CSA Special Publication

PLUS 13485

The ISO 13485 essentials — A practical handbook for implementing the ISO 13485 Standard for manufacturers of medical devices

CANADIAN STANDARDS ASSOCIATION

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Preface

The primary objective of this Handbook is to provide both novice and experienced quality practitioners with a concise, user-friendly guide to understanding and implementing the requirements of ISO 13485 as it relates to their quality management system (QMS).

The Canadian National Standard CAN/CSA-ISO 13485:03 is identical to its international counterpart, ISO 13485:03. To facilitate reading, the CAN/CSA prefix and year of issue have not been systematically included in the references to the Standard throughout this Handbook. Similarly, when ISO 9000 is used in the text, it refers to the 2000 edition. Please refer to the bibliography for the full title and designation of these Standards.

The numbering of this Handbook corresponds to the numbering of the clauses in ISO 13485, and each section contains

a) the actual text of ISO 13485;
b) definitions excerpted from ISO 9000, ISO 13485, and ISO 19011. The notes contained in these definitions are not always included in each section. Appendix 1 provides all definitions and accompanying notes in alphabetical order;
c) guidance, provided by ISO/TR 14969 or by other sources;
d) typical audit questions asked by auditors when registering the QMS to ISO 13485; and
e) self-assessment questions to be considered by an organization while developing its QMS.

Detailed guidance on the QMS registration process and implementation path, and other valuable information is found in PLUS 9001, *The ISO 9000 Essentials*, published by CSA. The information provided in *The ISO 9000 Essentials* is not reproduced here. (Contact CSA at 1-800-463-6727 for more information.)

The Layout of this Handbook

The format and layout used in this Handbook are as follows:

Text boxes with this icon contain all the clauses of ISO 13485.

Note 1: *In ISO 13485 the clauses that are identical to those in ISO 9001:2000 are presented in normal font. Where the text of ISO 13485 is not identical to ISO 9001:2000, it is shown in italics (in blue italics for the electronic version). This Handbook reproduces this format.*

Note 2: *ISO 13485 contains extensive informative annexes. Only Annex A, Table A.1 (Correspondence between ISO 13485:1996 and ISO 13485:2003 version), is reproduced here (Appendix 2 at the end of this Handbook). To consult Annex A, Table A.2 (Correspondence between ISO 13485:2003 and ISO 13485:1996 version), or Annex B (a 30-page table explaining the differences between ISO 13485:2003 and ISO 9001:2000), readers should refer to ISO 13485:2003, available at CSA.*

Definitions

Text boxes with this icon provide definitions from ISO 9000, ISO 13485, and ISO 19011. The notes contained in these definitions are not always included in the text box. Appendix 1 supplies all definitions and their notes in alphabetical order.

Guidance

Sections preceded by boxes with this icon contain guidance excerpted from ISO/TR 14969 and other sources. ISO/TR 14969 explains its use of terminology as follows:

> NOTE The terms "should", "can" and "might" within this Technical Report are used as follows. "Should" is used to indicate that, amongst several possibilities to meet a requirement in ISO 13485, one is recommended as being particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required. "Can" and "might" are used to indicate possibilities or options. These terms do not indicate requirements.

This guidance can be used to better understand the requirements of ISO 13485 and illustrate some of the varity of methods and approaches available for meeting the requirements of ISO 13485. (ISO/TR 14969, 1.1)

Sections preceded by this icon contain typical questions asked by auditors when registering the QMS to ISO 13485.

Sections preceded by this icon contain self-assessment questions to be considered by an organization while developing its QMS.

PLUS 13485 — The ISO 13485 Essentials

0 Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices and the design, development, and provision of related services.

It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.

Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products.

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.

Guidance

ISO/TR 14969 provides the following introduction to quality management systems and ISO 13485:

0.1.1

This Technical Report provides guidance to assist in the development, implementation and maintenance of quality management systems that aim to meet the requirements of ISO 13485 for organizations that design and develop, produce, install and service medical devices, or that design, develop and provide related services. It provides guidance related to quality management systems for a wide variety of medical devices and related services. Such medical devices include active, non-active, implantable and non-implantable medical devices and *in vitro* diagnostic medical devices.

