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Quality management systems — Guidelines for quality plans

Systèmes de management de la qualité — Lignes directrices pour les plans qualité

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 10005:1995). It constitutes a technical revision of that edition, taking into account ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000.

Introduction

This International Standard was prepared to address the need for guidance on quality plans, either in the context of an established quality management system or as an independent management activity. In either case, quality plans provide a means of relating specific requirements of the process, product, project or contract to work methods and practices that support product realization. The quality plan should be compatible with other associated plans that may be prepared.

Among the benefits of establishing a quality plan are the increased confidence that requirements will be met, greater assurance that processes are in control and the motivation it can give to those involved. It may also give insight into opportunities for improvement.

This International Standard does not replace the guidance given in ISO 9004 or in industry-specific documents. Where quality plans are required for project applications, the guidance provided in this International Standard is intended to be complementary to the guidance provided in ISO 10006.

In terms of the process model shown in Figure 1, quality management system planning applies to the whole model. Quality plans, however, apply primarily to the path from customer requirements, through product realization and product, to customer satisfaction.

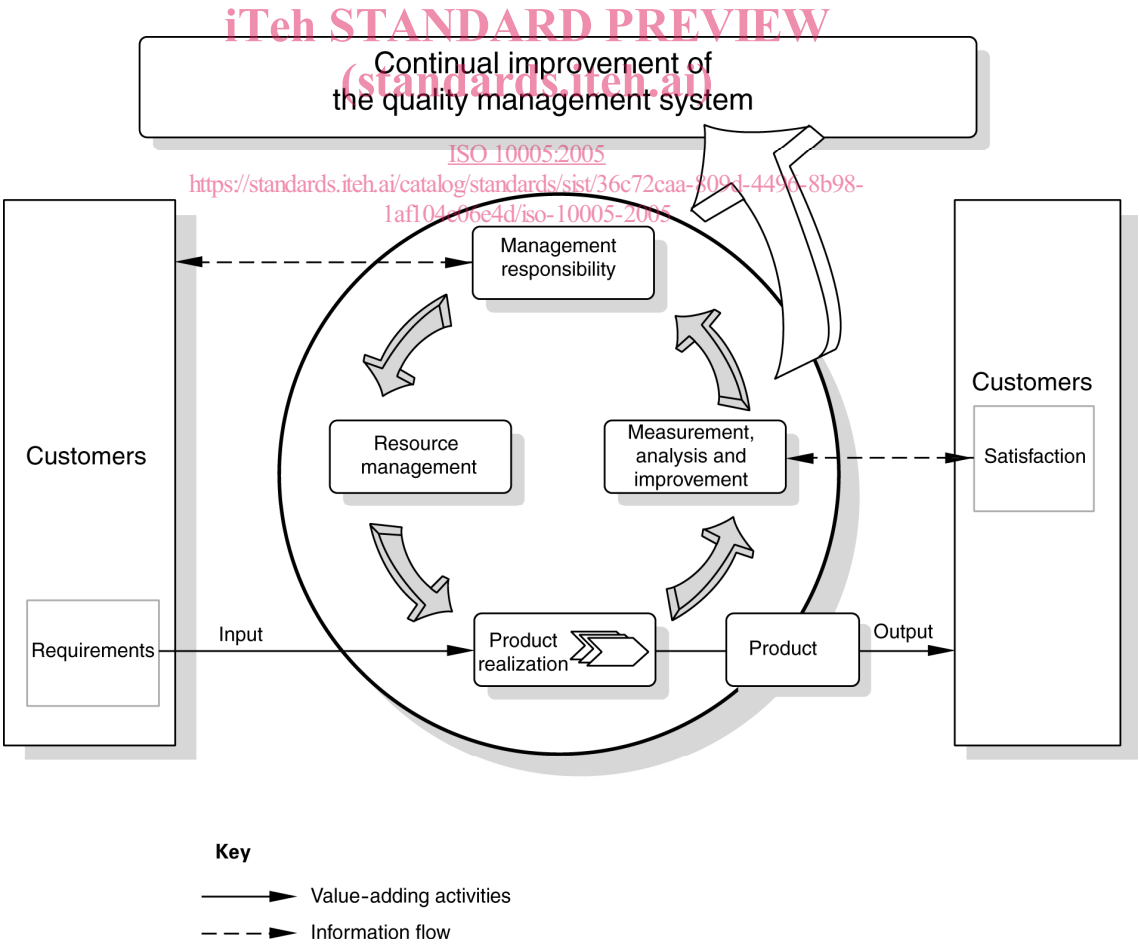

Figure 1 — Model of a process-based quality management system

Quality management systems — Guidelines for quality plans

1 Scope

This International Standard provides guidelines for the development, review, acceptance, application and revision of quality plans.

