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Guidelines for developing quality manuals

Lignes directrices pour l'élaboration des manuels qualité

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Contents

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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.

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.

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

Annexes A, B, C and D of this International Standard are for information only.

Introduction

The ISO 9000 family of International Standards includes requirements for quality systems which can be used to achieve common interpretation, development, implementation and application of quality management and quality assurance.

The ISO 9000 family of International Standards requires the development and implementation of documented quality systems, including the preparation of quality manuals.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*, defines a quality manual as a document stating the quality policy and describing the quality system of an organization. This 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 or services, processes, contractual requirements, governing regulations or the organization itself.

It is important that the requirements and content of the quality system and quality manual address the quality standard they are intended to satisfy. This International Standard provides guidelines for developing such quality manuals.

Guidelines for developing quality manuals

1 Scope

This International Standard provides guidelines for the development, preparation and control of quality manuals tailored to the specific needs of the user. The resultant quality manuals will reflect documented quality system procedures required by the ISO 9000 family of International Standards. Detailed work instructions, quality plans, brochures and other quality system related documents are not covered by this International Standard. (See annex A, level C.)

NOTE 1 This International Standard may be used to develop quality manuals relating to quality system standards other than the ISO 9000 family.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 apply.

4 Documentation of quality systems

Annex A describes a typical quality system documentation hierarchy. The order of development of this hierarchy in an individual organization is dependent on that organization's circumstances, but usually starts with development of the organzation's quality policy and objectives.

4.1 Documented quality system procedures

Documented quality system procedures should form the basic documentation used for the overall planning and administration of activities which impact on quality. In accordance with the ISO 9000 family, these documented procedures should cover all the applicable elements of the quality system standard. They should describe (to the degree of detail required for adequate control of the activities concerned) the responsibilities, authorities and interrelationships of the personnel who manage, perform, verify or review work affecting quality, how the different activities are to be performed, the documentation to be used and the controls to be applied. (See annex A.)

4.1.1 Procedural scope

Each documented procedure should cover a logically separable part of the quality system, such as a complete quality system element or part thereof, or a sequence of interrelated activities connected with more than one quality system element. The quantity of documented procedures, the volume of each and the nature of their format and presentation are to be determined by the user of this International Standard; each usually reflects the complexity of the facility, organization and nature of business. Documented quality system procedures should not, as a rule, enter into purely technical details of the type normally documented in detailed work instructions.

4.1.2 Consistent approach

By arranging each documented procedure in the same structure and format, the users will become familiar with the consistent approach applied to each requirement and so improve the likelihood of systematic compliance with the standard.

4.2 Quality manuals

A quality manual should consist of, or refer to, the documented quality system procedures intended for the overall planning and administration of activities which impact on quality within an organization. A quality manual should cover all the applicable elements of the quality system standard required for an organization. It should describe, in adequate detail, the same control aspects mentioned in subclause 4.1. In some situations, the related documented quality system procedures and some sections of the quality manual may be identical. However, some degree of tailoring is usually required to ensure that only appropriate documented procedures (or sections thereof) are selected for the specific purposes of the quality manual being developed. The contents of quality manuals are addressed in detail in clause 7. Documented procedures related to the quality system, not dealt with in the selected quality system standard but necessary for the adequate control of the activities, should be added to the quality manual or be referenced as necessary. (See annex B.)

NOTE 2 Inclusion of proprietary information is at the discretion of the organization.

4.2.1 Purposes of quality manuals

Quality manuals may be developed and used by an organization for purposes including, but not limited to, the following:

a) communicating the organization's quality policy, procedures and requirements;

b) describing and implementing an effective quality system;

c) providing improved control of practices and facilitating assurance activities;

d) providing the documented bases for auditing the quality system;

e) providing continuity of the quality system and its requirements during changing circumstances;

f) training personnel in the quality system requirements and methods of compliance;

g) presenting the quality system for external purposes, such as demonstrating compliance with ISO 9001, 9002 or 9003;

h) demonstrating compliance of the quality system with quality requirements in contractual situations.

