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Quality management systems — Guidelines for configuration management

Systèmes de management de la qualité — Lignes directrices pour la gestion de la configuration

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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 10007 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 10007:1995), which has been technically revised.

This edition has sought to improve the alignment of ISO 10007 with the ISO 9000 family of International Standards and to simplify the structure of the document.

Introduction

The purpose of this International Standard 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.

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

Configuration management documents the product's 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.

Configuration management can be used to meet the product identification and traceability requirements specified in ISO 9001.

Quality management systems — Guidelines for configuration management

1 Scope

This International Standard gives guidance on the use of configuration management within an organization. It is applicable to the support of products from concept to disposal.

It first 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.

Since this International Standard is a guidance document, it is not intended to be used for certification/registration purposes.

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 definitions given in ISO 9000 and the following apply.

3.1
change control
activities for control of the product after formal approval of its **product configuration information** (3.9)

3.2
concession
permission to use or release a product that does not conform to specified requirements

NOTE 1 A concession is generally limited to the delivery of the product that has nonconforming characteristics within specified limits for an agreed time or quantity of that product.

[ISO 9000:2000, definition 3.6.11]

NOTE 2 Concessions do not affect the **configuration baseline** (3.4) and include permission to produce a product that does not conform to specified requirements.

NOTE 3 Some organizations use terms such as “waivers” or “deviations” instead of “concession”.

3.3
configuration
interrelated functional and physical characteristics of a product defined in **product configuration information** (3.9)

3.4
configuration baseline
approved **product configuration information** (3.9) that establishes the characteristics of a product at a point in time that serves as reference for activities throughout the life cycle of the product

3.5
configuration item
entity within a **configuration** (3.3) that satisfies an end use function

3.6
configuration management
coordinated activities to direct and control configuration

NOTE Configuration management generally concentrates on technical and organizational activities that establish and maintain control of a product and its **product configuration information** (3.9) throughout the life cycle of the product.

3.7
configuration status accounting
formalized recording and reporting of **product configuration information** (3.9), the status of proposed changes and the status of the implementation of approved changes

3.8
dispositioning authority
person or a group of persons assigned responsibility and authority to make decisions on the **configuration** (3.3)

NOTE 1 Dispositioning authority can also be called a “configuration control board”.

NOTE 2 Relevant interested parties within and outside the organization should be represented on the dispositioning authority.

3.9
product configuration information
requirements for product design, realization, verification, operation and support

4 Configuration management responsibility

4.1 Responsibilities and authorities

The organization should identify and describe responsibilities and authorities related to the implementation and verification of the configuration management process. The following should be considered:

— the complexity and nature of the product;

— the needs of the different product life cycle stages;

— the interfaces between activities directly involved in the configuration management process;

— the other relevant interested parties that may be involved, within and outside the organization;

— the identification of the responsible authority for verifying implementation activities;

— the identification of the dispositioning authority.

4.2 Dispositioning authority

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

— the proposed change is necessary, and the consequences would be acceptable,

— the change has been properly documented and categorized, and

— the planned activities for the implementation of the change into documents, hardware and/or software are satisfactory.

5 Configuration management process

5.1 General

The activities that are performed within the configuration management process are described below. It is essential that these activities be coordinated for this process to be effective.

The configuration management process should focus on customer requirements for the product and should take 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 procedures and the extent of their application during the life cycle of the product.

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 life cycle. The output of configuration management planning is the configuration management plan.

The configuration management plan for a specific product should

— be documented and approved,

— be controlled,

— identify the configuration management procedures to be used,

— make reference to relevant procedures of the organization wherever possible, and

— describe the responsibilities and authorities for carrying out configuration management throughout the life cycle of the product.

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 organization will need to require a supplier to provide a configuration management plan. The organization may wish to retain such plans either as stand-alone documents or to 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 and selection of configuration items

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

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

— statutory and regulatory requirements,

— criticality in terms of risks and safety,

— new or modified technology, design or development,

— interfaces with other configuration items,

— procurement conditions, and

— support and service.

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

5.3.2 Product configuration information

Product configuration information comprises both product definition and product operational information. This typically includes requirements, specifications, design drawings, parts lists, software documents and listings, models, test specifications, maintenance and operating handbooks.

Product configuration information should be relevant and traceable. Numbering conventions should be established that are unique and ensure proper control of configuration items. These should take into consideration the existing numbering conventions of the organization and the change control information, such as revision status.

5.3.3 Configuration baselines

A configuration baseline consists of the approved product configuration information that represents the definition of the product. Configuration baselines, plus approved changes to those baselines, represent the current approved configuration.

Configuration baselines should be established whenever it is necessary in the product life cycle to define a reference for further activities.

The level of detail to which the product is defined in a configuration baseline depends on the degree of control required.

5.4 Change control

5.4.1 General

After the initial release of product configuration information, all changes should be controlled. The potential impact of a change, customer requirements and the configuration baseline will affect the degree of control needed to process a proposed change or concession.

The process for controlling the change should be documented, and should include the following:

— a description of, justification for, and record of, the change;

— a categorization of the change, in terms of complexity, resources and scheduling;

— an evaluation of the consequences of the change;

— details of how the change should be dispositioned;

— details of how the change should be implemented and verified.

