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AAMI/ISO 13485:2016 Medical Devices

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About this handbook

All organizations face challenges when developing or updating their quality management system (QMS) and it is hoped that this handbook will be used to provide additional insight and understanding of the requirements in ISO 13485 [1], *Medical devices — Quality management systems — Requirements for regulatory purposes*. It is not expected that you will sit down and read this handbook in one sitting, but that you might use it as a reference when questions come up about specific requirements. Therefore, it is broken up into the sections outlined in the contents in line with the clause structure of ISO 13485. It is expected that you have basic practical experience with QMS and the applicable regulatory requirements within the medical devices sector to effectively understand the guidance provided. In this handbook, advice to guide understanding of ISO 13485 and its application is given by first listing the full text of ISO 13485, followed by the intent of that section and relevant guidance. Examples have been used wherever possible as an aid to understanding what the requirements mean.

This handbook has been written by a task group of technical experts from ISO's Technical Committee TC 210. A draft was circulated to all the member national standards bodies and liaison organizations of ISO/TC 210 to obtain feedback and comments; these have been considered by the task group prior to release of the final text. The requirements of ISO 13485 are general in nature and, with the exception of a few subclauses that are applicable to specific medical device types, are intended to be applicable to all medical device organizations, regardless of their type, size, or the product they provide. This handbook is intended to guide organizations that provide product, including services, that affect any part of the lifecycle or supply chain of a medical device. Such organizations can be manufacturers, importers, distributors, service providers or authorized representatives. In addition, this handbook can be useful to regulatory authorities and certification bodies concerned with conformity to ISO 13485.

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1) In this handbook, the reference to ISO 13485 pertains to the third edition published in 2016 unless a different date is included in the reference.

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The guidance given in this handbook describes concepts and methods that can be considered by your organization to assist in the development, implementation and maintenance of your QMS and this can be applicable to the design, development, production, installation, servicing and post market surveillance of medical devices. This handbook has taken into consideration requirements and guidance contained in documents as listed in the bibliography from the following organizations:

- International Medical Device Regulators Forum (IMDRF) including those documents maintained from the disbanded Global Harmonization Task Force (GHTF);
- International Organization for Standardization (ISO);
- European Committees for Standardization (CEN and CENELEC);
- National regulatory bodies.

This handbook does not define any requirements nor add to or otherwise change the requirements of ISO 13485 and is intended to assist interested parties with the application of ISO 13485. The guidance contained in this handbook is intended for educational purposes and is not intended to be used to assess or audit compliance with regulatory requirements or to be used for identifying specific deficiencies of a QMS, unless the guidance is voluntarily incorporated into the documentation describing and supporting your organization's QMS, or unless such guidance is specifically made part of the regulatory requirements relevant to your organization's operation. It should be noted that this handbook does not set out to provide specific guidance with respect to generic QMS requirements which are common to both ISO 13485 and ISO 9001.

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Foreword

Quality Management Systems (QMS) — General comments

A QMS is the way your organization directs and controls those activities that are related, either directly or indirectly, to achieving its intended results. Broadly, it consists of your organization's structure together with the planning, processes, resources and documents or records that you use to achieve your quality objectives (such as meeting your customers' and applicable regulatory requirements, establishing and maintaining your QMS, or improving your product).

Generic QMS requirements are defined in ISO 9001 and are intended to be applicable to any organization, regardless of its type or size, or the product it provides. However, the requirements of ISO 13485 are intended to be applicable to any medical device organization regardless of size and activity as a basis for demonstrating and supporting compliance with applicable regulatory requirements. User should also be aware that ISO 13485 is based on the format of its previous edition (ISO 13485:2003) and ISO 9001:2008 and not the High Level Structure for Management System Standards as defined in ISO/IEC Directive, Part 1, Annex SL used for ISO 9001:2015. Annex B of ISO 13485 contains a table cross-referencing the clauses of ISO 13485 and ISO 9001:2015.

Further reference can be sought from ISO 9000:2015 *Quality management systems — Fundamentals and vocabulary*, including the fundamental concepts, the quality management principles, as well as the terms and definitions for quality management. Any differences in definitions of terms between ISO 9000 and ISO 13485 are contained in Clause 3 of ISO 13485.

When putting a QMS in place, a good understanding of the detailed requirements for a QMS is necessary. There are several sources for information that you can use (see the bibliography), in addition to this handbook. The standards and other references provided in this handbook could be used by your organization to meet the applicable regulatory requirements, but that is a decision your organization should make and this handbook does not outline any requirements to adopt conformity to any standard.

One fundamental concept that your organization has to understand is the concept of quality. From ISO 9000:2015, the quality of product includes not

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only their intended function as well as safety and performance, but also their perceived value and benefit to the customer. From the perspective of the medical device industry, this includes the therapeutic benefit to a patient.

In general, QMS standards should not be confused with product standards. While product standards give explicit requirements for a particular product, including service, QMS standards specify requirements for good management practices in order to have a high probability to achieve quality, but generally without referencing any particular type of product. ISO 13485 does provide requirements for identified types of product (e.g., requirements for sterile medical devices, implantable medical devices).

The use of product standards, QMS standards and quality improvement approaches are all means of improving your organization's ability to meet customer and applicable regulatory requirements or the competitiveness of your organization (recognizing that these are not exclusive of each other).

Implementation of a QMS should not result in excessive bureaucracy, paperwork, or lack of flexibility. Nor should your QMS be an unreasonable financial burden. Expenditures relating to implementing and maintaining a QMS should be considered an investment with a return on investment in the form of benefits and improvements. Every organization will already have a management structure and this should be the basis on which its QMS is built.

What is an ISO 13485 Quality Management System?