ISO 13485 specifies the quality management requirements for medical devices for regulatory purposes (see Annex A). ISO 13485 accommodates the previous ISO 13488 by permissible exclusion as specified in ISO 13485:2003, 1.2.

When judging the applicability of the guidance in this Technical Report, one should consider the nature of the medical device(s) to which it will apply, the risk associated with the use of these medical devices, and the applicable regulatory requirements.

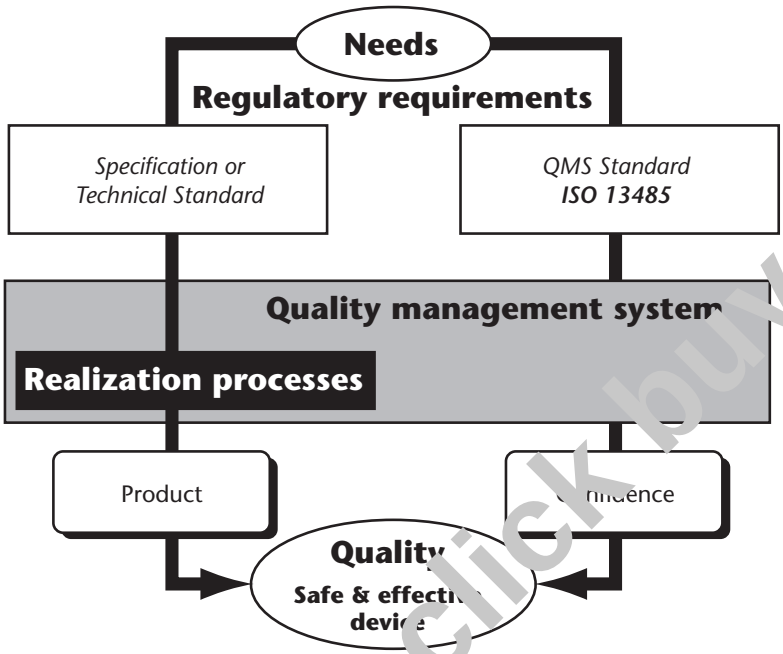
As used in this Technical Report, the term "regulatory requirement" includes any part of a law, ordinance, decree or national and/or regional regulation applicable to quality management systems for medical devices and related services.

This Technical Report provides some approaches that an organization can use to implement and maintain a quality management system which conforms with ISO 13485. Alternative approaches can be used if they also satisfy the requirements of ISO 13485. [ISO/TR 14969]

ISO/TR 14969 also notes the following:

The guidance contained in this Technical Report is not to be used for identifying specific deficiencies of quality management systems, unless such guidance is voluntarily incorporated by the organization into the documentation describing and supporting the organization's quality management systems, or unless such guidance is specifically made part of the regulatory requirements relevant to the organization's operation. [ISO/TR 14969, 0.1.3]

The relationships among regulatory requirements, technical standards (see Appendix 4), and requirements for the QMS are illustrated in the figure below. Conformity with these various requirements will lead to the manufacture and delivery of safe and effective quality medical devices.



Regulatory requirements — Technical Standards — QMS

0.2 Process approach

This International Standard is based on a process approach to quality management.

Any activity that receives inputs and converts them to outputs can be considered as a process.

For an organization to function effectively, it has to identify and manage numerous linked processes.

Often the output from one process 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".

