INTERNATIONAL STANDARD

ISO 10005

Redline version
compares Third edition to
Second edition

Quality management — Guidelines for quality plans

Management de la qualité — Lignes directrices pour les plans qualité

Reference number
ISO 10005:redline:2018(E)

IMPORTANT — PLEASE NOTE

This is a mark-up copy and uses the following colour coding:

Text example 1	— indicates added text (in green)
~~Text example 2~~	— indicates removed text (in red)
	— indicates added graphic figure
	— indicates removed graphic figure
1.x ...	— Heading numbers containg modifications are highlighted in yellow in the Table of Contents

DISCLAIMER

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.

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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~~The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the ~~rules given in~~editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This ~~second~~third edition cancels and replaces the ~~first~~second edition (ISO 10005:~~1995~~2005)~~. It constitutes a technical revision of that edition, taking into account~~, ~~ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000~~which has been technically revised.

The main changes compared with the previous edition are as follows.

a) It applies the terminology from ISO 9000:2015, which includes changes to key definitions, such as:

   1) for the definition of "quality plan" (see 3.2), which has been modified to replace the phrase "procedures and associated resources to be applied when and by whom" by "actions, responsibilities and associated resources";

   2) for the definition of "specific case" (see 3.3), which has been modified to make reference to "service", as ISO 9001:2015 now refers to "products and services" and no longer just to "products";

   3) the replacement of the terms "documentation" and "record" by the term "documented information", which is generally used in ISO management system standards to include both "procedures" and "records" which are not necessarily distinct from each other in a digital environment (documented information needed to support process operation is "maintained", which means that it is established and updated as required; documented information that provides evidence of conformity with requirements is "retained" which means that it is protected from unintended alterations).

Table 1 — Major changes to terms in this document since its previous edition

ISO 10005:2005	This document
Products	Products and services
Documentation Quality manual Documented procedures Records	Documented information
Purchased product	Externally provided processes, products and services
Supplier	External provider
Monitoring and measuring equipment	Monitoring and measuring resources

b) It is aligned to ISO 9001:2015, leading to:

1) a significant revision in the clause/subclause sequence, titles and the addition of new material, e.g. the inclusion of "5.2 Context of a quality plan", or the extension of 7.2 to also reference the monitoring of a quality plan;

2) the incorporation of "risk-based thinking".

c) A new clause (Clause 4) on using a quality plan.

Introduction

0.1 General

This ~~International Standard~~document 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, service, project or contract to work methods and practices ~~that support product realization. The quality plan should be~~. Quality plans are most effective when they are compatible with other associated plans ~~that may be prepared~~. The guidance in this document can also be used where quality plans are integrated with other management plans or quality management systems.

~~Among the benefits~~Benefits of establishing a quality plan ~~are the~~include 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~~might also give insight into opportunities for innovation and improvement.

The guidance on quality plans in this document is based on the quality management principles described in ISO 9000 and the concepts used in ISO 9001 for the establishment of quality management systems. Clause 6, which describes the typical contents of a quality plan, includes guidance to applying relevant ISO 9001 requirements. The guidance is limited to quality plans and does not replace guidance given in ISO 9000 on quality management concepts or ISO/TS 9002 on the application of ISO 9001 requirements within an organization.

This ~~International Standard~~document does not replace the guidance given in ~~ISO 9004 or in~~ industry-specific ~~documents~~documented information. Where quality plans are required for project applications, the guidance provided in this ~~International Standard~~document is intended to be complementary to the guidance provided in ISO 10006. Some terms used in this document have been changed with respect to its previous edition to improve alignment with ISO 9001:2015 and other management system standards. There is no need for the terms used by an organization, whether in specifying quality plan requirements or developing a quality plan, to be replaced by the terms used in this document.

In this document, the following verbal forms are used:

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated text.

NOTE See https://committee.iso.org/home/tc176sc2 for guidance on the topics in this Introduction.

0.2 Using this document

This Introduction explains some underlying concepts and changes to terms used in the previous edition of this document.

Clauses 1 to 3 provide basic information (Scope, Normative references, and Terms and definitions).

Clause 4 summarizes how quality plans can be used.

Clause 5 describes the process of developing a quality plan.

Clause 6 describes the typical contents of a quality plan.

Clause 7 describes the operation and control of a quality plan.

Annex A provides examples of simple quality plans.

Annex B provides a schematic representation of a process approach applied to a quality plan.

Annex C provides a correlation matrix between the clauses of this document and those of ISO 9001:2015.

Annex D provides a correlation matrix between the clauses of this document and the quality management principles from ISO 9000:2015.

The Bibliography includes a list of standards and other relevant information.

0.3 Process approach

The process approach means the systematic management of processes and their interactions to achieve intended results. Applying the process approach to quality plans assists organizations to manage the inputs, activities and outputs of each process within a coherent system of interrelated processes.