A QMS conforming with ISO 13485 requirements is a documented set of interrelated processes, including any forms or templates, that establish, implement, and maintain the provisions outlined in the requirements of the standard with the aim of meeting customer and applicable regulatory requirements for businesses operating in the medical device sector. These processes and their interactions are also subject to improvement as directed by top management to achieve quality objectives. The intent of the latest edition of ISO 13485 is not to impose new requirements on your organization, but to clarify existing requirements that were vague, confusing or implicit in nature to ensure common interpretation by all users. If your QMS already exists and is based on one of the older editions, it will need to be updated to ISO 13485. Whether

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you are implementing a new QMS or updating your existing QMS, the advice given in this handbook is relevant.

ISO 13485, Annex A provides some detailed commentary on the changes between the 2003 and 2016 editions. This annex is recommended reading prior to planning for transition as it will assist in the development of transition plans. However, the whole content of the respective clauses should be considered when determining what action is required and not just the topics listed in Annex A in order to ensure full compliance with the requirements.

Furthermore, ISO 13485, Annex B provides a correlation between ISO 13485 and ISO 9001:2015. This will be of particular use and benefit to your organization if it currently holds dual certification to both ISO 9001 and ISO 13485 and you wish to continue to hold dual certification. See the guidance on Clause 0.4 for additional information.

Why have a quality management system (QMS)?

The adoption of a QMS is a strategic decision that guides your organization to improve its overall performance and to provide a sound basis for its sustainable development initiatives. Clause 0.1 of ISO 13485 lists several reasons for having a QMS.

Many organizations implement a formal QMS after finding that their customers in both the private and public sectors want assurance that the product they intend to purchase will meet their requirements for quality. Those customers are looking for the confidence that can be provided by an organization offering product produced under a suitable, adequate and effective QMS, such as one conforming to ISO 13485.

For medical device organizations, compliance with ISO 13485 can support conformity assessment options that are used in different regulatory jurisdictions.

A QMS on its own will not necessarily lead to an improvement of work processes or to improvements of your product. It won't solve all your problems. It is a means for you to take a systematic approach to fulfilling your organization's objectives, which in turn should achieve such improvements.

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ISO 13485 contains requirements for improvement, using feedback from sources such as complaint handling, post market surveillance, handling of nonconformities, corrective actions and preventive actions. You use these processes to ensure that worthwhile and cost effective improvements are being achieved.

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Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support). The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this International Standard or can be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this International Standard expects that the organization:

— identifies its role(s) under applicable regulatory requirements;
— identifies the regulatory requirements that apply to its activities under these roles;
— incorporates these applicable regulatory requirements within its quality management system.

The definitions in applicable regulatory requirements differ from nation to nation and region to region. The organization needs to understand how the definitions in this International Standard will be interpreted in light of regulatory definitions in the jurisdictions in which the medical devices are made available.

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This International Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by the:

a) organizational environment, changes in that environment, and the influence that the organizational environment has on the conformity of the medical devices;
b) organization's varying needs;
c) organization's particular objectives;
d) product the organization provides;
e) processes the organization employs;
f) organization's size and organizational structure;
g) regulatory requirements applicable to the organization's activities.

It is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, uniformity of documentation or alignment of documentation to the clause structure of this International Standard.

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.

Intent

This section provides understanding that ISO 13485 specifies the QMS requirements for medical devices for regulatory purposes.

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Guidance

The way you run your organization is unique. ISO 13485 gives you a framework for good management practice that you can apply to your organization. The standard specifies requirements for a QMS that has been recognized as being aligned with internationally accepted good practice for running an organization with responsibilities in the lifecycle or supply chain for medical devices.

This section describes a set of points that can be addressed in your QMS, but does not say how you do them. Furthermore, this section indicates that you do not need to align your documentation with the clause structure of the standard. Hence, there is considerable freedom in meeting the requirements of the standard.

ISO 13485 specifies the QMS requirements for medical devices for regulatory purposes. Customers could make certification to ISO 13485 a requirement for you to do business with them. A QMS aims to give confidence to your customers that your organization can deliver a product or service that conforms to requirements. It requires you to prove your ability to meet both your customers' requirements and any associated regulatory requirements.

You can decide to have your QMS assessed for certification. While this is not mandatory or required by the standard, it could be a regulatory requirement in some jurisdictions. Your organization will still benefit from the implementation and maintenance of a suitable, adequate and effective QMS, regardless of whether or not assessment or certification by a third party is a regulatory requirement.

Medical device organizations included within the scope of ISO 13485 could consider the adoption of other management systems (e.g., ISO 14001 — Environmental Management System, ISO 27001 Information Security Management System or others). Since there are no requirements for your organization to conform the structure of its QMS to the structure of any management system standard and there is no direct conflict of requirements, your organization can integrate these systems without compromising conformity.

The scope of the edition explicitly covers areas of business including supply chain/distribution and other activities throughout the lifecycle of the medical device.

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When judging the applicability of the guidance in this handbook, you 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.

0.2 Clarification of concepts

In this International Standard, the following terms or phrases are used in the context described below.

- When a requirement is qualified by the phrase "as appropriate", it is deemed to be appropriate unless the organization can justify otherwise. A requirement is considered appropriate if it is necessary for:
  - product to meet requirements;
  - compliance with applicable regulatory requirements;
  - the organization to carry out corrective action;
  - the organization to manage risks.
- When the term "risk" is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.
- When a requirement is required to be "documented", it is also required to be established, implemented and maintained.
- When the term "product" is used, it can also mean "service". Product applies to output that is intended for, or required by, a customer, or any intended output resulting from a product realization process.
- When the term "regulatory requirements" is used, it encompasses requirements contained in any law applicable to the user of this International Standard (e.g. statutes, regulations, ordinances or directives). The application of the term "regulatory requirements" is limited to requirements for the quality management system and the safety or performance of the medical device.

