a practical guide

ISO 13485:2016

Medical devices

Advice from ISO/TC 210

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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.

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).

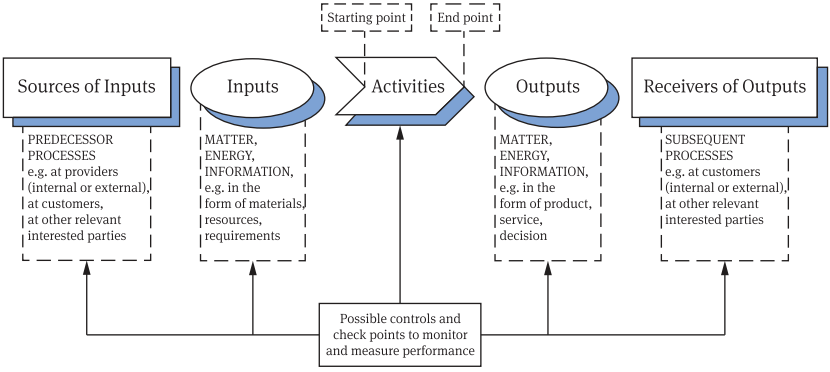

Figure 1 — Schematic representation of the elements of a single process (This figure is taken from ISO 9001:2015)

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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the same way as any other document, which means that they need to be kept up to date and archived versions of the document need to be retained for the required record retention period. The medical device files can contain whole documents, authorized copies of documents or be maintained as an index of relevant documents and records that are available elsewhere in the QMS.

Specific parts of the medical device file are often requested to be provided by the regulatory authorities or bodies in various jurisdictions as part of market clearance. The specific content of the file will be driven by the particular regulatory requirements of the applicable jurisdiction. The content of this file can include, but is not limited to:

- General description of the medical device and, as appropriate, the device classification and variants planned.
- Product specifications including drawings, composition, formulation, component specifications and medical device software specifications.
- Production process procedures, including equipment specifications, production methods, any special processing and infrastructure requirements.
- Quality assurance procedures and specifications including acceptance criteria and measuring equipment to be used.
- Packaging specifications, including methods and processes.
- Description of intended use/purpose.
- Design outputs used to fulfil appropriate regulatory requirements for the medical device.
- Records of risk management including the results of risk analysis, risk mitigations, resulting residual risk and risk/benefit analysis.
- Labelling, including any instructions for use.
- Procedures or instructions related to maintenance of product.
- Any unique device identification applied.
- A record of the language variants where the medical device is made available.
- Clinical data.
- Material and component data used in the construction of the medical device together with the biological safety and biocompatibility.
- Changes made to medical device performance or characteristic during the life time of the device together with any associated verification/validation data.

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- Any storage and transport requirements.
- A description of the accessories, other medical devices and other product that are not medical devices, which are intended to be used in combination with it.
- The standards applied or other methods employed to demonstrate conformance with the applicable general safety and performance requirements.
- The method(s) used to demonstrate conformity with each applicable general safety and performance requirement.
- The identification of the document providing evidence of the conformity with the general safety and performance requirements.
- Method(s) used to demonstrate the accuracy of any measuring function.
- Identification of incorporated medicinal substance or tissue of animal or human origin in the medical device and data on the tests conducted to show the safety, quality, and the usefulness of such substance; and
- Identification of any substance in the medical device that, if used alone, would be regulated as a medicinal product and data on the tests conducted to show the safety, quality, and the usefulness of such substance.

4.2.4 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5.

A documented procedure shall define the controls needed to:

a) review and approve documents for adequacy prior to issue;
b) review, update as necessary and re-approve documents;
c) ensure that the current revision status of and changes to documents are identified;
d) ensure that relevant versions of applicable documents are available at points of use;
e) ensure that documents remain legible and readily identifiable;
f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;

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g) prevent deterioration or loss of documents;
h) prevent the unintended use of obsolete documents and apply suitable identification to them.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable regulatory requirements.

Intent

This section defines the requirements for the control of documents.

The addition of clarification on the nature of external documents that have to be controlled is new in this edition of ISO 13485.

Guidance

The system established for the control of internal and external documents will, if appropriate:

- assign responsibilities for preparation, approval and issue of documents,
- ensure prompt withdrawal of obsolete copies of controlled documents,
- define a method for recording the implementation date of a document change, and
- allow controlled and non-controlled documents to be distinguished.

The QMS should also identify the location of controlled copies of documents. In identifying the location of controlled documents, consideration should be given to where the document will be used. Access at points of use should ensure

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that relevant documents are available to those personnel that need to use them, such as in manufacturing areas, laboratories and warehouses. Access should be convenient, so that personnel are not discouraged from accessing documents that they need to do their work effectively. Access to documents might be through access to electronic copies of documents through a computer, mobile device, built into automated manufacturing equipment or hard copies of the document itself. Organizations have to define how these documents will be access and ensure the applicable regulatory requirements are implemented when the complex and evolving area of electronic document access are used.

Documents can be reviewed at various times throughout the life of a document, for example, as a result of:

- facilities, process, product, personnel or organizational changes,
- internal and external audit activities,
- acquisitions,
- new product, technologies or software,
- a requirement of your organization's QMS for periodic review.

Document control procedures can be assisted by the adoption of a consistent structure for the documents within the QMS. These procedures should clearly indicate what document control information should be included in each document. Consideration should be given to the inclusion of:

- title and scope,
- document reference number,
- date of issue/date effective,
- revision status,
- review date or review frequency, as required by the QMS,
- revision history,
- originator or author,
- person(s) approving it,
- person(s) issuing it,
- distribution,
- pagination, and
- computer file reference, if applicable.

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ISO 13485 requires that documents of external origin, which your organization decides are necessary for planning or operating the QMS, are identified and their distribution controlled. Examples of such documents would include published standards such as your copy of ISO 13485 itself, other standards used as an input into the design and development process, copies of certificates granted to your organization or documents containing regulatory requirements. Your organization should identify those external documents that are important to you, for example in a list subject to document control, mark the controlled copy of the document, such as with an official stamp, and identify the place where the controlled copy will be kept for reference.

Your organization is required by ISO 13485 to define the lifetime of each of their medical devices for document and record control purposes. Medical device lifetime can be based on technical, legal, commercial or other considerations. The basis of the defined lifetime of the medical device should be documented. To assist in determining the lifetime of the medical device, the rationale for the determination should be recorded and can involve consideration of the following:

- shelf life of the medical device;
- expiry date for medical devices or components which are subject to degradation over time;
- number of cycles or periods of use of the medical device, based on life testing of the medical device;
- anticipated material degradation;
- stability of packaging material;
- for implantable devices, the residual risk that results from the entire period of residence of the medical device inside the patient's body;
- for sterile medical devices, the ability to maintain sterility;
- organization's ability/willingness or contractual or regulatory obligation to support service for the medical device;
- spare parts cost and availability;
- legal considerations including liability.

Document retention time should take into consideration the:

- period of time the medical device is expected to be in the market place,
- applicable regulatory requirements,

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- product liability and other legal considerations,
- need or advisability of keeping documents indefinitely,
- retention time of related records, and
- availability of spare parts.

Your organization should retain at least one copy of obsolete controlled documents for at least the minimum period of time required by regulation. Obsolete documents should also be retained for as long as necessary to understand the content of records which are related to the document (see 4.2.5).

ISO 13485 requires your organization to apply suitable identification to obsolete documents; such identification can be applied physically (as with a stamp) or electronically (as in a computerized database).

ISO 13485 recognizes that there might be applicable regulatory requirements for the retention of documents made obsolete by changes in medical devices or the QMS. Your organization should determine whether any market that it supplies has such regulatory requirements and should establish a system to ensure that such obsolete documents are retained for an appropriate period.

4.2.5 Control of records

Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

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The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

Intent

This section defines the specific requirements for control of records that demonstrate conformity to requirements and the effective operation of the QMS.

The reference to procedures to define the means of control for security and integrity of documents, for changes made to records to be identifiable and for controls to protect confidential health information are additions to this edition of the standard.

Guidance

Records can be in any format or type of medium.

Records can be considered as falling into one of three categories, as follows:

- those that relate to design and development, and the manufacturing processes, affecting all medical devices of a particular type;
- those that relate to the manufacture or distribution of an individual medical device or batch of medical devices;
- those that demonstrate the effective operation of the overall QMS (system records).

It is clear that records in categories a) and b) are related directly to particular medical devices. Those in category a) should be kept for a time at least equivalent to the lifetime of the medical device after manufacture of the last product made to that design. Those records in category b) should be kept for a time at least equivalent to the lifetime of that particular batch of medical devices.

Some system records can also have a retention period related to the lifetime of a medical device; for example, calibration and training of individuals. For some other system records, it is less straightforward to relate them to the

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lifetime of a medical device; for example, management review, internal audit, infrastructure, evaluation of some suppliers and analysis of data. In these cases, your organization is required by ISO 13485 to identify an appropriate retention period. In defining this retention period, your organization should take into account the nature of the medical device, the risks associated with its use, the records involved and applicable regulatory requirements.

Records should be stored safely, protected from unauthorized access, and protected from alteration. These records should be properly identified, collected, indexed and filed, and should be readily accessible as and if needed. They can be stored or copied in any suitable form (e.g. hardcopy or electronic media). If records are retained on electronic media, consideration of the retention times and accessibility of the records should take into account the degradation of the electronic data and the availability of devices and software needed to access the records. Such copies of records should contain all the relevant information captured in the original records. In addition, applicable regulatory requirements and guidance documents might address requirements for your organization to establish documented procedures specifically for control of electronic records. This could include, but is not limited to, access, storage, reproducibility, readability, audit trails and electronic signatures, if appropriate. Your organization should pay attention to Information Security requirements outlined in ISO 27001 including cybersecurity aspects, such as data security, encryption as necessary, data transmission or data storage.

Records that could contain confidential health information can be clinical report forms, customer complaints, electronic data in a medical device system (e.g. IVD devices, monitoring devices such as glucose measurement, blood analysis and dialysis machines that during service are exposed), clinical data from usability studies or design validation and patient information used for production of a custom medical device. Such confidential information might be subject to regulatory requirements for privacy in some jurisdictions.

Hand-written entries should be made by indelible medium. Persons making authorized entries on records or verifying such entries should do so in clear legible writing, and should confirm the entry by adding their initials, signature or equivalent, and the date.

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Good recording practices can include the following procedures, as appropriate:

- enter data and observations as they occur;
- do not pre-date or post-date records;
- do not use another person's initial, signature or equivalent;
- complete all fields or check-offs when using a form;
- refer to raw data when transferring data, and have the transcription verified by a second person;
- verify all entries for completeness and correctness;
- number pages to ensure completeness.

If an error is made or detected on a record, it should be corrected in such a manner that the original entry is not lost and the correction is initialled and dated. If appropriate, the reason for the correction should be recorded. Where electronic records systems are used in place of paper-based ones, these systems should, wherever possible, incorporate time-stamped, immutable, system-generated audit trails, for tracking changes. Such audit trails can include the identity of the authorized user, creations, deletions, modifications/ corrections, time and date, links and embedded comments.

Your organization can have alternative provisions for critical data entry of electronic records, for example,

- a second authorized person with logged name and identification, with time and date, can verify data entry via the keyboard, or
- systems with direct data capture can have the second check as a part of validated system functionality.

A system should be implemented that assures the integrity of electronic records and protects against unauthorized entries. The topic of electronic records is complex and evolving. Applicable regulatory requirements and guidance documents might address requirements for your organization to establish documented procedures specifically for control of electronic records.

In addition to considering the lifetime of the device (see 4.2.4) when determining record retention time, your organization should also consider applicable regulatory requirements, legal considerations, including liability, and the need or advisability of keeping records indefinitely.

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5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;
b) establishing the quality policy;
c) ensuring that quality objectives are established;
d) conducting management reviews;
e) ensuring the availability of resources.

Intent

This section assigns responsibility to top management for establishing and maintaining an effective QMS. In addition, this section defines in greater detail specific activities for which top management are responsible.

Guidance

It is important to note the emphasis on top management throughout this subclause. Top management is a person or group of people who directs and controls your organization at the highest level. Top management has the power to delegate authority and provide resources within your organization.

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If your QMS covers only part of a larger entity, for example a business unit or division of larger corporation, then top management refers to those individuals who direct and control that part of the entity under your QMS. This designation of top management is intended to ensure that the QMS is effective as a result of commitment on the part of management at the highest levels of your organization covered by this particular QMS. Top management makes decisions, authorizes actions and sets the priorities for your organization and therefore is ultimately responsible for quality of product. In addition, top management controls the resources required to implement an effective QMS. The positions that make up the top management and the responsibilities assigned need to be defined and documented. This documentation can be in the form of organizational charts and in job descriptions.

Remembering that the QMS is a set of interrelated processes, top management should ensure that processes operate as an effective network. Top management is not only responsible for establishing and maintaining a QMS, the members of top management are a component of the system and are expected to conform with applicable system requirements. Top management is expected to:

- Commit themselves to the QMS by defining a quality policy which expresses their commitment to implement and maintain a QMS compliant with ISO 13485 and the applicable regulatory requirements.
- Establish measurable objectives that ensure the QMS operates in compliance with ISO 13485 and the quality policy.
- Promote the QMS and communicate your organization's QMS values through quality policy, quality objectives, ensuring that QMS is functioning (in management reviews), supporting QMS training of staff, supporting the quality staff, leading by example, allocating resources for QMS.
- Review that the QMS is functioning (i.e. suitable, adequate and effective) through periodic reviews of the QMS elements, identifying QMS issues and addressing them by decisions, actions and provision of necessary resources (e.g. in management reviews).

Considerations should include, but not be limited to:

- ensuring that the sequence and interaction of processes are designed to achieve the planned results effectively,

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- ensuring that process inputs, activities and outputs are clearly defined and controlled,
- monitoring inputs and outputs to verify that individual processes are linked and operate effectively,
- identifying hazards and managing risks,
- conducting data analysis to facilitate necessary improvement of processes,
- identifying process owners and giving them responsibility and authority,
- managing each process to achieve the process objectives, and
- ensuring written agreements with 3rd parties are in place (see 7.4 for more details).

