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Quality management and quality system elements —

Part 1: Guidelines

*Management de la qualité et éléments de système qualité —
Partie 1: Lignes directrices*



Reference number
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Contents

	Page
1 Scope	1
2 Normative references	1
3 Definitions	1
4 Management responsibility	2
5 Quality system elements	3
6 Financial considerations of quality systems	7
7 Quality in marketing	8
8 Quality in specification and design	9
9 Quality in purchasing	12
10 Quality of processes	14
11 Control of processes	15
12 Product verification	16
13 Control of inspection, measuring and test equipment	16
14 Control of nonconforming product	17
15 Corrective action	18
16 Post-production activities	19
17 Quality records	19
18 Personnel	20
19 Product safety	21
20 Use of statistical methods	22
Annex	
A Bibliography	23

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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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9004-1 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This first edition of ISO 9004-1 cancels and replaces ISO 9004:1987, and has been prepared as a result of comments received on ISO 9004:1977. ISO requires that all its standards be reviewed every five years and, as ISO 9004 has been expanded into a series of standards, it was considered that the revision to the 1987 edition of ISO 9004 should become the first part in the series, i.e. ISO 9004-1.

Comments adopted by Working Group 12 of ISO/TC 176/SC 2 during the review were based on the following considerations.

- a) ISO 9004 is a document for internal use by an organization. It is not intended as guidance to ISO 9001, ISO 9002 or ISO 9003, for which ISO 9000-2 is available.
- b) For editorial reasons, the 1987 document structure was retained in the 1994 edition. The structure of all four standards ISO 9001, ISO 9002, ISO 9003 and ISO 9004 will be changed and aligned with each other in the next five-year major revision.
- c) This edition is essentially an editorial revision to align terminology with ISO 8402 and to reflect the need to serve better not only manufacturing but also process and service industries.
- d) This edition also introduces some newer general quality management concepts, such as that all activities can be considered as processes, with input and output.
- e) More emphasis has been placed on planning and preventive action. For this reason, activities such as handling, identification and packaging processes are now additionally dealt with under Quality in specifi-

cation and design (clause 8), Quality of processes (clause 10) and Control of processes (clause 11).

- f) Figure 1 has been updated to reflect quality activities in the life cycle of a product.
- g) New methods for the financial reporting of quality management effectiveness have been introduced.

ISO 9004 consists of the following parts, under the general title *Quality management and quality system elements*:

- *Part 1: Guidelines*
- *Part 2: Guidelines for services*
- *Part 3: Guidelines for processed materials*
- *Part 4: Guidelines for quality improvement*
- *Part 5: Guidelines for quality plans*
- *Part 6: Guidelines on quality assurance for project management*
- *Part 7: Guidelines for configuration management*
- *Part 8: Guidelines on quality principles and their application to management practices*

Annex A of this part of ISO 9004 is for information only.

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Introduction

0.1 General

This part of ISO 9004 and all other International Standards in the ISO 9000 family are generic and independent of any specific industry or economic sector. Collectively they provide guidance for quality management and models for quality assurance.

The International Standards in the ISO 9000 family describe what elements quality systems should encompass, but not how a specific organization should implement these elements. Because the needs of organizations vary, it is not the purpose of these International Standards to enforce uniformity of quality systems. The design and implementation of a quality system will be influenced by the particular objectives, products, processes and individual practices of the organization.

A primary concern of any organization should be the quality of its products. (See 3.5 for the definition of "product" which includes service.)

In order to be successful, an organization should offer products that:

- a) meet a well-defined need, use or purpose;
- b) satisfy customers' expectations;
- c) comply with applicable standards and specifications;
- d) comply with requirements of society (see 3.3);
- e) reflect environmental needs;
- f) are made available at competitive prices;
- g) are provided economically.

0.2 Organizational goals

In order to meet its objectives, an organization should ensure that the technical, administrative and human factors affecting the quality of its products will be under control, whether hardware, software, processed materials or services. All such control should be oriented towards the reduction, elimination and, most importantly, prevention of nonconformities.

A quality system should be developed and implemented for the purpose of accomplishing the objectives set out in the organization's quality policy.

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

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

0.3 Meeting customer/organization needs and expectations

A quality system has two interrelated aspects, as follows.

a) The customer's needs and expectations

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

b) The organization's needs and interests

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

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

0.4 Benefits, costs and risks

Benefit, cost and risk considerations have great importance for both the organization and customer. These considerations are inherent aspects of most products. The possible effects and ramifications of these considerations are given in a) to c).

a) Benefit considerations

For the customer, consideration has to be given to reduced costs, improved fitness for use, increased satisfaction and growth in confidence.

For the organization, consideration has to be given to increased profitability and market share.

b) Cost considerations

For the customer, consideration has to be given to safety, acquisition cost, operating, maintenance, downtime and repair costs, and possible disposal costs.

For the organization, consideration has to be given to costs due to marketing and design deficiencies, including unsatisfactory product, rework, repair, replacement, reprocessing, loss of production, warranties and field repair.

c) Risk considerations

For the customer, consideration has to be given to risks such as those pertaining to the health and safety of people, dissatisfaction with product, availability, marketing claims and loss of confidence.

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

0.5 Conclusions

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

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Quality management and quality system elements —

Part 1: Guidelines

1 Scope

This part of ISO 9004 provides guidance on quality management and quality system elements.

