifying compliance with planned arrangements (4.17.1)

The standard requires the supplier to *carry out audits to verify whether quality activities and related results comply with planned arrangements.*

The term *quality activities* is not defined in ISO 8402 and while it may seem obvious it can create confusion. If we list all the activities which can affect quality, we could say that these are all quality activities. But many of these are also design, purchasing, manufacturing, and installing activities. Can they also be quality activities? Quality activities are not restricted to the activities of the quality department or other similar departments. The only clue in the standard as to what quality activities are is in clause 4.1.2.1 where it requires the responsibility of all personnel who manage, perform, and verify work affecting quality to be defined. So a quality activity is any activity that affects the ability of a product or service to satisfy stated or implied needs.

The related results are the results produced by implementing the policies and procedures. They include documents, decisions, products, and services. It is not enough for internal audits to verify that procedures are being followed. They need to verify whether the outputs of these procedures comply with the prescribed requirements.

Planned arrangements is another unusual term, especially when throughout the standard the terms *documented quality system* and *documented procedures* have been used. However, so that audits are not restricted to documented procedures and policies, the term *planned arrangement* has been used. It encompasses contracts, specifications, plans, objectives, strategies – in fact any arrangement made by the organization to satisfy customer needs. You therefore need to define what constitutes your planned arrangements.

One aspect often overlooked in carrying out audits is the working environment. The working environment becomes important when it can affect the product – such as cleanliness in the microelectronics and coatings industries.

However, there are aspects which directly affect the product such as handling, cleanliness, temperature, etc. and those that indirectly affect the product such as lighting, housekeeping, ventilation, etc. If the personnel cannot see, or become dizzy through fumes, then the product may be damaged or nonconforming product may be released. If personnel could be injured and blood drip onto the product then obviously this needs to be prevented. The methods used to provide a safe and suitable working environment should be a part of your planned arrangements and be included in your audit checklists.

The scope of the working environment should not be limited to manufacturing areas but include the working environment in the marketing, design, purchasing, quality assur-

ance departments, etc. In these areas there may be an indirect effect on product quality if we take into account noise, housekeeping, and staff discipline. It is difficult to concentrate and make the right decisions when the working area is noisy and other colleagues cause distraction.

Audits can take several forms:

- The *system audit*: to verify that the quality system complies with the appropriate part of ISO 9000. The system audit is a composite of a documentation audit and implementation audit (see below). This is now required in ISO/TS 16949 clause 4.17.2.2. VDA 6.1 provides general guidance and VDA 6.2 addresses services.
- The *strategic quality audit*: to verify that the strategic plans of the organization address specified legal, environmental, safety, and market quality requirements.
- The *policy audit*: to verify that the documented policies promulgate the requirements of the standard and the objectives of the business.
- The *organization audit*: to verify that the organization is equipped and resourced to implement the policies and achieve the stated objectives.
- The *documentation audit*: to verify that the documented practices implement the approved policies and the relevant requirements of the standard.
- The *implementation audit*: to verify that the documented practices are being followed and that there are no undocumented practices employed that affect quality. This can be divided into two parts, one addressing upper management and their implementation of the strategic plans and one addressing staff and their implementation of the procedures.
- The *process audit*: to verify that the result-producing processes control products and service within the defined limits. This is now required in ISO/TS 16949 clause 4.17.2.3. VDA 6.3 provides guidance.
- The *product or service audit*: to verify that the resultant products and services meet the prescribed requirements. This is now required in ISO/TS 16949 clause 4.17.2.4. VDA 6.5 provides guidance.

Determining the effectiveness of the system (4.17.1)

The standard requires the supplier to *carry out audits to determine the effectiveness of the system*.

Even when you have verified that policies are being met, documented procedures are implementing policies, and these procedures are being implemented etc., you need a means of determining whether the system is being effective. You could be doing everything you say you will do but still not be satisfying customers.

The requirement is also somewhat duplicated in clause 4.1.3 on management reviews. You are required to conduct management reviews to ensure quality system effectiveness and conduct internal quality audits to determine the effectiveness of the system. It would appear that the audit collects the evidence and the review ensures that it is collected.

There are two dimensions to effectiveness: the results gained by measuring effectiveness and the effectiveness of the method used to determine the results. There are several methods which can be used to determine the effectiveness of the quality system:

- Quality audit
- Performance monitoring
- Quality costing
- Customer surveys

Management should not be surprised by what customers are saying about them. They should know how good their products and services are and how well they satisfy customer needs. Part of this confidence should come from the quality audit. Audits should be providing management with knowledge they don't possess, not telling them what they already know as a fact. The audit and not the customer should be the first to reveal any problems. If audits only report historic facts they are ineffective. If having conducted an audit, problems are later revealed which were clearly present when the audit was conducted, the audit has not been effective. If subsequent audits reveal facts that should have been detected during previous audits, measures should be taken to adjust the auditing method or the audit plan.

Effectiveness is concerned with doing the right things rather than with doing things right. So if the system enabled management to stop the development of products for which there was no requirement, discover a potential safety problem, anticipate customer needs ahead of the competition, cut waste by 50%, successfully defend a product

liability claim, meet all the delivery targets agreed with the customer, you would probably say that the system was pretty effective. If on the other hand the system allowed the shipment of defective products every day, lost one in three customers, allowed the development of unsafe products to reach the market, or the failure of a revolutionary power plant, you would probably say that the system was pretty ineffective. So the first thing you need to do is establish what you want the quality system to do, because without a yardstick as a measure, you can't determine whether the system is effective or not. Many systems are only designed to meet the standard with the result that you can deliver defective product providing you also deliver some which are not defective. The standard cannot and should not tell you what targets to meet; that is why you need to define your quality objectives (see Part 2 Chapter 1) and use performance monitoring as a means of determining whether these objectives are being achieved. One measure of quality is the cost of nonconformance.

In order to discover whether you are doing the right things a measure of the distribution of effort would help. If you are spending 50% of the effort on appraisal and corrective activities, clearly your operations are not effective or efficient. Quality costs can help reveal this data and while it should not be used as a measure of absolute costs, it does help in determining whether there have been improvements if you take measurements before and after the introduction of change. So while not a requirement, it can be argued that quality costs should be used as one of the methods of determining the effectiveness of the quality system.

Scheduling quality audits (4.17.1)

The standard requires the supplier to *schedule audits on the basis of the status and importance of the activity*.

Status of the activity

Status has three meanings in this context: the first to do with the relative position of the activity in the scheme of things; the second to do with the maturity of the activities; and the third to do with the performance of activities. There is little point in conducting in-depth audits on activities that add least value. There is also little point auditing activities that have only just commenced. You need objective evidence of compliance and that may take some time to be collected. Where the results of previous audits have revealed a higher than average performance in any area (such as zero nonconformities on more than two occasions), the frequency of audits may be reduced. However, where the results indicate a lower than average performance (such as a much higher than average number of nonconformities), the frequency of audits should be increased.

Importance of the activity

On the importance of the activity, you need to establish to whom is it important: to the customer, the managing director, the public, your immediate superior? You also need to establish the importance of the activity upon the effect of noncompliance with the planned arrangements. For example, not ordering the correct grade of steel may only delay fabrication if you are lucky but, if not detected in time, may result in the component failing in service. Getting the purchase specification correct is important so this activity should be audited.

Importance also applies to what may appear minor decisions in the planning or design phase. If such decisions are incorrect they could result in major problems downstream. If not detected, getting the decimal place wrong or the units of measure wrong can have severe consequences. Audits should verify that the appropriate controls are in place to detect such errors before it is too late.

Previously on the subject of the comprehensiveness of audits, it was suggested that you ensure all procedures and policies are verified in all areas at least once every one to three years. The status and importance of the activities will determine whether the audit is scheduled once a month, once a year, or left for three years.

The independence of auditors (4.17.1)

The standard requires that *internal quality audits be carried out by personnel independent of those having direct responsibility for the activity being audited.*

By being independent of the audited activities, the auditor is unaware of the pressures, the excuses, the informal instructions handed down and can examine operations objectively without bias and without fear of reprisals. It is for this reason that it was considered appropriate for the auditor to have no direct responsibility for the work being audited: i.e. audits carried out by a manager, supervisor, or foreman of his/her own department or section do not qualify as internal quality audits in ISO 9001:1994. However, they will qualify under ISO 9000:2000.

To ensure their independence, auditors need not be placed in separate organizations. Although it is quite common for quality auditors to reside in a quality department it is by no means essential. There are several solutions to retaining impartiality:

- Auditors can be from the same department as the activities being audited, provided they are not responsible for the activities being audited.

- Separate independent quality audit departments could be set up, staffed with trained auditors.
- Implementation audits could be carried out by trained line personnel supervised by an experienced quality auditor.

You can show compliance with this requirement by defining where the auditors fit into the organization by means of an organization chart and by giving position titles in the reports of the audit.

As internal audits can comprise documentation audits, implementation audits, product audits, process audits, etc., it is not necessary to train everyone assigned to carry out audits in the auditing techniques defined in ISO 10011. This is one of the ambiguities in the series of standards. The term *quality audit* is defined in such a way that encompasses *all* types of audit and yet ISO 10011 only applies to quality system audits where the objective evidence is obtained through interviewing personnel. When conducting product audits, knowledge and skill in reading specifications, planning tests, setting up and operating test and measuring equipment is more relevant. In fact the audits may well be carried out by an accredited test laboratory.

Reporting the results of audits (4.17.1)

The standard requires the *results of the audits to be recorded and brought to the attention of the personnel having responsibility in the area audited.*

Audits of practice against procedure or policy should be recorded as they are observed and you can either do this in note form to be written up later or directly onto observation forms especially designed for the purpose. Some auditors prefer to fill in the forms after the audit and others during the audit. The weakness with the former approach is that there may be some dispute as to the facts if presented some time later. It is therefore safer to get the auditee's endorsement to the facts at the time they are observed. In other types of audits there may not be an auditee present. Audits of procedure against policy can be carried out at a desk. You can check whether the documents of the quality system satisfy all the clauses of the standard at a desk without walking around the site, but you can't check whether the system is documented unless you examine the operations in practice. There may be many activities which make the system work that are not documented.

The audit report should state the results of the audit, what was found compliant as well as what was found noncompliant.

As the use of computer networks become more widespread, auditing the practice against procedure will be possible without leaving your desk and can be carried out without the auditee knowing.

Whichever the approach, the report should be presented to the manager of the area audited; if several managers are affected, the report should also be presented to the manager above them. However, audit reports should not be issued to a person's manager without their knowledge and agreement.

Taking timely corrective action (4.17.1)

The standard requires *the management personnel responsible for the area to take timely corrective action on the deficiencies found during the audit.*

Unless the auditee is someone with responsibility for taking the corrective action, the auditee's manager should determine the corrective actions required. If the action required is outside that manager's responsibility, the manager and not the auditor should seek out the appropriate authority and secure a corrective action proposal. Your policy manual should stipulate management's responsibility for taking timely corrective action and define what timely means. Timely to one person may be untimely to another. The standard should require timely and effective corrective action in order to yield the right result. The standard does not actually require that corrective actions be proposed and target dates set for their completion. Even clause 4.14 does not require corrective action proposals to be recorded but these omissions should not be cause for inaction. In reality the manager responsible should:

- Take remedial action to correct the particular nonconformity.
- Search for other examples of nonconformity and to establish how widespread the problem is.
- Establish the root cause of the nonconformity and prevent its recurrence.