4.2.2 Structure and format

Although there is no required structure or format for a quality manual, it should convey accurately, completely and concisely the quality policy, objectives and governing documented procedures of the organization (see clause 6). One of the methods of assuring that the subject matter is adequately addressed and located would be to key the sections of the quality manual to the quality elements of the governing quality system standard. Other approaches, such as structuring the manual to reflect the nature of the organization, are equally acceptable.

NOTE 3 For system clarity and assessment purposes, the intentional omission of any quality system element from the quality manual compared to the governing quality system standard should be explained.

4.2.3 Derivation of a quality manual

A quality manual may:

a) be a direct compilation of documented quality system procedures;

b) be a grouping or section of the documented quality system procedures;

c) be a series of documented procedures for specific facilities or applications;

d) be more than one document or level;

e) have a common core with tailored appendices;

f) stand alone or otherwise;

g) have other numerous possible derivations based upon organizational need.

4.2.4 Special applications of quality manuals

The simple term "quality manual" is used when the same manual is employed for both quality management and quality assurance purposes. This usage is the most common application of a quality manual. However, in situations where an organization believes that a distinction of content or usage is needed, it is essential that manuals describing the same quality system are not in conflict.

Any quality manual should identify the management functions, address or reference the documented quality system and procedures and briefly cover all the applicable requirements of the quality system standard selected by the organization.

5 Process of preparing a quality manual

5.1 Responsibility for preparation

Once the management decision has been made to document a quality system in a quality manual, the actual process should begin with assignment of the coordination task to a management-delegated competent body, which may be an individual or a group of individuals from one or more functional organizations.

The actual writing activity should be performed and controlled from within the delegated competent body or from within various individual functional units, as appropriate. The use of existing documents and references can significantly shorten the quality manual development time, as well as being an aid to identifying those areas where quality system inadequacies need to be addressed and corrected.

The competent body may initiate the following actions as applicable:

a) establish and list existing applicable quality system policies, objectives and documented procedures, or develop plans for such;

b) decide which quality system elements apply according to the quality system standard selected;

c) obtain data about the existing quality system and practices by various means, such as questionnaires and interviews;

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

e) determine the structure and format for the intended manual;

f) classify existing documents in accordance with the intended structure and format;

g) use any other method suitable within the organization to complete the quality manual draft.

5.2 Use of references

Wherever appropriate, and to avoid unnecessary document volume, reference to existing recognized standards or documents available to the quality manual user should be incorporated.

5.3 Accuracy and completeness

The delegated competent body should be responsible for assuring the accuracy and completeness of the quality manual draft, as well as for the continuity and contents of the document.

6 Process of quality manual approval, issue and control

6.1 Final review and approval

Prior to issuing the manual, the document should be subjected to review by responsible individuals to ensure clarity, accuracy, suitability and proper structure. The intended users should also have the opportunity to assess and comment on the usability of the document. Release of the new quality manual should be approved by the management responsible for its implementation. Each copy should bear evidence of this release authorization. Electronic or other methods of release of the manual are acceptable, if evidence of approval is retained.

6.2 Distribution of the manual

The method of distribution of the authorized manual, whether in total or by sections, should provide assurance that all users have appropriate access. Proper distribution and control can be aided, for example, by serialization of copies for recipients. Management should ensure that individuals are familiar with those contents of the manual appropriate to each user within the organization.

6.3 Incorporation of changes

A method of providing for the initiation, development, review, control and incorporation of changes to the manual should be provided. This task should be assigned to an appropriate document control function. The same review and approval process used in developing the basic manual should apply when processing changes.

6.4 Issue and change control

Document issue and change control are essential to ensure that the content of the manual is properly authorized. The authorized content should be readily identifiable. Various methods may be considered for facilitating the physical process of making changes. To ensure that each manual is kept up to date, a method is needed to assure that all changes are received by each manual holder and incorporated into each manual. A table of contents, a separate

revision-status page or other suitable means may be used to assure the users that they have the authorized manual.

6.5 Uncontrolled copies

For the purposes of proposals, customer off-site usage, and other distribution of the quality manual where change control is not intended, all such distributed manuals should be clearly identified as uncontrolled copies.

