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Guidelines for quality management system documentation

Lignes directrices pour le développement de la documentation sur les systèmes de management de la 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 whom 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 3.

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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this Technical Report may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 10013 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

This first edition of ISO/TR 10013 cancels and replaces ISO 10013:1995, *Guidelines for developing quality manuals*.

Introduction

The ISO 9000 family of International Standards requires the quality management system of an organization to be documented.

This Technical Report promotes the adoption of the process approach when developing and implementing the quality management system and improving its effectiveness.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one of the processes directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the 'process approach'.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

An organization has flexibility in the way it chooses to document its quality management system. Each individual organization should develop that amount of documentation needed to demonstrate the effective planning, operation, control and continual improvement of its quality management system and its processes.

Quality management system documentation may relate to an organization’s total activities or to a selected part of those activities; for example, specified requirements depending upon the nature of products, processes, contractual requirements, governing regulations or the organization itself.

It is important that the requirements and content of the quality management system documentation address the quality standards they intend to satisfy.

The guidelines given in this Technical Report are intended to assist an organization with documenting its quality management system. They are not intended to be used as requirements for contractual, regulatory or certification/registration purposes.

One aspect of a quality management system is quality planning. Quality planning documents may include managerial and operational planning, preparing the application of the quality management system including organizing and scheduling, and the approach by which quality objectives are to be achieved.

Guidelines for quality management system documentation

1 Scope

This Technical Report provides guidelines for the development and maintenance of the documentation necessary to ensure an effective quality management system, tailored to the specific needs of the organization. The use of these guidelines will aid in establishing a documented system as required by the applicable quality management system standard.

This Technical Report may be used to document management systems other than that of the ISO 9000 family, for example environmental management systems and safety management systems.

NOTE When a procedure is documented, the term “written procedure ” or “documented procedure” is frequently used.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this Technical Report. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Technical Report are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document refered to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this Technical Report, the terms and definitions given in ISO 9000 and the following apply. An organization's quality management system may use different terminology for the defined types of documentation.

3.1
work instructions
detailed descriptions of how to perform and record tasks

NOTE 1 Work instructions may be documented or not.

NOTE 2 Work Instructions may be, for example, detailed written descriptions, flowcharts, templates, models, technical notes incorporated into drawings, specifications, equipment instruction manuals, pictures, videos, checklists, or combinations thereof. Work instructions should describe any materials, equipment and documentation to be used. When relevant, work instructions include acceptance criteria.

3.2
form
document used to record data required by the quality management system

NOTE A form becomes a record when data are entered.

4 Quality management system documentation

4.1 General

The arrangement of quality management system documentation typically follows either the processes of the organization or the structure of the applicable quality standard, or a combination of both. Any other arrangement that satisfies the organization's needs may also be used.

The structure of the documentation used in the quality management system may be described as a hierarchy. This structure facilitates the distribution, maintenance and understanding of the documentation. Annex A illustrates a typical hierarchy of quality management system documentation. The development of a hierarchy depends on the circumstances of the organization.

The extent of the quality management system documentation can differ from one organization to another due to

a) the size of the organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

The quality management system documentation may include definitions. The vocabulary used should be in accordance with standard definitions and terms, which are referenced in ISO 9000 or in general dictionary usage.

The quality management system documentation usually includes the following:

a) quality policy and its objectives;

b) quality manual;

c) documented procedures;

d) work instructions;

e) forms;

f) quality plans;

g) specifications;

h) external documents;

i) records.

Quality management system documentation may be in any type of media, such as hard copy or electronic media.

NOTE Some advantages of using electronic media are the following:

a) appropriate personnel have access to the same up-to-date information at all times;

b) access and changes are easily made and controlled;

c) distribution is immediate and easily controlled with the option of printing hard copies;

d) there is access to documents from remote locations;

e) withdrawal of obsolete documents is simple and effective.