It is applicable whether or not the organization has a management system in conformity with ISO 9001.

This International Standard is applicable to quality plans for a process, product, project or contract, any product category (hardware, software, processed materials and services) and any industry.

It is focused primarily on product realization and is not a guide to organizational quality management system planning.

This International Standard is a guidance document and is not intended to be used for certification or registration purposes.

NOTE To avoid undue repetition of "process, product, project or contract", this International Standard uses the term "specific case" (see 3.10).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply. Some of the definitions below are quoted directly from ISO 9000, but notes are in some cases omitted or supplemented.

3.1
objective evidence
data supporting the existence or verity of something

NOTE Objective evidence may be obtained through observation, measurement, test, or other means.

[ISO 9000:2000, definition 3.8.1]

3.2
procedure
specified way to carry out an activity or a **process** (3.3)

NOTE 1 Procedures can be documented or not.

NOTE 2 When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used. The document that contains a procedure can be called a "procedure document".

[ISO 9000:2000, definition 3.4.5]

3.3
process
set of interrelated or interacting activities which transforms inputs into outputs

NOTE Adapted from ISO 9000:2000, definition 3.4.1 (the Notes have not been included).

3.4
product
result of a **process** (3.3)

NOTE 1 There are four generic product categories, as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product "automobile" consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

NOTE 2 Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or **procedures** (3.2)

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

[ISO 9000:2000, definition 3.4.2]

3.5
project
unique **process** (3.3) 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

NOTE 1 An individual project can form part of a larger project structure.

NOTE 2 In some projects, the objectives are refined and the product characteristics defined progressively as the project proceeds.

NOTE 3 The outcome of a project may be one or several units of **product** (3.4).

[ISO 9000:2000, definition 3.4.3]

3.6
quality management system
management system to direct and control an organization with regard to quality

[ISO 9000:2000, definition 3.2.3]

3.7
quality objective
something sought, or aimed for, related to quality

NOTE 1 Quality objectives are generally based on the organization's quality policy.

NOTE 2 Quality objectives are generally specified for relevant functions and levels in the organization.

[ISO 9000:2000, definition 3.2.5]

3.8
quality plan
document specifying which **processes** (3.3), **procedures** (3.2) and associated resources will be applied by whom and when, to meet the requirements of a specific **project** (3.5), **product** (3.4), process or contract

NOTE 1 These procedures generally include those referring to quality management processes and to product realization processes.

NOTE 2 A quality plan often makes reference to parts of the quality manual or to procedure documents.

NOTE 3 A quality plan is generally one of the results of quality planning.

3.9
record
document stating results achieved or providing evidence of activities performed

NOTE Adapted from ISO 9000:2000, definition 3.7.6 (the Notes have not been included).

3.10
specific case
subject of the **quality plan** (3.8)

NOTE This term is used to avoid repetition of "process, product, project or contract" within this International Standard.

4 Development of a quality plan

4.1 Identifying the need for the quality plan

The organization should identify what need there may be for quality plans. There are a number of situations where quality plans may be useful or necessary, for example:

a) to show how the organization's quality management system applies to a specific case;

b) to meet statutory, regulatory or customer requirements;

c) in developing and validating new products or processes;

d) to demonstrate, internally and/or externally, how quality requirements will be met;

e) to organize and manage activities to meet quality requirements and quality objectives;

f) to optimize the use of resources in meeting quality objectives;

g) to minimize the risk of not meeting quality requirements;

h) to use as a basis for monitoring and assessing compliance with the requirements for quality;

i) in the absence of a documented quality management system.

NOTE There may or may not be a need to prepare a quality plan for a specific case. An organization with an established quality management system may be able to fulfil all of its needs for quality plans under its existing system; the organization may then decide that there is no need to prepare separate quality plans.

4.2 Inputs to the quality plan

Once the organization has decided to develop a quality plan, the organization should identify the inputs for preparation of the quality plan, for example:

a) the requirements of the specific case;

b) the requirements for the quality plan, including those in customer, statutory, regulatory and industry specifications;

c) the quality management system requirements of the organization;

d) risk assessments on the specific case;

e) the requirement for and availability of resources;

f) information on the needs of those engaged in carrying out activities covered by the quality plan;

g) information on the needs of other interested parties who will use the quality plan;

h) other relevant quality plans;

i) other relevant plans, such as other project plans, environmental, health and safety, security and information management plans.

4.3 Scope of the quality plan

The organization should determine what is to be covered by the quality plan and what is covered or to be covered by other documents. Unnecessary duplication should be avoided.

The scope of the quality plan will depend on several factors, including the following:

a) the processes and quality characteristics that are particular to the specific case, and will therefore need to be included;

b) the requirements of customers or other interested parties (internal or external) for inclusion of processes not particular to the specific case, but necessary for them to have confidence that their requirements will be met;

c) the extent to which the quality plan is supported by a documented quality management system.