A proposed corrective action may not remove the noncompliance, it may be a palliative leaving the problem to recur again at some future time. Target dates should be agreed for all corrective actions and the dates should be met as evidence of commitment. Third party auditors will search your records for this evidence so impress on your managers the importance of honoring their commitments. The target dates also have to match the magnitude of the deficiencies. Small deficiencies which can be corrected in minutes should be dealt with at the time of the audit otherwise they will linger on as sores and show a lack of discipline. Others which may take 10-15 minutes should be dealt with

within a day or so. Big problems may need months to resolve and require an orchestrated program to be implemented. The corrective action in all cases when implemented should remove the problem, i.e. restore compliance. A corrective action should not be limited to generating another form or procedure as it can be rejected by another manager, thereby leaving the deficiency unresolved.

Follow-up audits (4.17.1)

The standard requires that *follow-up audit activities record the implementation and effectiveness of the corrective action taken.*

The standard does not in fact require follow-up audits but clearly if follow-up action is necessary to verify any corrective actions that have been taken, it should do two things: verify that the agreed action has been taken and verify that the original nonconformity has been eliminated. Follow-up audits may be carried out immediately after the planned completion date of the corrective action or at some other agreed time. However, unless the audit is carried out relatively close to the agreed completion date, it will not be possible to ascertain if the action was timely.

The auditor who carries out the follow-up audit need not be the same as carried out the initial audit. In fact there is some merit in using different auditors in order to calibrate the auditors.

When all the agreed nonconformities have been eliminated the audit report can be closed. The audit remains incomplete until all actions have been verified as being completed. Should any corrective action not be carried out by the agreed date, the auditor needs to make a judgement as to whether it is reasonable to set a new date or to escalate the slippage to higher management. For minor problems, when there are more urgent priorities facing the managers, setting a new date may be prudent. However, you should not do this more than once. Not meeting the agreed completion date is indicative either of a lack of commitment or incompetent estimation of time and both indicate that there may well be a more deep-rooted problem to be resolved.

Auditor qualification (4.17.3)

The standard requires the supplier to *comply with customer requirements for internal system and process auditor qualification.*

Customers are likely to require internal auditors to at least have taken an Internal Auditor Training Course that meets the requirements of ISO 10011 but are unlikely to require Lead Auditor Registration. VDA 6.3 on *Process audits* requires the auditor to have at least two years' practical experience in process management in the automotive industry and to have performed at least three process audits with the support of a technical expert from the process area.

For product audits VDA 6 lists several technical and human characteristics of the auditor:

- Knowledge of the purpose of the product audit
- Product and quality specific knowledge
- Use of inspection, measuring, and test specifications
- Mastery of inspection, measuring, and test techniques
- Knowledge of handling of nonconformities
- Evaluating products
- Reporting skills
- Physical suitability (eye sight test etc.)
- Good intelligence
- Good intuition
- Personnel reliability
- Practical experience in manufacturing
- Knowledge of production processes and of their application
- Knowledge of and access to information about customer expectations

Task list

- 1 Decide on the scope of the audit program.
- 2 Produce an annual audit program.
- 3 Devise a method of determining when parts of the system were last audited.
- 4 Decide on the types of audits to be conducted and the level of staff to conduct them.
- 5 Determine the standards against which the organization is to be audited.
- 6 Train your quality auditors to a defined standard and train sufficient auditors to enable your program to be met.
- 7 Use auditing as a means of familiarizing staff with the operations of the organization.
- 8 Allocate trained auditors to the program.
- 9 Plan individual audits.
- 10 Produce audit procedures that cover products, processes, and organizations.
- 11 Provide forms for recording observations, recommendations, and corrective actions.
- 12 Conduct the audits to the defined plan and procedure with a clear objective.
- 13 Record the results of audits, both noncompliances and compliances.
- 14 Devise a means of tracking the status of corrective actions.
- 15 Provide a means for linking the corrective actions arising from audits to documentation changes, organization changes, process changes, design changes, etc.
- 16 Assess audit data periodically and determine the effectiveness of auditing.
- 17 Provide for changing audit methods and training should auditing be not as effective as expected.
- 18 Create checklists for assisting in following an audit trail through a department or process.
- 19 Audit your procedures immediately following their issue as a means of testing their auditability.
- 20 Conduct a system audit at least once a year to verify that the system is still intact and compliant with the standard.

Internal quality audits questionnaire

- 1 In which documents have you defined your procedures for planning and implementing internal quality audits?
- 2 How do you verify whether quality activities and related results comply with planned arrangements?
- 3 How do you determine the effectiveness of the quality system?
- 4 Which documents constitute the internal quality audit plans?
- 5 How do you ensure that audits are scheduled on the basis of the status and importance of the activity to be audited?
- 6 How do you ensure that all audits are carried out by personnel independent of those having responsibility for the activities audited?
- 7 In which documents are the results of quality audits recorded?
- 8 How do you ensure that the results of audits are brought to the attention of the personnel having responsibility in the area being audited?
- 9 How do you ensure that management personnel responsible for the area audited take timely corrective action on deficiencies found by the audit?
- 10 How do you verify the effectiveness of any corrective actions taken?

Do's and don'ts

- ⊗ Don't limit the scope of your audit program to the procedures.
- ☺ Do select your auditors carefully.
- ⊗ Don't use aggressive staff for auditing.
- ⊗ Don't persist in enforcing compliance with trivia.
- ☺ Do adjust the audit program to cover aspects that have attracted management attention.
- ⊗ Don't audit for the sake of it – define your objective and make it important enough for management to take notice of the results.
- ☺ Do keep a log of audits and a log of corrective action reports.
- ⊗ Don't go into an area unannounced – always give advanced warning.
- ☺ Do explain the purpose and objectives of the audit to the manager before you commence.
- ☺ Do review the relevant documents before you audit operations.
- ☺ Do follow audit trails to discover facts and don't break the trail until you have uncovered the facts.
- ☺ Do check downstream of the operation being audited to gather facts on its effectiveness.
- ☺ Do be helpful to the auditee (don't argue but don't accept everything at face value).
- ⊗ Don't be critical of anyone's work or how he/she operates.
- ☺ Do listen to what the auditee and his/her manager say.
- ⊗ Don't leave the scene of the audit without obtaining agreement to corrective actions and either setting a target date for their completion or agreeing on a date by which the target date will be set.
- ☺ Do act professionally, be courteous, tactful, and diplomatic, and avoid nit-picking.
- ☺ Do establish whether your audit objective has been achieved before completing the audit.
- ☺ Do reduce the frequency of audits if you have confidence in a particular area.
- ⊗ Don't copy the audit report to anyone other than the auditee's manager without the manager's consent.

Chapter 18

Training

Scope of requirements

The specification, achievement, control, and assurance of quality requires personnel who are competent to carry out these tasks and although this clause of the standard only addresses training, it is adequate training rather than education that will give personnel the skills they need. ISO 9004 identifies qualifications and motivation as well as training as key factors in achieving quality. Academic qualifications are often prerequisites for certain jobs but without training in the particular jobs in which they are engaged, personnel will not yield their full potential. Education imparts knowledge, whereas training imparts skills. However, without the right motivation any amount of qualifications and training will be wasted. (Motivation is addressed in Part 2 Chapter 1 under *Employee motivation, empowerment, and satisfaction*.) These requirements apply to all personnel performing activities affecting the quality of the products or services supplied. They include personnel in management, design, purchasing, production, installation, verification, servicing, auditing, and packing – in fact any activity that requires skill to perform well. They do not apply to the training of customers or users of equipment or services provided by the supplier to its customer. This is the customer's/user's responsibility.

The requirements in element 4.18 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 18.1.

It is not uncommon to find that organizations only train operational staff and not managers. Training as a formal activity is often only executed when the need is obvious such as when new technology is introduced. Training is therefore sometimes viewed as a tactical issue and not a strategic issue. As a strategic issue, training would feature in the business plan as a means to move the company forward towards new goals. However, there is a gray area between training and education. Training imparts skills and education imparts knowledge but one cannot practically undergo training without prior knowledge so the two are often delivered together. If you treat training and education as

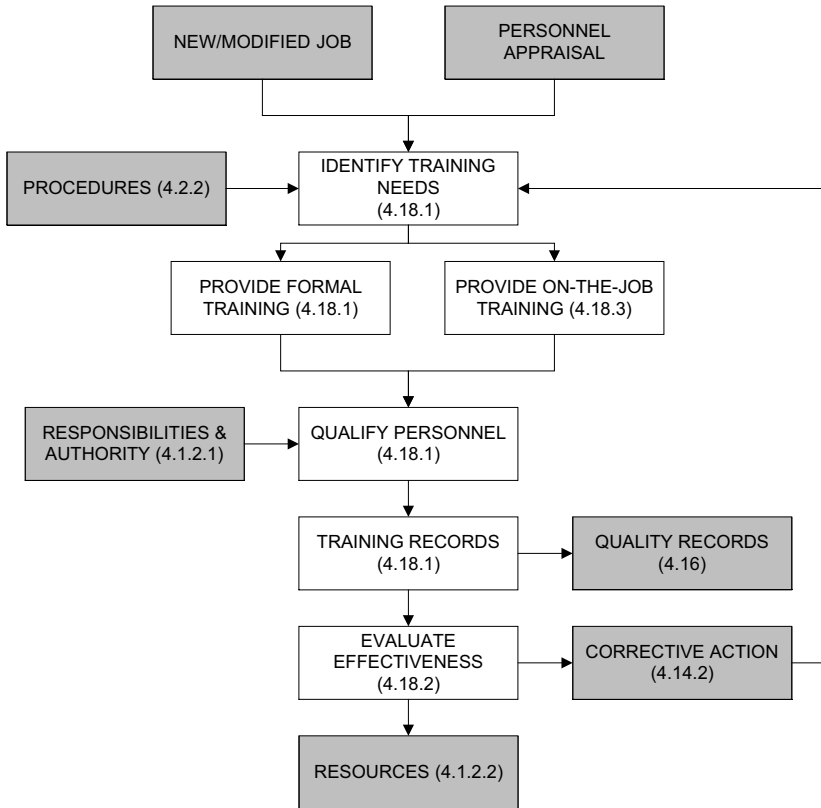


Figure 18.1 Clause relationships with the training element

one and the same, then it will become apparent that all employees will require training at some time or other.

No improvement comes about without change in some parameters of the business. It is futile to set goals tougher than last year without considering what has to be changed to meet them. Sometimes the changes will be in technology, in product design, in procedures, in attitudes and behavior but all will require people to do differently tomorrow what they did yesterday. To demonstrate you are in fact viewing training as a strategic issue, the CEO and executive managers will need to show how they have prepared their resources to meet the identified goals. One such item of preparation is the training and education of the people concerned. Company-wide initiatives require company-wide training programs with the necessary budgets approved by the executive managers. The CEO will need to show that the training has not been limited to operators but extends to all managers including the CEO.

Identifying training needs (4.18.1)

The standard requires the supplier to *establish and maintain documented procedures for identifying training needs*.