4.2 Purposes and benefits

The purposes and benefits of having quality management system documentation for an organization include, but are not limited to, the following:

a) describing the quality management system of the organization;

b) providing information for cross-functional groups so that they may better understand interrelationships;

c) communicating to employees management's commitment to quality;

d) helping employees to understand their role within the organization, thus giving them an increased sense of purpose and importance of their work;

e) providing mutual understanding between employees and management;

f) providing a basis for expectations of work performance;

g) stating how things are to be done in order to achieve specified requirements;

h) providing objective evidence that specified requirements have been achieved;

i) providing a clear, efficient framework of operation;

j) providing a basis for training new employees and periodic re-training of current employees;

k) providing a basis for order and balance within the organization;

l) providing consistency in operations based on documented processes;

m) providing a basis for continual improvement;

n) providing customer confidence based on documented systems;

o) demonstrating to interested parties the capabilities within the organization;

p) providing a clear framework of requirements for suppliers;

q) providing a basis for auditing the quality management system;

r) providing a basis for evaluating the effectiveness and continuing suitability of the quality management system.

4.3 Quality policy and its objectives

The quality policy and its objectives should be documented and may be an independent document or be included in the quality manual.

4.4 Quality manual

4.4.1 Contents

A quality manual is unique to each organization. This Technical Report allows for flexibility in defining the structure, format, content, or method of presentation for documenting the quality management system for all types of organizations.

A small organization may find it appropriate to include the description of its entire quality management system within a single manual, including all the documented procedures required by ISO 9001. Large, multinational

organizations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.

The quality manual should include the scope of the quality management system, the details of and justification for any exclusion, the documented procedures or reference to them, and a description of the processes of the quality management system and their interactions.

Information about the organization, such as name, location and means of communication, should be included in the quality manual. Additional information such as its line of business, a brief description of its background, history and size may also be included.

A quality manual should contain the elements described in 4.4.2 to 4.4.9, but not necessarily in the same order.

4.4.2 Title and scope

The title and/or scope of the quality manual should define the organization to which the manual applies. The manual should make reference to the specific quality management system standard on which the quality management system is based.

4.4.3 Table of contents

The table of contents of the quality manual should list the number and title of each section and its location.

4.4.4 Review, approval and revision

Evidence of the review, approval, revision status and date of the quality manual should be clearly indicated in the manual.

Where practicable, the nature of the change should be identified in the document or the appropriate attachments.

4.4.5 Quality policy and objectives

Where the organization elects to include the quality policy in the quality manual, the quality manual may include a statement of the quality policy and the objectives for quality. The actual quality goals to meet these objectives may be specified in another part of the quality management system documentation as determined by the organization. The quality policy should include a commitment to comply with requirements and continually improve the effectiveness of the quality management system.

Objectives are typically derived from the organization’s quality policy and are to be achieved. When the objectives are quantified they become goals and are measurable.

4.4.6 Organization, responsibility and authority

The quality manual should provide a description of the structure of the organization. Responsibility, authority and interrelation may be indicated by such means as organization charts, flow charts and/or job descriptions. These may be included or referenced in the quality manual.

4.4.7 References

The quality manual should contain a list of documents referred to but not included in the manual.

4.4.8 Quality management system description

The quality manual should provide a description of the quality management system and its implementation in the organization. Descriptions of the processes and their interactions should be included in the quality manual. Documented procedures or references to them should be included in the quality manual.

The organization should document its specific quality management system following the sequence of the process flow or the structure of the selected standard or any sequencing appropriate to the organization. Cross-referencing between the selected standard and the quality manual may be useful.

The quality manual should reflect the methods used by the organization to satisfy its policy and objectives.

4.4.9 Appendices

Appendices containing information supportive to the manual may be included.

4.5 Documented procedures

4.5.1 Structure and format

The structure and format of the documented procedures (hard copy or electronic media) should be defined by the organization in the following ways: text, flow charts, tables, a combination of the above, or any other suitable method in accordance with the needs of the organization. The documented procedures should contain the necessary information (see 4.5.2) and should contain a unique identification.

Documented procedures may make reference to work instructions that define how an activity is performed. Documented procedures generally describe activities that cross different functions, while work instructions generally apply to tasks within one function.

4.5.2 Contents

4.5.2.1 Title

The title should clearly identify the documented procedure.

4.5.2.2 Purpose

The purpose of the documented procedure should be defined.

4.5.2.3 Scope

The scope of the documented procedure, including the areas to be covered and areas not to be covered, should be described.