Where quality management procedures have not been established, they may need to be developed to support the quality plan.

There may be benefits from reviewing the scope of the quality plan with the customer or other interested parties, for example in order to facilitate their use of the quality plan for monitoring and measurement.

4.4 Preparation of the quality plan

4.4.1 Initiation

The person responsible for preparing the quality plan should be clearly identified. The quality plan should be prepared with the participation of people who are involved in the specific case, both within the organization and, where appropriate, external parties.

When preparing a quality plan, quality management activities applicable to the specific case should be defined and, where necessary, documented.

4.4.2 Documenting the quality plan

The quality plan should indicate how the required activities will be carried out, either directly or by reference to appropriate documented procedures or other documents (e.g. project plan, work instruction, checklist,

computer application). Where a requirement results in a deviation from the organization's management systems, this deviation should be justified and authorized.

Much of the generic documentation needed may already be contained in the organization's quality management system documentation, including its quality manual and documented procedures. This documentation may need to be selected, adapted and/or supplemented. The quality plan should show how the organization's generic documented procedures are applied, or alternatively modified or overridden by procedures in the quality plan.

A quality plan may be included as part of another document or documents, for example project quality plans are often included in project management plans (see ISO 10006).

4.4.3 Responsibilities

In preparing the quality plan, the organization should agree and define the respective roles, responsibilities and obligations both within the organization and with the customer, regulatory authorities or other interested parties. Those administering the quality plan should ensure that the persons it refers to are aware of the quality objectives and any specific quality issues or controls required by the quality plan.

4.4.4 Consistency and compatibility

The contents and format of the quality plan should be consistent with the scope of the quality plan, the inputs to the plan and the needs of the intended users. The level of detail in the quality plan should be consistent with any agreed customer requirement, the organization's method of operation and the complexity of the activities to be performed. The need for compatibility with other plans should also be considered.

4.4.5 Presentation and structure

The presentation of the quality plan may have any of several forms, for example a simple textual description, a table, a document matrix, a process map, a work flow chart or a manual. Any or all of these may be presented in electronic or hard-copy formats.

NOTE Examples of quality plans are provided in Annex A.

The quality plan may be broken up into several documents, each of which represents a plan for a distinct aspect. Control of the interfaces between the different documents needs to be clearly defined. Examples of these aspects include design, purchasing, production, process control or particular activities (such as acceptance testing).

An organization may wish to prepare a quality plan that conforms to applicable requirements of ISO 9001. A cross-reference matrix is provided in Annex B for guidance.

5 Content of the quality plan

5.1 General

The examples and lists provided in this clause should not be considered comprehensive or limiting in any way.

The quality plan for a specific case should cover the topics examined below as appropriate. Some topics in this guidance may not be applicable, for example where design and development are not involved.

5.2 Scope

The scope should be clearly stated in the quality plan. This should include:

a) a simple statement of the purpose and expected outcome of the specific case;

b) the aspects of the specific case to which it will be applied, including particular limitations to its applicability;

c) the conditions of its validity (e.g. dimensions, temperature range, market conditions, resource availability or quality management systems certification status).

5.3 Quality plan inputs

It may be necessary to list or describe the inputs to the quality plan (see 4.2), to facilitate, for example,

— reference to input documents by users of the quality plan,

— checking consistency with input documents during maintenance of the quality plan, and

— identification of changes to input documents that may necessitate a review of the quality plan.

5.4 Quality objectives

The quality plan should state the quality objectives for the specific case and how they will be achieved. Quality objectives may be established, for example, in relation to

— quality characteristics for the specific case,

— important issues for satisfaction of the customer or other interested parties, and

— opportunities for improvement of work practices.

These quality objectives should be expressed in measurable terms.

5.5 Management responsibilities

The quality plan should identify individuals within the organization who are responsible, in the specific case, for the following:

a) ensuring that the activities required for the quality management system or contract are planned, implemented and controlled, and their progress monitored;

b) determining the sequence and interaction of the processes applicable to the specific case;

c) communicating requirements to all affected departments and functions, subcontractors and customers, and resolving problems that arise at the interfaces between such groups;

d) reviewing the results of any audits conducted;

e) authorizing requests for exemption from the organization's quality management system requirements;

f) controlling corrective and preventive actions;

g) reviewing and authorizing changes to, or deviations from, the quality plan.

Reporting lines of those involved in implementing the quality plan may be presented in the form of a flow chart.

5.6 Control of documents and data

For documents and data applicable to the specific case, the quality plan should state:

a) how the documents and data will be identified;

b) by whom the documents and data will be reviewed and approved;