5.2 Customer focus

Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.

Intent

This section assigns the responsibility to top management for ensuring that customer and applicable regulatory requirements are determined and met, irrespective of who is assigned the work to determine and fulfil those requirements.

Guidance

This section emphasizes that the inputs to your QMS come from customer and regulatory requirements. It also makes it clear that, irrespective of who actually undertakes the interactions with customers and regulatory bodies, it is the responsibility of top management to make certain that these requirements are understood and that the necessary resources are available. In order to address this issue, inputs such as the following should be considered:

- regulatory requirements;
- international or national standards;

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- customer requirements for product or service, including usability requirements;
- customer complaints;
- feedback;
- benchmarking; and
- market trends, statistics and forecast information.

Examples of activities to process these inputs include:

- design and development process,
- risk management,
- management review,
- complaint investigation, and
- corrective action or preventive action.

As an output, your organization can consider such things as decisions and actions related to:

- design and development of new product,
- redesign of existing product,
- new or revised labelling,
- advisory notices or other actions,
- risk management reports/files,
- improvement,
- quality planning, and
- policy, process or procedure revision.

Top management needs to ensure that applicable actions are implemented to address risks and opportunities and expected results are achieved.If not, a plan-do-check-act (PDCA) approach is continued and responsibilities are assigned for implementing further improvements until customer requirements are met and compliance with applicable regulatory requirements are achieved.

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5.3 Quality policy

Top management shall ensure that the quality policy:

a) is applicable to the purpose of the organization;
b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;
c) provides a framework for establishing and reviewing quality objectives;
d) is communicated and understood within the organization;
e) is reviewed for continuing suitability.

Intent

This section assigns the responsibility to top management to define the quality policy to:

- establish and communicate throughout your organization a commitment to quality and the continuing suitability, adequacy and effectiveness of the QMS to meet customer and regulatory requirements, and
- provide a focus for QMS objectives.

Guidance

It is important that your organization's quality policy is considered when preparing the overall organization policies related to its business operations (e.g. marketing, sales, finance) to ensure that your organization policies are consistent and supportive of each other.

The quality policy should communicate your top management's commitment to quality and their overall vision of what quality means to your organization's business and customers. In order to demonstrate that your organization is committed to implementing its quality policy, it will need to identify clear quality objectives that are directly relevant to your organization and your customers.

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Top management's commitment to the quality policy should be visible, active and effectively communicated. For example, a publicly displayed copy of the quality policy signed by top management is one method to show that commitment to both employees and customers. When considering where to display the quality policy, access to all employees across your organization should be considered. Common display areas are on the manufacturing floor, conference rooms and break rooms, on employee badges and in routine communications. Another method is to present and discuss the quality policy at communication meetings for members of your organization held throughout the year. For instance, some organizations choose to make the quality policy the lead slide on every presentation.

All employees need to understand the quality policy and how it affects them. The employee should be able to recall key elements of the quality policy and explain how their work supports the quality policy. Top management should ensure that your organization decides on the methods which will be used to achieve this understanding.

The quality policy also needs to be reviewed from time to time to determine if it accurately reflects the current quality-related objectives of your organization. This review is, at minimum, carried out during management review (see 5.6).

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

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Intent

This section defines the requirement that top management ensures realistic and measurable quality objectives that are consistent with the quality policy are established throughout your organization. In addition, this section defines the requirement to establish quality plans to meet defined objectives.

Guidance

In order to put your organization's quality policy into effect, top management establishes clearly defined quality objectives. ISO 13485 calls for quality objectives not only for the QMS but also to meet applicable regulatory requirements and requirements for product provided by your organization. As described in ISO 9000, quality objectives do not include financial, health and safety or environmental objectives (you might choose to consider these independently) but are specific to the establishment, implementation and maintenance of your QMS to ensure that it remains suitable, adequate and effective.

The activities undertaken to reach these quality objectives do not need to be carried out personally by top management, but the responsibility to ensure action is taken to achieve them is still theirs.

Quality objectives should be realistic and related to achievable and measurable outcomes for the QMS, such as:

- meeting the requirements (customer, regulatory and other) for medical devices and related services,
- reducing errors,
- reducing closure times for action identified through internal audit, corrective action or preventive action,
- meeting planned schedules, and
- reducing handling time for customer complaints.

In setting quality objectives and any associated targets, as applicable, you should establish timeframes for achieving the targets.

To establish goals at the relevant levels within your organization, groups or functions within your organization typically establish group/function objectives

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which cascade from the overall organization objectives and relate to the specific activities of the group or function.

Your organization has to document the established quality objectives within your QMS documentation (e.g., in the quality manual or a separate document). One of the techniques often used in setting quality objectives is the SMART technique for setting objectives that are Specific, Measurable, Achievable, Relevant and Time-bound. The evaluation of results achieving specified objectives can be in performance appraisals or through other means such as project management with defined milestones, Key Performance Indicators (KPIs) or on-going review using feedback processes. Your top management formally reviews these quality objectives, including progress and resource needs to achieve the objectives, in their management review meetings (see Clause 5.6.1).

Quality objectives provide one of the inputs into QMS planning (see 5.4.2).

5.4.2 Quality management system planning

Top management shall ensure that:

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives;
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Intent

This section deals with planning related to the QMS in general, in contrast to planning required in other subclauses related to individual elements of the QMS.

Guidance

Planning will be undertaken at the initial stages of development and implementation of your QMS as well as when making significant changes to your

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QMS. This planning can assist your organization to fulfil its quality objectives. Since quality objectives can and do change over time this planning is likely to be ongoing and assists the QMS to continue to be effective during and after changes. Whenever you decide to carry out a change within your QMS, planning and implementing this change includes risk-based considerations of the effect the change will have on the integrity of your QMS.

Examples of inputs into QMS planning include:

- quality policy,
- quality objectives,
- regulatory requirements,
- organizational goals,
- QMS standards,
- changes required (e.g. as a result of management review, corrective action or preventive action).

Examples of outputs from QMS planning that demonstrate meeting the requirements of ISO 13485 include:

- the quality manual and supporting documentation,
- gap analyses,
- assessments of effect on QMS and product produced under that QMS,
- actions plans, or
- results of action plans.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.

Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.

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Intent

This section requires top management to establish responsibilities and authorities for those roles that directly affect quality as well as document the interrelationship between those roles.

Guidance

Consistent with the definition of top management, top management has the power to delegate the authority to meet these requirements. Delegation of this authority is usually achieved by means of documented position descriptions which include the scope of authorities and organizational charts which describe the interrelation of personnel. As this documentation forms part of your QMS, it has to be controlled. Authorities (including those for substitute personnel) can be included in documented procedures. Some organizations map QMS processes to show the linkages between processes and the authorities associated with activities to be performed.

For some activities (e.g. internal quality audits and design and development reviews), it is important that there be participation by individuals who have the required knowledge of, as well as organizational independence from, the subject being reviewed.

In order to address the definition of authority, inputs to be considered can include the:

- competence of persons, as consistency needs to be ensured between assigned roles and responsibilities and necessary competence;
- available resources, considering mainly human resources but also other resources that can affect responsibility assignment;
- regulatory requirements for the designation of specific roles and responsibilities;
- professional code of ethics for related roles and responsibilities;
- required qualifications for ensuring that any related requirements and responsibility assignment are met;
- performance objectives and evaluation results, in order to make sure that the right persons are committed to meet the expected performance level;

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- required functions within your organization and the organizational structure required to achieve product realization and QMS requirements; and
- structure and hierarchy of your organization that defines interactions and authorities or position responsibilities.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are documented;
b) reporting to top management on the effectiveness of the quality management system and any need for improvement;
c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

Intent

This section defines the requirement for assigning responsibility to an individual as the management representative with the associated duties regarding the QMS.

Guidance

Only one member of management is designated by top management as its management representative.

The responsibilities of your organization's management representative could be entirely related to QMS activities or be in conjunction with other responsibility within your organization.

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If the management representative has other responsibilities to perform, there should be no conflict of interest between these responsibilities and those relating to the QMS.

The management representative can delegate authority for activities within their responsibility for the QMS to others in your organization. The management representative is distinct from local responsible persons or authorised representative who are designated based on applicable regulatory requirements.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Intent

This section defines the requirement to establish processes that ensure understanding of the requirements and the effectiveness of your QMS.

Guidance

For your QMS to work effectively, open and active communication is essential. Your organization's top management needs to establish processes which encourage people within your organization to communicate at all levels about matters relating to your QMS and its effectiveness. This communication should go both ways, providing direction to your organization and allowing personnel to ask questions or make suggestions about improvement of your QMS. The communication processes should ensure feedback is provided to those interested in the question or suggestion in a timely manner with sufficient commentary to demonstrate questions or suggestions received adequate consideration.

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Information communicated about your QMS should be comprehensive and be delivered in such a manner that personnel receiving the information understand it. This information should relate to top management's expectations for the performance, implementation and effectiveness of your QMS (e.g. results of internal audits [see 8.2.4], management reviews [see 5.6], external assessments and regulatory inspections, external industry trends and events that affect your QMS).

Examples of communication methods include:

- message boards,
- employee meetings (to include question and answer),
- focus groups,
- employee surveys and survey results,
- suggestion boxes,
- quality alerts,
- websites, text, e-mail, and
- circulating information via hard copy.

Internal communication can be facilitated by personnel having familiarity with a variety of activities or functions within your organization. This familiarity can be enhanced, for example, by placing personnel from one function into another function as a part of their personal development.

5.6 Management review

5.6.1 General

The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.5).

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Intent

This section provides that the management review process is a fundamental requirement to support a suitable, adequate and effective QMS. It requires your organization's top management periodically to review the available data about your QMS, take appropriate steps (where required) to address any weaknesses or failures and introduce improvements. Management review includes a review of the quality policy and of quality objectives and includes discussion and analysis between top management and the management representative on the suitability, adequacy and effectiveness of your QMS.

Guidance

Your documented procedure for management review has to describe the requirements for the process of management review. The typical process is that the management representative collects data at planned intervals from the QMS covering at a minimum, the items from the list in 5.6.2. Other information could be presented to support your organization goals if desired in the process. It is a discussion and analysis between top management and the management representative on the health of your QMS. However, it is critical the required data is reviewed and analysed by top management to verify that your QMS is suitable and effective for regulatory purposes. The process is as follows:

- The management representative reports to your top management on the effectiveness of your QMS by reporting on the effectiveness of each QMS process defined by ISO 13485 and identifies any need for improvement (5.5.2). The information in this reporting is provided from the inputs listed in 5.6.2 and includes data analysis (e.g. statistical data, trends) defined in Clause 8.4.
- The top management reviews the information provided by the management representative and assesses the suitability, adequacy and effectiveness of your QMS, identifying any need for correction, improvement or allocating the necessary resources as required to carry out these activities.
- In addition, the top management reviews your organization's quality policy to ensure that it continues to be suitable and applicable to the purpose of

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your organization (5.3) and objectives related to your QMS to ensure they are established at relevant functions and levels within your organization (5.4.1).

Management reviews are held in planned intervals documented in your QMS. The length of these intervals should be based on the risk of your QMS not maintaining its suitability, adequacy or effectiveness and also factors in the status and maturity of your QMS and may be documented in the output of management review. The intervals are usually shortened whenever suitability, adequacy or effectiveness of your QMS is judged to be at risk of being compromised and can be extended when a steady state is achieved.

5.6.2 Review input

The input to management review shall include, but is not limited to, information arising from:

a) feedback;
b) complaint handling;
c) reporting to regulatory authorities;
d) audits;
e) monitoring and measurement of processes;
f) monitoring and measurement of product;
g) corrective action;
h) preventive action;
i) follow-up actions from previous management reviews;
j) changes that could affect the quality management system;
k) recommendations for improvement;
l) applicable new or revised regulatory requirements.

Intent

This section expands, updates and clarifies the list of management review inputs from the 2003 edition. This section also defines the inputs that provide

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information to the top management of your organization performing the management review of your QMS:

- To enable them to reach decisions in relation to the suitability, adequacy and effectiveness of the QMS, and
- To identify actions needed to maintain and improve the QMS and the product.

Guidance

The management representative is responsible for reporting to your top management on the suitability, adequacy and effectiveness of the QMS and on any need for improvement (5.5.2). The data for this reporting are derived from the inputs listed in this section although additional sources can also be identified and used. The data collected is analysed using appropriate statistical and non-statistical techniques as defined in your documented procedure relating to analysis of data (8.4). The results of the analysis should be presented in management reviews in a way that enables the top management to reach decisions about the suitability, adequacy and effectiveness of your QMS.

Your organization has procedures for what is provided as input for the management review, including relevant information from the improvement processes, such as improvement actions (corrective actions or preventive actions) as well as important corrections. Your organization needs to define what meaningful data are to be reported for a management review. Data should be specific to the quality objectives of your organization and reported regularly. Merely providing the number of improvement actions or the number of how many improvement actions are opened or closed to the management review process are not sufficient in assessing the suitability, adequacy and effectiveness of the processes. Included in this review would be an assessment of any opportunities for improvement of the medical device, manufacturing process, QMS or your organization itself. It should be noted that the management review discussions should not focus on the operational aspects of the listed inputs; rather, they should center on the information these inputs provide about the suitability, adequacy and effectiveness of the QMS processes defined by the requirements of the QMS standard.

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For example, when your internal audit process is reviewed by your top management, data relating to the suitability, adequacy and effectiveness of this system will be reviewed. For example, the questions being asked could be:

- Have all QMS, regulatory and other requirements been adequately documented?
- Is there evidence of these requirements being followed?
- Have the quality objectives been met?
- Have any opportunities for improvement been identified?
- What do our feedback mechanisms suggest?
- Have any internal or external audits identified any nonconformities or areas of improvement for this QMS process?
- Are there any nonconformities raised?
- What is the status of corrective actions or preventive actions for QMS processes?
- Are there any follow ups from previous management reviews?
- Have any changes occurred that affects or could affect QMS processes?
- Are there any new or revised regulatory requirements that could affect QMS processes?
- Are there adequate resources to support the QMS processes?