4.5.2.4 Responsibility and authority

The responsibility and authority of people and/or organizational functions, as well as their interrelations associated with the processes and activities described in the procedure, should be identified. These may be described in the procedure in the form of flow charts and descriptive text as appropriate for clarity.

4.5.2.5 Description of activities

The level of detail may vary depending on the complexity of the activities, the methods used, and the levels of skills and training of people that is necessary in order for them to accomplish the activities. Irrespective of the level of detail, the following aspects should be considered as applicable:

a) defining the needs of the organization, its customers and suppliers;

b) describing the processes in terms of text and/or flow charts related to the required activities;

c) establishing what is to be done, by whom or by which organizational function; why, when, where and how;

d) describing process controls and controls of the identified activities;

e) defining the necessary resources for the accomplishment of the activities (in terms of personnel, training, equipment and materials);

f) defining the appropriate documentation related to the required activities;

g) defining the input and output of the process;

h) defining the measurements to be taken.

The organization may decide that some of the above information is more appropriate in a work instruction.

4.5.2.6 Records

The records related to the activities in the documented procedure should be defined in this section of the documented procedure or in other related section(s). The forms to be used for these records should be identified as applicable. The method required to complete, file and keep the records should be stated.

4.5.2.7 Appendices

Appendices containing information supportive to the documented procedure may be included, such as tables, graphs, flow charts and forms.

4.5.3 Review, approval and revision

Evidence of review and approval, status and date of revision of the documented procedure should be indicated.

4.5.4 Identification of changes

Where practicable, the nature of the change should be identified either in the document or the appropriate attachments.

4.6 Work instructions

4.6.1 Structure and format

Work instructions should be developed and maintained to describe the performance of all work that would be adversely affected by lack of such instructions. There are many ways of preparing and presenting instructions.

Work instructions should contain the title and a unique identification. (This information is stated in 4.6.4.)

The structure, format and level of detail used in the work instructions should be tailored to the needs of the organization's personnel and depends on the complexity of the work, the methods used, training undertaken, and the skills and qualifications of such personnel.

The structure of the work instructions may vary from that of documented procedures.

The work instructions may be included in the documented procedures or referenced in them.

4.6.2 Contents

Work instructions should describe critical activities. Details which do not give more control of the activity should be avoided. Training can reduce the need for detailed instructions, provided the persons concerned have the information necessary to do their jobs correctly.

4.6.3 Types of work instructions

Although there is no required structure or format for work instructions, they generally should convey the purpose and scope of the work and the objectives, and make reference to the pertinent documented procedures.

Whichever format or combination is chosen, the work instructions should be in the order or sequence of the operations, accurately reflecting the requirements and relevant activities. To reduce confusion and uncertainty, a consistent format or structure should be established and maintained.

An example of work instructions is given in annex B.

4.6.4 Review, approval and revision

The organization should provide clear evidence of review and approval of work instructions and their revision level and date of revision.

4.6.5 Records

Where applicable, the records specified in the work instruction should be defined in this section or in other related section(s). The minimum records required are identified in ISO 9001. The method required to complete, file and keep the records should be stated. The forms to be used for these records should be identified as applicable.

4.6.6 Identification of changes

Where practicable, the nature of the change should be identified either in the document or the appropriate attachments.

4.7 Forms

Forms are developed and maintained to record the data demonstrating compliance to the requirements of the quality management system.

Forms should contain a title, identification number, revision level and date of revision. Forms should be referenced in, or attached to, the quality manual, documented procedures and/or work instructions.

4.8 Quality plans

A quality plan is a part of quality management system documentation.

The quality plan needs to refer only to the documented quality management system, showing how it is to be applied to the specific situation in question, and identify and document how the organization will achieve those requirements that are unique to the particular product, process, project or contract.

The scope of the quality plan should be defined. The quality plan may include unique procedures, work instructions, and/or records.

4.9 Specifications

Specifications are documents stating requirements. Specifications are not further detailed in this Technical Report because they are unique to the product/organization.

4.10 External documents

The organization should address external documents and their control in its documented quality management system. External documents can include customer drawings, specifications, statutory and regulatory requirements, standards, codes and maintenance manuals.