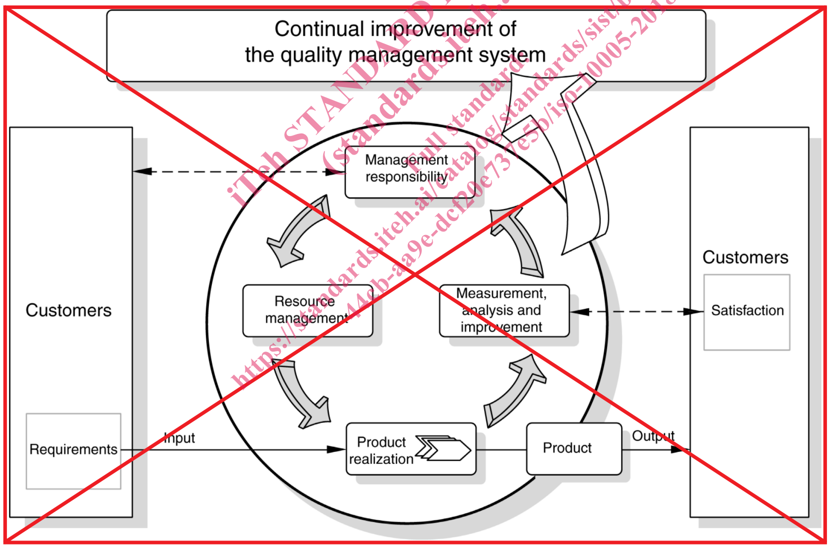
Processes referenced in a quality plan can interact with:

— each other (interactions among quality plan processes);

— other processes operated within the organization's management system;

— processes operated within other organizations (such as customers and external providers).

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 satisfactionWhen considering how to manage its processes and their interactions, the organization can address these through a quality plan whether or not it has a quality management system.



Key

Value-adding activities

Information flow

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

Annex B provides a schematic representation of a process approach applied to quality plans.

0.4 Risk-based thinking

Risk-based thinking means applying a systematic approach to considering risk (the effect of uncertainty) so that risks can be understood and managed appropriately.

The application of risk-based thinking to the development and use of a quality plan enables an organization to determine the importance of particular issues and take appropriate actions to manage both risks and opportunities.

A customer requesting that a provider prepares a quality plan can apply risk-based thinking to determine the minimum requirements for the type and extent of the monitoring activities.

When developing a quality plan, the organization can apply risk-based thinking in deciding the processes, resources and control methods to be used. Particularly where an organization uses a standard model or template for different quality plans, risk-based thinking can assist those involved to make each quality plan fit for its intended purpose.

Quality management — Guidelines for quality plans

1 Scope

This ~~International Standard provides guidelines for the development, review, acceptance, application and revision of~~document gives guidelines for establishing, reviewing, accepting, applying and revising quality plans.

This document is applicable to quality plans for any intended output, whether a process, product, service, project or contract, and any type or size of organization.

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~~document provides guidance and does not specify requirements.

It is focused primarily on ~~product realization~~the provision of outputs and is not a guide to ~~organizational~~the planning of quality management system ~~planning~~development.

~~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, service, project or contract", this ~~International Standard~~document uses the term "specific case" (see ~~3.10~~).

2 Normative references

The following ~~referenced~~ documents are ~~indispensable for the application of~~referred to in the text in such a way that some or all of their content constitutes requirements 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~~2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 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 1 to entry: Objective evidence may be obtained through observation, measurement, test, or other means.~~

~~[SOURCE: ISO 9000:2000, definition 3.8.1]~~

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

~~Note 1 to entry: Procedures can be documented or not.~~

~~Note 2 to entry: 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"~~.

~~[SOURCE: ISO 9000:2000, definition 3.4.5~~]

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

~~Note 1 to entry: Adapted from ISO 9000:2000, definition 3.4.1 (the Notes have not been included)~~.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

~~3.4~~3.1
~~product~~documented information
~~result of a *process* (3.3)~~information required to be controlled and maintained by an organization and the medium on which it is contained

Note 1 to entry: ~~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)~~Documented information can be in any format and media and from any source.

Note 2 to entry: ~~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~~Documented information can refer to:

— ~~an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired)~~the management system, including related *quality plans* (3.2) and processes;

~~— 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~~information created in order for the organization to operate (documentation);

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

~~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.~~

[SOURCE: ISO 9000:~~2000, definition 3.4.2~~2015, 3.8.6, modified — In Note 2 to entry, the first list item has been modified, and Note 3 to entry has been deleted.]

~~**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 to entry: An individual project can form part of a larger project structure.~~

~~Note 2 to entry: In some projects, the objectives are refined and the product characteristics defined progressively as the project proceeds.~~

~~Note 3 to entry: The outcome of a project may be one or several units of *product* (3.4).~~

~~[SOURCE: ISO 9000:2000, definition 3.4.3]~~

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

~~[SOURCE: ISO 9000:2000, definition 3.2.3]~~

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

~~Note 1 to entry: Quality objectives are generally based on the organization's quality policy.~~

~~Note 2 to entry: Quality objectives are generally specified for relevant functions and levels in the organization.~~

~~[SOURCE: ISO 9000:2000, definition 3.2.5]~~

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

~~Note 1 to entry: These procedures generally include those referring to quality management processes and to product realization processes.~~

~~Note 2 to entry: A quality plan often makes reference to parts of the quality manual or to procedure documents.~~

~~Note 3 to entry: A quality plan is generally one of the results of quality planning.~~

[SOURCE: ISO 9000:2015, 3.8.9, modified — The phrase “procedures and associated resources to be applied when and by whom” has been replaced by “actions, responsibilities and associated resources”, and the notes to entry have been deleted.]

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

~~Note 1 to entry: Adapted from ISO 9000:2000, definition 3.7.6 (the Notes have not been included).~~

~~3.10~~3.3
specific case
<quality plans> subject of ~~the~~a *quality plan* (~~3.8~~3.2)

Note 1 to entry: ~~This term is used to avoid repetition of “~~The specific case can be a process, product, ~~project or contract” within this International Standard~~service, project, contract or other intended output for the quality plan.