Although operational aspects relating to the internal audit process can be also discussed (e.g. summary of the number of internal audits being carried out and the number of auditors involved, the overall number of nonconformities raised, etc.) these discussions should not obscure the aim of the management review to assess the suitability, adequacy and effectiveness of the internal audit process.

5.6.3 Review output

The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to:

a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;
b) improvement of product related to customer requirements;

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c) changes needed to respond to applicable new or revised regulatory requirements;
d) resource needs.

Intent

This section defines the required outputs of the top management's review of your organization's QMS including how your organization provides evidence of conformity to requirements for management review as well as the suitability, adequacy and effectiveness of your QMS.

Guidance

The records of the output of management review are maintained for decisions and actions related to your QMS or product improvements, changes addressing new or revised regulatory requirements and resource needs as defined in 5.6.3. These records are typically maintained as meeting minutes.

These records can be in any format controlled by your organization and should identify the following:

- the date of the review;
- the persons taking part in the management review, including the top management or those delegates representing top management and any other required participants;
- a summary of the review of the information provided by the inputs listed in Clause 5.6.2 about your QMS;
- the decisions taken and the actions raised to:
  - improve your QMS and its processes,
  - improve the product in view of the customer requirements,
  - implement changes related to new or revised regulatory requirements,
  - determine the resources needed to implement your QMS and to maintain its effectiveness, and
  - meet applicable regulatory and customer requirements (6.1);
- the persons assigned the responsibility for the actions to be taken (5.5.1) and the target dates for completion of these actions (5.4.1);

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- an approval of the management review record;
- the record of distribution of the record of management review;
- a statement regarding the suitability, adequacy and effectiveness of your QMS;
- the planned interval for the next management review.

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6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed to:

a) implement the quality management system and to maintain its effectiveness;
b) meet applicable regulatory and customer requirements.

Intent

This section defines the requirements to ensure that adequate resources are planned for and provided for the effective initiation, maintenance and management of the QMS and its processes.

Guidance

Consideration has to be given by your organization's management to the identification and provision of adequate resources needed to implement its quality policy, to achieve its objectives and to satisfy customer and applicable regulatory requirements.

The provision and maintenance of adequate resources are a prerequisite to the effective creation, implementation, maintenance and management of your QMS and its processes. The nature and quantity of such resources are based on the types and complexity of your organization's product and processes as

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well as the risk associated with those product and processes. Responsibility for the provision of resources resides with your organization regardless of whether associated processes are performed by your organization itself or are provided by an external party.

Resources can be:

- people,
- infrastructure,
- work environments,
- information,
- individual knowledge and experiences,
- suppliers or partners,
- power sources (e.g. electricity), and
- finances.

Your organization has to review its resource needs on a regular basis. This is usually done as part of management review and when a new tender or contract is considered, when regulatory requirements change or when a new business strategy is considered.

6.2 Human resources

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

The organization shall:

a) determine the necessary competence for personnel performing work affecting product quality;
b) provide training or take other actions to achieve or maintain the necessary competence;
c) evaluate the effectiveness of the actions taken;

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d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
e) maintain appropriate records of education, training, skills and experience (see 4.2.5).

NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.

Intent

This section defines requirements to ensure that personnel within your organization whose positions directly or indirectly affect quality possess the necessary competence for personnel including the skills required for those positions, are provided with effective training to complete their work and are made aware of their effect on your QMS and product quality.

There is a new requirement for documenting processes of establishing competence, providing needed training and ensuring awareness of personnel.

Guidance

The first (and arguably most important) resource your organization needs is people. Your organization has to have enough people with necessary competence to do the work.

Your organization is required to document procedures describing the processes it uses for establishing competence requirements for personnel, determining the competence of personnel given work responsibilities, and taking action to establish or maintain the competence of those personnel, including an assessment of the effectiveness of the action taken. Your organization has to consider the experience, qualifications, capabilities and abilities of personnel, especially in those areas that can affect the safety and performance of the medical devices being designed and developed, manufactured and provided to customers. After consideration of the above information training is a common action taken to achieve or maintain competence. A process to describe

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development and maintenance of competence of personnel along with a method to plan a periodic review of their competence can be developed.

Since it is a common action, a training process should be developed to achieve and maintain employee competence as well as follow-up or refresher training to maintain the necessary competence. The process has to determine the appropriate methods and requirements for demonstrating effectiveness of the actions taken, including training (i.e., completion of the training establishes the necessary competence).

Your organization develops employee competence requirements (usually within job descriptions) by determining the experience, qualifications, capabilities and abilities required for that position in regards to the safety and performance of the medical devices being manufactured and provided to customers.

Processes have to be developed to identify the nature and extent of training required prior to performing a process based on the competence required for the personnel intended to perform that process. The risk of not performing a task or process adequately also has to be considered when determining the level of training effectiveness as well as demonstrated aptitude for performing a task or process prior to declaring the person competent.

For example, a professional extrusion specialist with practical experience would still require extensive training on the operation of the extrusion machine, as well as its interaction with the rest of the manufacturing process, as it is a critical process in which incorrect operation directly affects the safety and performance of the product. Thus the extrusion specialist should not be just qualified through the previous experience, even on the same extrusion machine. The specialist's qualifications and experience, however, provide the pre-requisite to be in the job.

Work allocation and assignment of personnel (6.2.1), management review (5.6), non-conformance reports (8.3), corrective action (8.5.2), preventive action (8.5.3) and internal quality audit (8.2.2) are all likely to identify areas that could indicate a need for improving the competence of personnel and the means for such improvement, be it replacement of personnel, further education or training.

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Personnel working within the QMS require a certain level of competence or training (internal or external) before they can perform tasks properly. It might be necessary for people to be further qualified or formally certified for some tasks (e.g., chemical or microbiological analysis, use of sources of radiation, laser operation, welding or soldering).

Organizations typically provide training to establish competence for full-time, part-time and contract personnel, tailored to the person's assignment. Such training should cover:

- the nature of the business,
- the quality policy and other internal policies,
- the function of the employee, and
- the procedures and instructions of relevance to them.

Training can be carried out in stages, and usually includes follow-up or refresher training, as needed and planned. Persons who are assigned responsibility in the documented procedures of the QMS should receive training on those procedures. For some low risk job assignments, training could be limited to requiring the person assigned to the job to read the content of procedures that describe the job assignment.

Organizations need to evaluate the effectiveness of training or other actions taken in order to ensure competence of the personnel. Your organization can use the following to evaluate the effectiveness based on the risks associated with the work for which the training or other action is being provided:

- surveying the trained personnel to assess whether he or she feels they have learned the required information,
- testing or questioning the trained personnel to assess their competence using objective criteria,
- evaluating the work performance of the trained personnel, or
- reviewing the trainer assessment of training effectiveness.

Your organization also needs to maintain records of personnel competence. This includes the records of actions taken or training a person has received and results of the action that contribute to the evidence of competence. The records to show that the action or training course has been successfully completed and that competence has been achieved can be as simple or complex as necessary.

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The method for evaluating competence is proportionate to the risk of the job. At their simplest, the records consist of list of procedures with a signature or initials to confirm that personnel self-assessed their competence to use certain equipment, carry out specific processes or follow certain procedures. The records should include a clear statement that a person is now deemed to be competent to do the task they intend to perform. The effectiveness of any further action, education or training should be re-evaluated, after a period, to confirm that the competence achieved is maintained.

Training or other action is carried out by personnel with appropriate expert skills, qualifications and practical experience in order to deliver effective training or take action to establish competence. Records are kept to document the competence of the trainers to demonstrate credibility.

6.3 Infrastructure

The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate:

a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).

The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.

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

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Intent

This section defines requirements to ensure your organization has the infrastructure that supports product and process conformity to including the appropriate facilities, facility layout and required utilities and process equipment as well as the required maintenance of those facilities, equipment and support systems.

A requirement that infrastructure prevents product mix-up and ensure orderly handling of product has been added together with the addition of information systems to the listing of supporting services.

Guidance

As well as providing for the various requirements of the workplace, your organization needs to consider ways to address risk by preventing possible problems (e.g., preventive maintenance on critical equipment) or plan for expected future needs.

Equipment has to be designed, constructed, correctly installed and located to facilitate proper operation, maintenance, adjustment and cleaning. The appropriate storage and handling conditions needed for the preservation of product (7.5.11) including its available space, environmental conditions and transport methods have to be specified. The required technical service equipment has to be specified to enable it being provided to the appropriate sites to enable servicing at the required locations, or delivered in a timely fashion to site to carry out technical servicing.

Your organization has to ensure that, if applicable, any inherent limitations or allowable tolerances of production, measurement, installation and servicing and test equipment are documented and are readily available to the operators.

Documented procedures have to be available for the maintenance, cleaning and checking of all equipment used in production, measurement, testing, servicing and for the control of the work environment. The determination of the necessary adjustments and maintenance intervals also has to be established.

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The maintenance schedule should normally be posted on or near the equipment, or should be readily available. Maintenance should be carried out on schedule.

Your organization needs to ensure that the buildings utilized are of suitable design and contain adequate space to facilitate cleaning, maintenance and other necessary operations (e.g., pest control processes). The premises should be laid out in such a way, and with sufficient allocation of space, to facilitate orderly handling and to prevent mixing between incoming material, in-process batches, material scrapped, re-worked, modified or repaired, any other nonconforming material, medical devices, manufacturing equipment, inspection aids, documents and drawings. Flow of product through the facility should be planned and documented. Software systems used in support of the QMS should be backed up periodically and recovery of data should be planned for.

6.4 Work environment and contamination control

6.4.1 Work environment

The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.

If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment.

The organization shall:

a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;
b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

NOTE Further information can be found in ISO 14644 and ISO 14698.

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Intent

This section defines requirements to ensure your organization plans for and provides a work environment suitable for the type of product produced and takes measures to prevent product damage or contamination.

Guidance

Product quality can be influenced by the production work environment. The most significant factors within the work environment that can affect product quality are:

- the process equipment,
- the conditions within the work environment established,
- the personnel within that work environment, and
- the storage conditions and conditions during the distribution cycle.

With regards to the work environment, your organization should consider the following:

- appropriate controls, parameters and indicators associated with the work location,
- appropriate customer waiting areas and facilities,
- maintenance of appropriate sanitation and hygiene for personnel (e.g., washrooms),
- separation of non-production related activities by personnel (e.g., food and drink preparation), and
- methods/mechanisms in place to reduce risk posed by potential hazards (e.g. electro-static discharge for electronic components, handling of animal derived material, other contamination of product or spillage from volatile chemicals).

These requirements apply to activities that directly affect product and service conformity.

The need for control of the work environment and the extent to which that control is exercised depends upon the type of the product being produced and external environmental factors. To control the work environment means to direct, regulate, coordinate and monitor activities and variables that affect the conditions such that the characteristics of the work environment are known.

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Qualified and quantified limits for the characteristics that define the work environment should be established and can be used to describe the extent to which control capabilities are implemented. The extent of the control required will influence the type of facility construction, equipment, resources and documentation needed to establish, monitor and maintain the work environment. An environmental control system should be validated if the resulting output cannot be verified (see 7.5.6), and should be regularly monitored to verify that the system is functioning properly. Such systems and inspections should be documented.

The various parts of ISO 14644 provide additional information regarding cleanrooms and associated environments particulate and ISO 14698 provides information on biocontamination control.

In line with 7.5.2, there are situations where the work environment can affect the product quality. Additional examples of situations in which the work environment can have an effect on product quality include medical devices which:

- are to be supplied labelled sterile (this also includes medical devices labelled "pyrogen free"),
- are to be supplied non-sterile and are intended to be sterilized before use,
- have a limited shelf life,
- have special handling or storage requirements,
- are susceptible to electrostatic discharge (ESD) due to electronic microcircuits or imbedded software, and
- are affected in their use by microbiological or particulate cleanness or other environmental conditions.

There are various parameters, indicators and controls associated with the work environment. Some examples of these are:

- temperature,
- humidity,
- airflow,
- air filtration,
- air ionization,
- pressure differentials,
- lighting (both spectral content and intensity),

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- sound,
- vibration,
- cleanliness of work surfaces and process,
- water quality, and
- number of people in the work environment.

Each of the parameters, indicators and controls should be considered for evaluation to determine if lack of control could increase the risk posed by product when put into use; i.e. the need and extent of environmental control should be traceable through records of risk management activities for product. If the environmental conditions are of significance in its manufacturing processes, your organization has to establish requirements for the work environment to which product is exposed. For some product it might also be necessary to ensure traceability to environmental exposure, such as records of continuous monitoring of environmental conditions even during times when product is not undergoing manufacturing processes (e.g. evenings or weekends).

Any personnel, including those entering the area on a temporary or transient basis, who can come in contact with product or work environment, has to be suitably clothed, clean and in good health if these factors could adversely affect the product. This is because individuals spread both microorganisms and particles, which constitute contamination risks.

Examples of persons who might enter the work environment are:
- manufacturing personnel, their supervisors and managers,
- material handlers,
- manufacturing engineers,
- design and development engineers,
- quality control, quality assurance, quality engineering personnel,
- suppliers of any material or service (including cleaning services),
- persons responsible for process equipment maintenance,
- customers,
- auditors, and
- visitors.

It is also important to remember that contact with product or work environment includes those times when product is not actually being produced, such as evenings, weekends and holidays.

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Persons who have a medical condition that can adversely affect the product have to be excluded from those operations or prevented from entry into such areas until they have recovered. Personnel are instructed and encouraged to report such conditions to their supervisor. This is of particular importance in the manufacture of medical devices which are to be supplied:

- sterile,
- for sterilization before use, or
- for purposes in which microbiological cleanliness is of significance.

Special training or supervision should be provided to persons required to perform work under special environmental conditions (e.g. in a room where the temperature or humidity is controlled to such high or low levels that prolonged exposure might be hazardous, or a room or area where exhaust fans keep hazardous fumes at an acceptable level) or within a controlled environment. Any personnel involved in manufacturing, maintenance, cleaning or repair that have not been trained for performing tasks in a controlled environment, are not allowed to enter unless supervised by an appropriate competent person. This restriction includes personnel entering the area on a temporary or transient basis.