NOTE 4 Failure to provide assurance of this process may cause unintended usage of obsolete documents.

7 What to include in a quality manual

7.1 General

A quality manual should normally contain the following:

a) title, scope and field of application;

b) table of contents;

c) introductory pages about the organization concerned and the manual itself;

d) the quality policy and objectives of the organization;

e) a description of the organizational structure, responsibilities and authorities;

f) a description of the elements of the quality system and any references to documented quality system procedures;

g) a definitions section, if appropriate;

h) a guide to the quality manual, if appropriate;

i) an appendix for supportive data, if appropriate.

NOTE 5 The order of the contents of the quality manual may be changed in accordance with user needs.

7.2 Title, scope and field of application

The title and scope of the quality manual should clearly define the organization to which the manual applies. This section of the quality manual should also define the application of the quality system elements. To ensure clarity and avoid confusion, the use of disclaimers (e.g. what is not covered by a quality manual and situations where it should not be applied) may also be appropriate. Some or all of this information may also be located on the title page.

7.3 Table of contents

The table of contents of a quality manual should show the titles of the sections within it and how they can be found. The numbering or coding system of sections, subsections, pages, figures, exhibits, diagrams, tables, etc., should be clear and logical.

7.4 Introductory pages

The introductory pages of a quality manual should provide general information about the organization concerned and the quality manual itself.

The minimum information about the organization should be its name, site, location and means of communication. Additional information about the organization, such as its line of business, a brief description of its background, history or size, may also be included.

The information about the quality manual itself should include:

a) the current issue or effectivity identification, date of issue, or effectivity and identification of amended contents;

b) a brief description of how the quality manual is revised and maintained, who reviews its content and how often, who is authorized to change the quality manual, and who is authorized to approve it; this information may also be given under the system element concerned; a method for determining the history of any change in procedure may be included, if appropriate;

c) a brief description of the documented procedures used to identify the status and to control the distribution of the quality manual, whether or not it contains confidential information, whether it is used only for the organization's internal purposes, or whether it can be made available externally;

d) evidence of approval by those responsible for authorization of the contents of the quality manual.

7.5 Quality policy and objectives

This section of a quality manual should state the organization's quality policy and objectives. This is where the organization's commitment to quality is presented and where the organization's objectives for quality are outlined. This section should also describe how the quality policy is made known to, and understood by, all employees and how it is implemented and maintained at all levels. Specific quality policy statements may also be included under the system element concerned.

NOTE 6 Subsequent sections or system elements of the manual may also be used to reflect implementation and linkage to the quality policy and objectives.

7.6 Description of the organization, responsibilities and authorities

This section of a quality manual should provide a description of the high-level structure of the organization. An organization chart indicating responsibility, authority and interrelationship structure may be included. Subsections within this section or in a referenced system element procedure should provide details of the responsibilities, authorities and hierarchy of all functions which manage, perform and verify work affecting quality.

7.7 Elements of the quality system

The remainder of the quality manual should describe all the applicable elements of the quality system. The description should be divided into logical sections revealing a well-coordinated quality system. This may be done by inclusion of, or reference to, documented quality system procedures.

A quality system and a quality manual are unique to each organization; as such, this International Standard is not intended to define a unique structure, format, content or method of presentation for the description of quality system elements which can be applied to all (or even some) products, including services.

Requirements for elements of quality systems are provided by the ISO 9000 family of International Standards or the applicable standard used by the organization. It is recommended that, whenever applicable, the description of the elements of the quality system be in a sequence similar to that in the selected standard. Other sequencing or cross-referencing, as appropriate to the organization, is acceptable.

After selecting the appropriate standard, each organization determines the quality system elements which are applicable and, based upon the requirements of those elements in the standard, defines how the organization intends to apply, accomplish and control each of the selected elements. In determining the most suitable approach for the organization, consideration should be given to such aspects as:

— the nature of the business, workforce and resources;

— the emphasis placed on the quality system documentation and quality assurance;

— the distinctions made between policies, procedures and work instructions; and

— the medium selected for the manual.

