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Quality management and quality system elements — Guidelines

Gestion de la qualité et éléments de système qualité — Lignes directrices

Reference number
ISO 9004 : 1987 (E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 9004 was prepared by Technical Committee ISO/TC 176, *Quality assurance.*

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Quality management and quality system elements — Guidelines

0 Introduction

0.1 General

A primary concern of any company or organization must be the quality of its products and services.

In order to be successful, a company must offer products or services that

a) meet a well defined need, use or purpose;

b) satisfy customers' expectations;

c) comply with applicable standards and specifications;

d) comply with statutory (and other) requirements of society (see 3.3);

e) are made available — at competitive prices;

f) are provided at a cost which will yield a profit.

0.2 Organizational goals

In order to meet its objectives, the company should organize itself in such a way that the technical, administrative and human factors affecting the quality of its products and services will be under control. All such control should be oriented towards the reduction, elimination and, most importantly, prevention of quality deficiencies.

A quality management system should be developed and implemented for the purpose of accomplishing the objectives set out in a company's quality policies.

Each element (or requirement) in a quality management system will vary in importance from one type of activity to another and from one product or service to another.

In order to achieve maximum effectiveness and to satisfy customer expectations, it is essential that the quality management system be appropriate to the type of activity and to the product or service being offered.

0.3 Meeting company/customer needs

A quality management system has two inter-related aspects :

a) The company's needs and interests

— For the company, there is a business need to attain and to maintain the desired quality at an optimum cost; the fulfilment of this quality aspect is related to the planned and efficient utilization of the technological, human and material resources available to the company.

b) The customer's needs and expectations

— For the customer, there is a need for confidence in the ability of the company to deliver the desired quality as well as the consistent maintenance of that quality.

Each of the above aspects of a quality management system requires objective evidence in the form of information and data concerning the quality of the system and the quality of the company's products.

0.4 Risks, costs and benefits

0.4.1 General

Risk, cost and benefit considerations have great importance for both company and customer. These considerations are inherent aspects of most products and services. The possible effects and ramifications of these considerations are given in 0.4.2 to 0.4.4.

0.4.2 Risk considerations

0.4.2.1 For the company

Consideration has to be given to risks related to deficient products or services which lead to loss of image or reputation, loss of market, complaints, claims, liability, waste of human and financial resources.

0.4.2.2 For the customer

Consideration has to be given to risks such as those pertaining to the health and safety of people, dissatisfaction with goods and services, availability, marketing claims and loss of confidence.

0.4.3 Cost considerations

0.4.3.1 For the company

Consideration has to be given to costs due to marketing and design deficiencies, including unsatisfactory materials, rework, repair, replacement, re-processing, loss of production, warranties and field repair.

0.4.3.2 For the customer

Consideration has to be given to safety, acquisition cost, operating, maintenance, downtime and repair costs, and possible disposal costs.

0.4.4 Benefit considerations

0.4.4.1 For the company

Consideration has to be given to increased profitability and market share.

0.4.4.2 For the customer

Consideration has to be given to reduced costs, improved fitness for use, increased satisfaction and growth in confidence.

0.4.5 Conclusion

An effective quality management system should be designed to satisfy customer needs and expectations while serving to protect the company's interests. A well-structured quality system is a valuable management resource in the optimization and control of quality in relation to risk, cost and benefit considerations.

1 Scope and field of application

This International Standard describes a basic set of elements by which quality management systems can be developed and implemented.

The selection of appropriate elements contained in this International Standard and the extent to which these elements are adopted and applied by a company depends upon factors such as market being served, nature of product, production processes, and consumer needs.

NOTES

1 This International Standard is not intended to be used as a checklist for compliance with a set of requirements.

2 ISO/TC 176, *Quality assurance*, is considering preparing a separate International Standard on the subject of service.

2 References

ISO 8402, *Quality — Vocabulary.*

ISO 9000, *Quality management and quality assurance standards — Guidelines for selection and use.*

ISO 9001, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002, *Quality systems — Model for quality assurance in production and installation.*

ISO 9003, *Quality systems — Model for quality assurance in final inspection and test.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 and the following definitions apply.

3.1 organization : A company, corporation, firm or enterprise, whether incorporated or not, public or private.

3.2 company : Term used primarily to refer to a business first party, the purpose of which is to supply a product or service.

3.3 requirements of society : Requirements including laws, statutes, rules and regulations, codes, environmental considerations, health and safety factors, and conservation of energy and materials.

3.4 customer : Ultimate consumer, user, client, beneficiary or second party.

4 Management responsibility

4.1 General

The responsibility for and commitment to a quality policy belongs to the highest level of management. Quality management is that aspect of the overall management function which determines and implements quality policy.

4.2 Quality policy

The management of a company should develop and state its corporate quality policy. This policy should be consistent with other company policies. Management should take all necessary measures to ensure that its corporate quality policy is understood, implemented and maintained.

4.3 Quality objectives

4.3.1 For the corporate quality policy, management should define objectives pertaining to key elements of quality, such as fitness for use, performance, safety and reliability.