Training should not be carried out just because a training course is available. Training is expensive and should be directed at meeting specific needs. Training needs can be identified in two ways: as requirements for training and as a plan for providing the required training. Requirements for training arise in several ways as a result of:

- Job specifications
- Process specifications, maintenance specifications, operating instructions, etc.
- Development plans for introducing new technologies
- Project plans for introducing new equipment, services, operations, etc.
- Marketing plans for launching into new markets, new countries, new products and services
- Contracts where the customer will only permit trained personnel to operate customer-owned equipment
- Corporate plans covering new legislation, sales, marketing, quality management, etc.
- An analysis of nonconformities, customer complaints, and other problems
- Developing design skills (4.4.2), problem solving skills (4.14.1), statistical skills (4.20.2)
- Introducing a quality system, thus requiring awareness of ISO 9000, the quality policies and objectives, and training in the implementation of quality system procedures, standards, guides, etc.

The procedures that govern these activities should include provisions for training. As a minimum they should specify the skills and knowledge required of a person carrying out the activities and where necessary the examination criteria for judging that the person has acquired an adequate level of proficiency. The training process is outlined in Figure 18.2 and shows that training needs arise out of business objectives and quality policy.

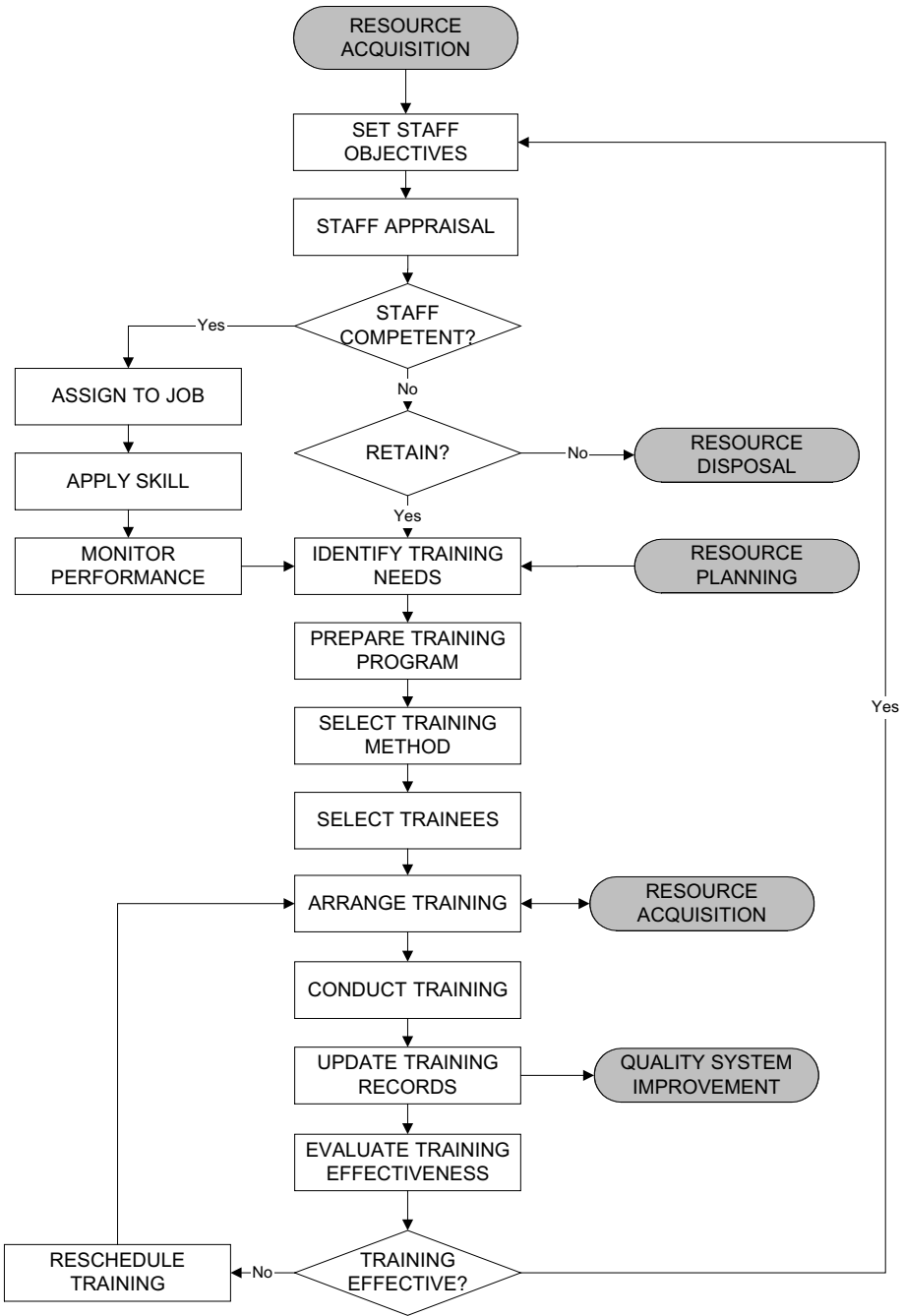


Figure 18.2 The personnel development process

While not specified in the standard, the requirement for identifying training needs has two dimensions: new training needs and retraining needs. Retraining should be identified by assessing the effectiveness of previous training, the recency of its application, and then scheduling the appropriate courses.

Once the training requirements have been specified, managers should plan the training needed for their staff. This requires a training plan. Although the standard does not specifically require a training plan, without one you may have difficulty demonstrating that you have identified the training needs. All plans must serve an objective. You train people for a purpose: to give them skills that you want them to have. The skills required must be specified in the first place. You could have several training plans, each covering a different subject. Technical training could be separate from managerial training and professional training separate from manual skill training. Each manager should plan for the training of his/her own staff so there may be department training plans, divisional training plans, company training plans, etc.

The training plans should identify the person responsible for coordinating the training, the type of training, the organization that will deliver the training, the course material to be provided, examination and certification arrangements, the venue, the dates of the courses, and the attendees.

It is interesting to note that the only procedures required are for identifying training needs and not for designing training courses, conducting training, or maintaining records.

This clause does not require suppliers to establish procedures for identifying personnel certification requirements. While unnecessary in most situations, personnel certification is necessary for special processes (see Part 2 Chapter 9 under *Special processes*). Certification would also be necessary for teachers, lecturers, and other personnel upon whose judgement the determination of quality depends.

Providing for training (4.18.1 and 4.18.3)

The standard requires the supplier to *provide for the training of all personnel performing activities affecting quality*. The supplementary requirement requires *provision of on-the-job training for personnel (including contractors) in any new or modified job affecting quality*.

This requirement can be rather onerous especially if your staff have not had any training that can be verified. Much training is carried out “on the job”. A person learns a trade or profession by practice and experience as well as by formal training. An individual will

have received some training before joining your organization; therefore it may not be necessary to provide all the training required to perform a specific job. Be sure to obtain objective evidence of previous training, either by copies of training certificates or by signed application forms declaring the training the individual claims to have received. The supplier need only provide the training that has been identified as relevant to the individual. Periodic staff appraisal should thereafter be used to assess the adequacy of a person's skills and knowledge and identify the need for retraining or re-assignment of tasks as appropriate.

Beware of training courses that are no more than talk and chalk sessions, where the tutor lectures the students, runs through hundreds of slides, and asks a few questions. There is little practical gain from these kinds of courses. A course that enables the participants to learn by doing, to learn by self discovery and insight is a *training* course. The participants come away having had an experience. Just look back on your life, and count the lessons you have learnt by listening and watching and compare that number with those you have learnt by doing. The latter will undoubtedly outnumber the former.

■ **Encourage your staff to make their mistakes in the classroom, not on the job!**

If training is necessary to improve skills involving the operation or maintenance of tools or equipment you need to ensure that any practical aids used during training:

- Represent the equipment that is in operational service.
- Adequately simulate the range of operations of the service equipment.
- Are designated as training equipment and only used for that purpose.
- Are recorded and maintained indicating their serviceability and their design standards, including records of repairs and modifications.

Students undertaking training may inadvertently damage equipment. It may also be necessary to simulate or inject fault conditions so as to teach diagnostic skills. Training activities may degrade the performance, reliability, and safety of training equipment and so it should be subject to inspection before and after training exercises. The degree of inspection required will depend on whether the equipment has been designated for use only as training equipment or whether it will be used either as test equipment or to provide operational spares. If it is to be used as test or operational equipment, it will need to be re-certified after each training session. During the training sessions, records will need to be maintained of any fault conditions injected, parts removed, and any other

act that may invalidate the verification status of the equipment. In some cases it may be necessary to refurbish the equipment and subject it to the full range of acceptance tests and inspections before its serviceability can be assured. Certification can only be maintained while the equipment remains under controlled conditions. As soon as it passes into a state where uncontrolled activities are being carried out, its certification is immediately invalidated. It is for such reasons that it is often more economical to allocate equipment solely for training purposes.

Qualification of personnel (4.18.1)

The standard requires *personnel performing specific assigned tasks be qualified on the basis of appropriate education, training, and/or experience, as required.*

This requirement is somewhat vague as it does not define what a specific assigned task is. Any task assigned to an individual could be a specific assigned task: e.g. window cleaning, typing, fitting, managing, designing, etc. Within organizations some staff are appointed to particular positions that are unique in the organization and others perform jobs that are common within a particular group. So the window cleaning, typing, and fitting jobs are not assigned to a specific individual whereas the manager, and sometimes the designer, is assigned a specific task unique to themselves. Such personnel make judgements upon which the determination of quality depends and so they should be *qualified* to make such judgements. To be qualified, a person should be able and competent to perform the required tasks at the time they are required to perform them. It follows therefore that a footballer with a broken leg would not be qualified to play football; similarly, a person who takes a training course but has not acquired the skills is also not qualified. A person who once had the skills but has not applied them for some time may also be considered not qualified for the task. This suggests that a person's current ability needs to be evaluated in order to qualify personnel for specific assigned tasks.

You will need to maintain documentary evidence that these personnel have the necessary education, training, and experience to carry out the tasks assigned to them. This is where job specifications can help. For each of these positions – not the individuals but the position they occupy – you should produce a job specification that specifies the requirements an individual must meet to occupy this position. It should include academic qualifications, training, and experience requirements, as well as personal characteristics, so that in recruiting for the position you have a specification with which to compare candidates.

Evaluation of training effectiveness (4.18.2)

The standard requires *training effectiveness to be periodically reviewed with special attention given to customer-specific requirements.*

If the education, training, and/or experience has not been effective, the person concerned could be considered to be unqualified. Therefore in order to ensure that staff are suitably qualified, the effectiveness of the education, training, and/or experience received should be evaluated.

The flowchart in Figure 18.1 shows an evaluation stage in the training process, but how do you do it?

There are three parts to the evaluation:

- An evaluation of the training course or training activity immediately on completion
- An evaluation of the training received weeks after the training
- An evaluation of the skills developed months after the training

Training course evaluation (the initial stage)

Course evaluation by the students themselves can only indicate how much they felt motivated by the training courses. It is not effective in evaluating what has been learnt. This is more likely to be revealed by examination at the end of the course or periodically throughout the course. However, the type of examination is important in measuring the effectiveness of the training; e.g. a written examination for a practical course may test the theories behind the skills but not the practical mastery of the skills themselves. A person may fail an exam by not having read the question, so examination by itself cannot be a valid measure of training effectiveness. You need to examine the course yourself before sending your staff on it. If you want information to be conveyed to your staff, a lecture with accompanying slide show may suffice. Slide shows are good for creating awareness but not for skill training. For the latter, practical opportunities are needed.