6.4.2 Contamination control

As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

Intent

This section defines requirements to ensure your organization plans to prevent contamination of the work environment, personnel or product. A requirement

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has been added related to control of contamination with microorganism or particulate matter for sterile medical devices.

Guidance

Examples of situations when your organization could handle contaminated product include:

- naturally contaminated materials used in the manufacturing process,
- contaminated product returned from customers for reuse,
- contaminated product returned from customers for servicing or complaint investigation.

In such situations, examples of actions to consider for special arrangements designed to prevent contamination of product, work environment or personnel, are:

- identifying contaminated or potentially contaminated product;
- providing segregated areas for handling such product; and
- implementing handling, cleaning, and decontamination procedures for product, work surfaces or personnel which have been or might have been contaminated.

During the manufacture of sterile product or product intended to be sterilized before use, or product for which viable or non-viable particulate contamination (including contamination with pyrogens) has significance in their manufacture or use, special consideration is paid to microbial and particulate contamination levels. Your organization ensures that, if the work environment could have an adverse effect on the fitness of product in use, this environment is controlled to limit contamination of product and to provide proper conditions for all operations performed. Such product should be produced and packaged in a qualified, controlled environment with established specifications. An exception to the need for a controlled environment during the entirety of manufacturing processes would be if contamination can be reduced to a known, consistent, controlled level by validated product cleaning, and maintained at this level by controlled packaging. However, even when a validated cleaning procedure is relied upon, a controlled environment might need to be established to control the validated cleaning and packaging process.

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7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;
b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment;
c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5).

The output of this planning shall be documented in a form suitable for the organization's method of operations.

NOTE Further information can be found in ISO 14971.

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Intent

This section outlines the importance of planning for product realization and documenting these planning activities. The need to ensure that there is documentation of the risk management processes used in product realization is highlighted. In addition to planning activities around product realization, your organization needs to address the handling, storage, distribution and traceability activities.

Guidance

Your organization needs to plan product realization to assure that medical devices produced under your QMS are safe and perform as intended. As part of your QMS, the product realization activities have a direct effect on medical device safety and performance. The plans need to be consistent with other QMS processes and can include:

- Specifying the inputs required.
- Determining the desired outcome for the process.
- Determining and documenting the sequence of activities, including target completion dates necessary to obtain the desired output.
- Allocating appropriate resources in terms of personnel and clearly assigning responsibilities, and
- Identifying the necessary measurement and monitoring of the process parameters.

The goal of the planning documentation is to provide your organization a clear understanding of the process and requirements to be successful in product realization activities. The output of planning will also define in product realization who is responsible for establishing the requirements for quality objectives; processes; documents, including records; and resources.

Risk management processes need to be documented where they are used in product realization, with risk assessments being performed at various stages and actions identified to reduce or control risks. Methods for generation and storage of the records arising from risk management need to be determined and implemented.

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Product risks are typically considered during the design and development phase of the product lifecycle and updated as the post-market knowledge of the product increases. A risk matrix can be prepared identifying the hazards that have to be addressed for the product to meet its safety and functionality expectations (e.g. general safety and performance requirements, essential principles, and other applicable regulatory requirements), assessing the risks associated with the hazards and identifying mitigating actions to reduce these risks. These matrices are often prepared by subject matter experts. It is important that experts with a suitable background (e.g. clinical) participate in the preparation or review of these risk assessments.

The risks of processes used throughout product realization need to be assessed. These include the production processes but can also include other QMS processes. Typically, process risk analyses are prepared, identifying the harms associated with the identified critical processes, estimating their risks and identifying actions that mitigate these risks to an acceptable residual level.

For example, the risk of the product causing infection can be estimated to be unacceptable and is mitigated by sterilizing the product prior to use. The hazard of the sterilization process not achieving sterility for the product is mitigated by conducting sterilization process validation and the activities defined by the applicable sterilization standards.

It is important to realize that the risk assessments are not static documents. They need to be used throughout the product life (e.g., during complaint investigation) and updated with the ever-increasing knowledge of the product or process. For example, when product nonconformity is alleged through a customer complaint, the personnel dealing with the complaint should be able to refer to an existing risk assessment to assist them with the planning of the actions to be taken. If no risk assessment is available for an identified hazard/harm, an update of the existing risk matrix should be considered. Similarly, when a process change is carried out, the change control includes a risk assessment of the change and the risk matrix should be updated accordingly.

Risk management documents need to be maintained as controlled documents, prepared using an approved protocol and updated with changes. In addition, risk management documents need to undergo periodic review.

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7.2 Customer-related processes

7.2.1 Determination of requirements related to product

The organization shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b) requirements not stated by the customer but necessary for specified or intended use, as known;
c) applicable regulatory requirements related to the product;
d) any user training needed to ensure specified performance and safe use of the medical device;
e) any additional requirements determined by the organization.

Intent

This section emphasizes the importance of identification of relevant requirements as the basis of new product realization. This section adds the requirement for determination of any user training needed to ensure specified performance and safe use of the medical device.

Guidance

This section deals with customer-related processes that provide design and development inputs, customer expectations for the delivery of existing product, and customer feedback and communication relative to orders placed or product delivered.

Product, including service, requirements can cover additional factors, such as:

- regulatory requirements including applicable medical device licensing or facility registration in the countries or regions where the product is placed on the market,
- intended use,
- performance expectations,

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- delivery schedules, and
- unspecified customer expectations.

For medical devices, an understanding of both stated intended use and any reasonably foreseeable misuse, and indications for use, is documented. This is of particular importance in the design and development of new product. The stated intended use and any reasonably foreseeable misuse should also be included in risk management activities (see 7.1 above regarding risk management activities).

7.2.2 Review of requirements related to product

The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

a) product requirements are defined and documented;
b) contract or order requirements differing from those previously expressed are resolved;
c) applicable regulatory requirements are met;
d) any user training identified in accordance with 7.2.1 is available or planned to be available;
e) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5).

When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

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Intent

The objective of this section is to ensure that, prior to committing to supply product to a customer, the customer's requirements are fully understood and documented. This section adds the requirement to make sure that any identified user training needed to ensure specified performance and safe use of the medical device is available or planned to be available.

Guidance

For your organization, the determination of the requirements for your product and design and development processes is an important activity when implementing, maintaining and improving your QMS.

Generally, a customer reviews product information and initiates interaction with your organization (online, by telephone or face-to-face) that will result in the determination of product requirements and the confirmation of an order. Some organizations have direct contact with their customers to determine product requirements and the confirmation of an order while others rely on their websites or other indirect communication for the interaction with their customers.

Written or electronic orders provide permanent evidence of the order details. Where verbal orders are received, special provisions should be made to retain evidence and confirm the requirements of the order (e.g. a confirmation e-mail sent to the customer).

All parts of customers' orders or contracts need to be reviewed to ensure that they can be met.

If all the transactions are carried out through a website, certain features can be included into the website's system to ensure this review occurs in an effective way before the payment is confirmed.

If part of a transaction is carried out directly between your organization and its customers, this review can be done in different ways (e.g. by telephone confirmation, quotation vs order confirmation). Some of the things to be verified are:

- location of product in the supply chain.

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- availability of parts or raw materials,
- your current equipment capacity,
- if product can be delivered by the customer's due date,
- if there are any processes controlled by external parties that need to be considered in the schedule.

If there are any requirements that are not covered by your usual work processes or might be unrealistic or unachievable, these requirements need to be resolved with the customer and both parties agree on any amendment. Therefore, good communication between your organization and the customer is essential to prevent and, if needed, resolve any difference. Where possible, communication processes should be developed and documented making clear who is authorized to liaise with customers to identify and resolve any such differences.

The evidence of a review can be as simple as a notation on a physical order that it can be fulfilled, together with the signature of the reviewer and the date. Where a more complex review is called for, how the results of the review are retained is discretionary, but it should at least include the main details. A record of the results of this review is required to be retained.

Where changes to an order or tender, or both, arise for whatever reason, the changes will need to be reviewed and agreed in the same manner as the original order/tender. If the changes are accepted, it is essential that everyone in your organization who is affected by the changes is informed. If any documents are affected by these changes, they will need to be amended as well.

Regulatory requirements relevant to the geographical region where the devices are to be made available need to be formally identified and documented, and any non-compliances with these need to be addressed. Regulatory requirements may relate to the device itself (e.g. medical device regulations, electrical/atomic/pressure safety, importation, etc), to the manufacture (e.g. environmental safety, QMS) and to distribution, handling and storage of the device (e.g. language, specific users, special security measures, distribution and authorised representative requirements, etc.). Devices for which regulatory noncompliance has not been resolved cannot be made available (see 7.2.3).

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7.2.3 Communication

The organization shall plan and document arrangements for communicating with customers in relation to:

a) product information;
b) enquiries, contracts or order handling, including amendments;
c) customer feedback, including complaints;
d) advisory notices.

The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

Intent

This section deals with the processes for communicating with external parties (e.g., customers and regulatory authorities) and the importance of maintaining appropriate information pathways in regards to pertinent product information, with emphasis on communication with regulatory authorities and planning and documenting communication arrangements.

Guidance

Your organization should be clear who is responsible for liaising with customers on product information, enquiries, contracts, advisory notices and customer complaints or feedback. More guidance on advisory notices is provided in 8.2.3 and 8.3.3.

This section focuses mainly on the product that your organization is going to provide to its customers. Product requirements can cover additional factors, such as intermediate deliverables (component, subassemblies) or provided services (e.g., passivation, cleaning or maintenance). The guidance in 7.3 will help your organization to determine if requirements for design and development apply.

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Medical device regulatory schemes existing in today's world markets have subtle differences in terms, definitions and reporting requirements with regard to complaints, corrective actions, preventive actions, changes to product or QMS changes. These schemes also have differing responsibilities for your organization, regulators, customers and third parties. It is very important that your organization make provisions to understand and comply with the regulatory schemes of each of the markets intended for its product. Customer communication can also have an effect on the ability of your organization to establish or verify traceability to an end user. This is particularly important for implantable medical devices for which there are specific traceability requirements (see 7.5.9) or other high-risk devices which might have tracking requirements put upon them by regulators.

Your organization should define responsibility and authority for communicating with applicable regulatory agencies throughout the lifecycle of the medical device; in the premarket stage (for example in submission for regulatory approval), in production (for example during a regulatory inspection or audit), or in the post-market stage (for example, in reporting adverse events that meet reporting criteria or advisory notices).

7.3 Design and development

7.3.1 General

The organization shall document procedures for design and development.

Intent

This section is updated for clarity by adding a general requirement (7.3.1) followed by new or renumbered and revised specific elements related to planning (7.3.2), inputs (7.3.3), outputs (7.3.4), review (7.3.5), verification (7.3.6), validation (7.3.7), transfer (7.3.8), control of changes (7.3.9) and files (7.3.10).

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In particular, this edition of ISO 13485 has added requirements to clarify design and development transfer activities. This addition highlights the need to consider manufacturability in the design and development process. Proper design and development processes that include plans for design and development transfer will increase the likelihood that product transferred to production will translate into a medical device that is appropriate for its intended use.

Guidance

The requirements in this section can be referred to as design control. Good design and development processes include systematic assessment of the outputs as an integral part of design and development. The requirements in this section are intended to describe design and development controls as an interrelated set of practices and procedures that are incorporated into the process.

The focus is to be sure that design and development inputs, based on user needs, are met by the design and development outputs. Systematic reviews of design and development activities are conducted to provide checks and balances. As a result of the reviews, deficiencies in requirements arising from design and development inputs and discrepancies between the proposed requirements and outputs are made evident and corrected earlier in the design and development process. Figure 2 below is the traditional diagram illustrating the key concepts of such a process.

In practice, this approach will provide designers and managers with enhanced understanding and improved visibility of the design and development process. Designers benefit both by enhanced understanding of the degree of conformance of outputs to user and patient needs, and by improved communication and coordination among all participants in the design and development process. With improved visibility, managers are empowered to direct the design and development process more effectively and to recognize problems earlier, make corrections, and adjust resource allocations.

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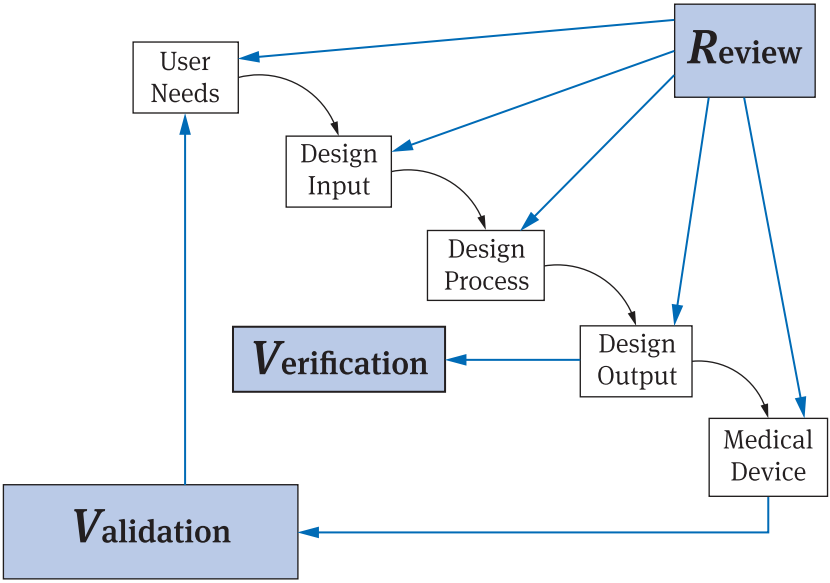

Figure 2 — Application of Design Control to the Design and Development Process

The design and development process depicted in Figure 2 is a traditional model in which design and development proceeds in a logical sequence of phases or stages. Basically, requirements are developed, and a medical device is created to meet those requirements. The medical device is then verified and validated, transferred to production, and the medical device is manufactured. In practice, feedback paths are necessary between each phase of the process and previous phases, representing the iterative nature of design and development. However, this detail has been omitted from Figure 2 to make the influence of design control on the design and development process more distinct.