The quality system elements are suitable for use in the development and implementation of a comprehensive and effective in-house quality system, with a view to ensuring customer satisfaction.

This part of ISO 9004 is not intended for contractual, regulatory or certification use. Consequently, it is not a guideline for the implementing of ISO 9001, ISO 9002 and ISO 9003. ISO 9000-2 should be used for that purpose.

The selection of appropriate elements contained in this part of ISO 9004 and the extent to which these elements are adopted and applied by an organization depends upon factors such as the market being served, nature of the product, production processes, and customer and consumer needs.

References in this part of ISO 9004 to a "product" should be interpreted as applicable to the generic product categories of hardware, software, processed materials or service (in accordance with the definition of "product" in ISO 8402).

NOTES

- 1 For further guidance, see ISO 9004-2 and ISO 9004-3.
- 2 For informative references, see annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9004. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9004 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use*.

3 Definitions

This revision of ISO 9004 has improved the harmonization of terminology with other International Standards in the ISO 9000 family. Table 1 shows the supply chain terminology used in these International Standards.

Table 1 — Relationships of organizations in the supply chain

ISO 9000-1	Sub-supplier	→	supplier or organization	→	customer
ISO 9001, ISO 9002, ISO 9003	Sub-contractor	→	supplier	→	customer
ISO 9004-1	Sub-contractor	→	organization	→	customer

Thus, the term “subcontractor” is used rather than the term “supplier” in this part of ISO 9004 to avoid confusion with the meaning of the term “supplier”, in ISO 9000 and ISO 9001. See ISO 9000-1 for a fuller explanation of the basis for usage of these terms.

For the purposes of this part of ISO 9004, the definitions given in ISO 8402 apply.

For the convenience of users of this part of ISO 9004, the following definitions are quoted from ISO 8402.

3.1 organization: Company, corporation, firm, enterprise or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

3.2 customer: Recipient of a product provided by the supplier.

NOTES

3 In a contractual situation, the customer is called the “purchaser”.

4 The customer may be, for example, the ultimate consumer, user, beneficiary or purchaser.

5 The customer can be either external or internal to the organization.

3.3 requirements of society: Obligations resulting from laws, regulations, rules, codes, statutes and other considerations.

NOTES

6 “Other considerations” include notably protection of the environment, health, safety, security, conservation of energy and natural resources.

7 All requirements of society should be taken into account when defining the requirements for quality.

8 Requirements of society include jurisdictional and regulatory requirements. These may vary from one jurisdiction to another.

3.4 quality plan: Document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, project or contract.

NOTES

9 A quality plan usually makes reference to the parts of the quality manual applicable to the specific case.

10 Depending on the scope of the plan, a qualifier may be used, for example, “quality assurance plan”, “quality management plan”.

3.5 product: Result of activities or processes.

NOTES

11 A product may include service, hardware, processed materials, software or a combination thereof.

12 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

13 A product can be either intended (e.g. offering to customers) or unintended (e.g. pollutant or unwanted effects).

3.6 service: Result generated by activities at the interface between the supplier and the customer and by supplier internal activities to meet the customer needs.

NOTES

14 The supplier or the customer may be represented at the interface by personnel or equipment.

15 Customer activities at the interface with the supplier may be essential to the service delivery.

16 Delivery or use of tangible products may form part of the service delivery.

17 A service may be linked with the manufacture and supply of tangible product.

4 Management responsibility

4.1 General

The responsibility for and commitment to a quality policy belongs to the highest level of management. Quality management encompasses 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, quality assurance and quality improvement within the quality system.

4.2 Quality policy

The management of an organization should define and document its quality policy. This policy should be consistent with other policies within the organization. Management should take all necessary measures to ensure that its quality policy is understood, implemented and reviewed, at all levels of the organization.

4.3 Quality objectives

4.3.1 Management should document objectives and commitments pertaining to key elements of quality, such as fitness for use, performance, safety and dependability.

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 should document specific quality objectives consistent with quality policy as well as other objectives of the organization.

4.4 Quality system

4.4.1 A quality system is the organizational structure, procedures, processes and resources needed to implement quality management.

4.4.2 The organization's management should develop, establish and implement a quality system to accomplish the stated policies and objectives.

4.4.3 The quality system should be structured and adapted to the organization's particular type of business and should take into account the appropriate elements outlined in this part of ISO 9004.

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

- a) the system is understood, implemented, maintained and effective;
- b) the products actually do satisfy customer needs and expectations;
- c) the needs of both society and the environment have been addressed;
- d) emphasis is placed on problem prevention rather than dependence on detection after occurrence.

5 Quality system elements

5.1 Extent of application

5.1.1 The quality system typically applies to, and interacts with, all activities pertinent to the quality of a product. It will involve all phases in the life cycle of a product and processes, from initial identification of market needs to final satisfaction of requirements. Typical phases are:

- a) marketing and market research;
- b) product design and development;
- c) process planning and development;
- d) purchasing;
- e) production, or provision of services;
- f) verification;
- g) packaging and storage;
- h) sales and distribution;
- i) installation and commissioning;
- j) technical assistance and servicing;
- k) after sales;
- l) disposal or recycling at the end of useful life.

NOTE 18 Figure 1 gives a schematic representation of the typical life-cycle phases of a product.

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

- determining and defining customer needs, expectations and other product requirements, and
- providing the concepts (including supporting data) for producing a product to documented specifications at optimum cost.