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In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;
— "should" indicates a recommendation;
— "may" indicates a permission;
— "can" indicates a possibility or a capability.

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

Intent

This section provides understanding of the concepts that have been adopted throughout ISO 13485. This understanding, together with correct interpretation, helps you apply the requirements in the standard correctly.

Guidance

Risk — Throughout ISO 13485 the use of the term risk is in the context of the safety and performance of the medical device and meeting applicable regulatory requirements. It is not to be confused with financial risks or risks to business performance. The revisions in this edition incorporate the concept of risk-based approaches to establish, implement, maintain and improve the QMS. The risks to the effective and compliant operation of the QMS should be understood. In identifying risks and opportunities, your organization should focus on preventing or reducing undesired effects through risk reduction or preventive actions. This risk-based approach should apply to all processes required for your QMS.

Services — The term product can include services. This is important as the standard now explicitly allows organizations, such as distributors, authorized agents, and providers of sterilization services, to apply the requirements in a similar way as the medical device manufacturers. These organizations do not produce a product but provide services important in the life-cycle or supply chain of medical devices.

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Notes — Throughout the standard and in this handbook the reader will see additional guidance in the format of a NOTE. There can be confusion that these notes provide the solution to a requirement and therefore are required to be used or met. It is important to understand that a NOTE cannot contain requirements. They are only for additional information and guidance to help the user. The notes in ISO 13485 are intended to provide clarification or information that can be helpful to understand a requirement but are not a requirement. Notes can also contain reference to the informative references given in the Bibliography to ISO 13485 that are repeated in the Bibliography to this handbook together with additional informative references referred to in this handbook. One other clarification is that the notes within the definitions (Note to entry) are different than the NOTE within the text of the standard as the note to entry is intended to modify the definition for clarity.

0.3 Process approach

This International Standard is based on a process approach to quality management. Any activity that receives input and converts it to output can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it needs to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach."

When used within a quality management system, such an approach emphasizes the importance of:

a) understanding and meeting requirements;
b) considering processes in terms of added value;
c) obtaining results of process performance and effectiveness;
d) improving processes based on objective measurement.

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Intent

This section outlines the use of the process approach within your QMS.

Guidance

The ISO 13485 QMS is process based. The processes described in the standard should not be treated as stand-alone processes. The processes interact and overlap. Together they define a system that ensures product is in conformity and that any deficiencies are addressed in an adequate manner. For this reason, it is essential that any quality considerations are made bearing in mind the various contributions of the relevant processes. A checklist approach to assessing the adequacy, suitability and effectiveness of your QMS should be avoided as this often introduces a bias towards a given process and leads to overlooking of the process interactions and other related processes. For example, some (but not all) of the expectations of the QMS are for:

- the requirements (organization, customer, QMS, regulatory) to be implemented into controlled documents,
- personnel to be assigned to carry out tasks as defined by these documents,
- competent personnel to be trained to follow these documents,
- personnel to follow these documents and to maintain records demonstrating compliance with the documented requirements,
- personnel to use appropriate equipment (calibrated, maintained, approved) and materials (identified, verified, of known status),
- processes and product to be appropriately monitored/measured or validated, and
- any nonconformities (whether identified through customer complaint, production, internal/external audit or other processes) to be appropriately investigated and handled through application of corrective actions.

A process can be seen as a set of related activities carried out step-by-step following a logical sequence that allows you or your organization to achieve a desired result. The desired result is good/high quality product that conforms to the customer's specified requirements. The model of a process based QMS is presented in ISO 13485, Clauses 4 to 8. Customers and regulatory authorities play a significant role in defining requirements as inputs. Monitoring of

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customer feedback requires the evaluation of information relating to whether your 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 13485 promotes the adoption of a process approach to identify and manage linked processes when developing, implementing and improving the suitability, adequacy and effectiveness of a QMS with the objective of providing medical devices that meet customer and regulatory requirements.

An effective organization 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 (see Figure 1).

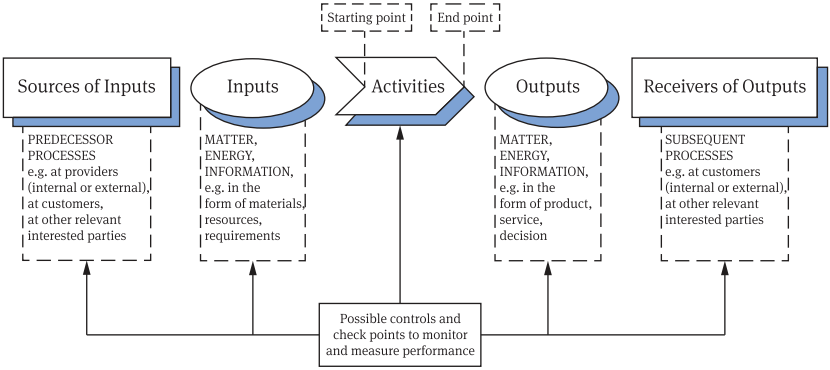

Figure 1 — Schematic representation of the elements of a single process (This figure is taken from ISO 9001:2015)

ISO 13485 employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based approach. The process approach enables your organization to plan its processes and their interactions. The PDCA cycle enables your organization to ensure that its processes are adequately resourced and managed, and that opportunity for improvement is determined and acted on. A risk-based approach enables your organization to determine

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the factors that could cause its processes and its QMS to deviate from the planned results and to put in place preventive measures to minimize negative effects.