Training effectiveness – short term (the intermediate stage)

On returning to work after the course, it is important that the skills and knowledge learnt are put to good effect as soon as possible. A lapse of weeks or months before the skills are used will certainly reduce the effectiveness. Little or no knowledge or skill may have been retained. Training is not about doing something once and once only. It is about

doing something several times and at frequent intervals. One never forgets how to ride a bicycle or drive a car regardless of the time lapse between each attempt, because the skill was embedded by frequency of opportunities to put the skill into practice in the early stages. Therefore to ensure effectiveness of training you ideally need to provide opportunities to put into practice the newly acquired skills as soon as possible. The person's supervisor should then examine the trainee's performance through sampling work pieces, reading documents he/she produces, and observing the person doing the job. If you have experts in the particular skills then in addition to appraisals by the supervisor, the expert should also be involved in appraising the trainee's performance. Pay particular attention to the trainee's understanding of customer requirements. Get this wrong and you could end up in trouble with your customer!

Training effectiveness – long term (the final stage)

After several months of doing a job and applying the new skills, the trainee will acquire techniques and habits. The techniques shown may not only demonstrate the skills learnt but also those being developed through self-training. The habits may indicate that some essential aspects of the training had not been understood and that some re-orientation is necessary. It is also likely that the person may have regressed to the old way of doing things and this may be due to matters outside his/her control. The environment in which people work and the attitudes of the people they work with can have both a motivating and demotivating effect on an individual. Again the supervisor should observe the trainee's performance and engage the expert to calibrate his/her judgement. Pay particular attention to customer requirements and whether the trainee really understands them. If there are significant signs of regression you will need to examine the cause and take corrective action.

Periodic evaluation

Once the skills have been acquired through evidence of a person's performance, the supervisor can revert to the annual appraisal of performance and identify retraining needs through that process.

Maintaining training records (4.18.1)

The standard requires the supplier to *maintain appropriate records of training*.

Whenever any training is carried out you should record on the individual's personal file, details of the course taken, the dates, duration, and exam results (if one was taken).

Copies of the certificate should be retained on file as evidence of training. You may find it useful to issue each individual with a personal training log, but do not rely on this being maintained or retained by the person. Often training records are held at some distance away from an individual's place of work and in certain cases, especially for certificated personnel performing special processes, individuals should carry some identification of their proficiency so as to avoid conflict if challenged.

Records of training should include records of formal training, where the individual attends a training course and on-the-job training, where the individual is given instruction while performing the job. The records should indicate whether the prescribed level of competence has been attained. In order to record competence, formal training needs to be followed by on-the-job examination. The records should also indicate who has conducted the training and there should be evidence that this person or organization has been assessed as competent to deliver and evaluate the training.

Training records should contain evidence that the effectiveness of training given has been evaluated and this may be accomplished by a signature and date from the supervisor against the three stages of evaluation – initial, intermediate, final. Periodic reviews of training records should be undertaken to clearly identify retraining needs.

You will need two types of training records: those records relating to a particular individual and those relating to particular activities. The former is used to identify an individual's competence and the latter to select by skill the competent people for specific assignments.

Increasing sensitivity to customer requirements (4.18.3)

The standard requires *personnel whose work affects quality to be informed of the consequences to the customer of nonconformities with quality standards.*

This requirement is tougher than you might think but you can make it easier. You have produced the Design FMEA and the Process FMEA and in these two documents you have the basic information you need to inform your staff. The FMEA should have identified the sources and causes of failure. Make your staff aware of these documents but also provide other information that enables them to see the effect a part failure has at system level or on the complete vehicle. Staff may have no idea of the function the part they are producing performs, where it fits, how important it is. This education is vital to increasing sensitivity. In many organizations this sensitivity is low. The manager's task is to heighten sensitivity so that everyone is in no doubt what effect a nonconformity has on the customer.

Task list

- 1 Identify jobs that require particular skills.
- 2 Document the training requirements for specific jobs.
- 3 Produce and maintain training plans to implement the training requirements.
- 4 Implement only that training defined in the training plans.
- 5 Monitor the effectiveness of training.
- 6 Maintain personal records of training.
- 7 Maintain skill or activity based records of training.
- 8 Review training records periodically to identify retraining.
- 9 Make skill records available to managers on site.
- 10 Identify equipment used for training purposes.
- 11 Provide procedures for controlling the standard of training equipment.
- 12 Prepare procedures for evaluating the effectiveness of training and recording the results.

Training questionnaire

- 1 How do you identify training needs?
- 2 How do you ensure that personnel performing specific assigned tasks are qualified on the basis of appropriate education, training, and/or experience?
- 3 How do you ensure that training is provided for all personnel performing work affecting quality?
- 4 How do you evaluate the effectiveness of training and how often is the evaluation performed?
- 5 In what documents do you record the training provided?

Do's and don'ts

- ⊗ Don't specify that training is required if it cannot be provided.
- ⊗ Don't assign personnel to tasks for which you have specified training requirements unless the personnel are appropriately trained.
- ⊗ Don't rely on a person's own training records.
- ☺ Do keep central records of staff training.
- ☺ Do provide managers with ready access to staff training records.
- ☺ Do provide a certificate to every person who has received specific training.
- ⊗ Don't send staff to a slide show if you want them to acquire practical skills.
- ☺ Do send them to workshops where they can learn by doing and make mistakes.
- ☺ Do ensure that any training equipment is of a representative standard before training commences.
- ⊗ Don't use training equipment for operational purposes unless it is certified to current design standards before operational use.
- ☺ Do assign people to jobs in which they can exercise the skills they have acquired from recent training.
- ⊗ Don't base your evaluation of training effectiveness on the student's evaluation – nothing may be more misleading.

Chapter 19

Servicing

Scope of requirements

Servicing is an activity that primarily applies to manufactured products. One services a motor car, a washing machine, or a photocopier. However, servicing, which is a post-delivery activity, can also include after-sales service, product support, help lines, customer service, and inquiry desks, etc. The term is not defined in ISO 8042; however, traditionally the term *to service* means to replenish consumables needed to keep an item in operating condition. Servicing is not a term that is used in the quality loop of ISO 9004. The only activity which comes between installation and operation and disposal is “technical assistance and maintenance”. If you carry out the type of servicing defined above, compliance with this clause of ISO 9001 is a relatively simple affair. If on the other hand you provide technical assistance or carry out maintenance, repair, product support, logistics support, or any other post-delivery activity the interpretation of these requirements presents a problem. Apart from the word “servicing” this clause conveys nothing which is not covered elsewhere in the standard. Note that your servicing operations also need to comply with the requirements of clause 4.9. You will also note that this requirement only applies when servicing is a specified requirement. The standard does not state which party may have specified it or where it may be specified. If technical assistance or maintenance is specified rather than servicing, it would appear that you do not strictly need to document your technical assistance and maintenance activities.

Servicing is a specified requirement when the contract requires you to service the products provided. If the contract does not require you to service your products or support the servicing of your products by others, then element 4.19 does not apply. On the other hand, if your core process is servicing and your contract is for servicing only then you cannot ignore the other elements of the standard; you need to apply all of them that are relevant, but the core of your business is covered by 4.9 on process control.

You may provide services to your customer such as an installation service, a technical support service, a laboratory service, diagnostic service, or customer training, etc. These are services and not servicing and should be addressed as activities governed by elements 4.1 through 4.18 and 4.20.

If servicing in its broader sense is concerned with keeping an item in operating condition, it follows that to do so must also include restoring an item to an operating condition should malfunction or failure occur. As with the motor car undergoing a 10,000 mile service, if the timing is out, the mechanic corrects it in order that the vehicle is restored to an operating condition. Servicing, therefore, becomes much more than the replenishment of consumables and involves design of the service, design of the tools, measuring, handling of the test equipment, purchasing of spares and consumables, preventive and corrective maintenance.

The requirements in element 4.19 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 19.1.

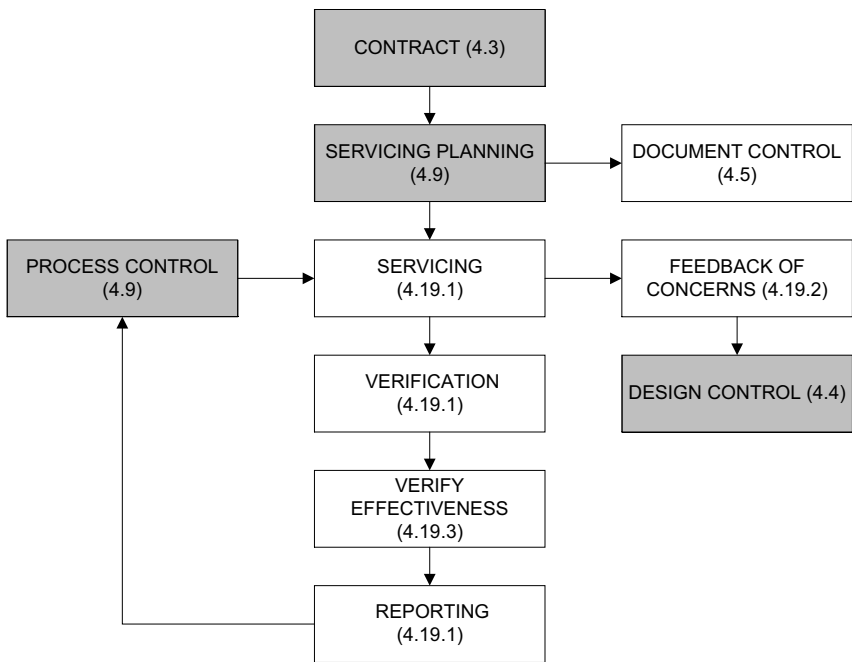


Figure 19.1 Clause relationships with the servicing element

Performing servicing (4.19.1)

Where servicing is a specified requirement the standard requires the supplier to *establish and maintain documented procedures for performing servicing*.

Applying the definition to servicing as in ISO 9004, servicing procedures would need to cover the following:

- Design and validation of special-purpose tools and equipment
- Control of measuring and test equipment
- Supply and verification of installation instructions
- Supply and verification of assembly instructions
- Supply and verification of commissioning instructions
- Supply and verification of operating instructions
- Supply and verification of spare parts lists
- Supply and verification of servicing instructions
- Logistics support service covering technical assistance, supply of spares, servicing

ISO 9001 covers the design, purchasing, handling, and measuring equipment activities in the appropriate clauses. The maintenance addressed in clause 4.9 relates only to processing equipment and not to the product that is an output of the process. To provide adequate procedures for product maintenance you will need to:

- Define maintenance requirements covering what is to be maintained, by whom, and to what depth.
- Define service restoration instructions covering the actions required to restore equipment or facilities into service, including restoration and response times. This is usually first line maintenance and may not require any repair action.
- Define maintenance instructions stating the performance parameters to be maintained, the frequency of maintenance, how it is to be conducted, the action to be taken in the event of failure, the procedures to be followed in carrying out repairs, and the training required of those performing the maintenance tasks.