4.3.2 The calculation and evaluation of costs associated with all quality elements and objectives should always be an important consideration, with the objective of minimizing quality losses.

4.3.3 Appropriate levels of management, where necessary, should define specialized quality objectives consistent with corporate quality policy as well as other corporate objectives.

4.4 Quality system

4.4.1 A quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

4.4.2 Management should develop, establish and implement a quality system as the means by which stated policies and objectives might be accomplished.

4.4.3 The quality system should be structured and adapted to the company's particular type of business and should take into account the appropriate elements outlined in this International Standard.

4.4.4 The quality system should function in such a manner as to provide proper confidence that

a) the system is well understood and effective;

b) the products or services actually do satisfy customer expectations;

c) emphasis is placed on problem prevention rather than dependence on detection after occurrence.

5 Quality system principles

5.1 Quality loop

5.1.1 The quality system typically applies to, and interacts with, all activities pertinent to the quality of a product or service. It involves all phases from initial identification to final satisfaction of requirements and customer expectations. These phases and activities may include the following :

a) marketing and market research;

b) design/specification engineering and product development;

c) procurement;

d) process planning and development;

e) production;

f) inspection, testing and examination;

g) packaging and storage;

h) sales and distribution;

i) installation and operation;

j) technical assistance and maintenance;

k) disposal after use.

See the figure for a schematic representation of the quality loop, which is similar in concept to the quality spiral.

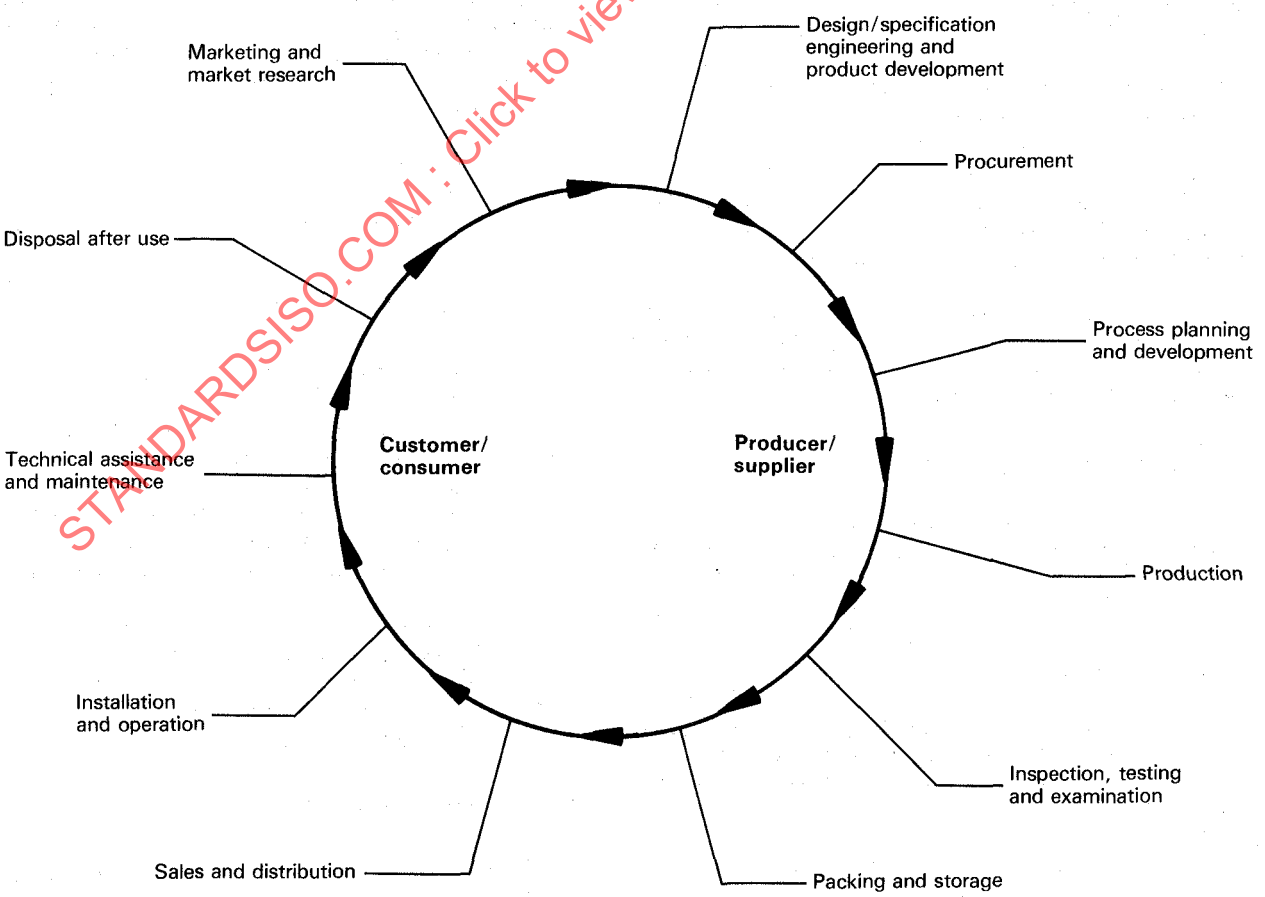

Figure — Quality loop

5.1.2 In the context of interacting activities within a company, marketing and design should be emphasized as especially important for

a) determining and defining customer needs, expectations and the product requirements;

b) providing the concepts (including back-up data) for producing a product or service to defined specifications at optimum cost.