The importance of the design and development inputs and verification of design and development outputs is illustrated by this example. When the input has been reviewed and determined to be acceptable, an iterative process of translating those inputs into a medical device begins. The first step is conversion of the inputs into system or high-level specifications. Thus, these specifications are a design and development output. Upon verification that the

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high-level specifications conform to the inputs, they become the design and development input for the next step in the design and development process, and so on. This basic technique is used repeatedly throughout the design and development process. Each input is converted into an output; each output is verified as conforming to its input; and it then becomes the input for another step in the process. In this manner, the inputs are translated into a medical device conforming to requirements.

The importance of design and development reviews is also illustrated by the example. The reviews are conducted at strategic points in the design and development process. For example, a review is conducted to assure that the inputs are adequate before they are converted into outputs. Another review is used to assure that the outputs are adequate before prototypes are produced for simulated use testing or clinical evaluation. Another review is conducted prior to transfer of the medical device to production. Generally, reviews are used to provide assurance that an activity or phase has been completed in an acceptable manner, and that the next activity or phase can begin. As Figure 2 illustrates, design and development validation extends the assessment to address whether medical devices produced in accordance with the design and development process actually satisfy user needs and intended uses.

An analogy to automobile design and development can help to clarify these concepts. Fuel efficiency is a common requirement. This could be expressed as the number of kilometers-per-liter of a particular grade of fuel for a specified set of driving conditions. As the design and development of the automobile proceeds, requirements are converted into system and subsystem specifications needed for the automobile, including the fuel efficiency requirement. As these various systems and subsystems evolve, verification methods are used to establish conformance to specifications. Because several factors directly affect fuel efficiency, many of the verification activities help to provide confirmation that the overall output will meet the fuel efficiency requirement. This might include simulated road testing of prototypes or actual road testing. This establishes that the output conforms to the fuel efficiency requirement using objective evidence. However, these verification activities alone are not sufficient to validate the fuel efficiency. The fuel efficiency could be validated when representative users have driven automobiles representative of production cars, under a specified range of driving conditions and

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judged the fuel efficiency to be adequate. This provides objective evidence that the particular requirement for a specific intended use can be consistently fulfilled.

Although the model in Figure 2 is a useful tool for introducing design control, its usefulness in practice is limited. The model does apply to the design and development of some simpler medical devices. However, for more complex medical devices, a concurrent engineering model is more representative of the design and development processes in use in the medical device industry.

In a traditional design and development scenario, the engineering department completes the design and development process and formally transfers the product specification to production. Subsequently, other groups or functions develop processes to manufacture and service the product. Historically, there has frequently been a divergence between the intent of the designer and the reality of the factory floor, resulting in such undesirable outcomes as low manufacturing yields, rework or redesign of product, or unexpectedly high cost to service the product.

One benefit of concurrent engineering is the involvement of production and service personnel throughout the design and development process, assuring the mutual optimization of the characteristics of a medical device and its related processes. While the primary motivations of concurrent engineering are shorter development time and reduced production cost, the practical result is often improved product quality.

Concurrent engineering encompasses a range of practices and techniques. From a design control standpoint, it is sufficient to note that concurrent engineering can blur the line between design and development and production. On the one hand, the concurrent engineering model properly emphasizes that the development of production processes is a design and development rather than a manufacturing activity. On the other hand, various components of a medical device could enter production before the specification of the medical device as a whole has been approved. Thus, concurrent engineering and other more complex models of design and development usually require a comprehensive matrix of design and development reviews and approvals to ensure that each component and process is validated prior to entering production and the medical device as a whole is validated prior to release.

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Risk management is the systematic application of management policies, procedures, and practices to the tasks of identifying, analyzing, controlling, and monitoring risk. It is intended to be a framework within which experience, insight, and judgment are applied to successfully manage risk. It is included in this guidance because of its effect on the design and development process.

Risk management begins with the identification of the design and development inputs. As the medical device proceeds through the design and development process, new risks could become evident. Your organization's system has to identify and, when necessary, reduce these risks. The risk management process is integrated into the design and development process. In this way, risks can be identified and managed earlier in the design and development process when changes are easier to make and less costly.

An example of this could be an exposure control system for a general-purpose x-ray system. The control function was intended to be achieved through software. If the risk management system discovered several failure modes that could not be controlled by the software until late in the design and development process, risk analysis of the system uncovered several failure modes that could not be controlled by the software and an expensive design change to add a back-up timer would have to be implemented to mitigate a potential overexposure to the patient to an acceptable level.

In addition to procedures and work instructions necessary for the implementation of design control, policies and procedures could also be needed for other determinants of medical device safety and performance that should be considered during the design and development process. Examples of topics for which policies and procedures could be appropriate are:

- risk management,
- medical device reliability,
- medical device durability,
- medical device maintainability,
- medical device serviceability,
- human factors engineering,
- software engineering,
- use of standards,

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- configuration management,
- compliance with regulatory requirements,
- medical device evaluation (which could include third party product certification or approval),
- clinical evaluation,
- document control,
- use of consultants,
- use of external parties,
- use of your organization's historical data.

7.3.2 Design and development planning

The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses.

During design and development planning, the organization shall document:

a) the design and development stages;
b) the review(s) needed at each design and development stage;
c) the verification, validation, and design transfer activities that are appropriate at each design and development stage;
d) the responsibilities and authorities for design and development;
e) the methods to ensure traceability of design and development outputs to design and development inputs;
f) the resources needed including necessary competence of personnel.

Intent

This section emphasizes the importance of planning in the design and development process, and the requirements for documenting design and development phases and elements of the process.

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Guidance

Your organization needs to plan and control the design and development of the product. This would include:

- determination of design and development stages and
- determination that the review, verification and validation are appropriate to each design and development stage.

It needs to be clear who has responsibility and authority for design and development. Generally, as different groups or functions within your organization are involved in design and development, clear and effective communication with distinct assignment of responsibilities across your organization is important.

As design and development progresses, the plan includes requirements that there will be evidence the plan has been updated, as appropriate.

Planning is needed to ensure that the design and development process is appropriately controlled and that the quality objectives of the medical device are met. The plan should be consistent with your organization's QMS provisions for quality planning and product realization requirements, including design and development controls.

The design and development plan should identify the review, verification and validation methods to be used, including who is to carry them out, how they are to be performed and what documents and records are to be retained. The following elements would typically be addressed in the design and development plan or plans:

- a description of the goals and objectives of the design and development program (i.e. what is to be developed);
- the markets intended (at least a broad preliminary assessment) for the product;
- an identification of QMS documents, procedures and resulting records applicable to controls for design and development;
- an identification of organizational responsibilities with respect to assuring quality during the design and development phase, to including interfacing with any suppliers;

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- the identification of the major tasks to be undertaken (or stages/phases of the design and development control), expected outputs (deliverables and records) resulting from each task or stage/phase, and individual or organizational responsibilities (staff and resources) for completing each task or stage/phase;
- the schedule of major tasks or stages/phases to meet overall programme time constraints;
- organizing design and development reviews, including the selection of reviewers, the composition of review teams, and procedures to be followed by reviewers appropriate to each task or stage/phase;
- the identification of appropriate existing and anticipated measurement and monitoring requirements for the development of specifications, verification, validation and production related activities (see also guidance given in 7.6 of this handbook);
- risk management activities;
- selection of suppliers.

Planning enables management to exercise control over the design and development process while providing for predictable timeframes and records. Planning accomplishes all this by clearly communicating policies, procedures and goals to members of the design and development team. It also provides a basis for measuring conformance to QMS objectives.

In deciding the number of design and development reviews necessary, you need to consider

- Are there obvious phases or natural stages in the design and development?
- If something goes wrong which is not detected until a much later stage, what are the likely consequences and what actions should you take?
- What is the time scale of the design and development?

The inter-relationship of the process for design and development with the development of the production process can, for some technologies, be very close, whereas for others, the relationship is remote. Irrespective of the closeness of the relationship, the transfer from design and development to production needs to be addressed in design and development planning. Design and development outputs should withstand variations in the manufacturing

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process, and the manufacturing process should be capable and stable to consistently produce product that is safe and performs as intended. Often this results in very interactive design and development and process development activities.

7.3.3 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include:

a) functional, performance, usability and safety requirements, according to the intended use;
b) applicable regulatory requirements and standards;
c) applicable output(s) of risk management;
d) as appropriate, information derived from previous similar designs;
e) other requirements essential for design and development of the product and processes.

These inputs shall be reviewed for adequacy and approved.

Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

NOTE Further information can be found in IEC 62366–1.

Intent

This section underscores the importance of proper determination and documentation of inputs into the design and development process, and that product requirements have to be able to be verified or validated. In addition, an explicit requirement to include usability requirements as a design input has been added.

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Guidance

A major consideration is the customer's needs, which cannot always be clearly stated. It is often just as important to be aware of the customer's unstated expectations, which could be even more critical to the design and development process. The review might result in additional information to be considered. Other factors that could need to be considered and recorded include the following:

- regulatory requirements relating to the product and service;
- standards;
- market surveys and research;
- benchmarking results;
- industry practice;
- past experience, including information derived from similar designs, where applicable;
- other requirements that your organization deems essential for design and development; and
- packaging and handling requirements.

All design and development inputs need to be reviewed and approved to ensure they are complete, unambiguous and compatible with each other. The compatibility means that your organization appropriately prioritizes the inputs to resolve conflict prior to final approval of design and development inputs.

Your organization needs to ensure they have current editions of applicable codes, regulations and standards, including regulatory requirements for safety and performance (see also 4.2.4).

Interface-related design and development requirements are going to define what or whom the product needs to be compatible with based on how it is used. For example, an interface that is important in every case is the user or patient interface. In addition, the interface requirements also relate to those characteristics of your medical device that are required as a result of its use with external systems that are outside of the control of your organization; for example, other equipment or medical devices with which your medical device is to be connected.

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For additional information, there is additional information in the international standard for human factors or usability developed jointly by ISO and IEC published as IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices.

7.3.4 Design and development outputs

Design and development outputs shall:

a) meet the input requirements for design and development;
b) provide appropriate information for purchasing, production and service provision;
c) contain or reference product acceptance criteria;
d) specify the characteristics of the product that are essential for its safe and proper use.

The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release.

Records of the design and development outputs shall be maintained (see 4.2.5).

Intent

This section describes requirements for the outputs of the design and development process.

Guidance

Your organization needs to ensure that the results of the design and development processes meet the design and development inputs.

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The design and development outputs can take a number of forms, for example:

- drawings and calculations;
- specifications for raw materials, component parts and sub-assemblies and medical devices;
- packaging and labelling specifications;
- parts list;
- customer training materials;
- process specifications;
- component parts and sub-assemblies and medical devices;
- product and process software;
- quality assurance procedures (including acceptance criteria);
- manufacturing and inspection procedures;
- work environment requirements;
- monitoring and measuring equipment needs;
- identification and traceability requirements (including procedures, if necessary);
- installation and servicing procedures and materials;
- documentation for submission to the regulatory authorities where the medical devices will be marketed, if appropriate; and
- records to demonstrate that the design and development process was carried out in accordance with the design and development plan.

In deciding what form your output should take, you will need to consider who is going to make use of it and in what circumstances. For example, a regulatory body could have a specific format, which needs to be complied with. See the guidance on traceability in design and development verification in 7.3.6.

Your organization needs to ensure that there is evidence of how verification of outputs will be determined, and that the records of the design and development outputs are provided in a form that enables verification against the design and development inputs.

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7.3.5 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to:

a) evaluate the ability of the results of design and development to meet requirements;
b) identify and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.

Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5).

Intent

This section underscores the importance of systematic reviews of the results of the design and development process.

Guidance

Design and development review is part of the design and development process that is undertaken to confirm that the implementation of the process as described in the design and development plan and that:

- the output of each design and development stage meets the design and development inputs,
- problems are identified, and
- solutions are developed.

Your organization has to complete design and development reviews as outlined in your design and development plan. These reviews can take place at any

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stage in the design and development process. For relatively simple product fewer reviews could be done. For example, in the design and development of a simple surgical instrument (e.g., scalpel or screwdriver), fewer reviews might be needed. For complex product, several reviews could be required. For example, in the design and development of software, you could need frequent reviews throughout the process, involving consultation with the customer.

Design and development reviews are not conducted just by the team directly undertaking the design and development project but should also include independent reviewers and the people who will be involved in producing the product. Some jurisdictions can require independent reviewers, those who do not have direct responsibility for the design and development stage being reviewed, to participate in the review of the design and development process. The review might include not only the people within your organization but, where relevant, those outside such as the customer and external providers involved. Suggested list of attendees could include: manufacturing, operations, sales, marketing, quality, regulatory, clinical, finance, service, technical support, or training. If the review reveals problems, you will need to decide what actions are to be taken to deal with these. The effect of the actions should be part of the next review.

You need to retain records of reviews using an appropriate method. For example, a complex design and development project might be reviewed in a formal meeting, and the minutes of such a meeting would constitute the records.

The records maintained have to show your organization:

- conducted systematic reviews of design and development at suitable stages that evaluate the extent to which the design and development process fulfils the requirements,
- identified problems with proposed necessary actions,
- identified who participated in the reviews, and
- ensured that representatives from the various stages of design and development were included as participants in the review.

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7.3.6 Design and development verification

Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.

The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.

Records of the results and conclusions of the verification and necessary actions shall be maintained (see 4.2.4 and 4.2.5).

Intent

This section outlines the requirements for verifying that design and development outputs meet the design and development inputs by meeting predetermined criteria using appropriate supporting objective evidence. Requirements for verification plans and considerations for medical device interfaces are included.

Guidance

Verification is the confirmation, through the provision of objective evidence, that the results at the end of the design and development process meet the requirements identified as necessary at the beginning of the process. For larger projects, the design and development process is often broken into stages and the verification can be carried out on a stage-by-stage basis. Verification plans are developed to direct all activities that will be carried out to demonstrate that the design and development outputs meet their respective inputs. These plans

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could include a traceability matrix that directly links the outputs to inputs. There can be multiple outputs to meet a single design and development input. This matrix is used often to ensure all inputs are addressed. Verification plans should address production as well as traceability requirements. In addition, the verification test methods should include qualification of those test methods.

