



SLOVENSKI STANDARD

SIST ISO 9004-3:1996

01-maj-1996

Vodenje kakovosti in elementi sistema kakovosti - 3. del: Smernice za predelane materiale

Quality management and quality system elements -- Part 3: Guidelines for processed materials

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Management de la qualité et éléments de système qualité -- Partie 3: Lignes directrices pour les produits issus de processus à caractère continu

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03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
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ISO
9004-3

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**Quality management and quality system
elements —**

Part 3:

Guidelines for processed materials

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Gestion de la qualité et éléments de système qualité —

Partie 3: Lignes directrices pour les matériels fabriqués

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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.

ISO 9004-3:1993(E)**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.
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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)

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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.

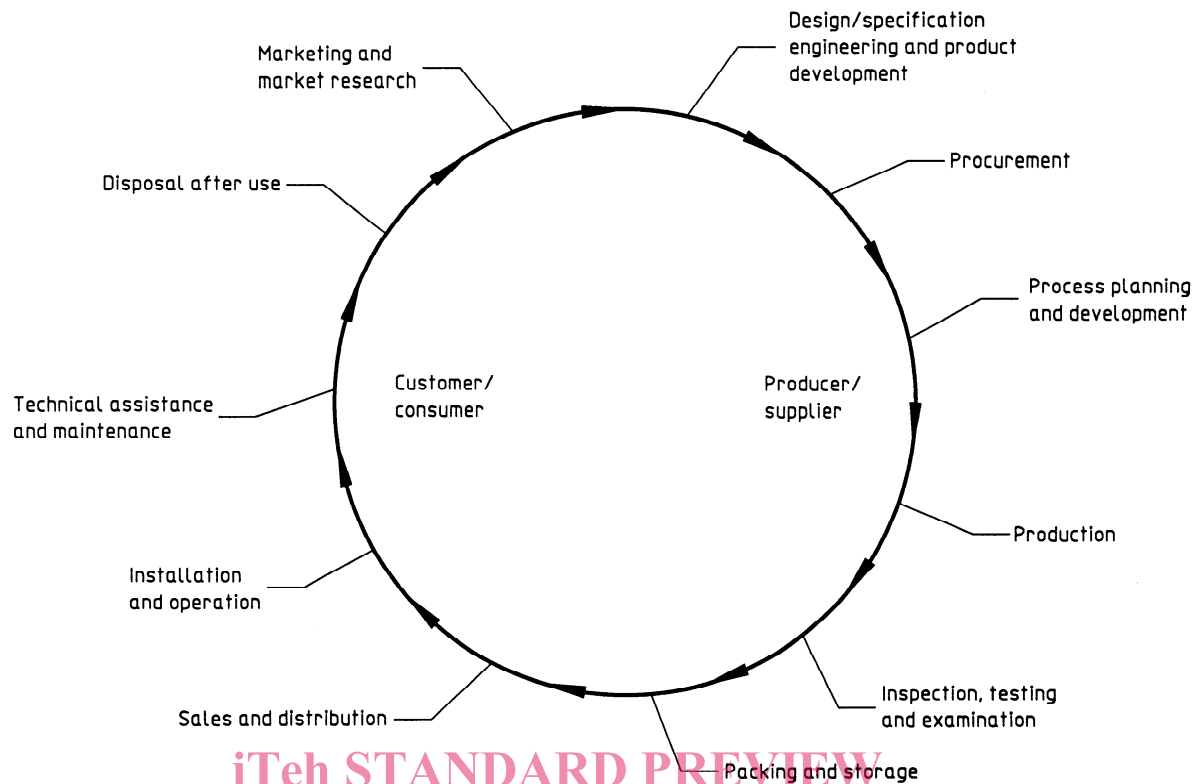


Figure 1 — Quality loop

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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:

- human resources and specialized skills;
- design and development equipment;
- manufacturing equipment;
- inspection, test and examination equipment;
- 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