The PDCA cycle can be applied to all processes and to the QMS as a whole. The PDCA cycle can be briefly described as follows:

- **Plan**: establish the objectives of the system and its processes; the resources needed to deliver results in accordance with customers' requirements; your organization's policies; and identify and address risks and opportunities.
- **Do**: implement what was planned.
- **Check**: monitor and (where applicable) measure processes and the resulting product against policies, objectives, requirements and planned activities, and report the results.
- **Act**: take actions to maintain and improve performance, as necessary.

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.

As used within a QMS, the process 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.

To conform to the requirements of ISO 13485, your organization needs to plan and implement actions to address risks. Addressing risks establishes a basis for increasing the suitability, adequacy and effectiveness of the QMS, achieving improved results and preventing negative effects. A risk-based approach is essential for achieving a suitable, adequate and effective QMS. The concept of a risk-based approach has been implicit in previous editions of ISO 13485 including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action that is appropriate for the effects of the nonconformity to prevent recurrence.

A deviation from the expected results can be the consequence of changes in the operational environment, lack of information, unknown information or

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a variety of aspects. The identification of these aspects and their effects on the performance of your organization, and the actions that can be identified to avoid or reduce the effect or the likelihood of occurrence, is important for being able to plan properly.

0.4 Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001:2008, which has been superseded by ISO 9001:2015. For the convenience of users, Annex B shows the correspondence between this International Standard and ISO 9001:2015.

This International Standard is intended to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device. This International Standard includes some particular requirements for organizations involved in the life-cycle of 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 system meets all the requirements of ISO 9001.

Intent

This section provides guidance on the compatibility of ISO 13485 with ISO 9001.

Guidance

ISO 9001 is the generic QMS standard upon which all other management system standards are based and incorporates modern quality management principles and practices. It does not provide specific requirements needed for regulatory purposes in the medical device sector. Guidance on ISO 9001 can be found, for example, in the ISO brochures, *ISO 9001 for Small Businesses —*

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What to do, and in *ISO 9000 Introduction and Package module* and on the ISO/TC 176/SC 2 public website: http://isotc.iso.org/livelink/livelink/open/tc176SC2public.

ISO 13485 has been written specifically to support regulatory requirements related to QMS relevant to industries involved in the provision of medical devices.

Both ISO 13485 and ISO 9001 have been written to be complimentary and not in conflict. However, the requirements of ISO 13485 are focused to support regulatory compliance in the medical devices sector and therefore contain specific requirements that cannot be met by ISO 9001 compliance alone. On the other hand, ISO 9001 includes some explicit requirements, such as those for continual improvement and for customer satisfaction, that were deemed not to be required for medical device regulatory purposes and that are, therefore, not included in ISO 13485.

To help you to correlate the requirements of the two standards, Annex B in ISO 13485 provides a correspondence of ISO 13485 and ISO 9001 and vice versa. This can help you integrate your ISO 13485 QMS with ISO 9001 or other management systems. This approach could be particularly relevant if you seek to operate under dual certification (i.e. ISO 13485 and ISO 9001).

0.5 Compatibility with other management systems

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.

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Intent

This section provides an outline of the relationship to other management system standards to outline the ability to meet the requirements of each in a common system.

Guidance

The relationship to ISO 9001 is outlined in the previous section. There are other sector-specific management system standards based on the requirements of the ISO 9000 series developed for a number of industries or sectors. Some of these standards specify QMS requirements, while others are limited to providing guidance to the application of the International Standard within the particular sector.

ISO 13485 was designed and written to be compatible with other management system standards. Examples of other management system standards are ISO/IEC 27001— Information Security Management and ISO 14001 — Environmental Management, where:

- ISO/IEC 27001:2013 specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system within the context of an organization. It also includes requirements for the assessment and treatment of information security risks tailored to the needs of that organization. The requirements set out in ISO/IEC 27001:2013 are generic and are intended to be applicable to all organizations, regardless of type, size or nature.
- ISO 14001 and its supporting standards such as ISO 14006 focus on environmental management systems. The other standards in this family focus on specific approaches such as audits, communications, labelling and life-cycle analysis, as well as environmental challenges such as climate change.

This handbook only provides guidance on the application of ISO 13485 and your organization will need to ensure you follow the requirements outlined in other management system standards if you choose to conform with them.

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1 Scope

Quality management systems — Requirements

1 Scope

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 and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product including quality management system-related services to such organizations.

Requirements of this International Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this International Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

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If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of this International Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.

Intent

The Scope explains the purpose of the standard. ISO 13485 establishes the QMS requirements to be met by your organization if you are involved with medical device provision. The requirements are not specific to types of product and focus attention on the ability of your organization to consistently provide product that meets customer and applicable regulatory requirements.

Guidance

The Scope highlights the responsibility of your organization whether the activity is conducted by you or by a third party on your behalf; therefore, relationships with external parties undertaking activities for your organization need to be managed accordingly. The scope of ISO 13485 has been explicitly clarified to allow it to be used by parties other than manufacturers such as those involved in the supply chain or delivering services. ISO 13485 is applicable to all organizations involved in the product life-cycle of a medical device, regardless of their type, size, or the product they provide.

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The Scope indicates the potential for exclusion or non-application of activities that are not included within the scope of the QMS due to your organization's role. It is important that your organization identify, justify and record any such exclusion or non-application of requirements.

Certain product realization requirements of ISO 13485 can legitimately be omitted in one of two ways: they can be excluded, or they might be not applicable. It is important to note, however, that any exclusion or non-applicability should be detailed and justified in your organization's quality manual or another appropriate quality management system document.

- **Exclusions**
  In some jurisdictions, regulatory requirements permit organizations to place certain medical devices on the market without having to demonstrate conformance with design and development controls (see ISO 13485, 7.3). The exclusion of requirements of 7.3 should be determined on a product-by-product and market-by-market basis.