5.2 Structure of the quality system

5.2.1 General

Input from the market should be used to improve new and existing products and to improve the quality system.

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 Responsibility and authority

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

- a) General and specific quality-related responsibilities should be explicitly defined.
- b) Responsibility and authority delegated to each activity contributing to quality should be clearly established. Responsibility, organizational freedom and authority to act 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) In organizing a well-structured and effective quality system, emphasis should be placed on the identification of potential or actual quality problems and the implementation of preventive or corrective action (see clauses 14 and 15).

5.2.3 Organizational structure

Functions related to the quality system should be clearly established within the overall organizational structure. The lines of authority and communication should be defined.

5.2.4 Resources and personnel

Management should identify resource requirements, and provide sufficient and appropriate resources essential to the implementation of the quality policy and the achievement of quality objectives. For example, these resources can 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-related factors affecting market position and objectives relative to products, processes or associated services, in order to allocate organization resources on a planned and timely basis.

Programmes and schedules covering these resources and skills should be consistent with the organization'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 quality system should emphasize preventive actions that avoid occurrence of problems, while maintaining the ability to respond to and correct failures should they occur.

Documented operational procedures coordinating different activities with respect to an effective quality system should be developed, issued and maintained to implement the quality policy and objectives. These documented procedures should specify the objectives and performance of the various activities having an impact on quality (see figure 1).

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

5.2.6 Configuration management

The quality system should include documented procedures for configuration management to the extent appropriate. This discipline is initiated early in the design phase and continues through the whole life cycle of a product. It assists in the operation and control of design, development, production and use of a product, and gives management visibility of the state of documentation and product during its life-time.

Configuration management can include: configuration identification, configuration control, configuration status accounting and configuration audit. It relates to several of the activities described in this part of ISO 9004.

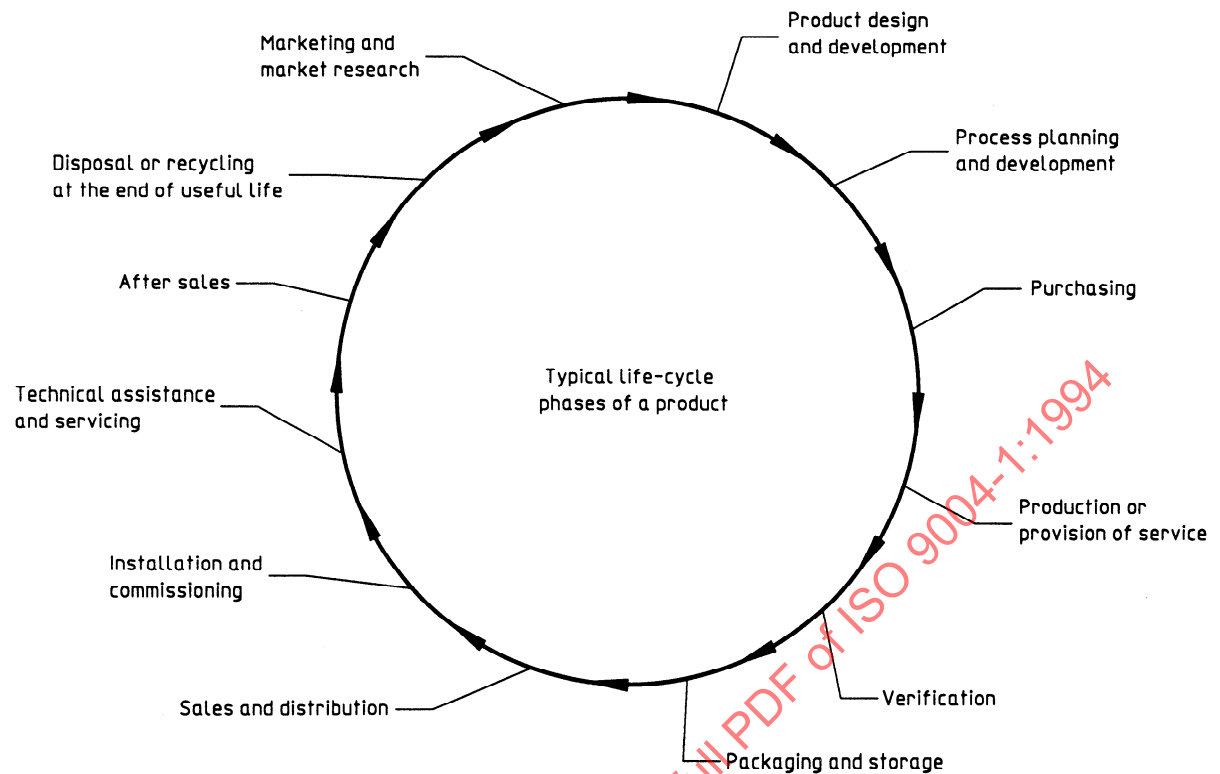


Figure 1 — Main activities having an impact on quality

5.3 Documentation of the quality system

5.3.1 Quality policies and procedures

All the elements, requirements and provisions adopted by an organization for its quality system should be documented in a systematic, orderly and understandable manner in the form of policies and procedures. However, care should be taken to limit documentation to the extent pertinent to the application.

The quality system should include adequate provision for the proper identification, distribution, collection and maintenance of all quality documents.

