NORMA ITALIANA

Sistemi di gestione per la qualità - Linee guida per la gestione della configurazione

UNI ISO 10007

FEBBRAIO 2018

Quality management - Guidelines for configuration management

La norma fornisce una guida per l'utilizzo della gestione della configurazione all'interno di un'organizzazione. Essa si applica a supporto dei prodotti e servizi, dal concetto fino allo smaltimento/interruzione dell'erogazione.

TESTO INGLESE

La presente norma è l'adozione nazionale in lingua inglese della norma internazionale ISO 10007 (edizione marzo 2017)

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PREMESSA NAZIONALE

La presente norma costituisce l'adozione nazionale, in lingua inglese, della norma internazionale ISO 10007 (edizione marzo 2017) che assume così lo status di norma nazionale italiana.

La norma internazionale ISO 10007 è stata elaborata dal Comitato Tecnico ISO/TC 176, "Quality management and quality assurance".

La presente norma è stata elaborata sotto la competenza della Commissione Tecnica UNI

Gestione per la qualità e metodi statistici

che ha giudicato la norma ISO 10007 rispondente, da un punto di vista tecnico, alle esigenze nazionali e ne ha proposto alla Commissione Centrale Tecnica dell'UNI l'adozione nella presente versione in lingua inglese.

La Commissione Centrale Tecnica dell'UNI ha dato la sua approvazione l'1 febbraio 2018.

La presente norma è stata ratificata dal Presidente dell'UNI ed è entrata a far parte del corpo normativo nazionale il 15 febbraio 2018.

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Quality management — Guidelines for configuration management

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.

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.

5.3.3 Configuration baselines

A configuration baseline consists of the approved configuration information that represents the definition of the product or service. 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 or service life cycle to define a reference for further activities or to satisfy a specific requirement for review.

The level of detail to which the product or service 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 configuration information, all changes should be controlled. The potential consequence 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) a description of, justification for and documented information of the change;

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

c) an evaluation of the consequences of the change;

d) details of how the change should be dispositioned;

e) details of how the change should be implemented and verified.

NOTE Some organizations use terms such as "waivers" or "deviations" instead of "concession".

5.4.2 Initiation, identification and documentation of the need for change

A change can be initiated by the organization, by a customer, or by an external provider. Prior to submission for evaluation to the dispositioning authority (see 4.2), all change proposals should be identified and retained as documented information.

Change proposals should typically include the following information:

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

b) a description of the proposed change;

c) details of other configuration items or information that can be affected by the change;

d) the interested party preparing the proposal and the date it was prepared;

e) the justification of the change;

f) the category of the change.

The status of change processing, the related decisions and the dispositions should be retained as documented information. A typical method for documenting change is 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 retained as documented information. The extent of any evaluation should be based on the complexity of the product or service and the category of the change, and it should include the following:

a) the technical benefits of the proposed change;

b) the risks associated with the proposed change;

c) the potential consequences on contract, schedule and costs;

d) the potential impact of not approving the proposed change.

5.4.3.2 In determining the consequences of the change, the following factors should also be considered:

a) the application of relevant statutory and regulatory requirements;

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

c) the interfaces between configuration items;

d) the manufacturing, test and inspection methods;

e) inventory and purchases;

f) delivery activities;

g) customer support requirements.

5.4.4 Disposition of change

A process should be established, implemented and maintained 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 retained as documented information. Notice of the disposition should be distributed to relevant internal and external interested parties.

5.4.5 Implementation and verification of change

The implementation of an approved change normally includes:

a) changes to the configuration information being released to relevant interested parties;

b) actions being taken by relevant internal and external interested parties that are affected by the change.

After implementation, compliance with the approved change should be verified. This verification should be retained as documented information to allow traceability.

5.5 Configuration status accounting

5.5.1 General

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

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

5.5.2 Documented Information

5.5.2.1 During the configuration identification and change control activities, configuration status accounting documented information will be created. This documented information allows for visibility and traceability and for the efficient management of the evolving configuration. They typically include details of:

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

b) the product or service configuration (such as part numbers, product design or build status);

c) the status of release of new configuration information;

d) the processing of changes.

5.5.2.2 The evolving configuration information should be retained as documented information 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 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:

a) that is commensurate with the conditions required (e.g. for computer hardware, software, data, documented information, drawings);

b) that provides protection from loss of integrity or unauthorized change;

c) that provides means for disaster recovery;

d) that it is available and suitable for use, where and when it is needed;

e) 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 or service.

Typical reports include:

a) a list of configuration information included in a specific configuration baseline;

b) a list of configuration items and their configuration baselines;

c) details of the current revision status and change history;

d) status reports on changes and concessions;

e) details of the status of a delivered and maintained configuration (e.g. part and traceability numbers and their revision status).

5.6 Configuration audit

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

Normally there are two types of configuration audits:

a) 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 configuration information;

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

A configuration audit can 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 specific sections addressing the topics given in Clauses A.2 to A.7 which also give guidance on content.

A.2 Introductory section

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

a) the purpose and scope of the configuration management plan;

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

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

d) a description of configuration management tools;

e) related documented information (e.g. configuration management plans from providers);

f) a listing of relevant documented information and their interrelationships.

A.3 Policies

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

a) policies on the practice of configuration management and related management activities;

b) the organization, responsibilities and authorities of relevant interested parties;

c) qualification and training;

d) the criteria for the selection of configuration items;

e) the frequency, distribution and control of reports;

f) terminology.

A.4 Configuration identification

The configuration management plan should detail:

a) a breakdown structure of configuration items, specifications and other documented information;

b) naming and numbering conventions to be adopted for specifications, drawings, concessions and changes;

c) the method for identification of the revision status;

d) the configuration baselines to be established, schedules and the type of configuration information to be included;

e) the use and allocation of serial numbers or other traceability identification;

f) documented information defining release processes (including any associated procedures) for configuration information.

A.5 Change control

The configuration management plan should detail:

a) the relationship of the dispositioning authority (see 4.2) of the organization with that of other relevant interested parties;

b) the documented information for the control of changes prior to the establishment of a contractual configuration baseline;

c) the methods for processing changes (including those for customer, or provider initiated changes) and concessions.

A.6 Configuration status accounting

The configuration management plan should detail

a) the methods for collecting, documenting, processing, maintaining, and archiving the data that are necessary for producing configuration status accounting documented information;

b) the definition of the content and format for all configuration status accounting reports.

A.7 Configuration audit

The configuration management plan should detail:

a) a list of configuration audits to be conducted and their occurrence within project schedules;

b) the configuration audit documented information to be used;

c) the responsibilities and authorities of relevant internal and external interested parties;

d) a definition of the format for configuration audit reports.

Bibliography

[1] ISO 9001:2015, *Quality management systems — Requirements*

[2] ISO 9004, *Managing for the sustained success of an organization — A quality management approach*

[3] ISO 10006, *Quality management systems — Guidelines for quality management in projects*