  For example, a regulation may allow a medical device to be designed and developed without conforming with the QMS requirements for design and development, based on the class of the medical device (e.g. low risk medical devices), or provided the medical device undergoes a specific conformity assessment procedure (e.g. type examination).

  It is important to note that even if your organization is permitted by regulations to exclude the requirements of 7.3, it still has the obligations to meet product realization requirements of clauses 7.2, 7.4, 7.5 and 7.6. Furthermore, outsourcing a process does not provide a justification for excluding it from your QMS. When several regulations apply to you and one of these regulations does not allow exclusion of design and development from the scope of the QMS for your medical device, 7.3 cannot be excluded.

- **Non-applicability**
  ISO 13485 provides for your organization to omit from its QMS those requirements that are not applicable due to the role of your organization or nature of your product. It is important for you to review carefully all the requirements in Clauses 6, 7 and 8 to identify those requirements that do not

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apply to activities performed by your organization or are not applicable to your product.

For example, if you only provide single-use sterile medical devices that do not require installation or servicing, you would not need to include within your QMS the requirements related to 7.5.3 and 7.5.4. Similarly, if your device is not intended to be implanted, 7.5.9.2 does not apply.

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2 Normative references

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*

Intent

This section identifies that ISO 9000 provides the terminology used by ISO 13485 unless otherwise defined in Clause 3 of ISO 13485.

Guidance

ISO 13485 has only one normative reference and that is ISO 9000:2015. The use of ISO 9000 is integral to ISO 13485. See the guidance in section 3 for a hierarchy of the use of terms and definitions. It could be necessary for you to refer to this document to understand and apply ISO 13485.

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3 Terms and definitions

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply.

Intent

This section indicates that the terms and definitions given in ISO 9000:2015 and ISO 13485 apply.

Guidance

This section defines the terms and definitions used by ISO 13485. In implementing your QMS, you should aim, wherever possible, to apply the terminology (or equivalent) defined in the applicable regulatory requirement, ISO 13485, and ISO 9000:2015. It is necessary to be aware that some definitions provided in ISO 13485 differ from the definition in ISO 9000 due to their application in the medical device sector (e.g., complaint, product and risk). If no definition is provided in either ISO 9000:2015 or ISO 13485, the appropriate dictionary definition applies. This establishes a hierarchy of how to understand a term or definition as used in the context of ISO 13485:

1) as provided by applicable regulatory requirement,
2) as provided in the definitions provided in ISO 13485,
3) as provided in ISO 9000:2015,
4) as provided in a standard dictionary.

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The ISO 9000 family of standards and ISO 13485 use generic terms to describe the relationship between the parties involved. You should think of yourself as the organization in this standard. In practice, any small, medium or large enterprise or business is an organization. It is understood that small or medium sized enterprises or businesses might not see themselves as an organization and often perceive an organization as something bigger. The reference to organization in this handbook is a general reference to the entity regardless of size. An organization includes everything defined within the scope of your organization's quality manual. Generally, external providers are people or organizations you receive product from, and customers are people or organizations who receive product from you. Your organization can, at the same time, be the external provider of product to another organization as well as the customer receiving product from a different organization

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4 Quality management system

4.1 General requirements

4.1.1 The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.

The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements.

The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.

NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.

Intent

This section presents the general framework of the QMS and the way that it is controlled. This section gives the essential instruction that your organization has to understand its role under the regulatory requirements applicable to it and that it needs to establish, implement and maintain any aspect applicable to the role that it documents in its QMS.

The need to establish, implement and maintain the documented QMS has become normative and allowed the text throughout the rest of the standard to be simplified to identify what has to be documented without repetition of 'establish, implement and maintain' in each location.

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The requirement to document the role of your organization under the applicable regulatory requirements had been added.

Guidance

One of the purposes of the QMS is to bring together regulatory requirements from a variety of jurisdictions into a single systematic approach that allows your organization to conform with these varied requirements. Being able to do this successfully depends on your organization having a clear definition of what activities it undertakes in the context of applicable regulatory requirements. Therefore, an important aspect for your organization is to define and document the role that it undertakes in the context of the lifecycle or supply chain of the product and regulatory requirements that apply. These regulatory requirements might take a number of legal forms including regulations, statutes, statutory instruments, directives or ordinances. Examples of regulatory requirements include the United States of America Quality System Regulation, Canadian Medical Device Regulations, and the European Medical Device Directives/Regulations.

Your organization can take one or more roles from a variety of different roles to which regulatory requirements apply in different jurisdictions, and the regulatory requirements for these roles can differ from one jurisdiction to another. Examples of roles include:

- manufacturer;
- specification developer;
- supplier of raw materials, components or subassemblies;
- contract manufacturer;
- provider of packaging, sterilization or logistics services;
- service provider for calibration of measuring devices;
- importer;
- distributor;
- authorized representative.

You need to establish, implement and maintain an effective QMS that is designed to enable you to provide medical devices that meet customer and regulatory requirements and that are safe and perform as intended. To establish such a QMS, you need to identify any relevant requirements and decide on the

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procedures, activities and arrangements that need to be in place to ensure these requirements are met. Once identified, these need to be documented, clearly describing what is to be done, who is to do it, the expected results/outcomes and how these will be monitored. The documented requirements should be clearly defined so that people in your organization can understand them and use them. The requirements to be considered include the regulatory requirements that apply to your organization (e.g. those required by medical device regulations as well as other requirements such as health and safety, environmental protection, device-related electrical safety, pressure vessel safety), customer requirements, your own requirements, and so on. Once the QMS is established and documented, ISO 13485 requires that the requirements documented in your own policies, procedures and work instructions are implemented and are managed so that they continue to be applicable as your organization undergoes internal and external changes. One important aspect of this implementation is training of your staff in their responsibilities and demonstrating they have the competence to undertake the activities assigned to them (see 6.2). Maintaining the suitability, adequacy and effectiveness of the QMS in its ability to meet customer and regulatory requirements will typically involve your organization responding effectively to external factors and internal issues.