The resultant quality manual will then reflect the organization's unique methods and means of satisfying the requirements stated in the selected quality standard and its quality system elements. The methods and means by which the organization makes a commitment to meet requirements should be clear to the users of the manual. (See annex C.)

7.8 Definitions

If a definitions clause is considered necessary in a manual, it is usually located immediately after the "Scope and field of application". Although it is recommended, when practical, to use standard definitions and terms which are referenced in recognized quality terminology documents or in general dictionary usage, this section of a quality manual should contain the definitions of terms and concepts that are uniquely used within that quality manual. Special attention should be given to words that have a different meaning to different people or a specific meaning to specific sectors of businesses. The definitions should provide for a complete, uniform and unambiguous understanding of the contents of the quality manual. The use of references to existing concepts, terminology, definitions and standards (e.g. ISO 8402) is highly recommended.

7.9 Guide to the quality manual

Consideration may be given to the inclusion of an index or a section giving a cross-reference between a subject and key words to the section or page numbers, or another such quick guide to "what and where in the quality manual". A guide may also provide a

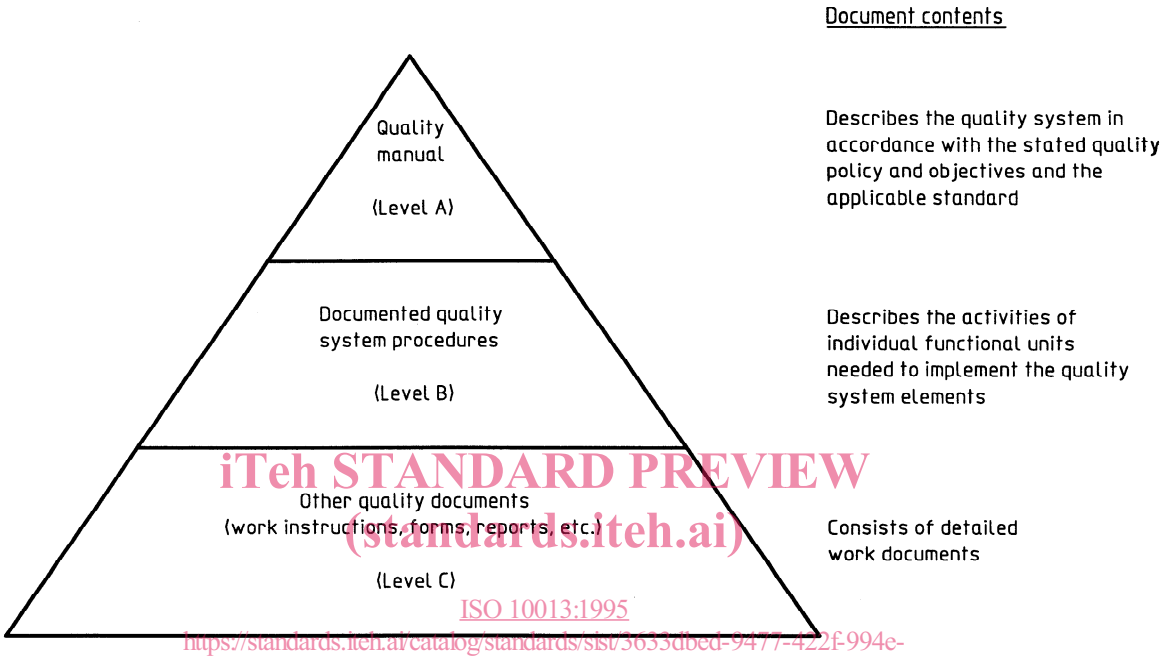
description of the organization of the quality manual and a short abstract of each of its sections. Readers who are interested only in parts of the quality manual should be able to identify, with the aid of this section, which parts of the quality manual may contain the information which they are seeking.

7.10 Appendix for supportive information

An appendix containing data supportive to the manual may be included.

Annex A
(informative)

Typical quality system document hierarchy



NOTE 7 Any document level in this hierarchy may be separate, used with references, or combined.