5.2 Structure of the quality system

5.2.1 General

Management is ultimately responsible for establishing the quality policy and for decisions concerning the initiation, development, implementation and maintenance of the quality system.

5.2.2 Quality responsibility and authority

Activities contributing to quality, whether directly or indirectly, should be identified and documented, and the following actions taken :

a) General and specific quality responsibilities should be explicitly defined.

b) Responsibility and authority delegated to each activity contributing to quality should be clearly established; authority and responsibility should be sufficient to attain the assigned quality objectives with the desired efficiency.

c) Interface control and coordination measures between different activities should be defined.

d) Management may choose to delegate the responsibility for internal quality assurance and for external quality assurance where necessary; the persons so delegated should be independent of the activities reported on.

e) In organizing a well structured and effective quality system, emphasis should be placed on the identification of actual or potential quality problems and the initiation of remedial or preventive measures.

5.2.3 Organizational structure

The organizational structure pertaining to the quality management system should be clearly established within the overall management of a company. The lines of authority and communication should be defined.

5.2.4 Resources and personnel

Management should provide sufficient and appropriate resources essential to the implementation of quality policies and the achievement of quality objectives. These resources may include

a) human resources and specialized skills;

b) design and development equipment;

c) manufacturing equipment;

d) inspection, test and examination equipment;

e) instrumentation and computer software.

Management should determine the level of competence, experience and training necessary to ensure the capability of personnel. (See clause 18.)

Management should identify quality factors affecting market position and objectives relative to new products, processes or services (including new technologies) in order to allocate company resources on a planned and timely basis.

Programmes and schedules covering these resources and skills should be consistent with the company's overall objectives.

5.2.5 Operational procedures

The quality system should be organized in such a way that adequate and continuous control is exercised over all activities affecting quality.

The management system should emphasize preventive actions that avoid occurrence of problems, while not sacrificing the ability to respond to and correct failures should they occur.

Operational procedures coordinating different activities with respect to an effective quality system should be developed, issued and maintained to implement corporate quality policies and objectives. These procedures should lay down the objectives and performance of the various activities having an impact on quality, e.g. design, development, procurement, production and sales.

All written procedures should be stated simply, unambiguously and understandably, and should indicate methods to be used and criteria to be satisfied.

5.3 Documentation of the system

5.3.1 Quality policies and procedures

All the elements, requirements and provisions adopted by a company for its quality management system should be documented in a systematic and orderly manner in the form of written policies and procedures. Such documentation should ensure a common understanding of quality policies and procedures (i.e. quality programmes/plans/manuals/records).

The quality management system should include adequate provision for the proper identification, distribution, collection and maintenance of all quality documents and records. However, care should be taken to limit documentation to the extent pertinent to the application. (See clause 17.)

5.3.2 Quality manual

5.3.2.1 The typical form of the main document used in drawing up and implementing a quality system is a "Quality Manual".

5.3.2.2 The primary purpose of a quality manual is to provide an adequate description of the quality management system while serving as a permanent reference in the implementation and maintenance of that system.

5.3.2.3 Methods should be established for making changes, modifications, revisions or additions to the contents of a quality manual.

5.3.2.4 In larger companies, the documentation relating to the quality management system may take various forms, including the following :

a) a corporate quality manual;

b) divisional quality manuals;

c) specialized quality manuals (e.g. design, procurement, project, work instructions).

5.3.3 Quality plans

For projects relating to new products, services or processes, management should prepare, as appropriate, written quality plans consistent with all other requirements of a company's quality management system.

Quality plans should define

a) the quality objectives to be attained;

b) the specific allocation of responsibilities and authority during the different phases of the project;

c) the specific procedures, methods and work instructions to be applied;

d) suitable testing, inspection, examination and audit programmes at appropriate stages (e.g. design, development);

e) a method for changes and modifications in a quality plan as projects proceed;

f) other measures necessary to meet objectives.

5.3.4 Quality records

Quality records and charts pertaining to design, inspection, testing, survey, audit, review or related results are important constituents of a quality management system (see 17.2 and 17.3).

5.4 Auditing the quality system

5.4.1 General

All elements, aspects and components pertaining to a quality system should be internally audited and evaluated on a regular basis. Audits should be carried out in order to determine whether various elements within a quality management system are effective in achieving stated quality objectives. For this purpose, an appropriate audit plan should be formulated and established by company management.

5.4.2 Audit plan

The format of the audit plan should cover the following points :

a) the specific activities and areas to be audited;

b) qualifications of personnel carrying out audits;

c) the basis for carrying out audits (e.g. organizational changes, reported deficiencies, routine checks and surveys);

d) procedures for reporting audit findings, conclusions and recommendations.