External factors can include:

- changes in regulatory requirements;
- customer feedback, including complaints and adverse event reports, and the results of post-market surveillance;
- innovation and technical developments such as new technologies, materials and equipment, patent expirations.

Internal issues can include:

- overall performance of your organization;
- business decision such as mergers and acquisitions, new product introductions, new business models;
- resource factors, including facilities, environment for the operation of the processes, manufacturing processes and equipment, including related software;
- human aspects such as competence of persons, including enhancing people skills and introducing new competence requirements, organizational culture, changes in key personnel;

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- operational factors such as process, production or delivery capabilities, performance of the QMS including software related to the QMS, customer evaluation;
- factors in the governance of your organization, such as rules and procedures for decision making or organizational structure;
- performance of product.

Your organization can maintain the suitability, adequacy and effectiveness of its established QMS through a range of activities. Examples of activities to maintain a QMS include:

- defining and promoting processes which lead to achieving regulatory compliance;
- acquiring and using process data and information on a continuing basis;
- determining and deploying resources, including human and information system resources;
- directing necessary changes to the QMS;
- responding to feedback;
- initiating corrective actions and preventive actions;
- receiving and responding to independent external assessments;
- using suitable evaluation methods such as internal audits and management reviews.

4.1.2 The organization shall:

a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization;
b) apply a risk based approach to the control of the appropriate processes needed for the quality management system;
c) determine the sequence and interaction of these processes.

Intent

This section establishes the use of the process approach and that your organization's QMS consists of interrelated processes that depend on what activities

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your organization undertakes, how your organization operates and the regulatory requirements that apply to your activities.

The explicit requirement for application of a risk-based approach in establishing, implementing and maintaining the QMS is new in this edition of ISO 13485.

Guidance

Bearing in mind the roles being undertaken by your organization, you need to determine the necessary processes, where they are to be used and by whom, the sequence in which they are to be used and how they interact with other processes. The level of control of these processes needs to be risk-based. The risks to the effective and compliant operation of the QMS that need to be addressed should be determined. In identifying risks, your organization should focus on preventing or reducing undesired effects through risk reduction or preventive actions. This is adopting a risk-based approach and your organization should apply this approach to all processes required for its QMS. Where the scope of your organization's QMS covers part of the lifecycle of the medical device, the considerations of risk apply to the processes that your organization undertakes. Throughout ISO 13485, the use of risk is in the context of the safety and performance of the medical device and meeting regulatory requirements and not financial risks or risks to business performance. ISO 13485:2003 required risk management throughout product realization. This requirement has been retained in ISO 13485 (see Clause 7.1).

In addition, 4.1.2 requires that the risk-based approach is also applied to and within the appropriate processes in your QMS. These processes need to be identified by you and be managed through your risk-based controls. The focus is on implementing a risk-based approach within those processes where failure could lead directly or indirectly to product that is unsafe or does not perform as intended with a secondary emphasis on meeting regulatory requirements. There is no requirement in ISO 13485 to use formal risk management in the identification of risks within the QMS processes themselves, but it is the implementation of a risk-based approach within the processes that is outlined. Your organization can choose the method or methods that suits its needs. At the strategic level tools such as Strengths, Weaknesses, Opportunities

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and Threats analysis (SWOT) and Porter's 5 Forces industrial analysis can be used. A simple approach can include asking "what if" questions. Application of Brainstorming techniques can be used as one of the effective tools for application of risk-based approach. Some techniques can be more popular for more detailed analysis, e.g. Failure, Mode and Effects Analysis (FMEA); Failure, Mode, Effects and Criticality Analysis (FMECA); Hazard, Analysis and Critical Control Points (HACCP); some root cause and decision analysis tools such as Fault-tree analysis (FTA) and 5-Whys can also be helpful. You should decide which methods or tools you will use and then establish, implement and maintain the necessary documented requirements for their use. When addressing risks, your organization should use a risk-based approach to establish, implement, maintain and improve the QMS and its associated processes, to:

- decide how risk is addressed in the design and development of product and processes to ensure the safety and performance of the medical device, improve process outputs and prevent undesirable results;
- improve the effectiveness of the QMS;
- maintain and manage a system that inherently addresses risk and delivers objectives.

An example of such an approach could be as follows: Your organization decides to review your QMS to improve or verify compliance. As a start, you apply a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis to each QMS process identifying areas of needed improvement. The identification of an area of improvement in the QMS process then triggers use of a more detailed analysis such as a Hazard, Analysis and Critical Control Points (HACCP) approach. This detailed analysis is then used to provide the information necessary to create a strong project plan for improvement to address identified weaknesses.

Particular sections in ISO 13485 specify risk considerations that need to be addressed in the appropriate processes within the QMS, for example the:

- method to determine the effectiveness of training of personnel (6.2);
- method of selection and monitoring of suppliers (7.4.1);
- extent of verification of purchased product (7.4.3);
- extent of validation, including validation of software (4.1.6, 7.5.6, 7.6).

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Additional examples of the application of the risk-based approach where ISO 13485 does not specifically outline risk considerations:

- interval for management review (5.6);
- control of production and service (7.5.1);
- disposition of nonconforming product and nature of correction necessary (8.3);
- determination of actions to prevent occurrence or recurrence of nonconformities (8.5.2, 8.5.3).