There should be defined acceptance criteria for design and development outputs to include acceptable variation around those acceptance criteria. These acceptance criteria should take into account the risk that would be created in the event the output would fail. Risk analysis output can be used to justify acceptance criteria.

Product used for verification is to be representative of the final product. Requirements should be established to demonstrate the design and development output is met in a consistent manner. Care should be taken when selecting statistical methods for analyzing data to ensure they are appropriate for the type of analysis to be done. The product requirements and statistical techniques are used when determining the quantity of product to be used for verification and number of tests to be performed.

Finally, verification plans should address actions that should be taken when acceptance criteria are not met. Where verification shows that the output does not meet the input, your organization will need to decide what to do about it. The effect of actions that your organization decides upon should form part of the next design and development review.

7.3.7 Design and development validation

Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

The organization shall document validation plans that include methods, acceptance criteria, and, as appropriate, statistical techniques with rationale for sample size.

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Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5).

As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.

Validation shall be completed prior to release for use of the product to the customer.

Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4 and 4.2.5).

Intent

This section outlines the requirements concerning the confirmation that user needs have been appropriately met by the outputs of the design and development process. Requirements for validation plans and considerations for medical device interfaces are included.

Guidance

Validation is the confirmation, through the provision of objective evidence, that the medical device is capable of meeting requirements for a specific intended use or application. Design and development validation plans are developed to direct all activities that will be carried out to demonstrate that the medical device meets customer requirements. Validation plans should address production

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as well as traceability requirements. In addition, validation plans should include qualification of those methods.

There should be defined acceptance criteria for design and development outputs to include acceptable variation around those acceptance criteria. These acceptance criteria should take into account the risk that would be created in the event the medical device would fail during use. Risk analysis output can be used to justify acceptance criteria.

The product used for validation study is representative of the medical device. Requirements should be established to demonstrate the medical device performs in a consistent manner. Care should be taken when selecting statistical methods for analyzing data to ensure they are appropriate for the type of analysis to be done. The medical device requirements and statistical techniques are used when determining the quantity of medical devices used for validation and the number of tests to be performed.

Finally, validation plans should address actions that should be taken when acceptance criteria are not met.

The medical devices employed for design and development validation need to be produced under the conditions specified as final for the product (e.g. initial production units recognizing that production equipment or processes might change between production for validation and production for commercial distribution). The validation is conducted under actual or simulated use conditions; this can involve clinical investigations in accordance with regulatory requirements. These points are important as design and development validations can be irrelevant or misleading if not done using product representative of the final product and process conditions, or not done under conditions of actual or simulated use. It is not always possible to determine the adequacy of product by building and testing prototypes or models produced in a laboratory setting.

Some national or regional regulations require clinical evaluations as part of design and development validation. Clinical evaluation can include one or more of the following to ensure that the medical device performs as intended:

- critical analysis of relevant scientific literature in relation to the medical device being designed and developed;

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- historical evidence that similar medical devices or materials are clinically safe;
- clinical investigation (or trial).

For additional requirement regarding clinical evaluations, a reference to the ISO 14155 series of standards could be helpful.

For medical devices used for in vitro diagnosis, evaluation of performance consists of in vitro studies undertaken to ensure that the medical device performs as intended in laboratories for medical analyses or other suitable environments outside of your organization's premises.

Where validation indicates that the product does not meet the requirements as outlined above, your organization will need to decide what it is going to do about it. The effect of actions that you decided upon will need to be part of the next design and development review.

The results of the validation processes should be fed back into each stage of the design and development process, as this can lead to changes and improvements (or even into the next design and development revision, or next generation of the product and service).

The validation method to be used needs to be recorded. The record should also demonstrate that the design and development validation has been performed in accordance with the planned arrangements, and demonstrate that the resulting product can fulfill the requirements for the specified or known intended use of the product. The result of the validation needs to be recorded, along with necessary actions.

Validation has to be completed before the delivery or implementation of the product.

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7.3.8 Design and development transfer

The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Results and conclusions of the transfer shall be recorded (see 4.2.5).

Intent

This entirely new section describes the process of taking the outputs of the design and development process and ensuring that they are translated appropriately into the manufacturing environment.

Guidance

The transfer of a product to production should occur after review and approval of specifications and procedures. Planning of product realization should take into account the production (ability to produce, parts/materials availability, production equipment needs, operator training, etc.) and possible conformity assessment requirements (procedures, methods, equipment). This planning should encompass all of the specifications to ensure that each specification is correctly incorporated into the specific processes or procedures associated with product realization. Failure to do so can lead to production delays and nonconforming product for reasons such as purchase of incorrect raw material grades or quantities, inappropriate manufacturing methods, unvalidated processes, unclear work instructions or incorrect labelling. The adequacy of specifications, methods and procedures can be demonstrated through process validation (see 7.5.6).

In planning for design and development transfer, the transfer plan is established, the sourcing activities start and the materials, as well as suppliers, are qualified according to procedures for purchasing. Process validation can be initiated before or during transfer.

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Design and development transfer ends when it is confirmed that the product has been correctly transferred into the manufacturing process(es). Your organization will need to ensure that there are documented procedures for, and records maintained of, the effective transfer of the design and development outputs to manufacturing.

7.3.9 Control of design and development changes

The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.

Design and development changes shall be identified. Before implementation, the changes shall be:

a) reviewed;
b) verified;
c) validated, as appropriate;
d) approved.

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.

Records of changes, their review and any necessary actions shall be maintained (see 4.2.5).

Intent

This section provides requirements for controlling and documenting design and development changes, including the requirement that the effect of the change is evaluated for product that is in process, as well as on the outputs of risk management and product realization processes. Also included is detail to

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consider in the determination of the significance of a design and development changes and the potential effect on the medical device.

Guidance

Your organization will need to ensure that the records include all changes to design and development of product. Your organization has to provide evidence that these changes have been reviewed, verified and validated, as appropriate, and approved before implementation. As part of the review your organization needs to evaluate the effect of the changes on the constituent parts and the delivered product, with input from all appropriate departments and personnel.

Usually there are two situations where design and development changes can be done:

1) during initial design and development, and
2) following product release.

Design and development changes made after the approval of the design and development inputs for incorporation into product, and those changes made to correct deficiencies once product has been released to production, have to be documented.

The records of these changes create a history of the evolution of the product, which can be invaluable for failure investigation and for facilitating the design and development of future product. Such records can prevent the repetition of errors and the development of unsafe or ineffective medical devices. The evaluation and documentation should be in direct proportion to the significance of the change. Procedures need to ensure that after the design and development requirements are established and approved, changes to the product, both pre-production and post-production, are reviewed, validated/verified as appropriate, and approved. Otherwise, a medical device could be rendered unable to perform properly and be unsafe or ineffective.

Throughout the design and development process, it is important that changes are documented and communicated to relevant function in your organization so that the total effect of the change can be determined.

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The following activities are important to consider:

- Identification of change(s).
- Review of the design and development plan and update as needed.
- Risk Management and risk analysis review or update.
- Review, verification and validation of changes.
- Review and approval of changes prior to implementation.
- Consideration in relation to product already produced and delivered.
- Documentation of changes and related activities.
- Update of the Medical Device File and regulatory filings.
- Follow up of effectiveness of the change.

When a change is made to a specification, method, or procedure, your organization should evaluate the change in accordance with a documented procedure to determine if the submission of a new or revised regulatory application is required. Records of this evaluation and its results are maintained.

7.3.10 Design and development files

The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

Intent

This entirely new section outlines records generated during the design and development process which are to be maintained as a file for each medical device type or family.

Guidance

The design and development file is a formal document that is prepared for each medical device or family of medical devices and describes the design history of a medical device. As this file provides history of the product, it is important

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that it is controlled and maintained. The file can be either a collection of the actual documents generated in the design and development process or an index of documents and their storage location. The compilation of the design and development records might also be known as the Design History File (DHF).

The file contains the design and development plan and contains or references all the records necessary to establish conformity with the design and development plan, including the design and development procedures. In contrast, the final design and development output includes the medical device, its labelling and packaging, medical device specifications and drawings, as well as all instructions and procedures for production, installation, maintenance, and servicing. Some of these same design and development outputs are also part of the Medical Device File (see 4.2.3).

The design and development file contains or references the records necessary to demonstrate that the medical device was developed in accordance with the approved plan, that it performs as intended and that the appropriate requirements for the medical device have been met. The file is necessary so that your organization can exercise control over and be accountable for the design and development process, thereby increasing the probability that the medical device conforms to the design and development requirements.

This file can include, but is not limited to:

- results of engineering, laboratory, simulated use, animal tests and evaluation of published literature applicable to the medical device or substantially similar medical devices regarding the safety of the medical device and its conformity with its specifications;
- detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test results and conclusions regarding:
  - biocompatibility (identifying all materials in direct or indirect contact with the patient or user);
  - physical, chemical and microbiological characteristics;
  - electrical safety and electromagnetic compatibility;
  - stability/shelf life;

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- software verification and validation describing the software design and development process and evidence of the validation of the software, including the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release, addressing all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer;
- evidence of application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances;
- the report on the clinical evaluation;
- post market clinical follow-up plan and post market clinical follow-up evaluation report;
- regulatory strategy and submission documentation.

7.4 Purchasing

7.4.1 Purchasing process

The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information.

The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

a) based on the supplier's ability to provide product that meets the organizations' requirements;
b) based on the performance of the supplier;
c) based on the effect of the purchased product on the quality of the medical device;
d) proportionate to the risk associated with the medical device.

The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.

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Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).

Intent

This section describes the purchasing process needed to assure requirements for purchased product are met. At a high level the typical steps in the purchasing process are supplier:

- selection,
- qualification, and
- monitoring.

A risk-based approach can be applied to each step based on the risk the purchased product, including service, has on the safety and performance of the medical device or the suitability, adequacy or effectiveness of your QMS. Each step can have several separate or linked processes to fulfil the requirements of ISO 13485 and the applicable regulatory requirements. For example, in the monitoring step your organization could use incoming inspection, auditing, and feedback processes.

Guidance

Each regulatory authority ultimately holds one organization primarily responsible for meeting applicable regulatory QMS requirements. This organization, with the ultimate responsibility for compliance with regulatory requirements, cannot delegate or otherwise give (contractually or otherwise) its obligation and responsibility over the conformity with the applicable regulatory requirement. This means the responsibility for complying with the regulatory requirements cannot be delegated to an external provider. This includes an external provider that is part of your organization's larger corporate entity but operates

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under a separate QMS. For example, if the external provider is not a part of your organization's internal audit scope, then the supplier is under a separate QMS and is considered an external provider or supplier.

Corporations or companies that have corporate quality policies and procedures do not necessarily place all divisions or groups under the same QMS. Therefore, one division or group can be an external supplier to another division or group within the same corporation/company. Such suppliers are to be controlled in a similar way as other external suppliers are controlled. On the other hand, if your organization does have a single Quality Management System, then all business units, divisions and groups are covered within your QMS, regardless of their geographical location, are deemed to be part of the organization or internal providers covered by your organization's QMS. See ISO 9000 for additional definition of this concept.

Some suppliers can undergo some form of oversight either by a regulatory authority, or a third-party operating on behalf of a regulatory authority (for example contract sterilizers, contract laboratories, pharmaceutical manufacturers, other medical device manufacturers, etc.). This oversight does not relinquish your organization's responsibility to establish controls and provide evidence for product obtained from suppliers.

Regulatory authorities and third parties will inspect/audit your organization to confirm that objective evidence of control over product from suppliers is present, or readily available. Failure to have any evidence, or provide access to any objective evidence of the controls associated with product from suppliers could result in your organization's QMS being non-compliant.

The control of suppliers is a process consisting of establishing criteria, evaluating, selecting, ongoing monitoring and reevaluating. The application of the process depends on the nature and risk associated with the product, including service and processes (see 4.1), being purchased or otherwise received from an external provider. The process of establishing controls for product obtained from suppliers typically comprises seven phases, which includes:

- Planning.
- Selection of potential supplier(s).
- Supplier evaluation and acceptance.

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- Finalization of controls.
- Delivery, measurement and monitoring.
- Feedback and communication, including Corrective Action and Preventive Action process.
- Reevaluation.

Figure 3 illustrates key activities that your organization would perform, along with examples of the type of objective evidence that could be generated to help demonstrate your organization's control. Some of these activities might be performed in parallel. The list provided is not meant to be all-inclusive and other examples may be added. In addition, some of these activities can occur within other QMS processes. For example, planning for supplier control can be part of quality planning. The examples of objective evidence given in the diagram could be subject to regulatory audits only in regard to the safety and performance of the medical device.

This figure is taken from GHTF/SG3/N17:2008 and additional information may be reference in that document.

When your organization decides that a particular supplier is to be used, it documents the criteria and basis for the evaluation and selection. Questions you might want to ask in selecting suppliers could include one or more of the following:

- Do they have the necessary resources (e.g. equipment and personnel)?
- Do they have a QMS and is that QMS certified?
- How reliable are they?
- Can they provide what you want?
- Do they have the appropriate capability?
- Is the quoted delivery time acceptable?
- Have you used them before successfully?
- Do they have a good reputation?
- Do they have a good credit rating?
- Are changes occurring to them (e.g. are they being bought out and going to be under new management or new ownership; are they moving location; have they acquired new equipment; have any of their key personnel left or been reassigned)?

