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Ledningssystem för kvalitet – Vägledning för konfigurationsledning (ISO 10007:2017, IDT)

Quality management – Guidelines for configuration management (ISO 10007:2017, IDT)

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SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

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Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standard-paket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

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Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.

Standards make the world go round

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Den internationella standarden ISO 10007:2017 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av ISO 10007:2017.

Denna standard ersätter SS-ISO 10007:2004, utgåva 1.

The International Standard ISO 10007:2017 has the status of a Swedish Standard. This document contains the official version of ISO 10007:2017.

This standard supersedes the Swedish Standard SS-ISO 10007:2004, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för ISO 10000-serien, SIS/TK 304/AG 3.4.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

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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 10007:2003), which has been technically revised. This edition aligns ISO 10007 with ISO 9000:2015 and ISO 9001:2015.

Introduction

The purpose of this document is to enhance common understanding of the subject, to promote the use of configuration management and to assist organizations applying configuration management to improve their performance.

This document outlines the responsibilities and authorities before describing the configuration management process that includes configuration management planning, configuration identification, change control, configuration status accounting and configuration audit.

Configuration management is a management activity that applies technical and administrative direction over the life cycle of a product and service, its configuration identification and status, and related product and service configuration information.

Configuration management documents the product or service configuration. It provides identification and traceability, the status of achievement of its physical and functional requirements, and access to accurate information in all phases of the life cycle.

Configuration management can be implemented based on the size of the organization and the complexity and nature of the product or service and reflects the needs of specific lifecycle phases.

Configuration management can be used to meet the product and service identification and traceability requirements specified in ISO 9001:2015, 8.5.2.

Quality management — Guidelines for configuration management

1 Scope

This document provides guidance on the use of configuration management within an organization. It is applicable to the support of products and services from concept to disposal.

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 and the following apply.

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

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

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

3.1
configuration
interrelated functional and physical characteristics of a product or service defined in *configuration information* (3.5)

3.2
configuration baseline
approved *configuration information* (3.5) that establishes the characteristics of a product or service at a point in time that serves as reference for activities throughout the life cycle of the product or service

3.3
configuration item
entity within a *configuration* (3.1) that satisfies an end use function

3.4
configuration status accounting
formalized recording and reporting of *configuration information* (3.5), the status of proposed changes and the status of the implementation of approved changes

3.5
configuration information
requirements for product or service design, realization, verification, operation and support

4 Configuration management responsibility

4.1 Responsibilities and authorities

The organization should identify, describe and assign responsibilities and authorities, including accountability, related to the configuration management process. The following should be considered:

a) the complexity and nature of the product or service;

b) the needs of the different product or service life cycle stages;

c) the interfaces between activities directly involved in the configuration management process;

d) the other relevant interested parties that are (or need to be) involved, both within and outside the organization;

e) the identification of the responsible authority for verifying implementation activities;

f) the identification of the dispositioning authority.

4.2 Dispositioning authority

Prior to approval of a change, the dispositioning authority should verify that:

a) the proposed change is necessary and the consequences would be acceptable;

b) the change has been properly documented and categorized;

c) the planned activities for the implementation of the change into documented information, hardware and/or software are satisfactory.

5 Configuration management process

5.1 General

The organization should establish, implement and maintain a configuration management process. The organization should coordinate the activities of the configuration management process in order for it to be effective.

The configuration management process should be focused on product or service requirements (including those of customers or relevant interested parties), as well as the application of statutory and regulatory requirements, while taking into account the context in which it will be performed. The configuration management process should be detailed in a configuration management plan. This should describe any project-specific documented information and the extent of their application during the life cycle of the product or service.

5.2 Configuration management planning

Configuration management planning is the foundation for the configuration management process. Effective planning coordinates configuration management activities in a specific context over the product or service life cycle. The output of configuration management planning is the configuration management plan.

The configuration management plan for a specific product or service should:

a) be documented and approved;

b) be controlled;

c) identify the configuration management documented information to be used;

d) make reference to relevant documented information of the organization wherever possible;

e) describe the required resources and any responsibilities and authorities (including accountability), for carrying out configuration management throughout the life cycle of the product or service.

The configuration management plan may be a stand-alone document, or a part of another document, or composed of several documents.

In some situations, the configuration management plan will be provided by an external provider. The organization may retain such plans either as stand-alone documents or incorporate them into its own configuration management plan.

Annex A describes a potential structure and content for a configuration management plan.

5.3 Configuration identification

5.3.1 Product structure or service capability and selection of configuration items

The selection of configuration items and their inter-relationships should describe the product structure or service capability.

Configuration items should be identified using established selection criteria. Configuration items should be selected whose functional and physical characteristics can be managed separately to achieve the overall end-use performance of the item.

Selection criteria should consider:

a) life-cycle of the configuration;

b) the application of statutory and regulatory requirements;

c) criticality in terms of risks and safety;

d) new or modified technology, design or development;

e) interfaces with other configuration items;

f) procurement conditions;

g) support and service.

The number of configuration items selected should optimize the ability to control the product or service. The selection of configuration items should be initiated as early as possible in the product or service life cycle. The configuration items should be reviewed as the product or service evolves.

5.3.2 Configuration information

Configuration information comprises both definition and operational information. This typically includes requirements, specifications, design drawings, parts lists, data models, test specifications, handbooks (for commissioning, maintenance and operation), plus any specific requirements concerning decommissioning and disposal.

Configuration information should be relevant and traceable. Naming and numbering conventions should be established that are unique and ensure proper control of both configuration items and data and items associated with them. These should take into consideration the existing naming and numbering conventions of the organization and the change control information, such as revision status.