Having identified the risks that can affect the QMS, your organization should plan actions to address them. The determined actions need to be incorporated into the processes of the QMS and the effectiveness of the actions evaluated. These actions can include, for example, establishing appropriate controls for the existing processes of the QMS. The extent to which a process needs to be detailed depends on the complexity and stability of the activities that constitute the process:

- Simple processes might require only simple explanations.
- Complex processes will require sufficient explanation to enable your people to understand the activities and tasks, and the inter-relationships, to the extent necessary to implement their roles effectively.

There are many actions that your organization can take to address risk and these are often covered by requirements in ISO 13485. For example:

- defining responsibilities and authorities;
- implementing inspection or other monitoring and measuring of processes and product;
- implementing process validation;
- calibrating measuring and monitoring devices;
- implementing product and process design and development;
- implementing corrective actions, and making sure that these are extended to other relevant areas of your organization;
- documenting specified methods and work instructions;
- identifying training needs, implementing training and assigning competent persons.

While ISO 13485 does not require formal risk management in identification of risk at the QMS level, 7.1 requires you to document a process or series of

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processes for risk management in product realization. This relates to risk management in regards to the safety and performance of the medical device from design and development through post-production activities. ISO 14971 provides specific information on product risk management for medical devices. The Global Harmonization Task Force (GHTF) has also published guidance on implementation of risk management principles and activities within a QMS (GHTF/SG3/N15R8) that provides information on risk management in product realization.

4.1.3 For each quality management system process, the organization shall:

a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes;
d) monitor, measure as appropriate, and analyse these processes;
e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).

Intent

This section sets out the requirements for the processes of the QMS, how they are implemented and the evidence of conformity that is retained.

Guidance

Having identified the processes needed for the QMS, and the risks associated with each process, your organization can look in detail at the processes. There are some essential elements that need to be addressed for each process. These can be addressed by considering the following example questions:

- How will your organization know whether the process is effective?

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- What does it need to do to make sure that the process is operating effectively?
- What controls are necessary to monitor the process?
- How will your organization know that the controls on the process are effective?
- What human and physical resources are needed for the operation and control of the process?
- Who is responsible for the process and what competence requirements are there for the position(s)?
- What information is needed to effectively implement and control the process?
- Are the controls on the process covering all the requirements identified in the planning activities?
- How will the outputs of monitoring of the process be analysed?

4.1.4 The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be:

a) evaluated for their impact on the quality management system;
b) evaluated for their impact on the medical devices produced under this quality management system;
c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.

Intent

This section establishes requirements to maintain control of the QMS and the medical devices that are outputs of your organization whenever changes are made.

This requirement to manage changes in the QMS is now explicitly stated as a requirement.

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Guidance

The processes in the QMS need to be managed to demonstrate that they continue to be effective in meeting customer and regulatory requirements as well as the objectives of your organization. One important element of managing the process is dealing with change. When the need for change to the QMS is identified, it needs to be assessed prior to implementation to ensure that the change does not disrupt the effective operation of the QMS or have an undesired consequence. In particular, your organization has to consider whether the change affects the safety or performance of the medical device(s) that are produced under the control of that QMS or affects compliance with regulatory requirements.

ISO 13485 includes a number of specific requirements for elements of change, including:

- Change to documents (4.2.4);
- Making changes to records (4.2.5);
- Planning changes to the QMS (5.4.2);
- Top management responsibility for change management including inclusion in management review (5.4.2; 5.6.1);
- Changed/new regulatory requirements (5.6.3);
- Change to customer requirements (7.2.2);
- Design and development changes (7.3.9);
- Changes in purchased product (7.4);
- Validation of changes (7.5.6, 7.5.7);
- Identification of need for change (8.5.1).

Depending on applicable regulatory requirements and the significance of the change, you could be required to report the change (see 7.2.3).

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4.1.5 When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.

Intent

This section defines the principle that your organization retains responsibility for processes that an external party undertakes on your organization's behalf and requirements to implement controls on these external parties.

The explicit reference to risk-based controls of outsourced processes and the need to have documented agreements with external parties providing such processes has been added to this edition of the standard.

Guidance

Outsourcing is the use of an external provider to undertake an activity on behalf of your organization. Outsourcing is a strategic decision of your organization and implies a deeper relationship between the two parties than a straightforward supplier-customer purchasing interaction of placing an order and receiving materials. In deciding whether an activity is outsourced, consideration is given to the breadth of the responsibility of the external provider. For example, a decision to have an external party perform the entire design and development of a new medical device, do all the manufacturing processes for a medical device or provide calibration services for an entire facility implies a deeper relationship than a supplier preparing some drawings for design and development, executing one manufacturing step or calibrating a single off-the-shelf piece of equipment. Examples of activities that your organization

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could decide to arrange to be provided by an external party to an extent that could constitute outsourcing include:

- human resources,
- customer interfaces such as call centres,
- logistics,
- manufacturing,
- sterilization,
- design and development,
- calibration,
- maintenance,
- servicing,
- installation,
- auditing.

The relationship with the external provider of outsourced activities is managed through a written quality agreement and in accordance with the purchasing controls specified in 7.4, with the level of control being determined based on the risk of the activity on the safety and performance of the medical device and the contribution of the activity to regulatory compliance. Outsourcing does not remove your organization's responsibility for the activity being outsourced and your organization has to maintain the necessary oversight to make sure that the activity is undertaken in accordance with the agreed requirements. For this reason, ISO 13485 requires that there is a written quality agreement that defines the responsibilities of each party. Quality agreements can be in various forms including information provided on purchase orders or attachments to purchase orders (e.g., terms and conditions, specifications, drawings, other documented information about quality requirements or roles and responsibilities) or a formal documented separate quality agreement. Quality agreements should be terms that both parties approve and agree to depending on the outsourced activity and the risks of those activities. These agreements would usually allow your organization access to review activities and data on performance of the external provider and provide agreement on meeting applicable regulatory requirements.