Guidance

ISO/TR 14969 outlines the process approach of ISO 13485 as follows:

> ISO 13485 promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, with the objective of meeting customer and regulatory requirements, and providing medical devices that meet customer and regulatory requirements.
>
> 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 process 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 which it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.
>
> If used within a quality management system, such an approach emphasizes the importance of
> — understanding and meeting requirements,
> — considering processes in terms of added value,
> — obtaining results of process performance and effectiveness, and
> — improving processes based on objective measurement.
>
> The model of a process-based quality management system shown in Figure 1 ["Model of a processed-based quality management system", reproduced below] illustrates the process linkages presented in ISO 13485:2003, Clauses 4 to 8. This illustration shows that customers and regulatory authorities play a significant role in defining requirements as inputs. Monitoring of customer feedback requires the evaluation of information relating to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of ISO 13485, but does not show processes at a detailed level. [ISO/TR 14969, 0.2]

Source: ISO/TR 14969

Model of a process-based quality management system

Definition

process
set of interrelated or interacting activities which transforms inputs into outputs [ISO 9000, 3.4.1]

ISO/TR 14969 outlines the Plan-Do-Check-Act methodology as follows:

> In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.
>
> Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.
>
> Do: implement the processes.
>
> Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.
>
> Act: take actions to improve process performance. [ISO/TR 14969, 0.2]

0.3 Relationship with other standards

0.3.1 Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001.

Those clauses or subclauses that are quoted directly and unchanged from ISO 9001 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B.

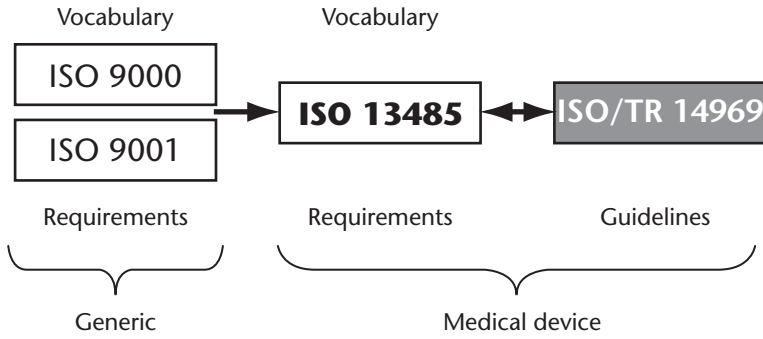
Where the text of this International Standard is not identical to the text of ISO 9001, the sentence or indent containing that text as a whole is shown in italics (in blue italics for electronic versions). The nature and reasons for the text changes are noted in Annex B.

0.3.2 Relationship with ISO/TR 14969

ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485.

Guidance

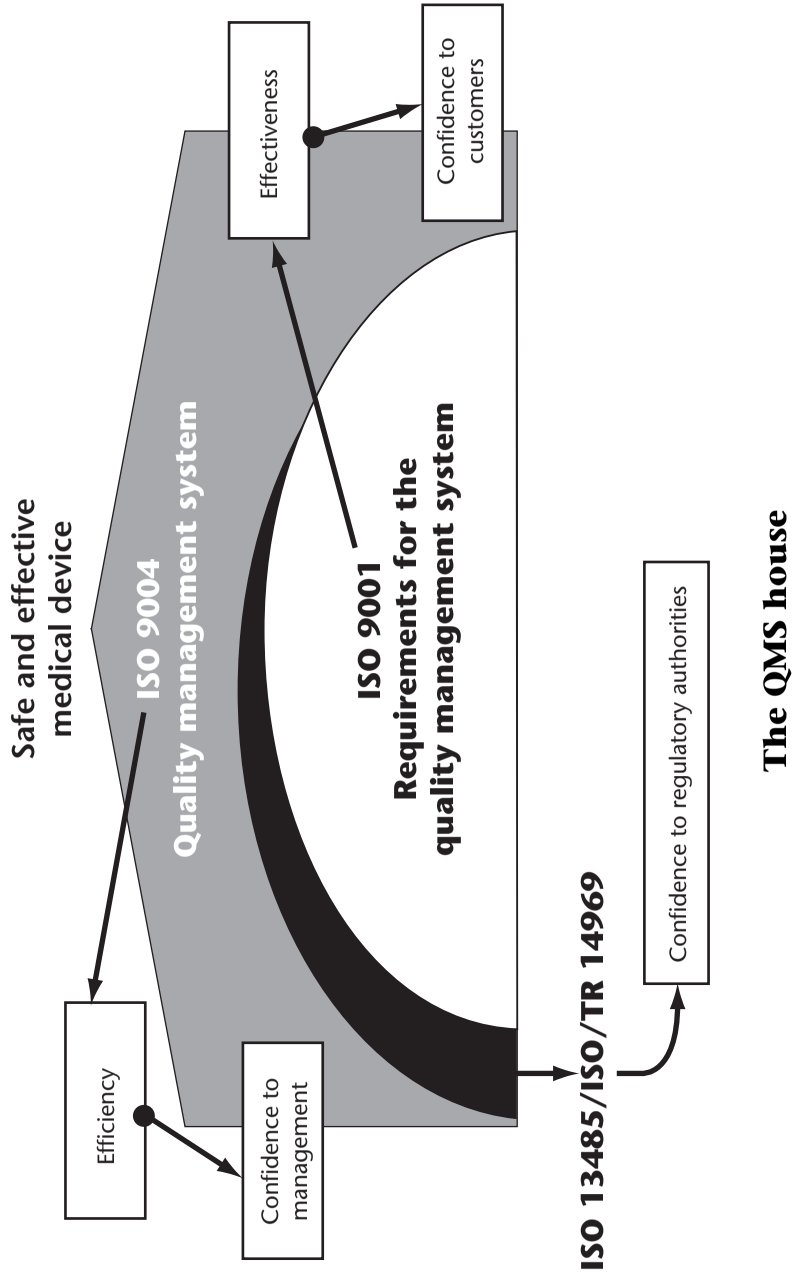
The figure below represents the relationships among ISO 13485 and other standards, guidelines, and requirements.