5.3.2 Quality system documentation

5.3.2.1 The typical form of the main document used to demonstrate or describe a documented quality system is a "quality manual". For further guidance, see ISO 10013.

5.3.2.2 The primary purpose of a quality manual is to define an outline structure of the quality system while serving as a permanent reference in the implementation and maintenance of that system.

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

5.3.2.4 Supporting the quality manual are documented quality system procedures (e.g. design, purchasing and process work instructions). These documented procedures can take various forms, depending on

- the size of the organization,
- the specific nature of the activity, and
- the intended scope and structure of the quality manual.

Documented procedures may apply to one or more parts of the organization.

5.3.3 Quality plans

For any product or process, management should ensure that documented quality plans are prepared and maintained. These should be consistent with all other requirements of the organization's quality system, and should ensure that specified requirements for a product, project or contract are met. A quality plan may be a part of a larger overall plan. A quality plan is par-

ticularly necessary for a new product or process, or when there is significant change to an existing product or process.

Quality plans should define:

- a) the quality objectives to be attained (e.g. characteristics or specifications, uniformity, effectiveness, aesthetics, cycle time, cost, natural resources, utilization, yield and dependability);
- b) the steps in the processes that constitute the operating practice of the organization (a flowchart or similar diagram can be used to demonstrate the elements of the process);
- c) the specific allocation of responsibilities, authority and resources during the different phases of the project;
- d) the specific documented procedures and instructions to be applied;
- e) suitable testing, inspection, examination and audit programmes at appropriate stages (e.g. design and development);
- f) a documented procedure for changes and modifications in a quality plan as projects proceed;
- g) a method for measuring the achievement of the quality objectives;
- h) other actions necessary to meet the objectives.

Quality plans may be included or referenced in the quality manual, as appropriate.

To facilitate achievement of the objectives of a quality plan, documented operational control as described in this part of ISO 9004 should be used.

5.3.4 Quality records

Quality records, including charts pertaining to design, inspection, testing, survey, audit, review or related results, should be maintained as important evidence to demonstrate conformance to specified requirements and the effective operation of the quality system (see clause 17).

5.4 Auditing the quality system

5.4.1 General

Audits should be planned and carried out to determine if the activities and related results of the organization's quality system comply with planned arrangements, and to determine the effectiveness of the quality system. All elements should be internally audited and evaluated on a regular basis, considering the status and importance of the activity to be audited. For this purpose, an appropriate audit programme should be established and implemented by the organization's management.

5.4.2 Audit programme

The audit programme should cover:

- a) planning and scheduling the specific activities and areas to be audited;
- b) assignment of personnel with appropriate qualifications to conduct audits;
- c) documented procedures for carrying out audits, including recording and reporting the results of the quality audit and reaching agreement on timely corrective actions on the deficiencies found during the audit.

Apart from planned and systematic audits, other factors necessitating audits can be organizational changes, market feedback, nonconformity reports and surveys.

5.4.3 Extent of audits

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

- a) organizational structures;
- b) administrative, operational and quality system procedures;
- c) personnel, equipment and material resources;
- d) work areas, operations and processes;
- e) products being produced (to establish the degree of conformance to standards and specifications);
- f) documentation, reports and record-keeping.

Personnel conducting audits of quality system elements should be independent of those having direct responsibilities for the specific activities or areas being audited. An audit plan should be prepared and documented to include the items listed in a) to f).

5.4.4 Audit reporting

Audit observations, conclusions and agreements on timely corrective action should be recorded and submitted for appropriate action by the management responsible for the area audited, and communicated for the information of management with executive responsibility for quality.

The following items should be covered in the audit report:

- a) all examples of nonconformities or deficiencies;
- b) appropriate and timely corrective action.

5.4.5 Follow-up action

Implementation and effectiveness of corrective actions resulting from previous audits should be assessed and documented.

NOTE 19 For further guidance on quality auditing, qualifications of auditors and management of audit programmes, see parts 1 to 3 of ISO 10011.

5.5 Review and evaluation of the quality system

The organization's management should provide for independent review and evaluation of the quality system at defined intervals. The reviews of the quality policy and objectives should be carried out by top management, and the review of supporting activities should be carried out by management with executive responsibilities for quality and other appropriate members of management, utilizing competent independent personnel as decided on by the management.

Reviews should consist of well-structured and comprehensive evaluations which include:

- a) results from internal audits centred on various elements of the quality system (see 5.4.3);
- b) the overall effectiveness in satisfying the guidance of this part of ISO 9004 and the organization's stated quality policy and objectives;
- c) considerations for updating the quality system in relation to changes brought about by new technologies, quality concepts, market strategies, and social or environmental conditions.

Observations, conclusions and recommendations reached as a result of review and evaluation should be documented for necessary action.

5.6 Quality improvement

When implementing a quality system, the management of an organization should ensure that the system will facilitate and promote continuous quality improvement.

Quality improvement refers to the actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes to provide added benefits to both the organization and its customers.

In creating an environment for quality improvement, consideration should be given to:

- a) encouraging and sustaining a supportive style of management;
- b) promoting values, attitudes and behaviour that foster improvement;
- c) setting clear quality improvement goals;
- d) encouraging effective communication and teamwork;
- e) recognizing successes and achievements;
- f) training and educating for improvement.

NOTE 20 Further guidance is given in ISO 9004-4.

