SLOVENSKI STANDARD
SIST ISO 10005:1998

01-oktober-1998

Vodenje kakovosti - Smernice za plane kakovosti

Quality management -- Guidelines for quality plans

Management de la qualité -- Lignes directrices pour les plans qualité

Ta slovenski standard je istoveten z: **ISO 10005:1995**

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance

SIST ISO 10005:1998 **sl,en**

INTERNATIONAL STANDARD

ISO 10005

First edition
1995-09-15

Quality management — Guidelines for quality plans

Management de la qualité — Lignes directrices pour les plans qualité

Reference number
ISO 10005:1995(E)

Contents

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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 10005 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

Annexes A and B of this International Standard are for information only.

Introduction

This International Standard was prepared to address the need for a mechanism to relate generic requirements on quality system elements to the specific requirements of a particular product, project or contract. Its provisions should be considered advisory and not requirements.

A quality plan may be used within an organization to ensure that specific requirements for quality are being appropriately planned and addressed for identified products during production. A quality plan may be used to indicate the specific application of a quality system to a given development project, whether for a marketable product or for an in-house facility. A quality plan may also be used by the supplier in a contractual situation to demonstrate to the customer how the specific requirements for quality of a particular contract will be met. In many cases, it may be beneficial to obtain customer input to the development of the quality plan.

The quality plan should be compatible with other plans that may be prepared.

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Quality management — Guidelines for quality plans

1 Scope

1.1 This International Standard provides guidelines to assist suppliers in the preparation, review, acceptance and revision of quality plans.

It is intended for use in two situations:

a) as guidance to a supplier organization in meeting the requirements of ISO 9001, ISO 9002 or ISO 9003 relative to the preparation of a quality plan; or

b) as guidance to a supplier organization in preparing a quality plan when the supplier does not have such a quality system.

In both situations, the quality plan is supplemental to the supplier's generic quality system documentation and should not duplicate the generic documentation. For convenience in situations of type b), this International Standard includes features that are covered in the generic requirements of ISO 9001, ISO 9002 and ISO 9003.

Quality plans provide a mechanism to tie specific requirements of the product, project or contract to existing generic quality system procedures. They do not require the development of a comprehensive set of procedures or instructions over and above those already existing, although some additional documented procedures may be necessary.

1.2 This International Standard is applicable where a quality plan is to be used for a particular product, project or contract. A quality plan may be applicable to any product of the generic product categories (hardware, software, processed materials and services) or industry/economic sectors.

A quality plan may be used to monitor and assess adherence to the requirements for quality, but these guidelines are not intended to be used as a checklist for compliance with requirements. A quality plan may also be used where a documented quality system does not exist, in which case procedures may need to be developed to support the quality plan.

NOTE 1 Annex B contains a bibliography of International Standards which provide information that may prove helpful to those involved in the preparation and review of quality plans.

2 Normative reference

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

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

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402, together with the following definitions, apply. Terms which are repeated here for clarity but have been defined in other International Standards are identified by the placement of the number of the standard after the term being defined.

3.1 contract: Agreed requirements between a supplier and customer transmitted by any means.

[ISO 9001]

3.2 project: Unique process consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.

NOTES

2 An individual project may form part of a larger project structure.

3 In some types of projects, the objectives are refined and the project characteristics defined progressively as the project proceeds.

4 The outcome of a project may be one or several units of a product.

3.3 type test: Test or series of tests directed towards approval of a design conducted to determine that it is capable of meeting the requirements of the product specification.

3.4 witness testing: Testing of a product in the presence of the customer's representative or a third party.

3.5 procedure: Specified way to perform an activity.

NOTES

5 In many cases, procedures are documented (e.g. quality system procedures).

6 When a procedure is to be documented, the term "written procedure" or "documented procedure" is frequently used.

7 A written or documented procedure usually contains the purpose and scope of an activity; what shall be done and by whom; when, where and how it shall be done; what materials, equipment and documents shall be used; and how it shall be controlled and recorded.

[ISO 8402]

3.6 product: Result of activities or processes.

