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Sistemi vodenja kakovosti - Smernice za plane kakovosti

Quality management systems - Guidelines for quality plans

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

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Quality management — Guidelines for quality plans

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.

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 editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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.

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

This third edition cancels and replaces the second edition (ISO 10005:2005), 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 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. Quality plans are most effective when they are compatible with other associated plans. The guidance in this document can also be used where quality plans are integrated with other management plans or quality management systems.

Benefits of establishing a quality plan 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 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 document does not replace the guidance given in industry-specific documented information. Where quality plans are required for project applications, the guidance provided in this 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).

When 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.

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 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 document provides guidance and does not specify requirements.

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

NOTE To avoid undue repetition of "process, product, service, project or contract", this document uses the term "specific case".

2 Normative references

The following documents are 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 9000:2015, *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.

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/

3.1
documented information
information required to be controlled and maintained by an organization and the medium on which it is contained

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

Note 2 to entry: Documented information can refer to:

— the management system, including related *quality plans* (3.2) and processes;

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

— evidence of results achieved.

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

3.2
quality plan
specification of the actions, responsibilities and associated resources to be applied to a specific object

[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.]

3.3
specific case
<quality plans> subject of a *quality plan* (3.2)

Note 1 to entry: The specific case can be a process, product, service, project, contract or other intended output for the quality plan.

4 Using a quality plan

4.1 Introduction

A quality plan describes how an organization will provide an intended output, whether that output is a process, product, service, project or contract (termed the "specific case" in this document).

Quality plans are developed where they are considered necessary to meet needs and expectations related to a specific case.

Where the organization has an established management system, quality plans might be necessary if requested by a customer or considered useful for other reasons. On the other hand, where no established management system exists, quality plans can provide a framework for meeting the requirements of the specific case. They can also assist the organization to develop its own management system and its processes.

The organization should decide where there is need for quality plans. There are a number of situations where quality plans can be useful or necessary, for example:

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

b) to meet customer, other interested parties or the organization's own requirements;

c) to develop and validate new products, services or processes;

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

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

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

g) to minimize the risk of not meeting requirements;

h) to control the establishment of a new or modified organization, site or partnering arrangement;

i) as a basis for monitoring and assessing compliance with the requirements for quality;

j) in the absence of an established management system.

4.2 Requesting external provider quality plans

An organization may choose to request that an external provider or a prospective external provider submit a quality plan related to a specific case (this can relate to external providers who are part of the same organization, e.g. a separate division). Both the organization requesting a quality plan and the prospective external provider should consider the reasons for using a quality plan and the benefits that might be achieved through its use.