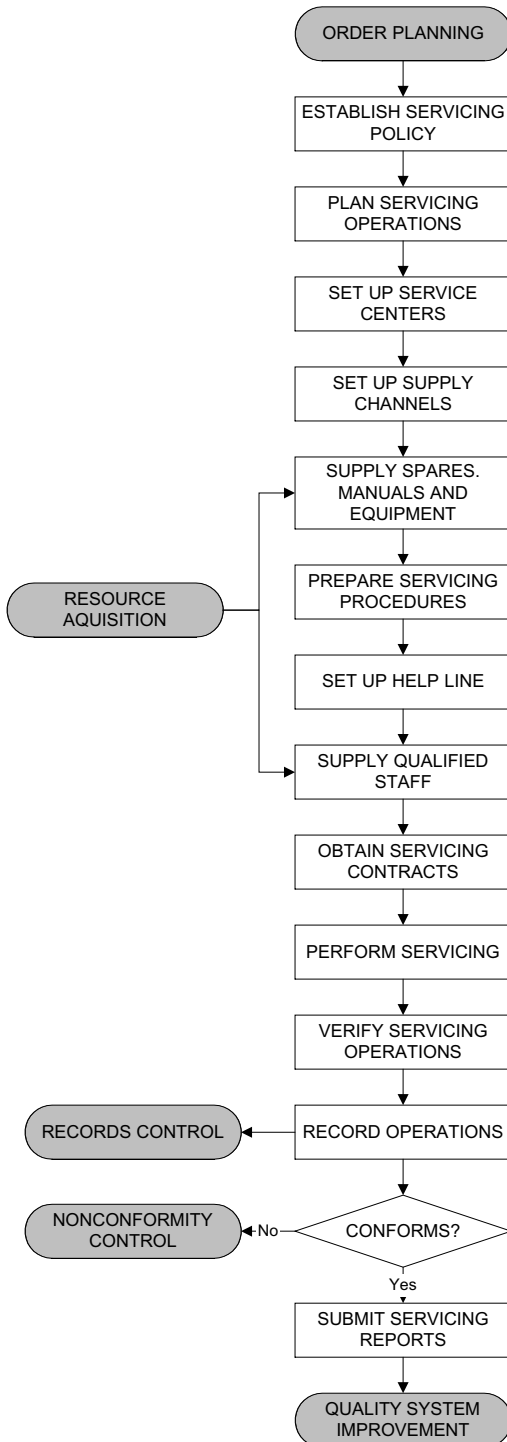


Figure 19.2 The servicing process

- Define spares schedules listing the spares by identification number, manufacturer, and quantity required on site to maintain the specified service availability.
- Produce or acquire handbooks that detail the equipment to be maintained and procedures on fault finding, repair, and verification after repair.

A typical servicing process is illustrated in Figure 19.2.

If your operation is such that your after-sales service consists of technical assistance, in order to provide adequate procedures for technical assistance you will need to:

- Specify the service in terms of its scope, what is included, what is excluded, response times, the action in the event of a complaint, etc.
- Define operating procedures covering the receipt and recording of calls or letters, their acknowledgement, and who to route them to for action.
- Provide technical support covering problem logs, actions taken, advice given, promises made, and details of follow-up on the product or service.
- Establish a complaints procedure covering the recording, investigation, and resolution of complaints.

Reporting that services meet specified requirements (4.19.1)

The standard requires that the supplier *establish and maintain documented procedures for reporting that servicing meets specified requirements*.

It is of interest to note that no reference is made to clause 4.16 of the standard regarding quality records. The servicing reports therefore are not classed as quality records but are included in the list of documents to be used to detect, analyze, and eliminate potential causes of nonconformities (see clause 4.14.3).

Servicing reports should specify the following as applicable:

- The identity of the product to the service activity
- The date on which the service took place
- The organization responsible for performing the service

- The condition of the product prior to servicing and any running time, mileage, or other indication of life expired
- The specification defining the service or maintenance carried out, quoting the relevant part if not all requirements were verified
- The items exchanged, consumables used, item repaired, adjusted, etc.
- The duration of the activity and the name of who performed it
- Details of any inspections and tests carried out to verify serviceability of the item

This information is likely to be recorded at the time the service is carried out and may well be remote from the parent plant; therefore allowance for this should be made in the procedures. Provision needs to be made for this information to be collected, stored, and any corrective actions taken as a result of unusual trends being detected (see Part 2 Chapter 14).

The standard does not specify the intended destination of servicing reports. Who should receive these reports? It is through an analysis of servicing operations that opportunities for improvement in design and manufacturing techniques can be identified. If the manufacturer services the products supplied, the servicing reports should be routed to design and manufacturing managers for analysis and subsequent corrective or preventive action.

Where servicing is subcontracted or franchised to other organizations, you need to collect information generated by the servicing organizations and convey it to those who can use it to improve the product and the manufacturing processes. This means that you will need to establish liaison links with servicing organizations and enlist their support in reporting to you any concerns they have about the serviceability or maintainability of the product, the availability of spare parts, and the usability of the manuals and other information you have provided.

You should set up a common entry point for such data and put in place an evaluation function to convey appropriate data to the manufacturing, engineering, and design activities. A corrective action form or improvement form could be used to convey the data and obtain a written response of the action to be taken. A log of servicing reports would assist in tracking servicing concerns and demonstrate you were making effective use of the data.

Verifying that servicing meets specified requirements (4.19.1)

Where servicing is specified in the contract, the standard requires the supplier to *establish and maintain documented procedures for verifying that servicing meets specified requirements*.

Whatever your definition of servicing, you will need to verify that you provide the service you say you provide. This can be achieved in several ways.

If your service is maintenance, you need to monitor the restoration and response times and determine your performance. You will also need to verify that the maintenance performed was effective by monitoring the incidence of recall to fix.

If your service is simply technical assistance, you need to monitor inquiries, complaints, tributes, and problems, their distribution frequency and significance, and the action to be taken to improve performance.

Communication of service concerns (4.19.2)

The standard requires *a procedure to be established and maintained for communicating information on service concerns to manufacturing, engineering, and design activities*.

While you may not service your products, others may well do so and the standard requires that you collect information generated by the servicing organizations and convey it to those who can use it to improve the product and the manufacturing processes. This means that you will need to establish liaison links with servicing organizations and enlist their support in reporting to you any concerns they have about the serviceability or maintainability of the product, the availability of spare parts, and the usability of the manuals and other information you have provided.

You should set up a common entry point for such data and put in place an evaluation function to convey appropriate data to the manufacturing, engineering, and design activities. A corrective action form or improvement form could be used to convey the data and obtain a written response of the action to be taken. A log of servicing reports would assist in tracking servicing concerns and demonstrate that you were making effective use of the data.

Servicing agreements with customer (4.19.3)

The standard requires that *when there is a servicing agreement with the customer, the supplier verifies the effectiveness of any supplier service centers, special-purpose tools, and training of servicing personnel.*

This requirement is fairly straightforward. What you need to do is establish the conditions of the servicing agreement and check that they have been conveyed to those affected by them, and that these personnel are in fact adhering to the requirements. However, meeting such requirements may require the setting up of a service organization, designing the necessary processes and equipping them with the relevant resources.

Task list

- 1 Define the service levels that you intend to provide up to and after warranty expires.
- 2 Define the measures you need to take to honor your obligations to service products supplied to your customers.
- 3 Provide servicing staff with current instruction manuals for the equipment they are servicing.
- 4 Create forms for reporting servicing calls, time spent, components changed, etc.
- 5 Set up a mechanism for analyzing service reports so as to determine response times, time to repair, and total downtime.
- 6 Provide a means whereby servicing staff can use the in-house calibration service for their equipment.
- 7 Train servicing staff in the operation and maintenance of the equipment.
- 8 Prepare procedures for the receipt, repair, and return into service (or disposal) of components removed by servicing staff.
- 9 Prepare procedures for collecting, analyzing, and diagnosing servicing concerns.
- 10 Convey any servicing agreements to those who will be affected by them.
- 11 Include servicing centers in the audit program.

Servicing questionnaire

This questionnaire is somewhat limited as there are only three specific servicing requirements in the standard. As other parts of the standard apply to servicing you should consult the relevant questionnaires to help establish your policies in this area.

- 1 How do you ensure that servicing is performed in a way that meets the specified requirements?
- 2 How do you report servicing activities?
- 3 How do you ensure that servicing is verified in a way that meets the specified requirements?
- 4 How do you ensure that information from servicing organizations is collected and used to effect improvement?

Do's and don'ts

- ☹ Don't specify levels of service beyond your capability.
- ☺ Do allocate adequate resources to provide the specified services.
- ☺ Do provide staff with adequate instructions on how to carry out the servicing.
- ☺ Do collect data on your servicing performance.
- ☺ Do create a means whereby servicing staff can keep abreast of changes in the quality system.
- ☺ Do institute a means of controlling servicing documentation and equipment.

Chapter 20

Statistical techniques

Scope of requirements

Statistical techniques can be used for a variety of reasons, from sampling product on receipt to market analysis. Any technique that uses statistical theory to reveal information is a statistical technique, but not all applications of statistics are governed by the requirements of this part of the standard. Techniques such as Pareto Analysis and cause and effect diagrams are regarded as statistical techniques in ISO 9000-2 and although numerical data is used, there is no probability theory involved. These techniques are used for problem solving, not for making product acceptance decisions.

The only statistical techniques which need control are those used to determine the acceptability of a product or service or the capability of a process that produces the product or service. Any activity where you rely on statistical evidence rather than physical measurement is an activity which should be governed by these requirements. The use of recognized techniques is important to the confidence one has in the result. It is similar to the use of measuring equipment that has been calibrated against known standards of accuracy. Unless you actually check every product, measure every attribute or variable you cannot be 100% certain. But that is costly and you can be 99.99% certain by using statistical techniques; 99.99% may be sufficiently accurate for your needs.

The requirement may not apply to all product acceptance decisions. If your acceptance of the end product does not depend upon acceptance decisions being made on its component parts, any sampling carried out on receipt inspection or in-process is not important to the product acceptance decision and can therefore be ignored in your documented quality system. This is a wise course of action if you can be sure this will always be the case but if you can't, and more often than not you won't know, it is prudent to encompass *all* sampling activities in your quality system.