6 Financial considerations of quality systems

6.1 General

It is important that the effectiveness of a quality system be measured in financial terms. The impact of an effective quality system upon the organization's profit and loss statement can be highly significant, particularly by improvement of operations, resulting in reduced losses due to error and by making a contribution to customer satisfaction.

Such measurement and reporting can provide a means for identifying inefficient activities, and initiating internal improvement activities.

By reporting quality system activities and effectiveness in financial terms, management will receive the results in a common business language from all departments.

6.2 Approaches to financial reporting of quality system activities

6.2.1 General

Some organizations find it useful to report the financial benefits using systematic quality financial reporting procedures.

The approach(es) to financial reporting selected and used by particular organizations will be dependent upon their individual structures, their activities, and the maturity of their quality systems.

6.2.2 Approaches

There are various approaches to gathering, presenting and analysing the elements of financial data. The approaches given in a) to c) have been found to be useful, but do not exclude others, or adaptations or combinations of them.

a) Quality-cost approach

This approach addresses quality-related costs, which are broadly divided into those arising from internal operations and external activities.

Cost elements for internal operations are analysed according to the PAF (prevention, appraisal, failure) costing model.

Prevention and appraisal costs are considered as investments, while failure costs are considered as losses. The components of the costs are:

- 1) prevention: efforts to prevent failures;
- 2) appraisal: testing, inspection and examination to assess whether requirements for quality are being fulfilled;
- 3) internal failure: costs resulting from a product failing to meet the quality requirements prior to delivery (e.g. re-performing a service, re-processing, rework, retest, scrap);
- 4) external failure: costs resulting from a product failing to meet the quality requirements after delivery (e.g. product maintenance and repair, warranties and returns, direct costs and allowances, product recall costs, liability costs).

b) Process-cost approach

This approach analyses the costs of conformity and the costs of nonconformity for any process,

both of which can be the source of savings. These are defined as:

- 1) cost of conformity: cost to fulfil all of the stated and implied needs of customers in the absence of failure of the existing process;
- 2) cost of nonconformity: cost incurred due to failure of the existing process.

c) Quality-loss approach

This approach focuses on internal and external losses due to poor quality and identifies tangible and intangible loss types. Typical external intangible losses are loss of future sales due to customer dissatisfaction. Typical internal intangible losses arise from lower work efficiency due to rework, poor ergonomics, missed opportunities, etc. Tangible losses are internal and external failure costs.

6.3 Reporting

The financial reporting of quality activities should be regularly provided to and monitored by management, and be related to other business measures such as "sales", "turnover" or "added value" in order to provide for a realistic, entrepreneurial

- evaluation of the adequacy and effectiveness of the quality system,
- identification of additional areas requiring attention and improvement, and
- establishment of quality and cost objectives for the following period.

The elements of financial quality reports are in many cases already available in the organization, but in other forms. Their reporting as a financial quality report can require regrouping of individual elements from other reports.

7 Quality in marketing

7.1 Marketing requirements

The marketing function should establish adequately defined and documented requirements for the quality of the product. Particularly at this early stage in the product life cycle, it is important to consider the requirements for all the elements of the total product, whether hardware, software, processed materials or services. In fact, all products involve some element

of service, and many products involve several generic product categories. The marketing function should:

- a) determine the need for a product;
- b) define the market demand and sector, so that product grade, quantity, price and timing can be determined;
- c) determine specific customer requirements, or review general market needs; actions include assessment of any unstated expectations or biases held by customers;
- d) communicate all customer requirements within the organization;
- e) ensure that all relevant organizational functions agree that they have the capability to meet customer requirements.

7.2 Defining product specification

The marketing function should provide the organization with a formal statement or outline of product requirements. Specific customer and general market requirements and expectations should be translated into a preliminary set of specifications as the basis for subsequent design work. Among the elements that may be included are the following requirements:

- a) performance characteristics (e.g. environmental and usage conditions and dependability);
- b) sensory characteristics (e.g. style, colour, taste, smell);
- c) installation, arrangement layout or fit;
- d) applicable standards and statutory regulations;
- e) packaging;
- f) quality verification and/or assurance.

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 customers' use of and satisfaction with the quality of a product should be analysed, collated, interpreted, verified and reported in accordance with documented procedures. Such information will help to determine the nature and extent of product problems in relation to customer experience and expectations. In addition,

the feedback information can lead to management action resulting in product improvement or to new product offerings (see also 8.8, 8.9, clause 15 and 16.6).

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 into technical specifications for materials, products and processes. This should result in a product that provides customer satisfaction at an acceptable price that gives a satisfactory financial return for the organization. The specification and design should be such that the product 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 prepare plans that define the responsibility for each design and development activity inside and/or outside the organization, and ensure that all those who contribute to design are aware of their responsibilities in relation to the full scope of the project.

8.2.2 In its delegation of responsibilities and authority 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 specified requirements.

8.2.3 Management should establish time-phased design programmes with holdpoints appropriate to the nature of the product and process. The extent of each phase, and the position of the holdpoints at which evaluations of the product or the process will take place, can depend upon several elements, such as

- the product's application,
- its design complexity,
- the extent of innovation and technology being introduced, and
- the degree of standardization and similarity with past proven designs.

8.2.4 In addition to customer needs, consideration should be given to the requirements relating to safety, environmental and other regulations, including items in the organization's quality policy which may go beyond existing statutory requirements (see also 3.3).