4.11 Records

Quality management system records state results achieved or provide evidence indicating that the activities indicated in the documented procedures and work instructions are performed. The records should indicate the compliance with the requirements of the quality management system and the specified requirements for the product. The responsibilities for preparation of records should be addressed in the quality management system documentation.

NOTE Records are not generally under revision control as records are not subject to change.

5 Process of preparing quality management system documentation

5.1 Responsibility for preparation

Quality management system documentation should be developed by those persons involved with the processes and activities. This will lead to a better understanding of the necessary requirements and provide a sense of involvement and ownership by personnel.

The review and utilization of existing documents and references can significantly shorten the quality management system documentation development time, as well as being an aid in identifying those areas where quality management system inadequacies need to be addressed and corrected.

5.2 Method of preparation of quality management system documentation

Organizations that are in the process of implementing, or have yet to implement, a quality management system should

a) identify the processes necessary for the effective implementation of the quality management system,

b) understand the interactions between these processes, and

c) document the processes to the extent necessary to assure their effective operation and control.

Analysis of the processes should be the driving force for defining the amount of documentation needed for the quality management system. It should not be the documentation that drives the processes.

The sequence of preparation of quality management system documentation does not necessarily follow the hierarchy illustrated in annex A, since documented procedures and work instructions are often prepared prior to finalizing of the quality manual.

The following represents examples of actions which may be initiated, as applicable:

a) decide which quality management system documentation requirements apply according to the selected quality management system standard;

b) obtain data about the existing quality management system and processes by various means, such as questionnaires and interviews;

c) establish and list existing applicable quality management system documents and analyse them to determine their usefulness;

d) train the individuals involved regarding the preparation of documentation and the applicable quality management system standard requirements or other selected criteria;

e) request and obtain additional source documentation or references from operational units;

f) determine the structure and format for the intended documents;

g) prepare flowcharts covering processes within the scope of the quality system; see annex B;

h) analyse the flowcharts for possible improvements and implement these improvements;

i) validate the documentation through trial implementation;

j) use any other method suitable within the organization to complete the quality management system documentation; and

k) review and approve documentation before release.

5.3 Use of references

Whenever appropriate, and to limit the size of the documentation, reference to existing recognized quality management system standards or documents available to the document user should be incorporated.

When using references, specifying the revision status should be avoided in order to preclude changing the referencing document when revision status of the referenced document is changed.

6 Process of approval, issue and control of quality management system documents

6.1 Review and approval

Prior to issue, the documents should be reviewed by authorized individuals to ensure clarity, accuracy, adequacy and proper structure. The intended users should also have the opportunity to assess and comment on the usability of the documents and on whether the documents reflect actual practices. Release of documents should be approved by the management responsible for their implementation. Each copy should have evidence of this release authorization. Evidence of approval of documents should be retained.

6.2 Distribution

The method of distribution of the documents by authorized personnel should ensure that pertinent issues of appropriate documents are available to all personnel who will need the information included in the documents. Proper distribution and control may be aided, for example, by using serial numbers of individual copies of the documents for recipients. Distribution of documents such as the quality manual and quality plan may include external parties (e.g. customers, certification bodies and regulatory authorities).

6.3 Incorporation of changes

A process for the initiation, development, review, control and incorporation of changes to the documents should be provided. The same review and approval process used in developing the original documents should apply when processing changes.

6.4 Issue and change control

Document issue and change control are essential to ensure that the contents of the documents are properly approved by the authorized personnel and that the approval is readily identifiable.

Various methods may be considered for facilitating the physical process of making changes.

A process should be established to ensure that only the appropriate documents are in use. Under certain circumstances, the appropriate document to be used may not be the latest revision of the document. Revised documents should be replaced by the latest revision. A document master list with revision level may be used to assure the users that they have the correct issue of authorized documents.

The organization should consider recording the history of changes to the documents for legal and/or knowledge preservation purposes.