5.4.3 Carrying out the audit

Objective evaluations of quality system elements by competent personnel may include the following activities or areas :

a) organizational structures;

b) administrative and operational procedures;

c) personnel, equipment and material resources;

d) work areas, operations and processes;

e) items being produced (to establish degree of conformance to standards and specifications);

f) documentation, reports, record-keeping.

Personnel carrying out audits of quality system elements should be independent of the specific activities or areas being audited.

5.4.4 Reporting and follow-up of audit findings

Audit findings, conclusions and recommendations should be submitted in documentary form for consideration by appropriate members of company management.

The following items should be covered in the reporting and follow-up of audit findings :

a) Specific examples of non-compliance or deficiencies should be documented in the audit report; possible reasons for such deficiencies, where evident, may be included.

b) Appropriate corrective actions may be suggested.

c) Implementation and effectiveness of corrective actions suggested in previous audits should be assessed.

5.5 Review and evaluation of the quality management system

Provision should be made by company management for independent review and evaluation of the quality system. Such reviews should be carried out by appropriate members of company management or by competent independent personnel as decided on by company management.

Reviews should consist of well structured and comprehensive evaluations which include

a) findings of audits centred on various elements of the quality system (see 5.4.3);

b) the overall effectiveness of the quality management system in achieving stated quality objectives;

c) considerations for up-dating the quality management system in relation to changes brought about by new technologies, quality concepts, market strategies, and social or environmental conditions.

Findings, conclusions and recommendations reached as a result of review and evaluation should be submitted in documentary form for necessary action by company management.

6 Economics — Quality-related cost considerations

6.1 General

The impact of quality upon the profit-and-loss statement can be highly significant, particularly in the long term. It is, therefore, important that the effectiveness of a quality system be measured in a business-like manner. The main objective of quality cost reporting is to provide means for evaluating effectiveness and establishing the basis for internal improvement programmes.

6.2 Selecting appropriate elements

A portion of total business costs is earmarked for meeting the quality objectives. In practice, the combination of selected elements from this portion of total costs can provide the necessary information for marshalling efforts towards achieving quality goals. It is now common practice to identify and measure "quality costs". Both costs of activities directed at achieving appropriate quality and resultant costs from inadequate control should be identified.

6.3 Types of quality-related costs

6.3.1 General

Quality costs can be broadly divided into operating quality costs (see 6.3.2) and external assurance quality costs (see 6.3.3).

6.3.2 Operating quality costs

Operating quality costs are those costs incurred by a business in order to attain and ensure specified quality levels. These include the following :

a) Prevention and appraisal costs (or investments)

— prevention : Costs of efforts to prevent failures

— appraisal : Costs of testing, inspection and examination to assess whether specified quality is being maintained

b) Failure costs (or losses)

— internal failure : Costs resulting from a product or service failing to meet the quality requirements prior to delivery (e.g. reperforming of service, reprocessing, rework, retest, scrap)

— external failure : Costs resulting from a product or service failing to meet the quality requirements after delivery (e.g. product service, warranties and returns, direct costs and allowances, product recall costs, liability costs)

6.3.3 External assurance quality costs

External assurance quality costs are those costs relating to the demonstration and proof required as objective evidence by customers, including particular and additional quality assurance provisions, procedures, data, demonstration tests, and assessments (e.g. the cost of testing for specific safety characteristics by recognized independent testing bodies).

6.4 Management visibility

Quality costs should be regularly reported to and monitored by management and be related to other cost (ratio) measures, such as "sales", "turnover", or "added value" so as to

a) evaluate the adequacy and effectiveness of the quality management system;

b) identify additional areas requiring attention;

c) establish quality and cost objectives.

7 Quality in marketing

7.1 Marketing requirements

The marketing function should take the lead in establishing quality requirements for the product. It should

a) determine the need for a product or service;

b) accurately define the market demand and sector, since doing so is important in determining the grade, quantity, price and timing estimates for the product or service;

c) accurately determine customer requirements by a review of contract or market needs : actions include an assessment of any unstated expectations or biases held by customers;

d) communicate all customer requirements clearly and accurately within the company.

7.2 Product brief

The marketing function should provide the company with a formal statement or outline of product requirements, e.g. a product brief. The product brief translates customer requirements and expectations into a preliminary set of specifications as the basis for subsequent design work. Among the elements that may be included in the product brief are the following requirements :

a) performance characteristics (e.g. environmental and usage conditions and reliability);

b) sensory characteristics (e.g. style, colour, taste, smell);

c) installation configuration or fit;

d) applicable standards and statutory regulations;

e) packaging;

f) quality assurance/verification.

7.3 Customer feedback information

The marketing function should establish an information monitoring and feedback system on a continuous basis. All information pertinent to the quality of a product or service should be analysed, collated, interpreted and communicated in accordance with defined procedures. Such information will help to determine the nature and extent of product or service problems in relation to customer experience and expectations. In addition, feedback information may provide clues to possible design changes as well as appropriate management action. (See also 8.8, 8.9 and 16.3.)