8.2.5 The design should unambiguously and adequately define characteristics important to quality, such as the acceptance criteria. Both fitness for purpose and safeguards against misuse should be considered. Product definition can also include dependability 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. These should include the following:

- a) performance target values, tolerances and attribute features;
- b) acceptance criteria;
- c) test and measurement methods, equipment and computer software (see clause 13).

8.4 Design review

8.4.1 General

At the conclusion of each phase of design development, a formal, documented, systematic and critical review of the design results should be planned and conducted. This should be distinguished from a project progress meeting. 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.

8.4.2 Elements of design reviews

As appropriate to the design phase and product, the elements outlined in a) to c) should be considered.

a) Items pertaining to customer needs and satisfaction

- 1) comparison of customer needs expressed in the product specification 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) unintended uses and misuses;
- 5) safety and environmental compatibility;
- 6) compliance with regulatory requirements, national and International Standards, and organization practices;
- 7) comparisons with competitive designs;
- 8) comparison with similar designs, especially analysis of the history of internal and external problems to avoid repeating problems.

b) Items pertaining to product specification

- 1) dependability and serviceability requirements;
- 2) permissible tolerances and comparison with process capabilities;
- 3) product acceptance 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 mode and effect analysis, 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 specification

- 1) ability to produce product conforming to 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 subcontractors as well as availability;
- 4) packaging, handling, storage and shelf-life requirements, especially safety factors relating to incoming and outgoing items.

8.4.3 Design verification

All designs should be verified to ensure that product specifications are fulfilled (see 7.2). In addition to design review, design verification should include one or more of the following methods:

- a) performing alternative calculations, made to verify the correctness of the original calculations and analyses;
- b) testing and demonstrations (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.

8.5 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 effect analysis), fault tree analysis or risk assessment, as well as inspection and test of prototype models and/or actual production samples. The amount and degree of testing (see 8.3) should be related to the identified risks. Independent evaluation can be used, as appropriate, to verify original calculations, provide alternative calculations or perform tests. A number 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 and dependability under expected storage and operational conditions;

- b) inspections to verify that all design features conform to defined user needs 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 nonconformity and failure analysis.

8.6 Final design review and production release

The final design should be reviewed and the results appropriately documented in specifications and drawings, which then form the design baseline. Where appropriate, this should include a description of initial test units and any modifications made to correct deficiencies identified during the qualification test programmes. The total document package that defines the design baseline (output) should require approval at appropriate levels of management affected by or contributing to the product. This approval constitutes the production release and signifies that the design can be realized.

8.7 Market-readiness review

A determination should be made as to whether the organization has the capability to deliver the new or redesigned product. Depending upon the type of product, the review can cover the following points:

- a) availability and adequacy of installation, operation, maintenance and repair manuals;
- b) existence of adequate distribution and customer after-sales service;
- c) training of field personnel;
- d) availability of spare parts;
- e) field trials;
- f) 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

The quality system should include documented procedures for controlling the release, change and use of documents that define the design input and the design baseline (output), and for authorizing the necessary work to be performed to implement changes and modifications that can affect product during its entire life cycle, including changes in software and service instructions. 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. These procedures should handle emergency changes necessary to prevent production or delivery 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 evaluation of product should be performed in order to ensure that the design is still valid. 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 evaluation 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 degradation of product quality for example, and that proposed changes are evaluated for their impact on all product characteristics in the original product specification.

8.10 Configuration management in design

This discipline may be initiated once the requirements have been defined, but is most useful during the design phase. It continues through the whole life cycle of a product (see 5.2.6).

9 Quality in purchasing

9.1 General

Purchases become part of the organization's product and directly affect the quality of its product. All purchasing activities should be planned and controlled by documented procedures. Purchased services such as testing, calibration and subcontracted processing

should also be included. A close working relationship and feedback system should be established with each subcontractor. In this way, continual quality improvements can be maintained and disputes avoided or settled quickly. This close working relationship and feedback system will benefit both parties.

The quality system for purchasing should include the following elements as a minimum:

- a) the applicable issue of specifications, drawings, purchase documents and other technical data (see 9.2);
- b) selection of acceptable subcontractors (see 9.3);
- c) agreement on quality assurance (see 9.4);
- d) agreement on verification methods (see 9.5);
- e) provisions for settlement of disputes (see 9.6);
- f) receiving inspection procedures (see 9.7);
- g) receiving controls (see 9.7);
- h) receiving quality records (see 9.8).

9.2 Requirements for specifications, drawings and purchase documents

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

The purchasing function should develop documented procedures to ensure that the requirements for the supplies are clearly defined, communicated and, most importantly, are completely understood by the subcontractor. These methods may include documented procedures for the preparation of specifications, drawings and purchase documents, meetings with subcontractors prior to the release of the purchase document, and other activities appropriate for the supplies being procured.

Purchasing documents should contain data clearly describing the product ordered. Typical elements are as follows:

- a) precise identification of type, class and grade;
- b) inspection instructions and applicable issue of specifications;
- c) quality system standard to be applied.

Purchasing documents should be reviewed and approved for accuracy and completeness prior to release.

9.3 Selection of acceptable subcontractors

Each subcontractor should have a demonstrated capability to furnish product which meets all the requirements of the specifications, drawings and purchase documents.