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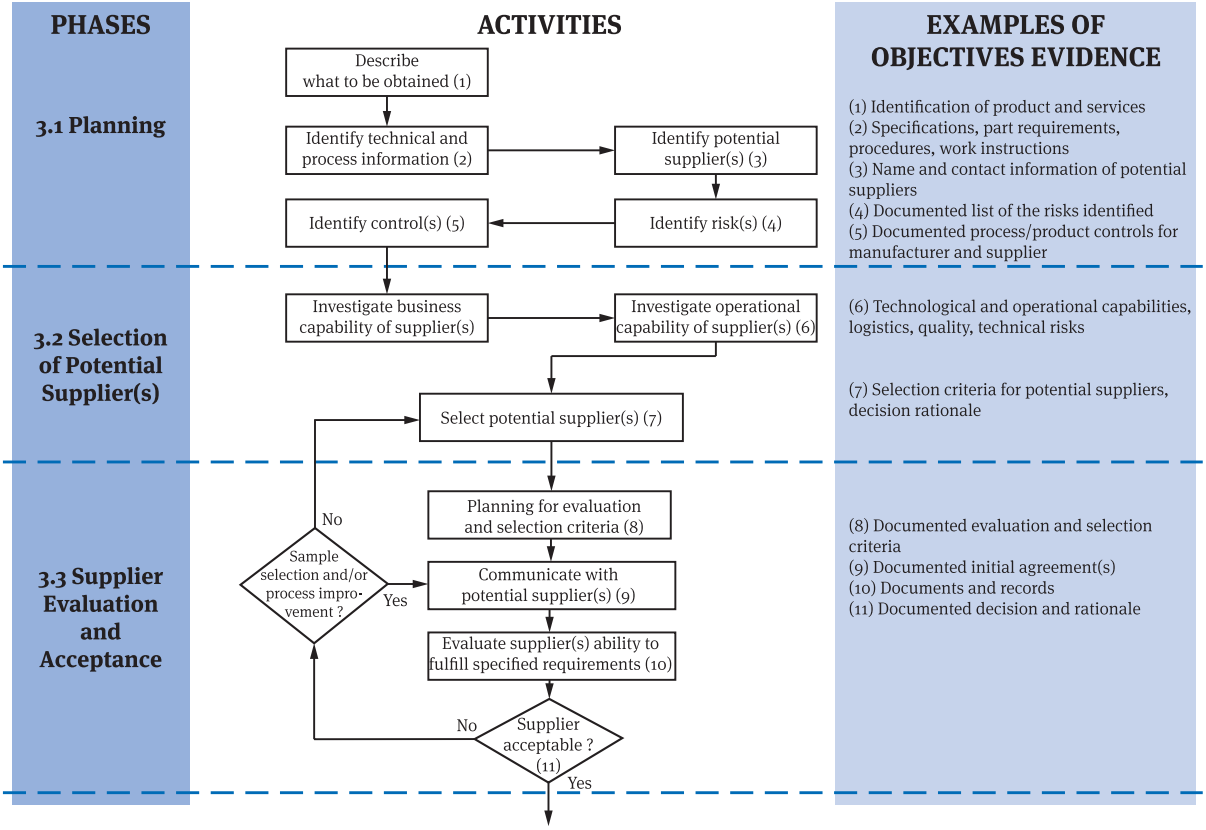

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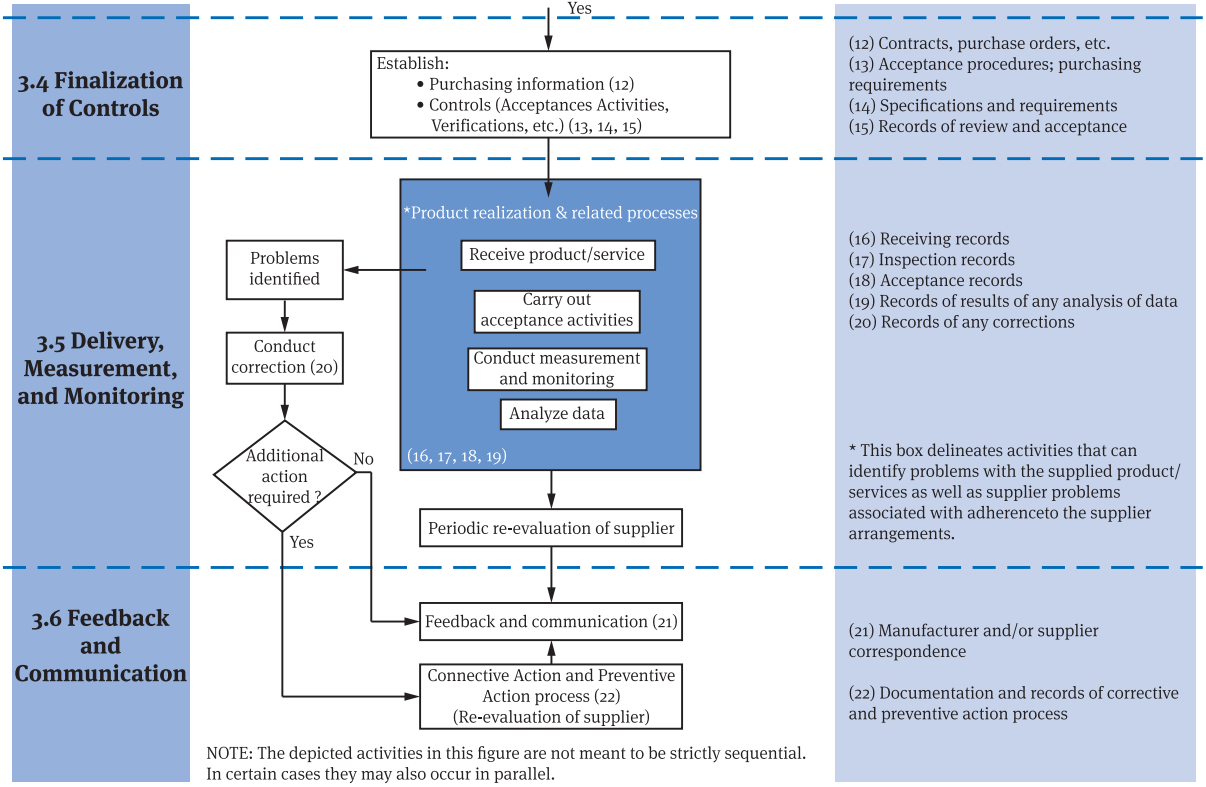

NOTE: The depicted activities in this figure are not meant to be strictly sequential. In certain cases they may also occur in parallel.

Figure 3 — Example of a supplier control process

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The process of planning and selection, and associated controls might differ when applied to, for example:

- an original equipment manufacturer (OEM),
- a logistics service,
- an information technology service,
- a contract sterilizer,
- a supplier of material to your organization's specifications,
- a design and development service,
- a clinical evaluator,
- a consultant,
- a testing and calibration service, or
- a supplier of off-the-shelf components.

Your organization needs to also monitor the performance of its suppliers, to ensure that they still meet the original evaluation and selection criteria or any new/revised criteria.

The evaluation of a supplier can include:

- testing of product to be provided,
- review of third-party evaluation reports,
- review of historical data, such as records of past performance,
- certification by a third party of the supplier's QMS, or
- auditing of the supplier's QMS by your organization.

Regardless of the method of evaluation, your organization is required to demonstrate that it has control over the purchased product or activity by possessing objective evidence that the selection of a supplier was based on appraisal appropriate to the product or activity being purchased and the supplier's ability to enable your organization to meet the customer and applicable regulatory requirements associated with the medical device.

The extent to which your organization monitors a supplier's performance depends on how critical the process or product being provided is to the safety and performance of your product and the suitability, adequacy or effectiveness of your QMS. The nature and risk associated with the medical device should be taken into account.

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When monitoring the performance of suppliers, your organization should consider a supplier's third-party certification status, compliance trends and conformance history. Your organization should define the re-evaluation frequency of supplier performance. Your organization should also include in the supplier monitoring activities the need for your registration body to visit the supplier to obtain objective evidence that external processes are under control and that the product, including service, conform to your organization's specified requirements. These requirement could include customer and applicable regulatory requirements.

When requirements are not met by the supplier, appropriate steps should be taken to manage the situation and prevent recurrence, potentially including:

- notification of the supplier,
- increasing inspection sample size,
- initiation of a supplier corrective action request,
- replacement of the supplier.

If your organization is looking for additional information related to supplier controls and the control over purchased product, a place to look, among others, is GHTF/SG3/N17:2008, Quality Management System — Medical Devices — Guidance on the Control of Products and Services Obtained from Suppliers.

7.4.2 Purchasing information

Purchasing information shall describe or reference the product to be purchased, including as appropriate:

a) product specifications;
b) requirements for product acceptance, procedures, processes and equipment;
c) requirements for qualification of supplier personnel;
d) quality management system requirements.

The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier.

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Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).

Intent

This section provides the details on the communication and documentation of purchasing requirements, including a new requirement for written notification of changes to purchased product.

Guidance

To get what your organization needs, the information submitted to the suppliers should be clear on what you want, when it needs to be provided and what specific controls and measures are needed. Normally, this information is given as a written order (e.g., purchase order with specification) or electronic communication.

The degree to which the details listed in items a) to d) in the requirement apply depends on the extent to which the externally provided processes and product, including services, being requested affect your organization's ability to consistently meet customer and applicable regulatory requirements.

It is essential that all relevant requirements have been established and communicated at the time of ordering. These can include product specifications, drawings, catalog or model numbers, as well as packaging and shipping requirements including the required delivery date and place. In some cases, the complete description could be covered by a catalog number, or a part number. Other factors that should be clearly stated could relate to data or information requirements including labelling, certificates of analysis or test results. While it

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is essential to describe what your organization wants, unnecessary or unclear detail can lead to misunderstanding and incorrect delivery.

Your organization can make reference to applicable technical information such as national or international standards, applicable regulations and test methods. Another approach is for information to be clearly and precisely stated to the supplier on the purchase order. Responsibility for reviewing and approving the purchasing data needs to be clearly assigned to appropriate personnel to prevent the purchase of incorrect materials. The revision status of documents referenced in the purchasing data is identified to ensure that the correct versions of materials are purchased.

As appropriate to facilitate the relationship with your organization's suppliers, the introduction of quality agreements (see 4.1.5) can provide a good baseline of expectations for supplied product, including services.

Quality agreements can be in various forms including information provided on purchase orders (e.g., terms and conditions, specifications, other documented information) or a separate formal document that both parties approve. At a minimum, the agreement should include a provision that the supplier will not change the product or the process provided without prior written notification. Any specific controls, (e.g., inspection, test, verification/validation, process requirements) can also be outlined by your organization in the quality agreement to ensure the appropriate controls are applied by your supplier. In addition, if your organization requires supplier personnel to have and maintain specific competence or qualification, this can be in the agreement as well.

Depending on your organization's traceability requirements, purchasing documents and records could need to be identified and retained; i.e. when evaluating the traceability requirements, consideration should be given to what purchasing information and records could also need to be retained to facilitate traceability. For example, it may be important to know to what revision of a specification a purchased part was ordered. If that is true, then this information should be kept as part of the purchasing documents or records.

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7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.

When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information.

Records of the verification shall be maintained (see 4.2.5).

Intent

This section contains requirements to confirm your organization's requirements for purchased product have been met. Furthermore, the controls your organization puts in place are to be proportionate to the risk associated with the purchased product.

Guidance

Most organizations have some form of control and evaluation, on a regular basis, of product provided by their suppliers, from a simple check that what is delivered is what was ordered, a process of incoming inspection, to going to the supplier's premises to verify or inspect what you have ordered. Based on the relevance of the externally provided processes or product, including services, it is up to your organization to decide on the appropriate type and extent of its control and evaluation activities.

Your organization's documented procedures should specify the method of verifying that product received is in accordance with specifications, is complete

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has proper identity, and is undamaged. The procedures should also include provisions for verifying that incoming product has the required supporting documentation (e.g. certificates of conformity, acceptance test reports) and that documentation is available to your organization.

If purchased product is claimed to conform to the supplier's specification, your organization should check that the product meets the agreed specification. This check can be accomplished by various approaches, such as certification of suppliers, certificates of conformance, skip lot testing, 100 % or sampling inspection, as determined by the requirements of your organization's QMS.

Your organization is responsible to ensure service provided by external providers meets your requirements. For example, calibration services have to meet your requirements.

Inspection on receipt is one method for your organization to verify that purchased product delivered to your organization's facilities fulfils specified requirements. This section does not imply that incoming product has to be inspected and tested by your organization. Incoming inspection might not be required if the necessary confidence in the product can be obtained by appropriate supplier controls (see 7.4.1) and other defined processes or procedures, particularly if the information given by a supplier is considered sufficient.

Appropriate action in the event of nonconformities should be specified so that the nonconformity can be dealt with in a consistent manner (including identification, segregation and documentation) and without undue delay.

When a supplier makes changes to their product, the product should be evaluated to ensure no adverse or unintended effects. This evaluation should consider effect on design and development verification, design and development validation, or process validation.

Analysis of previous receiving inspection data, in-plant rejection history or customer complaints will influence your organization's decisions regarding the amount of inspection required and the need to reassess a supplier.

These requirements apply to all product received from outside your organization's QMS, whether payment occurs or not, and whether the purchased product or the outcome of a process performed by an external party is intended

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to be received at your organization or at another site (including directly at the customer).

7.5 Production and service provision

7.5.1 Control of production and service provision

Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to:

a) documentation of procedures and methods for the control of production (see 4.2.4);
b) qualification of infrastructure;
c) implementation of monitoring and measurement of process parameters and product characteristics;
d) availability and use of monitoring and measuring equipment;
e) implementation of defined operations for labelling and packaging;
f) implementation of product release, delivery and post-delivery activities.

The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

Intent

The intent of this section is to ensure that appropriate controls have been established and documented for producing product or providing services throughout the lifecycle of a medical device.

Guidance

To ensure consistency in production methods and outputs, detailed documented procedures are utilized for all manufacturing and inspection processes. Reference materials or standards used for these processes can be

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physical or visual. These can include, product samples indicating permissible color variation or images of known non-conformities. Flowcharts or checklists can also be of value. Reference materials should be available at the point of use.

In considering which controlled conditions are applicable for a given process, your organization should consider the effect on quality or compliance with regulatory requirements. If you determine that, in the absence of the control, an adverse or potentially adverse effect on quality or regulatory compliance could be seen, then control is necessary. The amount of control and level of detail should be commensurate with the degree of criticality (e.g. based on the output of risk management activities) of the process in achieving the requirements for product.