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4.1.6 The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

Records of such activities shall be maintained (see 4.2.5).

Intent

This new section makes explicit that the application of computer software used in the QMS has to be validated, consistent with product software, process control software and software used for monitoring and measurement.

Guidance

The validation of software is covered in different parts of ISO 13485 depending on the use to which the software will be put (e.g., for processes in the QMS, as an element of the product or as the product itself, for the control of production or service provision, or for monitoring and measurement). Throughout the standard, the requirements for validation of the application of computer software are consistent irrespective of the use.

For guidance on validation of the application of software used in your QMS, you can find additional information in ISO/TR 80002-2.

Computer software can be used to implement, monitor, measure or analyze the QMS. Software applications can be used for design and development of product, testing, production, labelling, distribution, inventory control, document management, data management, complaint handling, equipment calibration and maintenance, corrective action or preventive action.

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This section addresses software used in the QMS itself, such as:

- an element of enterprise resource planning (ERP) platforms;
- managing documents and records;
- computer aided design (CAD);
- managing product lifecycle activities from initial conception to final decommissioning and disposal;
- managing projects;
- managing information from automated production/inspection processes;
- managing and recording complaints, nonconformities, corrective actions or preventive actions;
- managing and recording internal audits;
- managing actions arising from external audits;
- managing calibration of measuring equipment;
- managing maintenance activities; or
- analyzing data on the performance of the QMS.

The important aspects of validation of software in this context are demonstrating the way that the software is used (its application) is suitable and that the outcome meets the requirements. For example, a spreadsheet might be programmed to perform specific calculations when data is entered as part of data analysis; the results of the calculations need to be verified and the spreadsheet protected from inadvertent changes.

The following are not normally considered to be the subject of this clause:

- Software used by your organization but is not related to the conformity to the QMS or product requirements, or compliance with the applicable regulatory requirements for medical devices, e.g. software used for accounting.
- Software used for clerical works that do not affect quality, performance or safety of medical devices e.g., word processor software.

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4.2 Documentation requirements

4.2.1 General

The quality management system documentation (see 4.2.4) shall include:

a) documented statements of a quality policy and quality objectives;
b) a quality manual;
c) documented procedures and records required by this International Standard;
d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;
e) other documentation specified by applicable regulatory requirements.

Intent

This section describes the documentation required for the QMS.

Guidance

Documented QMS procedures are required by ISO 13485. It is important to recognize that the structure and level of detail required in these procedures should be tailored to the needs of your organization.

The documentation can be in any form or type of medium as defined by your organization.

The extent of the QMS documentation can differ from one organization to another due to

- the size of your organization;
- the type of activities undertaken;
- the complexity of processes and their interactions;
- the skills and qualifications of the personnel performing the activities in question (see also 6.2.2); and
- other risks to be mitigated.

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Procedures or instructions can be presented in text, graphic or audio-visual form. Frequently a simple set of pictures can convey the requirements more accurately than a lengthy detailed description.

Documented procedures, including work instructions and flowcharts, should be stated simply, unambiguously and understandably, and should indicate methods to be used and criteria to be satisfied. These procedures typically define activities and describe:

- what is to be done, and by whom,
- when, where and how it is to be done,
- what materials, equipment and documents are to be used,
- how an activity is to be monitored and measured, and
- what records are required.

Documentation should be evaluated with respect to the effectiveness of the QMS against criteria, such as:

- fitness for purpose,
- ease of understanding and use,
- resources required,
- quality policy and objectives, and
- interfaces used by your organization's customers and suppliers.

Regulatory requirements can specify processes that have to be described in documented procedures or the use of particular types of medium for documents, for example as part or all of the medical device file (see 4.2.3), activities such as the conduct of clinical evaluations (see 7.3.7) or review of post market experience (8.2.1). The documents that need to be generated to meet specific regulatory requirements, the documents required by ISO 13485 and those determined by your organization as necessary for the effective control of their activities together with the associated records, form the QMS documentation and are subject to the requirements for control of documents, including records, in 4.2.4 and 4.2.5.

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4.2.2 Quality manual

The organization shall document a quality manual that includes:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application;
b) the documented procedures for the quality management system, or reference to them;
c) a description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

Intent

This section defines the elements that have to be included in your organization's Quality Manual.

Guidance

The Quality Manual is a specific QMS document that provides an overview of your organization, your QMS and the processes that make up your QMS. Additional information relating to quality manuals is available in ISO/TR 10013.

The scope of the QMS, as defined in the Quality Manual, is likely to be influenced by the role or roles that your organization has under the regulatory requirements that apply to it (see also 4.1.1). In particular, the role that your organization takes will influence whether there are exclusions or non-applicability from the requirements of the standard; you will need to document any such exclusion or non-applicability in the Quality Manual and an appropriate rationale could be provided by the role of your organization and the activities that it undertakes. The scope of the QMS should also define the locations covered by the QMS together with the processes or activities that are undertaken at each location, if your organization has QMS activities undertaken at different locations.

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4.2.3 Medical device file

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;
b) specifications for product;
c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;
d) procedures for measuring and monitoring;
e) as appropriate, requirements for installation;
f) as appropriate, procedures for servicing.

Intent

This section provides a general outline of the documents that are needed to meet the regulatory requirements for medical devices. The inclusion of a separate numbered subclause and the detail in points a) to f) are additions to this edition of ISO 13485.

Guidance

The file for each type or model of medical device referred to in ISO 13485, 4.2.3 is sometimes referred to by different names, for example, technical file or device master file. This file can contain, or give reference to, documentation relevant to the design and development, and manufacture of that product to meet applicable regulatory requirements.

Medical device files are the roadmap showing how the product is supported by the QMS. Therefore, the content of medical device files needs to be controlled in

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