INTERNATIONAL STANDARD

ISO 9004-3

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Quality management and quality system elements —

Part 3:
Guidelines for processed materials

Gestion de la qualité et éléments de système qualité —

Partie 3: Lignes directrices pour les matériels fabriqués

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Contents

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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 9004-3 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Sub-Committee SC 2, *Quality systems*.

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: Guide to quality assurance for project management*

— *Part 7: Guidelines for configuration management*

Part 1 is a revision of ISO 9004:1987.

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

Introduction

0.1 General

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

In order to be successful, a company should 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;

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.

With processed materials, control of the process itself is of primary concern.

A quality 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 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 system be appropriate to the type of activity and to the process, product or service being offered.

0.3 Meeting company/customer needs

A quality 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 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

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 as follows.

a) **Risk considerations**

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, safety, waste of human and financial resources.

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.

b) **Cost considerations**

For the company: Consideration has to be given to costs due to marketing and design deficiencies, including unsatisfactory materials, rework, repair, replacement, reprocessing, loss of production, warranties and field repair.

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

c) **Benefit considerations**

For the company: Consideration has to be given to increased profitability and market share.

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

0.5 Conclusions

An effective quality 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.

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Quality management and quality system elements —

Part 3:
Guidelines for processed materials

1 Scope

This part of ISO 9004 gives guidance on the application of quality management to processed materials.

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

This part of ISO 9004 is not intended to be used as a checklist for compliance with a set of requirements.

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:—[1], *Quality management and quality assurance — Vocabulary.*

ISO 9004:1987, *Quality management and quality system elements — Guidelines.*

3 Definitions

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

3.1 processed materials: Products (final or intermediate) prepared by transformations, consisting of solids, liquids, gases, or combinations thereof, including particulate materials, ingots, filaments or sheet structures.

NOTE 1 Processed materials are typically delivered in bulk systems, such as pipelines, drums, bags, tanks, cans or rolls.

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 a corporate quality policy, management should define objectives pertaining to key elements of quality, such as fitness for use, performance, safety and reliability. Objectives pertaining to process control, process capability, process performance, safety and reliability of the process should also be defined.

1) To be published. (Revision of ISO 8402:1986)

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

4.4.2 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 part of ISO 9004.

4.4.3 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 system elements

5.1.1 The quality system typically applies to, and interacts with, all activities pertinent to the quality of a product, process 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) technical research and development;

c) design/specification engineering and product development;

d) procurement;

e) process planning and development;

f) production process measurement, control and adjustment;

g) production;

h) process maintenance;

i) inspection, testing and examination;

j) packaging and storage;

k) sales and distribution;

l) customer use;

m) technical assistance;

n) disposal after use.

See figure 1 for a schematic representation of the quality system elements.

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 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, either directly or indirectly, should be identified and documented, and the following actions taken.

a) General and specific responsibilities should be explicitly defined.

b) Responsibility and authority delegated to each activity contributing to quality should be clearly established; that 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.

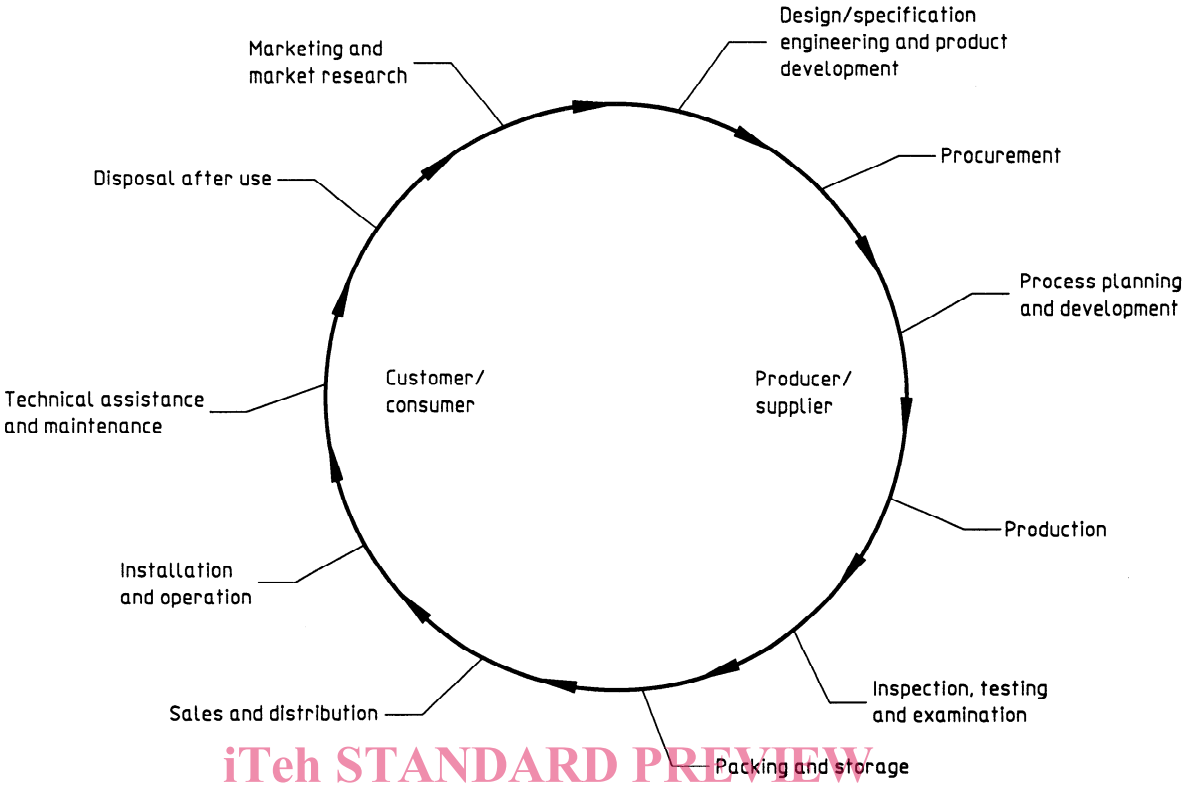

Figure 1 — Quality loop

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 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.

It should emphasize preventive actions that avoid occurrence of problems, whilst 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 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 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, development, 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 the following:

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 making changes and modifications to a quality plan as projects proceed;

f) other measures necessary to meet objectives.

A quality plan may form part of a detailed operating procedure.

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 system are effective in achieving stated quality objectives. For this purpose, an appropriate audit plan should be formulated and established by company management. (For further details, see parts 1, 2 and 3 of ISO 10011.)

5.4.2 Audit plan

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

a) specific activities and areas to be audited;

b) qualifications of personnel carrying out the audits;

c) the basis for carrying out the 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 conformance to standards and specifications);

f) documentation, reports and 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) implementation and effectiveness of corrective actions suggested in previous audits should be assessed;

c) appropriate corrective actions may be suggested if requested.

5.5 Review and evaluation of the quality 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 system in achieving stated quality objectives;

c) considerations for up-dating the quality 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 businesslike 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 the costs of activities directed at achieving appropriate quality and the 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 the specified quality is being maintained;