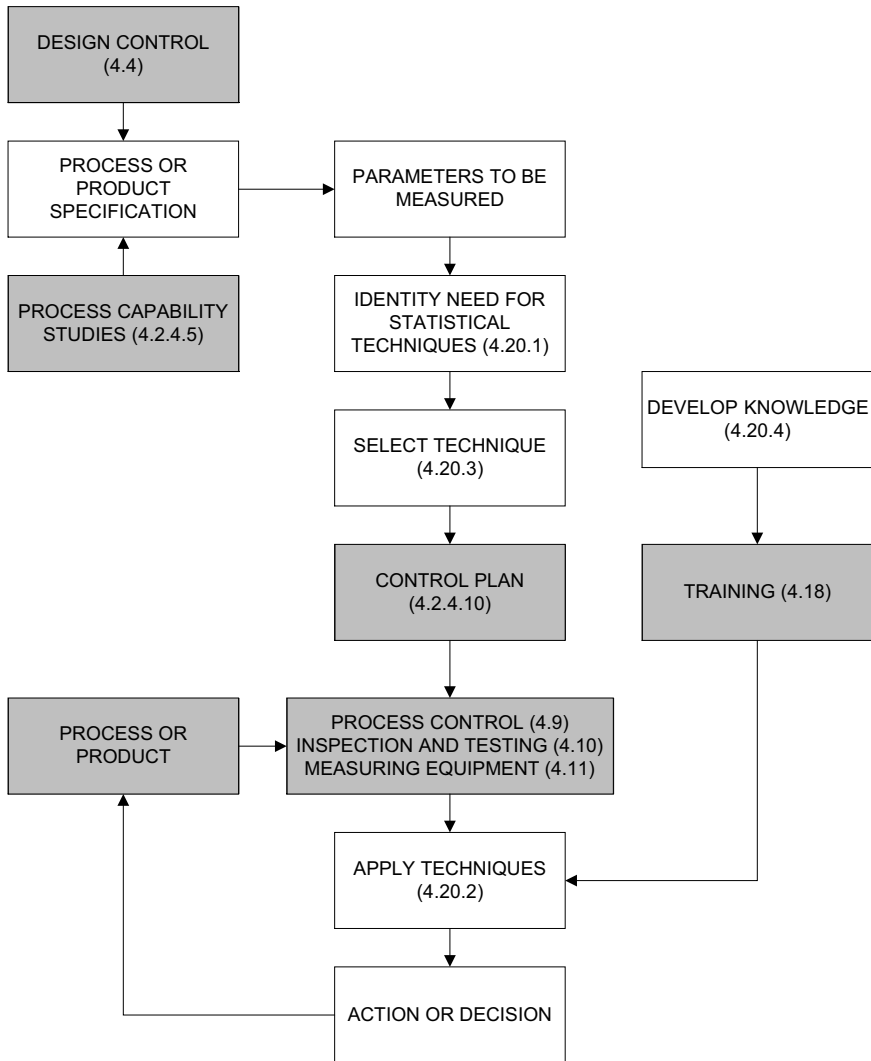


Figure 20.1 Clause relationships with the statistical techniques element

The requirements in element 4.20 are linked with other elements of the standard even when there is no cross reference. This relationship is illustrated in Figure 20.1.

Identifying the need for statistical techniques (4.20.1)

The standard requires the supplier to *identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.*

The supplementary requirements require *statistical tools to be identified for each process during the advanced quality planning phase and included in the control plan.*

The standard does not require you to use statistical techniques but identify the need for them. Within your procedures you will therefore need a means of determining when statistical techniques will be needed to determine product characteristics and process capability. One way of doing this is to use checklists when preparing customer specifications, design specifications, and verification specifications and procedures. These checklists need to prompt the user to state whether the product characteristics or process capability will be determined using statistical techniques and if so which techniques are to be used.

Techniques for establishing and controlling process capability are essentially the same – the difference lies in what you do with the results. Firstly you need to know if you can make the product or deliver the service in compliance with the agreed specification. For this you need to know if the process is capable of yielding conforming product. Statistical Process Control techniques (SPC) will give you this information. Secondly you need to know if the product or service produced by the process actually meets the requirements. SPC will also provide this information. However, having obtained the results you need the ability to change the process in order that all product or service remains within specified limits and this requires either real-time or off-line process monitoring to detect and correct variance. To verify process capability you rerun the analysis periodically using sampling techniques by measuring output product characteristics and establishing that the results demonstrate that the process remains capable.

There are many uses for statistical techniques in establishing and controlling product characteristics.

- Receipt inspection – a technique for verifying product characteristics where sampling can be used on large quantities to reduce inspection costs and improve throughput.
- SPC – a technique for controlling product characteristics as well as controlling processes.
- Reliability prediction – a technique for establishing product characteristics where the reliability targets cannot be measured without testing many hundreds of products over many thousands of hours. (On long production runs of low value items, reliability testing is possible but with one-off systems of high value it is not cost effective; hence reliability has to be predicted using statistical techniques.)

- Market analysis – a technique for establishing product characteristics where the customer requirements are revealed by market survey and determined by statistical techniques for inclusion in specifications.
- Design by experiment – a technique where product characteristics are established by conducting experiments on samples or by mathematical modeling to simulate the effects of certain characteristics and hence determine suitable parameters and limits.

When carrying out quality planning you will be examining intended product characteristics and it is at this stage that you will need to consider how achievement is to be measured and what tool or technique is to be used to perform the measurement. When you have chosen the tool, you need to describe its use in the control plan.

Implementing and controlling the application of statistical techniques (4.20.2)

The standard requires that the supplier *establish and maintain documented procedures to implement and control the application of statistical techniques.*

Where statistical techniques are used for establishing, controlling, and verifying process capability and product characteristics, procedures need to be produced for each application. You might for instance need a Process Control Procedure, Process Capability Analysis Procedure, Receipt Inspection Procedure, Reliability Prediction Procedure, Market Analysis Procedure, etc. The procedures need to specify when and under what circumstances the techniques should be used and provide detailed instruction on the sample size, collection, sorting, and validation of input data, the plotting of results and application of limits. Guidance will also need to be provided to enable staff to analyze and interpret data, convert data, and plot the relevant charts as well as make the correct decisions from the evidence they have acquired. Where computer programs are employed, they will need to be validated to demonstrate that the results being plotted are accurate. You may be relying on what the computer tells you rather than on any direct measurement of the product.

Knowledge of basic statistical concepts (4.10.4)

It is not sufficient to train staff solely in the techniques they need to use – a wider appreciation of the concepts will facilitate improved application. The staff assigned to quality planning need an even wider appreciation of statistical concepts and it is probably use-

ful to have an expert in your company upon whom staff can call from time to time. If the primary technique is SPC then you should appoint an SPC coordinator who can act as mentor and coach to the other operators of SPC techniques.

All managers need a basic appreciation but those in production ought to be able to apply the techniques their staff use in order to be able to detect when they are not being applied correctly. Auditors need to be able to determine whether the right techniques are being applied and whether the techniques are being applied as directed. Remember that the auditor's task is to determine whether the system is effective, so the ability to differentiate between the use of inappropriate techniques is essential.

Task list

- 1 Identify product and process acceptance decisions that are based on statistical techniques.
- 2 Determine and document the statistical theory or national standards used.
- 3 Provide instructions, charts, and other data to enable staff to use the techniques properly.
- 4 Review the techniques periodically and revise them (if necessary) to take advantage of new developments in the field.
- 5 Monitor the effectiveness of the decisions and adjust your rules accordingly.
- 6 Perform studies in the pre-production period to determine the capability of the manufacturing processes.
- 7 Perform studies to show that the combination of measurement equipment tolerances or variations in the design tolerances cannot result in nonconforming product.
- 8 Perform studies to prove the soundness of acceptable quality levels.

Statistical techniques questionnaire

- 1 How do you identify the need for statistical techniques required for establishing process capability?
- 2 How do you identify the need for statistical techniques required for controlling and verifying process capability?
- 3 How do you identify the need for statistical techniques required for establishing product characteristics?
- 4 How do you identify the need for statistical techniques required for controlling and verifying product characteristics?
- 5 How do you control the application of identified statistical techniques and ensure training of personnel using them?
- 6 What documented procedures exist for implementing the identified statistical techniques?

Do's and don'ts

- ⊗ Don't rely on statistical techniques unless you have evidence that they are valid.
- ⊗ Don't claim emphatically that all products meet the specification if conformance is determined solely by statistical techniques.
- ☺ Do record the basis on which decisions are made when using statistical techniques.
- ⊗ Don't flinch results on the borderline, take more samples.
- ⊗ Don't derive your sampling plans from unproven statistical methods.
- ☺ Do locate control charts where they will provide use as a nonconformity prevention tool.

Appendix A

Glossary of terms

This appendix contains a glossary of nearly 200 common and uncommon terms and phrases used in ISO/TS 16949 and the *Rules for Achieving IATF Recognition*. It contains many terms and phrases not defined in ISO 8402 or ANSI/ASQC A3. Some alternative definitions are provided for clarification. The explanations are given for the context in which the terms are used.

Acceptance criteria	The standard against which a comparison is made to judge conformance.
Activities affecting quality	Any activity which affects the determination of product or service features and characteristics, their specification, achievement, or verification, or means to plan organize, control, assure, or improve them.
Adequate	Suitable for the purpose. The term “adequate” appears several times in the standard allowing the assessor to vary the criteria for adequacy and hence not use a finite process to verify that the requirements have been met.
Adequacy audit	An audit carried out to establish that the quality system documentation adequately addresses the requirements of a prescribed standard; also referred to as a <i>documentation audit</i> .
Accreditation	A process by which organizations are authorized to conduct certification of conformity to prescribed standards.
Appropriate	Appropriate means “appropriate to the circumstances” and requires knowledge of these circumstances. Without criteria, an assessor is left to decide what is or is not appropriate.
Approved	Confirmed as meeting the requirements.
Assessment	The act of determining the extent of compliance with requirements.
Assurance	Evidence (verbal or written) that gives confidence that something will or will not happen or has or has not happened.

Audit	An examination of records or activities to verify their accuracy, usually by someone other than the person responsible for them.
Authority	The right to take actions and make decisions.
Authorized	A permit to do something or use something that may not necessarily be approved.
Benchmarking	A technique for measuring an organization's products, services, and operations against those of its competitors, resulting in a search for best practice that will lead to superior performance.
Calibrate	To standardize the quantities of a measuring instrument.
Capability index C_p	The capability index for a stable process defined as the quotient of tolerance width and process capability where process capability is the 6σ range of a process's inherent variation.
Capability index C_{pk}	The capability index which accounts for process centering for a stable process using the minimum upper or lower capability index.
Capability index P_{pk}	The performance index which accounts for process centering and defined as the minimum of the upper or lower specification limit minus the average value divided by 3σ .
Certification	A process by which a product, process, person, or organization is deemed to meet specified requirements.
Certification body	See <i>Registrar</i> .
Class	A group of entities having at least one attribute in common. A group of entities having the same generic purpose but different functional use.
Clause of the standard	A numbered paragraph or subsection of the standard containing one or more related requirements, such as 4.10.3. Note that each item in a list is also a clause. (See also <i>Quality system element</i> .)
Codes	A systematically arranged and comprehensive collection of rules, regulations, or principles.
Commitment	An obligation a person or organization undertakes to fulfill: i.e. doing what you say you will do.
Comparative reference	A standard used to determine differences between it and another entity.
Compliance audit	See <i>Implementation audit</i> .

Concession	Permission granted by an acceptance authority to supply product or service that does not meet the prescribed requirements. (Note: the term <i>waiver</i> is used in the USA and has the same meaning.)
Concurrent engineering	See <i>Simultaneous engineering</i> .
Conformance audit	See <i>Implementation audit</i> .
Conforms to specified requirements	Meets the requirements that have been specified by the customer or the market.
Contract	<p>An agreement formally executed by both customer and supplier (enforceable by law) which requires performance of services or delivery of products at a cost to the customer in accordance with stated terms and conditions.</p> <p>Agreed requirements between a supplier and customer transmitted by any means (ISO 9000-2).</p>
Contractual requirements	Requirements specified in a contract.
Control	The act of preventing or regulating change in parameters, situations, or conditions.
Control charts	A graphical comparison of process performance data to computed control limits drawn as limit lines on the chart.
Control methods	Particular ways of providing control which do not constrain the sequence of steps in which the methods are carried out.
Control procedure	A procedure that controls product or information as it passes through an organization.
Controlled conditions	Arrangements which provide control over all factors that influence the result.
Corrective action	Action planned or taken to stop something from recurring.
Criteria for workmanship	Acceptance standards based on qualitative measures of performance.
Critical success factors	Those factors upon which the achievement of specified objectives depend. For product and service quality they are also referred to as <i>quality characteristics</i> .
Cross-functional team	See <i>Multidisciplinary team</i> .
Customer complaints	Any adverse report (verbal or written) received by a supplier from a customer.