8 Quality in specification and design

8.1 Contribution of specification and design to quality

The specification and design function should provide for the translation of customer needs from the product brief into technical specifications for materials, products and processes. This should result in a product that provides customer satisfaction at an acceptable price that enables a satisfactory return on investment for the enterprise. The specification and design should be such that the product or service is producible, verifiable and controllable under the proposed production, installation, commissioning or operational conditions.

8.2 Design planning and objectives (defining the project)

8.2.1 Management should specifically assign responsibilities for various design duties to activities inside and/or outside the organization and ensure that all those who contribute to design are aware of their responsibilities for achieving quality.

8.2.2 In its delegation of responsibilities for quality, management should ensure that design functions provide clear and definitive technical data for procurement, the execution of work and verification of conformance of products and processes to specification requirements.

8.2.3 Management should establish time-phased design programmes with checkpoints appropriate to the nature of the product. The extent of each phase and the stages at which design reviews or evaluations will take place may depend upon the product's application, its design complexity, the extent of innovation and technology being introduced, the degree of standardization and similarity with past proven designs.

8.2.4 In addition to customer needs, the designer should give due consideration to the requirements relating to safety, environmental and other regulations, including items in the company's quality policy which may go beyond existing statutory requirements.

8.2.5 The quality aspects of the design should be unambiguous and adequately define characteristics important to quality, such as the acceptance and rejection criteria. Both fitness for purpose and safeguards against misuse should be considered. Product definition may also include reliability, maintainability and serviceability through a reasonable life expectancy, including benign failure and safe disposability, as appropriate.

8.3 Product testing and measurement

The methods of measurement and test, and the acceptance criteria applied to evaluate the product and processes during both the design and production phases should be specified. Parameters should include the following :

a) performance target values, tolerances, and attribute features;

b) acceptance and rejection criteria;

c) test and measurement methods, equipment, bias and precision requirements, and computer software considerations.

8.4 Design qualification and validation

The design process should provide periodic evaluation of the design at significant stages. Such evaluation can take the form of analytical methods, such as FMEA (Failure Mode and Effects Analysis), fault tree analysis or risk assessment, as well as inspection or test of prototype models and/or actual production samples. The amount and degree of testing should be related to the risks identified in the design plan (see 8.2). Independent evaluation may be employed, as appropriate, to verify original calculations, provide alternative calculations or perform tests. Adequate numbers of samples should be examined by tests and/or inspection to provide adequate statistical confidence in the results. The tests should include the following activities :

a) evaluation of performance, durability, safety, reliability and maintainability under expected storage and operational conditions;

b) inspections to verify that all design features are as intended and that all authorized design changes have been accomplished and recorded;

c) validation of computer systems and software.

The results of all tests and evaluations should be documented regularly throughout the qualification test cycle. Review of test results should include defect and failure analysis.

8.5 Design review

8.5.1 General

At the conclusion of each phase of design development, a formal, documented, systematic and critical review of the design results should be conducted. This should be distinguished from a project progress meeting, which is primarily concerned with time and cost. Participants at each design review should include representatives of all functions affecting quality as appropriate to the phase being reviewed. The design review should identify and anticipate problem areas and inadequacies, and initiate corrective actions to ensure that the final design and supporting data meet customer requirements.

8.5.2 Elements of design reviews

As appropriate to the design phase and product, the following elements outlined below should be considered :

a) Items pertaining to customer needs and satisfaction

1) comparison of customer needs expressed in the product brief with technical specifications for materials, products and processes;

2) validation of the design through prototype tests;

3) ability to perform under expected conditions of use and environment;

4) considerations of unintended uses and misuses;

5) safety and environmental compatibility;

6) compliance with regulatory requirements, national and international standards, and corporate practices;

7) comparisons with competitive designs;

8) comparison with similar designs, especially analysis of internal and external problem history to avoid repeating problems.

b) Items pertaining to product specification and service requirements

1) reliability, serviceability and maintainability requirements;

2) permissible tolerances and comparison with process capabilities;

3) product acceptance/rejection criteria;

4) installability, ease of assembly, storage needs, shelf-life and disposability;

5) benign failure and fail-safe characteristics;

6) aesthetic specifications and acceptance criteria;

7) failure modes and effects analyses, and fault tree analysis;

8) ability to diagnose and correct problems;

9) labelling, warnings, identification, traceability requirements and user instructions;

10) review and use of standard parts.

c) Items pertaining to process specifications and service requirements

1) manufacturability of the design, including special process needs, mechanization, automation, assembly and installation of components;

2) capability to inspect and test the design, including special inspection and test requirements;

3) specification of materials, components and sub-assemblies, including approved supplies and suppliers as well as availability;

4) packaging, handling, storage, and shelf-life requirements, especially safety factors relating to incoming and outgoing items.

8.5.3 Design verification

Design verification may be undertaken independently or in support of design reviews by applying the following methods :

a) alternative calculations, made to verify the correctness of the original calculations and analyses;

b) testing, e.g. by model or prototype tests — if this method is adopted, the test programmes should be clearly defined and the results documented;

c) independent verification, to verify the correctness of the original calculations and/or other design activities.