ISO 13485 and key standards

ISO/TR 14969 summarizes its relationship with ISO 13485 and other general standards as follows:

> The relationship between ISO 13485, this Technical Report [i.e., ISO/TR 14969] and general standards for quality management systems (ISO 9001 and ISO 9004) is summarized as follows.
>
> a) This Technical Report provides guidance on the application of ISO 13485.
>
> b) ISO 13485 specifies requirements for quality management systems in order to achieve regulatory compliance in the medical devices industries. It follows the format, structure and process approach of ISO 9001. It differs from ISO 9001 in that it specifies additional requirements but does not include the explicit requirements for continual improvement and customer satisfaction.
>
> c) ISO 9001 is an International Standard for quality management systems in general.
>
> d) ISO 9004 gives guidance on a wider range of objectives of quality management systems than does this Technical Report, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is suitable as a guide for organizations whose top management wishes to move beyond the requirements of ISO 13485, in pursuit of continual performance improvement and customer satisfaction. However, it is not intended for certification or for contractual purposes. [ISO/TR 14969, 0.3]



The QMS house

ISO 9000 provides the normative generic vocabulary to deal with the subject of quality management systems.

ISO/TR 14969 recognizes guidance from various sources, as follows:

> Guidance provided in Technical Report has taken into consideration requirements and guidance contained in documents from the following organizations:
> — Global Harmonization Task Force (GHTF);
> — International Organization for Standardization (ISO);
> — European Committees for Standardization (CEN and CENELEC);
> — national regulatory bodies.
>
> Many of these documents are listed in the Bibliography. [ISO/TR 14969, 0.3]

0.4 Compatibility with other management systems

This International Standard follows the format of ISO 9001 for the convenience of users in the medical device community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management.

However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Guidance

ISO/TR 14969 notes that the following should be taken into account:

> Conformance to ISO 13485 quality management system requirements does not automatically constitute conformity with national or regional regulatory requirements. It is the organization's responsibility to identify and establish compliance with relevant regulatory requirements. [ISO/TR 14969, 0.4]

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001 (see Annex B).

Guidance

Clause 1.1 defines the scope of ISO 13485. This should not be confused with the scope of the QMS, which is a term commonly used within the context of QMS certification/registration to describe the products and product realization processes to which the QMS applies.

The scope of the QMS should be based on the nature of the organization's products and their realization processes, the result of risk assessment, commercial considerations, and contractual, statutory, and regulatory requirements. An organization is not obliged to include all the products that it provides within the scope of its QMS or to address the realization processes for products that are not included within the QMS.