The methods of establishing this capability can include, but are not limited to, any combination of the following:

- a) on-site evaluation of subcontractor's capability and/or quality system;
- b) evaluation of product samples;
- c) past history with similar products;
- d) test results of similar products;
- e) published experience of other users.

9.4 Agreement on quality assurance

The organization should develop a clear agreement with subcontractors for the assurance of product supplied. This can be achieved by one or more of the following:

- a) reliance on subcontractor's quality system;
- b) submission of specified inspection/test data and process control records with shipments;
- c) 100 % inspection/testing by the subcontractor;
- d) lot acceptance inspection/testing by sampling by the subcontractor;
- e) implementation of a formal quality system by the subcontractor as specified by the organization; in certain cases, a formal quality assurance model may be involved (see ISO 9001, ISO 9002 and ISO 9003 for further information);
- f) periodic evaluation of subcontractor quality practices by the organization or by a third party;
- g) in-house receiving inspection or sorting.

9.5 Agreement on verification methods

A clear agreement should be developed with the subcontractor on the methods by which conformance

to 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 disputes

Systems and procedures should be established by which settlement of disputes regarding quality can be reached with subcontractors. 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 organization and the subcontractor on matters affecting quality.

9.7 Receiving inspection planning and control

Appropriate measures should be established to ensure that received materials are properly controlled. These procedures should include quarantine areas or other appropriate methods to prevent unintended use or installation of nonconforming materials (see 14.3).

The extent to which receiving inspection will be performed should be carefully planned. The characteristics to be inspected should be based on the cruciality of the product. The capability of the subcontractor should also be considered, taking into account the factors listed in 9.3. The level of inspection should be selected so as to balance the costs of inspection against the consequences of inadequate inspection.

It is also necessary to ensure, before the incoming product arrives, that all the necessary tools, gauges, meters, instruments and equipment are available and properly calibrated. Personnel should be adequately trained.

9.8 Quality records related to purchasing

Appropriate quality records related to product received should be maintained. This will ensure the availability of historical data to assess subcontractor 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 of processes

10.1 Planning for process control

10.1.1 Planning of processes should ensure that these proceed under controlled conditions in the specified manner and sequence. Controlled conditions include appropriate controls for materials, approved production, installation and servicing equipment, documented procedures or quality plans, computer software, reference standards/codes, suitable approval of processes and personnel, as well as associated supplies, utilities and environments.

The operation of processes 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).

Common practices that can be beneficially applied throughout the organization should be documented and referenced in all appropriate procedures and instructions. These should describe the criteria for determining satisfactory work completion and conformity to specification and standards of good workmanship. Workmanship criteria should be stipulated in the clearest practical manner by written standards, photographs, illustrations and/or representative samples.

10.1.2 Verification of the quality status of a hardware product, process, software, processed material, service 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 process control (see also 12.2).

10.1.3 Monitoring and control of processes should relate directly to finished product specifications or to an internal requirement, as appropriate. If verification of the process variables through some measurement procedure is not physically or economically practical or feasible, then verification will have to depend primarily on verification of final product characteristics. In all cases, relationships between in-process controls, their specifications and final product specifications should be developed, communicated to the personnel concerned and then documented.

10.1.4 All in-process and final verifications should be planned and specified. Documented test and inspection procedures should be maintained for each quality characteristic to be checked. These should in-

clude the specific equipment to perform such checks and tests, and the specified requirements and workmanship criteria.

10.1.5 The appropriate methods of cleaning and preserving, and the details of packing, including moisture elimination, cushioning, blocking and crating, should be established and maintained in documented procedures.

10.1.6 Efforts to develop new methods for improving process quality should be encouraged.

10.2 Process capability

Processes should be verified as being capable of producing product in accordance with 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 the specification, or that appropriate modifications or changes are made.

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

10.3 Supplies, utilities and environment

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

10.4 Handling

The handling of product requires proper planning, control and a documented system for incoming, in-process and final product; this applies not only during delivery but up to the time of being put into use.

The methods of handling of product should provide for the correct selection and use of suitable pallets, containers, conveyors and vehicles to prevent damage or deterioration due to vibration, shock abrasion, corrosion, temperature or any other conditions occurring during the production or delivery processes.

11 Control of processes

11.1 General

Product quality should be addressed in each phase of the life cycle (see 5.1.1).

11.2 Material control, traceability and identification

11.2.1 Material control

All materials and parts should conform to specified requirements before being introduced into a process. However, in determining the amount and nature of receiving inspection necessary, consideration should be given to cost impact and the effect that standard material quality will have on production flow.

In-process product, including that in in-process inventory stockrooms, should be appropriately stored, segregated, handled and preserved to maintain its suitability. Special consideration should be given to shelf-life and deterioration control, including assessment of product in stock at appropriate intervals. (For final product storage, see 16.1.)

11.2.2 Traceability

Where traceability of product is important, appropriate identification should be maintained throughout the process, from receipt and during all stages of production, delivery and installation, to ensure traceability to original material identification and verification status (see 11.7 and 14.2).

11.2.3 Identification

The marking and labelling of materials should be legible, durable and in accordance with specifications. Materials should be uniquely identified from the time of initial receipt, to delivery and installation at the final destination. The identification should be in accordance with documented procedures, and should be recorded. This should enable a particular product to be identified in the event that a recall or special inspection becomes necessary.