8.6 Design baseline and production release

The results of the final design review should be appropriately documented in specifications and drawings that define the design baseline. Where appropriate, this should include description of qualification test units "as built" and modified to correct deficiencies during the qualification test programmes for configuration control throughout the production cycle. The total document package that defines the design baseline should require approval at appropriate levels of management affected by or contributing to the product. This "approval" constitutes the production release and signifies concurrence that the design can be realized.

8.7 Market readiness review

The quality system should provide for a review to determine whether production capability and field support are adequate for the new or redesigned product. Depending upon the type of product, the review may cover the following points :

a) availability and adequacy of installation, operation, maintenance and repair manuals;

b) existence of an adequate distribution and customer service organization;

c) training of field personnel;

d) availability of spare parts;

e) field trials;

f) certification of the satisfactory completion of qualification tests;

g) physical inspection of early production units and their packaging and labelling;

h) evidence of process capability to meet specification on production equipment.

8.8 Design change control (Configuration management)

The quality system should provide a procedure for controlling the release, change and use of documents that define the design baseline (resultant product configuration) and for authorizing the necessary work to be performed to implement changes that may affect product during its entire life cycle. The procedures should provide for various necessary approvals, specified points and times for implementing changes, removing obsolete drawings and specifications from work areas, and verification that changes are made at the appointed times and places. This control process is referred to as "configuration management". These procedures should handle emergency changes necessary to prevent production of nonconforming product. Consideration should be given to instituting formal design reviews and validation testing when the magnitude, complexity or risk associated with the change warrant such actions.

8.9 Design requalification

Periodic re-evaluation of product should be performed in order to ensure that the design is still valid with respect to all specified requirements. This should include a review of customer needs and technical specifications in the light of field experiences, field performance surveys, or new technology and techniques. The review should also consider process modifications. The quality system should ensure that any production and field experience indicating the need for design change is fed back for analysis. Care should be taken that design changes do not cause product/quality degradation and that proposed changes are evaluated for their impact on all product characteristics in the design baseline definition.

9 Quality in procurement

9.1 General

Purchase materials, components and assemblies become part of the company's product and directly affect the quality of its product. Quality of services such as calibration and special processes should also be considered. The procurement of purchased supplies should be planned and controlled. The purchaser should establish a close working relationship and feedback system with each supplier. In this way, a programme of continual quality improvements can be maintained and quality disputes avoided or settled quickly. This close working relationship and feedback system will benefit both the purchaser and the supplier.

The procurement quality programme should include the following elements as a minimum :

a) requirements for specification, drawings and purchase orders (see 9.2);

b) selection of qualified suppliers (see 9.3);

c) agreement on quality assurance (see 9.4);

d) agreement on verification methods (see 9.5);

e) provisions for settlement of quality disputes (see 9.6);

f) receiving inspection plans (see 9.7);

g) receiving controls (see 9.7);

h) receiving quality records (see 9.8).

9.2 Requirements for specification, drawings and purchase orders

The successful procurement of supplies begins with a clear definition of the requirements. Usually these requirements are contained in the contract specifications, drawings and purchase orders which are provided to the supplier.

The procuring activity should develop appropriate methods to ensure that the requirements for the supplies are clearly defined, communicated and, most importantly, are completely understood by the supplier. These methods may include written procedures for the preparation of specifications, drawings and purchase orders, vendor/purchaser conferences prior to purchase order release, and other methods appropriate for the supplies being procured.

Purchasing documents should contain data clearly describing the product or service ordered. Elements that may be included are as follows :

a) precise identification of style and grade;

b) inspection instructions and applicable specifications;

c) quality system standard to be applied.

Purchasing documents should be reviewed for accuracy and completeness before release.

9.3 Selection of qualified suppliers

Each supplier should have a demonstrated capability to furnish supplies which can meet all the requirements of the specifications, drawings and purchase order.

The methods of establishing this capability may include any combination of the following :

a) on-site assessment and evaluation of supplier's capability and/or quality system;

b) evaluation of product samples;

c) past history with similar supplies;

d) test results of similar supplies;

e) published experience of other users.

9.4 Agreement on quality assurance

A clear understanding should be developed with the supplier on quality assurance for which the supplier is responsible. The assurance to be provided by the supplier may vary as follows :

a) the purchaser relies on supplier's quality assurance system;

b) submission of specified inspection/test data or process control records with shipments;

c) 100 % inspection/testing by the supplier;

d) lot acceptance inspection/testing by sampling by the supplier;

e) implementation of a formal quality assurance system as specified by the purchaser;

f) none — the purchaser relies on receiving inspection or in-house sorting.

The assurance provisions should be commensurate with the needs of the purchaser's business and should avoid unnecessary costs. In certain cases, formal quality assurance systems may be involved (see ISO 9000, ISO 9001, ISO 9002 and ISO 9003). This may include periodic assessment of supplier quality system assurance by the purchaser.

9.5 Agreement on verification methods

A clear agreement should be developed with the supplier on the methods by which conformance to purchaser's requirements will be verified. Such agreements may also include the exchange of inspection and test data with the aim of furthering quality improvements. Reaching agreement can minimize difficulties in the interpretation of requirements as well as inspection, test or sampling methods.