Customer supplied product	Hardware, software, documentation, or information owned by the customer which is provided to a supplier for use in connection with a contract and which is returned to the customer either incorporated in the supplies or at the end of the contract.
Data	Information that is organized in a form suitable for manual or computer analysis.
Define and document	To state in written form, the precise meaning, nature, or characteristics of something.
Demonstrate	To prove by reasoning, objective evidence, experiment, or practical application.
Department	A unit of an organization which may perform one or more functions. Units of organization regardless of their names are also referred to as functions (see <i>Functions</i>).
Design	A process of originating a conceptual solution to a requirement and expressing it in a form from which a product may be produced or a service delivered.
Design and development	Design creates the conceptual solution and development transforms the solution into a fully working model.
Design of experiments	A technique for improving the quality of both processes and products by effectively investigating several sources of variation at the same time using statistically planned experiments.
Design review	A formal documented and systematic critical study of a design by people other than the designer.
Disposition	The act or manner of disposing of something.
Documentation audit	See <i>Adequacy audit</i> .
Documented procedures	Procedures that are formally laid down in a reproducible medium such as paper or magnetic disk.
Effectiveness of the system	The extent to which the (quality) system fulfills its purpose.
Employee empowerment	An environment in which employees are free (within defined limits) to take action to operate, maintain, and improve the processes for which they are responsible using their own expertise and judgement.
Ensure	To make certain that something will happen.

Entity	That which can be individually described and considered (ISO 8402).
Establish and maintain	To set up an entity on a permanent basis and retain or restore it in a state in which it can fulfill its purpose or required function.
Evaluation	To ascertain the relative goodness, quality, or usefulness of an entity with respect to a specific purpose.
Evidence of conformance	Documents which testify that an entity conforms with certain prescribed requirements.
Executive responsibility	Responsibility vested in those personnel who are responsible for the whole organization's performance. Often referred to as top management.
Failure modes and effects analysis	A technique for identifying potential failure modes and assessing existing and planned provisions to detect, contain, or eliminate the occurrence of failure.
Final inspection and testing	The last inspection or test carried out by the supplier before ownership passes to the customer.
Finite element analysis	A technique for modeling a complex structure.
First party audits	Audits of a company or parts thereof by personnel employed by the company. These audits are also called <i>internal audits</i> .
Follow-up audit	An audit carried out following and as a direct consequence of a previous audit to determine whether agreed actions have been taken and are effective.
Functions	In the organizational sense, a function is a special or major activity (often unique in the organization) which is needed in order for the organization to fulfill its purpose and mission. Examples of functions are design, procurement, personnel, manufacture, marketing, maintenance, etc.
Geometric dimensioning and tolerancing	A method of dimensioning the shape of parts that provides appropriate limits and fits for their application and facilitates manufacturability and interchangeability.
Grade	Category or rank given to entities having the same functional use but different requirements for quality (ISO 8402); e.g. hotels are graded by star rating, automobiles are graded by model.
Identification	The act of identifying an entity, i.e. giving it a set of characteristics by which it is recognizable as a member of a group.
Implement	To carry out a directive.

Implementation audit	An audit carried out to establish whether actual practices conform to the documented quality system; also referred to as a <i>conformance audit</i> or <i>compliance audit</i> .
Importance of activities (in auditing)	The relative importance of the contribution an activity makes to the fulfillment of an organization's objectives.
In-process	Between the beginning and the end of a process.
Indexing	A means of enabling information to be located.
Inspection, measuring, and test equipment	Devices used to perform inspections, measurements, and tests.
Inspection	The examination of an entity to determine whether it conforms to prescribed requirements.
Inspection authority	The person or organization who has been given the right to perform inspections.
Installation	The process by which an entity is fitted into a larger entity.
Issues of documents	The revision state of a document.
Major nonconformity	<p>The absence or total breakdown of a system to meet an ISO/TS requirement. A number of minor nonconformities against one requirement can represent a total breakdown of the system and thus be considered a major nonconformity.</p> <p>Any noncompliance that would result in the probable shipment of nonconforming product. A condition that may result in the failure or materially reduce the usability of the products or services for their intended purpose.</p> <p>A noncompliance that judgement and experience indicate is likely to result in the failure of the quality system or to reduce materially its ability to assure controlled processes and products (<i>Rules for achieving IATF recognition</i>).</p>
Manage work	To manage work means to plan, organize, and control the resources (personnel, financial, and material) and the tasks required to achieve the objective for which the work is needed.
Management representative	The person management appoints to act on their behalf to manage the quality system.
Master list	An original list from which copies can be made.
Measurement capability	The ability of a measuring system (device, person, and environment) to measure true values to the accuracy and precision required.

Measurement uncertainty	The variation observed when repeated measurements of the same parameter on the same specimen are taken with the same device.
Minor nonconformity	A failure to comply with ISO/TS 16949 which, based on judgement and experience, is not likely to result in the failure of the quality system or reduce its ability to assure controlled processes or products (<i>Rules for achieving IATF recognition</i>).
Modifications	Entities altered or reworked to incorporate design changes.
Monitoring	To check periodically and systematically. It does not imply that any action will be taken.
Multidisciplinary team	A team comprising representatives from various functions or departments in an organization, formed to execute a project on behalf of that organization.
Nationally recognized standards	Standards of measure that have been authenticated by an accredited national body.
Nature of change	The intrinsic characteristics of the change (what has changed and why).
Objective	The result that is to be achieved, usually by a given time.
Objective evidence	Information that can be proven true, based on facts obtained through observation, measurement, test, or other means (ISO 8402).
Obsolete documents	Documents that are no longer required for operational use. They may be useful as historic documents.
OEM	Original Equipment Manufacturer.
Operating procedure	A procedure that describes how specific tasks are to be performed.
Organizational goals	Where the organization desires to be, in markets, in innovation, in social and environmental matters, in competition, and in financial health.
Organizational interfaces	The boundary at which organizations meet and affect each other, expressed by the passage of information, people, equipment, materials and the agreement to operational conditions.
Plan	Provisions made to achieve an objective.
Planned arrangements	All the arrangements made by the supplier to achieve the customers' requirements. They include the documented policies and procedures and the documents derived from such policies and procedures.

Policy	A guide to thinking, action, and decision.
Positive recall	A means of recovering an entity by giving it a unique identity.
Positively identified	An identification given to an entity for a specific purpose which is both unique and readily visible.
Potential nonconformity	A situation which if left alone will in time result in a nonconformity.
Pre-launch	A phase in the development of a product between design validation and full production (sometimes called pre-production) during which the production processes are validated.
Predictive maintenance	Work scheduled to monitor machine condition, predict pending failure, and make repairs on an as-needed basis; e.g. monitoring machine vibration.
Prevent	To stop something from occurring by a deliberate planned action.
Preventive action	Action proposed or taken to stop something from occurring.
Preventive maintenance	Maintenance carried out at predetermined intervals to reduce the probability of failure or performance degradation; e.g. replacing oil filters at defined intervals.
Procedure	A sequence of steps to execute a routine activity.
Process capability	The ability of a process to maintain product characteristics within preset limits.
Process	A sequence of tasks which combine the use of people, machines, methods, tools, environment, instrumentation, and materials to convert given inputs into outputs of added value.
Process parameters	Those variables, boundaries, or constants of a process which restrict or determine the results.
Product	Anything produced by human effort, natural, or man-made processes. Result of activities or processes (ISO 9000-2).
Production	The creation of products.
Proprietary designs	Designs exclusively owned by the supplier and not sponsored by an external customer.
Prototype	A model of a design that is both physically and functionally representative of the design standard for production and used to verify and validate the design.

Purchaser	One who buys from another.
Purchasing documents	Documents that contain the supplier's purchasing requirements.
Qualification	Determination – by a series of tests and examinations of a product, related documents, and processes – that the product meets all the specified performance capability requirements.
Qualified personnel	Personnel who have been judged as having the necessary ability to carry out particular tasks.
Quality	The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs (ISO 8402).
Quality activities	Any activity that affects the ability of a product or service to satisfy stated or implied needs or the organization's ability to satisfy those needs. If the quality system defines the activities that need to be executed to achieve quality then any activity specified in the documented quality system is also a quality activity.
Quality assurance	All the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality (ISO 8402).
Quality characteristics	Any characteristic of a product or service that is needed to satisfy customer needs or achieve fitness for use.
Quality conformance	The extent to which the product or service conforms with the specified requirements.
Quality control	Operational techniques and activities that are used to fulfill requirements for quality (ISO 8402). A process for maintaining standards of quality that prevents and corrects change in such standards so that the resultant output meets customer needs and expectations.
Quality costs	Costs incurred because failure is possible. The actual cost of producing an entity is the no-failure cost plus the quality costs. The no-failure cost is the cost of doing the right things right first time. The quality costs are the prevention, appraisal, and failure costs.
Quality function deployment	A technique to deploy customer requirements (the true quality characteristics) into design characteristics (the substitute characteristics) and deploy them into subsystems, components, materials, and production processes. The result is a grid or matrix that shows how and where customer requirements are met.

Quality improvement	Actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to both the organization and its customers (ISO 8402).
Quality management	All activities of the overall management function that determine the quality policy, objectives, and responsibilities and implement them by means such as quality planning, quality control, and quality improvement within the quality system (ISO 8402).
Quality manual	A document stating the quality policy and describing the quality system of an organization (ISO 8402).
Quality objectives	Those results which the organization needs to achieve in order to improve its ability to meet current and future customer needs and expectations.
Quality plans	Plans produced to define how specified quality requirements will be achieved, controlled, assured, and managed for specific contracts or projects.
Quality planning	Provisions made to prevent failure to satisfy customer needs and expectations and organizational goals.
Quality policy	The overall intentions and direction of an organization with regard to quality, as formally expressed by top management (ISO 8402).
Quality problems	The difference between the achieved quality and the required quality.
Quality records	Objective evidence of the achieved features and characteristics of a product or service and the processes applied to its development, design, production, installation, maintenance, and disposal as well as records of assessments, audits, and other examinations of an organization to determine its capability to achieve given quality requirements.
Quality requirements	Those requirements that pertain to the features and characteristics of a product or service which are required to be fulfilled in order to satisfy a given need, want, expectation, or requirement.
Quality system	The organization structure, procedures, processes, and resources needed to implement quality management (ISO 8402).
Quality system assessments	External audits carried out by second or third parties. They include a documentation audit, implementation audit, and the determination of the effectiveness of the system.