5.4.2 Initiation, identification and documentation of the need for change

A change may be initiated by the organization, by a customer, or by a supplier. Prior to submission for evaluation to the dispositioning authority (see 4.2), all change proposals should be identified and documented.

Change proposals should typically include the following information:

— configuration item(s) and related information to be changed, including details of their title(s) and current revision status;

— a description of the proposed change;

— details of other configuration items or information that may be affected by the change;

— the interested party preparing the proposal, and the date it was prepared;

— the reason for the change;

— the category of the change.

The status of change processing, the related decisions and the dispositions should be documented. A typical method for documenting change may be the use of a standard form that is given a unique identification number for ease of identification and traceability.

5.4.3 Evaluation of change

5.4.3.1 Evaluations concerning the proposed change should be performed and documented. The extent of any evaluation should be based on the complexity of the product, the category of the change, and should include the following:

— the technical merits of the proposed change;

— the risks associated with the change;

— the potential impact on contract, schedule and costs.

5.4.3.2 In determining the impact, the following factors should also be considered:

— the relevant statutory and regulatory requirements;

— the interchangeability of configuration items and the need for their re-identification;

— the interfaces between configuration items;

— the manufacturing, test and inspection methods;

— inventory and purchases;

— delivery activities;

— customer support requirements.

5.4.4 Disposition of change

A process should be established for the disposition of change that identifies the dispositioning authority (see 4.2) for each proposed change. This should take into account the category of the proposed change.

After a proposed change has been evaluated, the dispositioning authority should review the evaluation and should decide upon the disposition of the change.

The disposition should be recorded. Notice of the disposition should be circulated to relevant interested parties within and outside the organization.

5.4.5 Implementation and verification of change

The implementation of an approved change normally includes

— changes to the product configuration information being released to relevant interested parties, and

— actions being taken by relevant interested parties (both within and outside the organization) that are affected by the change.

After implementation, compliance with the approved change should be verified. This verification should be recorded to allow traceability.

5.5 Configuration status accounting

5.5.1 General

The configuration status accounting activity results in records and reports that relate to a product and its product configuration information.

The organization should perform configuration status accounting activities throughout the life cycle of the product in order to support and enable an efficient configuration management process.

5.5.2 Records

5.5.2.1 During the configuration identification and change control activities, configuration status accounting records will be created. These records allow for visibility and traceability and for the efficient management of the evolving configuration. They typically include details of

— the product configuration information (such as identification number, title, effective dates, revision status, change history and its inclusion in any baseline),

— the product's configuration (such as part numbers, product design or build status),

— the status of release of new product configuration information, and

— the processing of changes.

5.5.2.2 The evolving product configuration information should be recorded in a manner that identifies the cross-references and interrelationships necessary to provide the required reports (see 5.5.3).

5.5.2.3 To protect the integrity of the product configuration information and to provide a basis for the control of change, it is recommended that configuration items and related information be held in an environment

— that is commensurate with the conditions required (e.g. for computer hardware, software, data, documents, drawings),

— that provides protection from corruption or unauthorized change,

— that provides means for disaster recovery, and

— that permits retrieval.

5.5.3 Reports

Reports of varying types will be needed for configuration management purposes. Such reports may cover individual configuration items or the complete product.

Typical reports include

— a list of product configuration information included in a specific configuration baseline,

— a list of configuration items and their configuration baselines,

— details of the current revision status and change history,

— status reports on changes and concessions, and

— details of the status of delivered and maintained products concerning part and traceability numbers and their revision status.

5.6 Configuration audit

Configuration audits should be performed in accordance with documented procedures to determine whether a product conforms to its requirements and product configuration information.

Normally there are two types of configuration audits:

— a functional configuration audit; this is a formal examination to verify that a configuration item has achieved the functional and performance characteristics specified in its product configuration information;

— a physical configuration audit; this is a formal examination to verify that a configuration item has achieved the physical characteristics specified in its product configuration information.

A configuration audit may be required before the formal acceptance of a configuration item. It is not intended to replace other forms of verification, review, test or inspection, but will be affected by the results of these activities.

Annex A
(informative)

Structure and content of a configuration management plan

A.1 General

A configuration management plan should be structured to allow for discrete sections addressing the topics given in A.2 to A.7, which also give guidance on content.

A.2 Introduction

A configuration management plan will need to include an introductory section giving general information. The following topics are typically addressed in such a section:

— the purpose and scope of the configuration management plan;

— a description of the product and configuration item(s) to which the plan applies;

— a schedule to provide guidance on the time-scale of important configuration management activities;

— a description of configuration management tools (e.g. information technology);

— related documents (e.g. configuration management plans from suppliers);

— a listing of relevant documents and their interrelationships.

A.3 Policies

The configuration management plan should detail the configuration management policies that have been agreed with the customer or suppliers. This should provide the basis for configuration management activities within the contract, such as

— policies on the practice of configuration management and related management activities,

— the organization, responsibilities and authorities of relevant interested parties,

— qualification and training,

— the criteria for the selection of configuration items,

— the frequency, distribution and control of reports, both internally and to the customer, and

— terminology.

A.4 Configuration identification

The configuration management plan should detail

— a family tree of configuration items, specifications and other documents,

— the numbering conventions to be adopted for specifications, drawings, concessions and changes,