9.6 Provisions for settlement of quality disputes

Systems and procedures should be established by which settlement of disputes regarding quality can be reached with suppliers. Provisions should exist for dealing with routine and non-routine matters.

A very important aspect of these systems and procedures is the provision of improved communication channels between the purchaser and the supplier on matters affecting quality.

9.7 Receiving inspection planning and controls

Appropriate measures should be established to ensure that supplies which have been received are properly controlled. These procedures should include quarantine areas or other appropriate methods to prevent unqualified supplies from being inadvertently used. (See 14.4.)

The extent to which receiving inspection will be performed should be carefully planned. The level of inspection, when inspection is deemed necessary, should be selected with overall cost being borne in mind.

In addition, when the decision has been made to perform an inspection, it is necessary to select with care the characteristics to be inspected.

It is also necessary to ensure, before the supplies arrive, that all the necessary tools, gauges, meters, instruments and equipment are available and properly calibrated, along with adequately trained personnel.

9.8 Receiving quality records

Appropriate receiving quality records should be maintained to ensure the availability of historical data to assess supplier performance and quality trends.

In addition, it may be useful and, in certain instances, essential to maintain records of lot identification for the purposes of traceability.

10 Quality in production

10.1 Planning for controlled production

10.1.1 Planning of production operations should ensure that these proceed under controlled conditions in the specified manner and sequence. Controlled conditions include appropriate controls for materials, production equipment, processes and procedures, computer software, personnel, and associated supplies, utilities and environments.

Production operations should be specified to the necessary extent by documented work instructions.

Process capability studies should be conducted to determine the potential effectiveness of a process (see 10.2).

Provisions for common practice that apply throughout the production facility should be similarly documented and referenced in individual work instructions. These instructions should describe the criteria for determining satisfactory work completion and conformity to specification and standards of good workmanship. Workmanship standards should be defined to the necessary extent by written standards, photographs and/or physical samples.

10.1.2 Verification of the quality status of a product, process, software, material or environment should be considered at important points in the production sequence to minimize effects of errors and to maximize yields. The use of control charts and statistical sampling procedures and plans are examples of techniques employed to facilitate production/process control (see also 12.2).

10.1.3 Verifications at each stage should relate directly to finished product specifications or to an internal requirement, as appropriate. If verification of characteristics of the process itself is not physically or economically practical or feasible, then verification of the product should be utilized. In all cases, relationships between in-process controls, their specifications, and final product specifications should be developed, communicated to production and inspection personnel, and documented.

10.1.4 All in-process and final inspections should be planned and specified. Documented test and inspection procedures should be maintained, including the specific equipment to perform such checks and tests, as well as the specified requirement(s) and/or workmanship standard(s) for each quality characteristic to be checked.

10.1.5 Efforts to develop new methods for improving production quality and process capability should be encouraged.

10.2 Process capability

Production processes should be verified as capable of producing in accordance with product specifications. Operations associated with product or process characteristics that can have a significant effect on product quality should be identified. Appropriate control should be established to ensure that these characteristics remain within specification or that appropriate modifications or changes are made.

Verification of production processes should include material, equipment, computer system and software, procedures and personnel.

10.3 Supplies, utilities and environments

Where important to quality characteristics, auxiliary materials and utilities, such as water, compressed air, electric power and chemicals used for processing, should be controlled and verified periodically to ensure uniformity of effect on the process. Where a production environment, such as temperature, humidity and cleanliness, is important to product quality, appropriate limits should be specified, controlled and verified.

11 Control of production

11.1 General

*The quality loop involves the control of quality in a manufactur*ing cycle. (See also 5.1 in which the interaction of various quality system functions is outlined.)

11.2 Material control and traceability

*All materials and parts should conform to appropriate specifica*tions and quality standards before being introduced into production. However, in determining the amount of test and/or inspection necessary, consideration should be given to cost impact and the effect that substandard material quality will have on production flow (see clause 9). Materials should be appropriately stored, segregated, handled and protected during production to maintain their suitability. Special consideration should be given to shelf-life and deterioration control. Where in-plant traceability of material is important to quality, appropriate identification should be maintained throughout the production process to ensure traceability to original material identification and quality status (see 11.7 and 16.1.3).

11.3 Equipment control and maintenance

All production equipment, including fixed machinery, jigs, fixtures, tooling, templates, patterns and gauges, should be proved for bias and precision prior to use. Special attention should be paid to computers used in controlling processes, and especially the maintenance of the related software (see 13.1).

Equipment should be appropriately stored and adequately protected between use, and verified or recalibrated at appropriate intervals to ensure its bias and precision.

A programme of preventive maintenance should be established to ensure continuing process capability. Special attention should be given to equipment characteristics that contribute to key product quality characteristics.