Quality system element	<p>A distinct part of the system which is governed by a set of requirements.</p> <p>A subsection of the standard identified by a two-digit number, such as 4.1, 4.2, 4.3, etc.</p>
Quality system requirements	Requirements pertaining to the design, development, implementation, and maintenance of quality systems.
Quarantine area	A secure space provided for containing product pending a decision on its disposal.
Registrar	An organization that is authorized to certify organizations. The body may be accredited or non-accredited.
Registration	A process of recording details of organizations of assessed capability which have satisfied prescribed standards.
Regulatory requirements	Requirements established by law pertaining to products or services.
Related results	Results that arise out of performing an activity or making a decision. In the context of quality activities they may be documents, records, approval and acceptance decisions, disapproval and reject decisions, products, processes.
Remedial action	Action proposed or taken to remove a nonconformity (see also <i>Corrective action</i> and <i>Preventive action</i>).
Repair	Action taken on a nonconforming product so that it will fulfill the intended usage requirements, although it may not conform to the originally specified requirements. Repair includes remedial action to restore for usage a once conforming but now nonconforming product (ISO 8402).
Representative sample	A sample of product or service which possesses all the characteristics of the batch from which it was taken.
Requirements for quality	An expression of the needs or their translation into a set of quantitatively or qualitatively stated requirements for the characteristics of an entity to enable its realization and examination (ISO 8204).
Requirement of the standard	A sentence containing the word <i>shall</i> . Note that some sentences contain multiple requirements such as “to establish, document, and maintain”. This is in fact three requirements.
Requirements of society	Obligations resulting from law, regulations, rules, codes, statutes, and other considerations (ISO 8402).
Responsibility	An area in which one is entitled to act on one’s own accord.

Review	Another look at something.
Rework	Action taken on a nonconforming product so that it will fulfill the specified requirements (ISO 8402).
Scheduled maintenance	Work performed at a time specifically planned to minimize interruptions in machine availability; e.g. changing a gearbox when machine is not required for use (includes predictive and preventive maintenance).
Second party audits	Audits carried out by customers upon their suppliers.
Service	The result generated by activities at the interface between the supplier and the customer and by supplier internal activities to meet customer needs (ISO 8402).
Service reports	Reports of servicing activities.
Servicing	Action to restore or maintain an item in an operational condition.
Shall	A provision that is binding.
Should	A provision that is optional.
Simultaneous engineering	A method of reducing the time taken to achieve objectives by developing the resources needed to support and sustain the production of a product in parallel with the development of the product itself. It involves customers, suppliers, and each of the organization's functions working together to achieve common objectives.
Specified requirements	Requirements prescribed by the customer and agreed by the supplier or requirements prescribed by the supplier that are perceived as satisfying a market need (ISO 9000-2).
Status	The relative condition, maturity, or quality of something.
Status of an activity (in auditing)	The maturity or relative level of performance of an activity to be audited.
Subcontract requirements	Requirements placed on a subcontractor which are derived from requirements of the main contract.
Subcontractor	A person or company that enters into a subcontract and assumes some of the obligations of the prime contractor. An organization that provides a product to the supplier (ISO 8402).
Subcontractor development	A technique for promoting continuous improvement of subcontractors by encouraging customer-supplier relationships and communication across all levels of the involved organizations.

Supplier	A person or company who supplies products or services to a customer (ISO 8402).
System audit	An audit carried out to establish whether the quality system conforms to a prescribed standard in both its design and its implementation.
System effectiveness	The ability of a system to achieve its stated purpose and objectives.
Technical interfaces	The physical and functional boundary between products and services.
Tender	A written offer to supply products or services at a stated cost.
Theory of constraints	A thinking process optimizing system performance. It examines the system and focuses on the constraints that limit overall system performance. It looks for the weakest link in the chain of processes that produce organizational performance and seeks to eliminate it and optimize system performance.
Third party audits	External audits carried out by personnel who are neither employees of the customer nor the supplier and are usually employees of certification bodies or registrars.
Total quality management	A management approach of an organization centered on quality, based on the participation of all its members, and aiming at long-term success through customer satisfaction and benefits to all members of the organization and to society (ISO 8402).
Traceability	The ability to trace the history, application, use, and location of an individual article or its characteristics through recorded identification numbers.
Unique identification	An identification which has no equal.
Validation	A process for establishing whether an entity will fulfill the purpose for which it has been selected or designed.
Value engineering	A technique for assessing the functions of a product and determining whether the same functions can be achieved with fewer types of components and materials and the product produced with less resources. Variety reduction is an element of value engineering.
Verification	The act of establishing the truth or correctness of a fact, theory, statement, or condition.
Verification activities	A special investigation, test, inspection, audit, review, demonstration, analysis, or comparison of data to verify that a system, product, service, or process complies with prescribed requirements.

Verification requirements	Requirements for establishing conformance of a product or service with specified requirements by certain methods and techniques.
Waiver	<i>See Concession.</i>
Work instructions	Instructions which prescribe work to be executed, who is to do it, when it is to start and be complete, and how, if necessary, it is to be carried out.
Workmanship criteria	Standards on which to base the acceptability of characteristics created by human manipulation of materials by hand or with the aid of hand tools.
Zero defects	The performance standard achieved when every task is performed right first time with no errors being detected downstream.

Appendix B

Acronyms

AB	Accreditation Body
AIAG	Automotive Industry Action Group
ANFIA	Associazione Nazionale Fra Industrie Automobilistiche (National Association of Automobile Industries)
ASN	Advance Shipment Notification
AVSQ	Anfia Valutazione Sistemi Qualità (ANFIA Evaluation of Quality Systems)
CAD	Computer Aided Design
CAE	Computer Aided Engineering
CB	Certification Body
CCFA	Comité des Constructeurs Français d'Automobiles (French Automobile Constructors Committee)
CUSUM	Cumulative Sum
DFA	Design for Assembly
DFM	Design for Manufacturing
DOE	Design of Experiments
EAC	European Accreditation of Certification
EAQF	Evaluation Aptitude Qualité Fournisseurs (Evaluation of supplier quality capability)
FEA	Finite Element Analysis
FIEV	Fédération des Industries des Equipements pour Véhicules (The French Vehicle Equipment Industries Association)
FIFO	First In First Out
FMEA	Failure Mode and Effects Analysis
GD & T	Geometric Dimensioning and Tolerancing
GM	General Motors
IATF	International Automotive Task Force
MSA	Measurement Systems Analysis
OEM	Original Equipment Manufacturer
PPAP	Production Part Approval Process
QFD	Quality Function Deployment
SMMT	Society of Motor Manufacturers and Traders
SPC	Statistical Process Control
VDA	Verband der Automobilindustrie (German Automobile Industry Association)

Appendix C

Bibliography

- AQ-002** *Advanced product quality planning and control plan reference manual*
- AVSQ** ANFIA evaluation of quality systems – checklist
ANFIA evaluation of quality systems – guidelines for use
Benchmarking, Sylvia Coding (Gower, 1998)
Business systems engineering, Gregory H Watson (Wiley, 1994)
- EAQF** Evaluation Aptitude Qualité Fournisseur
Fundamental statistical process control reference manual (GM, Ford, Chrysler)
Guidelines to failure modes and effects analysis (SMMT)
Guidelines to Statistical process control Parts 1 & 2 (SMMT)
- ISO 10005** Quality management – guidelines for quality plans
- ISO 10007** Quality management – guidelines for configuration management
- ISO 10011-1** Guidelines for auditing quality systems – auditing
- ISO 10011-2** Guidelines for auditing quality systems – qualification criteria of quality system auditors
- ISO 10011-3** Guidelines for auditing quality systems – management of audit programs
- ISO 10012** Quality assurance requirements for measuring equipment
- ISO 10013** Guidelines for developing quality manuals
- ISO 8402** Quality management and quality assurance – vocabulary
ISO 9000 Quality System Development Handbook, David Hoyle (Butterworth-Heinemann, 1998)
ISO 9000 Quality Systems Handbook, 3rd edition, David Hoyle (Butterworth-Heinemann, 1998)
- ISO 9000-1** Guidelines for selection and use
- ISO 9000-2** Guidelines for the application of ISO 9001, ISO 9002, and ISO 9003
- ISO 9000-3** Guidelines for the application of ISO 9001 to the development, supply, and maintenance of software.
- ISO 9000-4** Guide to dependability program management

- ISO 9001** Model for quality assurance in design/development, production, installation, and servicing.
- ISO 9002** Model for quality assurance in production and installation.
- ISO 9003** Model for quality assurance in final inspection and test.
- ISO 9004-1** Quality management and quality system elements – guidelines
- ISO 9004-2** Quality management and quality system elements – guidelines for services
- ISO 9004-3** Quality management and quality system elements – guidelines for processed materials
- ISO 9004-4** Quality management and quality system elements – guidelines for quality improvement
- Measurement systems analysis (MSA)* (GM, Ford, Chrysler)
- Organizational Behaviour and Analysis*, Rollinson, Broadfield, and Edwards (Addison Wesley, 1998)
- Potential failure mode and effects analysis (FMEA)* (GM, Ford, Chrysler)
- Practical benchmarking, The complete guide*, M Zaire and P Leonard (Chapman & Hall)
- Production part approval process (PPAP)* (GM, Ford, Chrysler)
- QS-9000** Quality system requirements, 3rd edition (GM, Ford, Chrysler)
- The ISO Survey of ISO 9000 and ISO 14000 certificates – eighth cycle 1998* available on line at www.iso.ch
- VDA 1** Quality evidence – guidelines for documenting and archiving quality requirements
- VDA 2** Quality assurance of supplies – supplier selection/sampling/quality performance in the series
- VDA 3** Ensuring reliability of car manufacturers and suppliers
- VDA 4 Part 1** Quality assurance prior to serial application – partnerships, processes, methods
- VDA 4 Part 2** Quality assurance prior to serial application – system FMEA
- VDA 4 Part 3** Quality assurance prior to serial application – project planning
- VDA 6** Basics for quality audits, auditing, and certification
- VDA 6 Part 1** Quality system audit basics
- VDA 6 Part 2** System audit services
- VDA 6 Part 3** Process audit
- VDA 6 Part 4** Product audit
- VDA 7** Basics for interchange of quality data – electronic transfer of quality data
- VDA 8** Guidelines for quality assurance of trailer, superstructure, and container manufacturers
- VDA 9** Emissions and consumption
- Work and Motivation*, VH Vroom (John Wiley, New York, 1964)

Appendix D

Relationship of clauses

Some clauses of ISO/TS 16949 address particular phases in the quality loop and others are independent of any phase. It should not be assumed that, for example, all the requirements that apply to purchasing are in clause 4.6. This matrix should help identify which requirements apply to any given phase.

PHASE INDEPENDENT	PHASE DEPENDENT						
	Contract Review	Design	Purchasing	Production	Delivery	Installation	Servicing
Management Responsibility	X	X	X	X	X	X	X
Quality System	X	X	X	X	X	X	X
Document and Data Control	X	X	X	X	X	X	X
Customer Supplied Product			X	X	X	X	X
Product Identification & Traceability		X	X	X	X	X	X
Inspection & Testing		X	X	X	X	X	X
Inspection, Measuring, & Test Equipment		X	X	X	X	X	X
Inspection & Test Status		X	X	X	X	X	X
Control of Nonconforming Product		X	X	X	X	X	X
Corrective and Preventive Action	X	X	X	X	X	X	X
Handling, Packaging, Preservation, & Storage		X	X	X	X	X	X
Control of Quality Records	X	X	X	X	X	X	X
Internal Quality Audits	X	X	X	X	X	X	X
Training	X	X	X	X	X	X	X
Statistical Techniques		X	X	X	X		

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