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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.

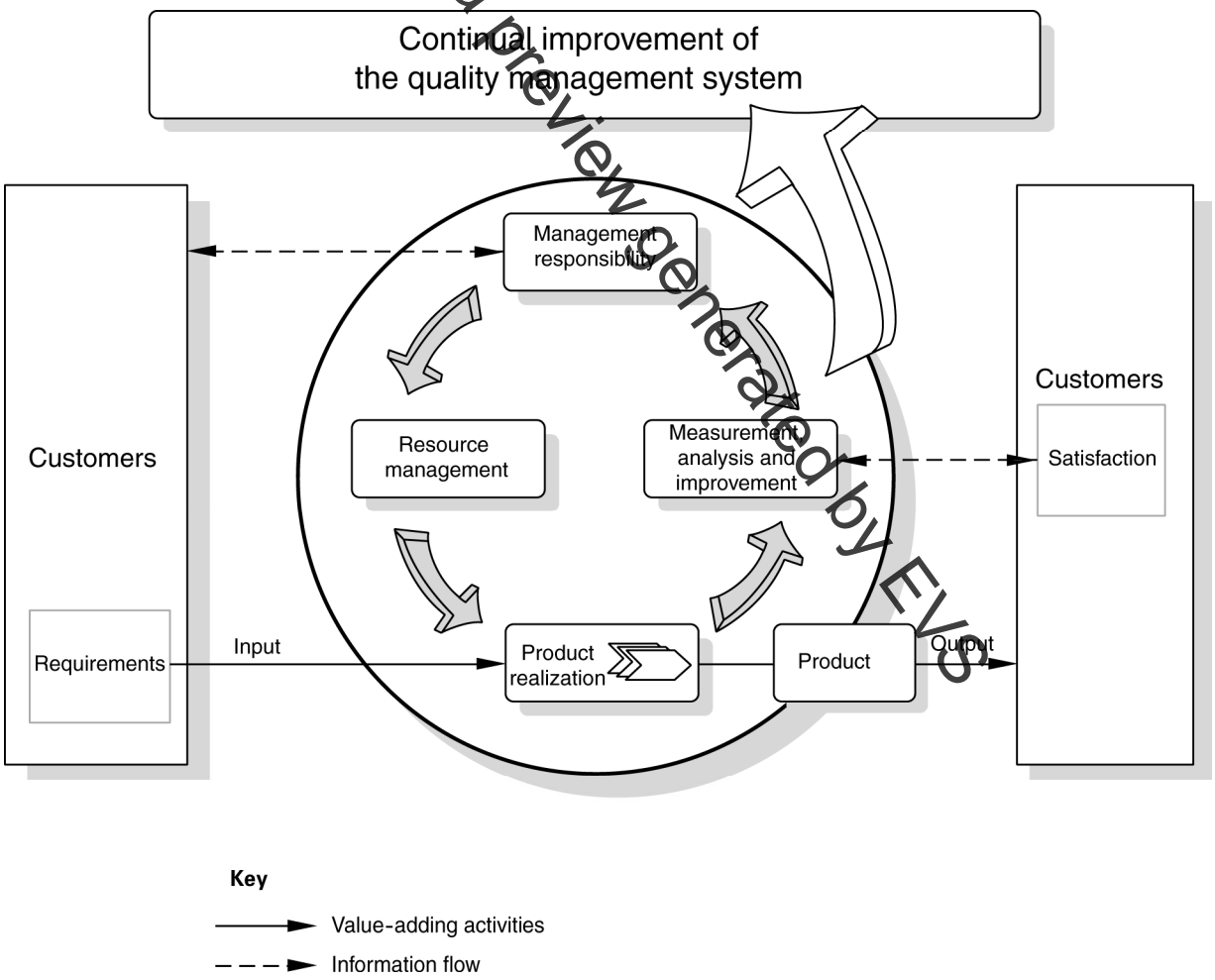

Figure 1 — Model of a process-based quality management system

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]