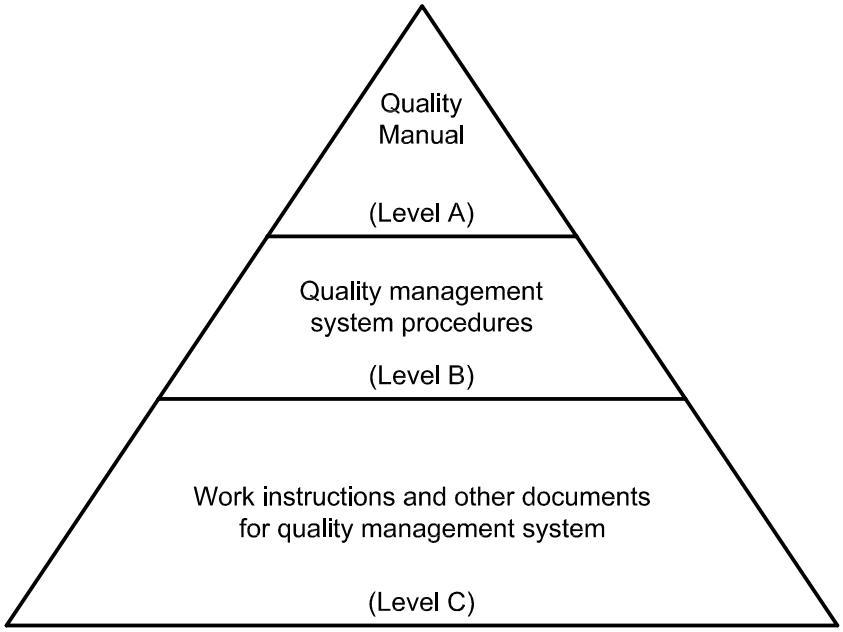
6.5 Uncontrolled copies

For the purpose of tenders, customer off-site usage and other special distribution of documents where change control is not intended, such distributed documents should be clearly identified as uncontrolled copies.

NOTE Failure to provide assurance of this process can cause unintended usage of obsolete documents.

Annex A

Typical quality management system documentation hierarchy



Document contents

A: Describes the quality management system in accordance with the stated quality policy and objectives (see 4.3 and 4.4).

B: Describes the interrelated processes and activities required to implement the quality management system.

C: Consists of detailed work documents.

NOTE 1 The number of levels may be adjusted to meet the organization's needs.

NOTE 2 Forms may be applicable at all levels of the hierarchy.

Annex B

Example of structured text work instructions

B.1 Work instructions for sterilization of instruments

Number: Ttv 2.6 Date: Sept. 15, 1997 Revision: 0

B.2 Disposable instruments

Place disposable instruments (e.g. syringes, needles, knives and stitch-removal instruments) into a special container. The container shall be destroyed according to the waste disposal programme.

B.3 Hot-air sterilized instruments

B.2.1 Wipe secretions by using disposable tissue.

B.2.2 Dip instruments into a 10 % chlorine solution (1 dl Klorilli liquid and 9 dl water). The liquid shall be replaced twice a week.

B.2.3 Soak the instruments for at least 2 h.

B.2.4 Wash the instruments with a brush using protection gloves.

B.2.5 Rinse and dry the instruments.

B.2.6 Check that the instruments are in good condition. Damaged instruments shall be sent for service.

B.2.7 Sterilization in a bag:

— place the instruments into a hot-air resistant bag;

— protect the sharp edges with gauze;

— fold the bag edge several times to obtain a tight seal;

— seal the bag with heat-resistant tape;

— mark the date and set a hot-air indicator onto the bag;

— put the bag into the hot air oven and leave it for 30 min at a temperature of 180 °C.

The instruments are usable one month after sterilization if they are stored in a properly sealed bag.

B.2.8 Sterilization in a metal container:

— place a hot-air-resistant tissue at the bottom of the container to protect the instruments;

— put the instruments at the bottom of the container;

— set a hot-air indicator into the container;

— allow the container stay for 30 min at a temperature of 180 °C.

One out of the two containers is used in turn every day.

B.4 Other instruments (e.g. otoscopes)

Rinse the instruments after soaking in chlorine solution for 2 h.

Bibliography

[1] ISO 9001:2000, *Quality management systems — Requirements*

[2] ISO 9004:2000, *Quality management systems — Guidlines for performance improvements*

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