11.4 Special processes

Special consideration should be given to production processes in which control is particularly important to product quality. Such special consideration may be required for product characteristics that are not easily or economically measured, for special skills required in their operation or maintenance, or for a product or process the results of which cannot be fully verified by subsequent inspection and test. More frequent verification of special processes should be made to keep a check on

a) the accuracy and variability of equipment used to make or measure product, including settings and adjustments;

b) the skill, capability and knowledge of operators to meet quality requirements;

c) special environments, time, temperature or other factors affecting quality;

d) certification records maintained for personnel, processes and equipment, as appropriate.

11.5 Documentation

Work instructions, specifications and drawings should be controlled as specified by the quality system (see 5.3 and 17.2).

11.6 Process change control

Those responsible for authorization of process changes should be clearly designated and, where necessary, customer approval should be sought. As with design changes, all changes to production tooling or equipment, materials or processes should be documented. The implementation should be covered by defined procedures.

A product should be evaluated after any change to verify that the change instituted had the desired effect upon product quality. Any changes in the relationships between process and product characteristics resulting from the change should be documented and appropriately communicated.

11.7 Control of verification status

Verification status of material and assemblies should be identified throughout production. Such identification may take the form of stamps, tags or notations on shop travellers or inspection records that accompany the product. The identification should include the ability to distinguish between verified and unverified material and indication of acceptance at the point of verification. It should also provide traceability to the unit responsible for the operation.

11.8 Control of nonconforming materials

Provision should be made for the positive identification and control of all nonconforming material (see clause 14).

12 Product verification

12.1 Incoming materials and parts

The method used to ensure quality of purchased materials, component parts and assemblies that are received into the

production facility will depend on the importance of the item to quality, the state of control and information available from the supplier and impact on costs (see clause 9, in particular subclauses 9.7 and 9.8).

12.2 In-process inspection

Inspections or tests should be considered at appropriate points in the process to verify conformity. Location and frequency will depend on the importance of the characteristics and ease of verification at the stage of production. In general, verification should be made as close as possible to the point of production of the feature or characteristic.

Verifications may include the following checks :

a) set-up and first piece inspection;

b) inspection or test by machine operator;

c) automatic inspection or test;

d) fixed inspection stations at intervals through the process;

e) patrol inspection by inspectors monitoring specified operations.

12.3 Completed product verification

To augment inspections and tests made during production, two forms of final verification of completed product are available. Either or both of the following may be used, as appropriate :

a) Acceptance inspections or tests may be used to ensure that items or lots produced have met performance and other quality requirements. Reference may be made to the purchase order to verify that product to be shipped agrees in type and quantity. Examples include screening (100 % of items), lot sampling and continuous sampling.

b) Product quality auditing of sample units selected as representative of completed production lots may be either continuous or periodic.

Acceptance inspection and product quality auditing may be used to provide rapid feedback for corrective action of product and process. Deficiencies or deviations should be reported, and reworked or repaired. Modified products should be reinspected or retested.

13 Control of measuring and test equipment

13.1 Measurement control

Sufficient control should be maintained over all measurement systems used in the development, manufacture, installation and servicing of a product to provide confidence in decisions or actions based on measurement data. Control should be exercised over gauges, instruments, sensors, special test equipment and related computer software. In addition, manufacturing jigs, fixtures and process instrumentation that can affect the specified characteristics of a product, process or service should be suitably controlled (see 11.3). Procedures should be established to monitor and maintain the measurement process itself under statistical control, including equipment, procedures and operator skills. Measurement error should be compared with requirements and appropriate action taken when precision and/or bias requirements are not achieved.

13.2 Elements of control

The control of measuring and test equipment and test methods should include the following factors, as appropriate :

a) Correct specification and acquisition, including range, bias, precision, robustness and durability under specified environmental conditions for the intended service.

b) Initial calibration prior to first use in order to validate the required bias and precision; the software, and procedures controlling automatic test equipment, should also be tested.

c) Periodic recall for adjustment, repair and recalibration, considering manufacturer's specification, the results of prior calibration, the method and extent of use, to maintain the required accuracy in use.

d) Documentary evidence covering identification of instruments, frequency of re-calibration, calibration status, and procedures for recall, handling and storage, adjustment, repair, calibration, installation and use.

e) Traceability to reference standards of known accuracy and stability, preferably to national or international standards, or, in industries or products where such do not exist, to specially developed criteria.

13.3 Supplier measurement controls

The control of measuring and test equipment and procedures extend to all suppliers furnishing goods and services.

13.4 Corrective action

Where measuring processes are found to be out of control or where measuring and test equipment is found to be outside the required calibration limits, corrective action is necessary. Evaluation should be made to determine the effects on completed work and to what extent reprocessing, retesting, recalibration or complete rejection may be necessary. In addition, investigation of cause is important in order to avoid recurrence. This may include review of calibration methods and frequency, training, and adequacy of test equipment.

13.5 Outside testing

The facilities of outside organizations may be used for measurement, testing or calibration services to avoid costly duplication or additional investment, provided that the requirements given in 13.2 and 13.4 are satisfied.

14 Nonconformity

14.1 General

The steps outlined in 14.2 to 14.7 should be taken as soon as indications occur that materials, components or completed product do not or may not meet the specified requirements.