11.3 Equipment control and maintenance

All equipment, including fixed machinery, jigs, fixtures, tooling, templates, patterns and gauges, should be proved for accuracy prior to use. Attention should be paid to computers used in controlling processes, and 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 that the requirements concerning accuracy (trueness and precision) are fulfilled.

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

11.4 Process control management

Processes which are important to product quality should be planned, approved, monitored and controlled. Particular consideration should be given to product characteristics which cannot be easily or economically measured, and those requiring special skills.

Process variables should be monitored, controlled and verified at appropriate frequencies to assure:

- a) the accuracy and variability of equipment used;
- b) the skill, capability and knowledge of operators;
- c) the accuracy of measurement results and data used to control the process;
- d) process environment and other factors affecting quality, such as time, temperature and pressure;
- e) appropriate documentation of process variables, equipment and personnel.

In some cases, for example where process deficiencies may become apparent only after the product is in use, the results of processes cannot be directly verified by subsequent inspection or test of the product itself. Such processes require prequalification (validation) to ensure process capability and control of all critical variables during process operation.

11.5 Documentation

Documentation should be controlled as specified by the quality system (see 5.3 and 17.3).

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 process output should be identified. Such identification should be suitable means, such as stamps, tags, notations or inspection records that accompany the product, or by computer entries or physical location. The identification should distinguish among unverified, conforming or nonconforming product. It should also identify the organizational unit responsible for verification.

11.8 Control of nonconforming product

Provision should be made for the identification and control of all nonconforming products and materials (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 subcontractor and impact on costs (see clause 9, in particular 9.7 and 9.8).

12.2 In-process verification

Verification, typically by 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 during processing. In general, verification should be made as close as possible to the point of realization of the characteristic.

Verifications for hardware products may include the following:

- set-up and first-piece inspection;
- inspections or tests by machine operator;
- automatic inspection or test;
- fixed inspection stations at intervals throughout the process;

- monitoring specific operations by patrolling inspectors.

Product should not be released for further use until it has been verified in accordance with the quality plan, except under positive recall procedures.

12.3 Finished product verification

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

- Acceptance inspections or tests may be used to ensure that finished product conforms to the specified requirements. Reference may be made to the purchase order to verify that the product to be shipped agrees in type and quantity. Examples include 100 % inspection of items, lot sampling and continuous sampling.
- Product quality auditing of sample units selected as representative of completed 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, process or the quality system. Nonconforming product should be reported and reviewed, removed or segregated, and repaired, accepted with or without concession, reworked, regraded or scrapped (see clause 14). Repaired and/or reworked products should be re-inspected or retested.

No product should 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.

13 Control of inspection, measuring and test equipment

13.1 Measurement control

Control should be maintained over all measuring systems used in the development, production, installation and servicing of 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 test software. In addition, manufacturing jigs, fixtures such as test hardware, comparative references, and process instrumentation that can affect the specified

characteristics of a product or process should be suitably controlled (see 11.3).

Documented procedures should be established to monitor and maintain the measurement process itself in a state of statistical control, including equipment, procedures and operator skills. Inspection, measuring and test equipment, including test software, should be used in conjunction with documented procedures to ensure that measurement uncertainty is known and is consistent with the required measurement capability. Appropriate action should be taken when accuracy is not adequate to measure properly the process and product.

13.2 Elements of control

The procedures for control of inspection, measuring and test equipment and test methods should include, as appropriate:

- a) suitable specification and selection, including range, accuracy and robustness, under specified environmental conditions;
- b) initial calibration prior to first use in order to validate the required accuracy (accuracy and precision); the software and procedures controlling automatic test equipment should also be tested;
- c) periodic recall for adjustment, repair and recalibration, considering the manufacturer's specification, the results of prior calibration, and the method and extent of use, to maintain the required accuracy in use;
- d) documentary evidence covering unique identification of instruments, frequency of recalibration, calibration status, and procedures for recall, handling, preservation and storage, adjustment, repair, calibration, installation and use;
- e) traceability to reference standards of known accuracy and stability, preferably to nationally or internationally recognized standards; where such standards do not exist, the basis used for calibration should be documented.

13.3 Subcontractor measurement controls

The control of measuring and test equipment and test methods may be extended to all subcontractors.

13.4 Corrective action

Where measuring processes are found to be out of control, or where inspection, measuring and test

equipment are found to be out of calibration, appropriate 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 can 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 inspection, measurement, testing or calibration to avoid costly duplication or additional investment, provided that the conditions given in 13.2 and 13.4 are satisfied. (For further information, see ISO 10012-1.)

14 Control of nonconforming product

14.1 General

The steps for dealing with nonconforming product should be established and maintained in documented procedures. The objectives of procedures for nonconformity control are to prevent the customer from inadvertently receiving nonconforming product and to avoid the unnecessary costs of further processing nonconforming product. 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, conform to the specified requirements.

14.2 Identification

Suspected nonconforming items or lots should be immediately identified and the occurrence(s) recorded.

Provision should be made as necessary to examine or re-examine previous lots.

14.3 Segregation

The nonconforming items should be segregated, when practical, from the conforming items and adequately identified to prevent further unintended use of them until the appropriate disposition is decided.

14.4 Review

Nonconforming product should be subjected to review by designated persons to determine whether it can be accepted with or without repair by concession, repaired, reworked, regraded or scrapped. Persons carrying out the review should be competent to