NOTES

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

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

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

[ISO 8402]

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

NOTES

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

12 Depending on the scope of the plan, a qualifier may be used, for example, "quality assurance plan", "quality management plan".

[ISO 8402]

3.8 quality system: Organizational structure, procedures, processes and resources needed to implement quality management.

NOTES

13 The quality system should be as comprehensive as needed to meet the quality objectives.

14 The quality system of an organization is designed primarily to satisfy the internal managerial needs of the organization. It is broader than the requirements of a particular customer who evaluates only the relevant part of the quality system.

15 For contractual or mandatory quality assessment purposes, demonstration of the implementation of identified quality system elements may be required.

[ISO 8402]

4 Preparation, review, acceptance and revision of the quality plan

4.1 Preparation

When preparing a quality plan, quality activities applicable to the situation should be defined and documented.

Much of the generic documentation needed may be contained in the supplier's quality manual and documented procedures. This documentation may need to be selected, adapted and/or supplemented. The quality plan shows how the supplier's generic documented procedures are related to and applied to any necessary additional procedures peculiar to the product, project or contract in order to attain specified quality objectives.

The quality plan should indicate, either directly or by reference to appropriate documented procedures or other documents, how the required activities are to be carried out.

The format and level of detail in the plan should be consistent with any agreed customer requirement, the supplier's method of operation and the complexity of the activities to be performed. The plan should be as brief as possible, consistent with meeting the provisions of this International Standard. (Simplified examples of alternative presentations of quality plans are contained in annex A.)

A quality plan may be a stand-alone document when a supplier does not have a documented quality system. A quality plan may also be included as part of another document or documents (e.g. product or project plan), depending on such things as customer requirements or the business practices of a specific supplier. It may be necessary to develop a quality plan that consists of a number of parts, each of which represents a plan for a distinct stage, such as for design, purchasing, production, or inspection and test, or for particular activities such as the dependability plan.

NOTE 16 When drafting a textural quality plan, the following conventions may be used:

— "shall" to express a provision that is binding between two or more parties;

— "will" to express a declaration of purpose or intent by one party;

— "should" to express a recommendation among other possibilities;

— "may" to indicate a course of action permissible within the limits of the quality plan.

4.2 Review and acceptance

The quality plan should be reviewed for adequacy and formally approved by an authorized group that includes representatives from all affected functions within the supplier's organization.

In contractual situations, a quality plan may be submitted to the customer by the supplier for review and acceptance, either as part of the precontract award-bidding process or after the contract has been awarded.

If the plan is submitted as part of the bidding process and a contract is subsequently awarded, the plan should be reviewed and, where appropriate, revised to reflect any changes in requirements that may have occurred as a result of precontract negotiations.

When a quality plan is required by a contract, it should normally be submitted prior to the start of the required activities. Where the contract is conducted in stages, the supplier should submit the quality plan for each stage to the customer prior to the start of that stage.

Procedures referenced in the plan should be made available to the customer, where agreed in the contract.

4.3 Revision

The supplier should revise the plan, when appropriate, to reflect changes that have been made to the product, project or contract, changes to the manner in which the product is produced or the service is provided, or changes in quality assurance practices.

Changes to the quality plan should be reviewed for impact and adequacy by the same authorized group which conducted the review of the original quality plan.

Subject to the specific requirements of a contract, proposed changes to the plan should be submitted to the customer for review and acceptance before they are implemented.

5 Contents of the quality plan

a) **Structure**

The contents of the quality plan should be based on this International Standard and the supplier's documented quality system. It is not essential that the quality plan follow the structure and numbering of any ISO 9000 standards and the alignment of the paragraphs in this International Standard is only intended to ease use and understanding.

The elements described in the following subclauses should be addressed, where relevant to the requirements of the product, project or contract.

b) **Scope of the quality plan**

The scope of the quality plan should be defined and should include, but not be limited to:

— the product or project to which it is to be applied;

— the scope of the contract to which it is to be applied;

— the product, project and or contract quality objectives (these quality objectives should be expressed in measurable terms wherever possible);