Your organization needs to qualify the infrastructure needed for production activities. The infrastructure includes buildings, workspace and associated utilities, process equipment and supporting services (see Clause 6.3). The process equipment needs to be designed and selected so that the manufacturing process and the manufactured product specifications can be met. New or significantly modified equipment should be verified to meet purchasing specifications and to be capable of operation within its defined limits as well as the process operation limits.

Your organization needs to implement monitoring of relevant production processes (see 8.2.5) and of the required product characteristics (see 8.2.6). Monitoring of processes should include consideration of both independent and dependent variables. Process parameters affecting product characteristics should be specified, recorded and assessed for consistency, proportionate to the risk, where product safety or performance could be affected.

Your organization needs to ensure you implement operations with defined requirements for packaging and labelling. The risk of labelling and packaging errors can be minimized by the introduction of appropriate controls such as:

- segregation of packaging and labelling operations from other manufacturing (or other packaging and labelling) operations,
- control of product placement into packaging to avoid misalignment or detrimental interaction of product with packaging.

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- avoidance of packaging and labelling product of similar appearance in close proximity,
- use of production line identification,
- application of line clearance procedures,
- destruction of unused batch-coded materials on completion of packaging and labelling, use of roll-feed labels,
- use of a known number of labels and reconciliation of usage,
- on-line printing, including batch coding,
- use of electronic code encoders/readers and label counters,
- use of labels designed to provide clear product differentiation,
- inspection of label content before use, and
- proper storage of labels in areas of restricted access.

Your organization needs to maintain records that facilitate traceability and review of the manufacture of individual batches of product (note that batch can be a single medical device). These records are to be made throughout the product realization process(es) and can be referred to as batch records, device history records, batch manufacturing records, lot history records, lot records or other similar terms. These records are frequently collated in a single file. If it is not practical to include all of the relevant documents in a single file, then a record should list the relevant documents and their location. Batch records should be prepared from the currently approved versions of the specifications.

The forms that constitute the batch records should be designed and reproduced by an appropriate method to avoid clerical errors. A batch record should have unique batch identification and relate to an individual manufacturing batch.

During manufacture, relevant information should be entered onto the batch record. Such information can include the:

- quantity of raw materials, components and intermediate product, and their batch number, if appropriate,
- production records including operating parameters,
- date of start and completion of different stages of production, including sterilization records if appropriate,

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- quantity of product manufactured,
- signed results of all inspections and tests,
- designation of the product line used,
- product or process nonconformances including any correction, and
- deviation from the manufacturing specifications.

If your production activities are performed for you or your behalf by an external provider, you need to demonstrate adequate control of this external provider (see 7.4.1).

7.5.2 Cleanliness of product

The organization shall document requirements for cleanliness of product or contamination control of product if:

a) product is cleaned by the organization prior to sterilization or its use;
b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use;
c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;
d) product is supplied to be used non-sterile, and its cleanliness is of significance in use;
e) process agents are to be removed from product during manufacture.

If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.

Intent

This section outlines that cleanliness of product is likely a critical requirement. Furthermore, this section outlines how those cleanliness requirements are to be established.

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Guidance

Your organization is required to define the product cleanliness requirements (also see guidance provided in 6.3 and 6.4). To support these requirements, your organization needs to establish processes and documents, provide resources specific to the product, including infrastructure and work environment, implement required verifications, validations, monitoring, measurement, inspection and testing, handling, storage, distribution and traceability activities specific to the type of product together with the criteria for product acceptance (see 7.1).

Process agents, also known as ancillary materials, manufacturing materials or auxiliary materials, are any materials or substances used in, or used to facilitate, a manufacturing process, such as cleaning agents, mould-release agents, lubricating oils, or other substances which are not intended to be included in the medical devices. Process agents should be adequately identified and labelled to avoid confusion and processing errors.

7.5.3 Installation activities

The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate.

If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation.

Records of medical device installation and verification of installation performed by the organization or its suppliers shall be maintained (see 4.2.5).

Intent

This section outlines the required activities relative to the installation of medical devices.

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Guidance

Installation is the activity of putting a medical device into the location where it will be used including connection to appropriate infrastructure (e.g. electrical supply, plumbing, waste disposal). Final testing of installed medical devices is carried out after it is in its location for use and connected to all relevant services. The responsibility for installation should be clearly defined to ensure proper functioning of the medical device. Installation does not mean implantation in, or fitting to, a patient.

If a medical device is to be assembled or installed at the user's site, instructions should be provided by your organization to guide correct assembly, installation, testing or calibration. Special attention needs to be paid to ensure correct installation of safety control mechanisms and safety control circuits along with implementation of final testing requirements.

In certain cases (e.g. if required by a regulation, or if performance parameters of a medical device have to be controlled), your organization needs to provide instructions which allow the installer to confirm correct operation of the device. The results of installation or commissioning tests need to be recorded (see 4.2.5). If the functionality of product depends on installation for their proper use, and if your organization provides for some or all installation by either contract or under warranty, then your organization's QMS needs to include provisions for the type and extent of installation provided. The following activities are considered, as appropriate:

- clarification of installation responsibilities among your organization, suppliers, distributors and users;
- planning of installation activities, whether carried out by your organization or by a supplier to your organization;
- validation of special-purpose tools or equipment for installation;
- control of measuring and test equipment used in installation and tests;
- provision and suitability of documentation, including instructions for use in installation, dealing with the spares or parts lists;
- provision for adequate back-up, to include technical advice and support, customer training, and spares or parts supply;
- training of installation personnel;
- provision of competent installation personnel;

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- feedback of information which would be useful for improving product or installation processes;
- other customer support activities.

Your organization needs to establish a system for receiving installation reports to determine if there are customer complaints or requirements that are not being met. In addition, this information needs to be assessed and elevated to corrective action or preventive action in accordance with applicable QMS processes for improvement.

> **7.5.4 Servicing activities**
>
> If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met.
>
> The organization shall analyse records of servicing activities carried out by the organization or its supplier:
>
> a) to determine if the information is to be handled as a complaint;
> b) as appropriate, for input to the improvement process.
>
> Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).

Intent

This section presents the requirements associated with any servicing activities for a medical device, including analysis of servicing records.

Guidance

If the functionality of product depends on servicing or maintenance for proper use of product, and if your organization provides for some or all of the servicing by either warranty or contract, then your organization's QMS should include

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provisions for the type and extent of servicing provided. The following activities are considered, as appropriate:

- clarification of servicing responsibilities among your organization, distributors and users;
- planning of service activities, whether carried out by your organization or by a separate agent;
- design and development validation of special-purpose tools or equipment for handling and servicing product;
- control of measuring and test equipment used in field servicing and tests;
- provision and suitability of documentation, including instructions for use in dealing with the spares or parts lists, and in servicing of the product;
- provision for adequate back-up, to include technical advice and support, customer training, and spares or parts supply and these spares should be in accordance with the original specification in order to ensure the medical device continues to function within performance requirements;
- training of servicing personnel;
- provision of competent servicing personnel;
- feedback of information which would be useful for improving product or servicing design;
- other customer support activities.

Even when not specified in a contract, the guidance given here can be helpful to your organization.

Some medical devices might need to be cleaned or decontaminated prior to servicing to ensure that employees and other product are not exposed to some form of contamination (see also 6.4.1 and 7.5.2). In such cases, they should be decontaminated by appropriate, approved procedures. In addition, these medical devices could also need to be cleaned after servicing to prevent exposure of the user or patient to potential contaminants.

Your organization's QMS should ensure:

- Service records are analysed to determine if the service performed is a complaint. Also, consideration for reporting to applicable regulatory authorities is required.

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- Quality data from repair and service activities are reviewed to identify potential problem or improvements, as appropriate. If trends occur, investigation and correction or corrective action are required.

7.5.5 Particular requirements for sterile medical devices

The organization shall maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices.

Intent

This section outlines requirements for records of the sterilization process as applicable.

Guidance

The process variables and records to be maintained for sterilization processes usually applied to medical devices are identified in the relevant International Standards for validation and routine control of the applicable sterilization process.

If your organization is seeking additional information regarding sterilization, some additional requirement can be found in ISO 11135, ISO 11137, ISO 13408, ISO 14160, ISO 14937, ISO 17655, ISO 20857 or ISO 25424.

7.5.6 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

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Validation shall demonstrate the ability of these processes to achieve planned results consistently.

The organization shall document procedures for validation of processes including:

a) defined criteria for review and approval of the processes;
b) equipment qualification and qualification of personnel;
c) use of specific methods, procedures and acceptance criteria;
d) as appropriate, statistical techniques with rationale for sample sizes;
e) requirements for records (see 4.2.5);
f) revalidation, including criteria for revalidation;
g) approval of changes to the processes.

The organization shall document procedures for the validation of the application of computer software used in production and service provision. 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 including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

Intent

This section provides requirements for process validation.

Guidance

Process validation is the mechanism or activity used by your organization to ensure that a process whose output is not fully verified is capable of consistently providing product that meets specifications. In addition, your organization can choose to validate those processes that could be verified when aligned with your organization's objectives.

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Process validation includes the development of a plan, the staged conduct of a number of evaluations of a particular process and the collection and interpretation of recorded data. These activities can be considered to fall into a model consisting of four phases:

- review and approval of equipment specifications;
- initial qualification of the equipment used and provision of necessary services — also known as installation qualification (IQ);
- demonstration that the process will produce acceptable results and establishment of limits (worst case) of the process parameters — also known as operational qualification (OQ);
- establishment of long-term process stability — also known as performance qualification (PQ).

Table 1 lists examples of processes that normally should be validated, can be satisfactorily covered by verification, or need individual consideration of the circumstances of use and the controls in place to determine whether some or all the elements of validation are required.

Table 1 — Examples of processes and their validation or verification need or status

Should be validated	Can Be Satisfactorily covered by verification	Need individual consideration
• sterilization, • aseptic processing, • welding, • molding, • extrusion, • forming of sterile barrier systems, • lyophilization, and • heat-treatment.	• manual cutting, • testing for colour, turbidity, total pH for solutions, • visual inspection of printed circuit boards, and • manufacturing and testing of wiring harnesses.	• cleaning, • manual assembly, • numerical control cutting, and • filling.

When introducing a new process or changing a process (for example, following a corrective action), the process should be evaluated to determine whether validation is necessary.

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Planning of process validation should include, but not be limited to, the following considerations:

- accuracy and variability of the process parameters, including the settings of the equipment used;
- skill, capability and knowledge of operators needed to conform to quality requirements;
- adequacy of control of all process parameters, including environmental parameters;
- qualification of processes and equipment, as appropriate;
- acceptance criteria and the process for handling process performance that does not meet these criteria;
- circumstances that require process revalidation; or
- handling changes to the process.

There are many statistical methods and tools which can be used in process validation. Your organization should choose the appropriate method or methods to apply. Control charts, capability studies, designed experiments, tolerance analysis, robust design methods, sampling plans and mistake-proofing are some examples. Rationale for sample sizes can be based on the associated risk and supported by documents such as risk analyses.

Cleaning processes might be required to remove process agents or other contamination. Such cleaning processes should be validated as to the effectiveness of the process for removing the contamination in accordance with a documented procedure. The process parameters used for the cleaning processes should be routinely monitored in accordance with documented procedures.

When a cleaning process is intended to remove contamination (e.g. microbiological, viral, chemical, radioactive), the validation protocol, the results of the validation and the final operating procedure should be reviewed and approved by a person with the requisite technical knowledge and competence.

Your organization could find some additional information regarding monitoring of microbial contamination on medical devices in ISO 11737-1.

Some processes require that operators have extra training or be specially qualified, or that the process itself should have specific approval, as in the following example.

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When qualifying an operator in heat sealing of a pouch used as part of a sterile barrier system, if visual or other non-destructive examination for soundness of the seal would give no information on seal strength, the operator is required to be trained and qualified to carry out the sealing process according to a validated process procedure in order to provide assurance of seal strength.

Your organization could determine that periodic revalidation is necessary to manage the risk of drift in performance of validated processes. In addition, applicable regulatory requirements or standards could require periodic revalidation of particular processes (e.g. sterilization).

The need for revalidation should be evaluated and documented. This evaluation should include historical results from quality indicators, product changes, process changes, changes in external requirements (regulations or standards) and other such circumstances.

Revalidation might not be as extensive as the initial validation if the situation does not require that all aspects of the original validation be repeated. Some elements of OQ or PQ could need to be repeated, for example, depending on the effect of the new equipment.

Another example is a change in supplier of a raw material. The effect of that change on the process and resultant product should be considered. Parts of OQ and PQ might need to be redone, as the interaction between the new raw material and the process might not be fully understood.

If you are looking for additional guidance on process validation, see GHTF. SG3.N99-10 among other references.

The requirements of ISO 13485 regarding the validation of the application of computer software used in process control apply, regardless of how obtained. Such software may be purchased, developed, maintained, or modified for automated production or process control purposes. For some additional information relating to the validation of the application of computer software see the Good Automated Manufacturing Practice (GAMP) guidelines or ISO/TR 80002-2 among other references.

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7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems

The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems.

Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate.

Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

NOTE Further information can be found in ISO 11607-1 and ISO 11607-2.

Intent

The importance of sterilization and associated sterile barrier systems is highlighted by this section, which underscores the requirements for validation of these processes.

Guidance

Sterilization processes, including aseptic processes, are processes that cannot be verified by inspection and testing of the medical device. Therefore, these processes need to be performed in accordance with documented procedures, validated before use and closely controlled and monitored. International Standards are available covering the development, validation and routine control of sterilization process and aseptic processes for sterile medical devices.

Additional information regarding sterilization and aseptic process validation is available in ISO 11135, ISO 11137, ISO 13408, ISO 14160, ISO 14937, ISO 17665, ISO 20857 and ISO 25424.

It is important to be aware that exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with ensuring

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that the medical device is sterile. It can also be important that attention be given to the microbiological status of incoming raw materials and their subsequent storage, and to the control of the environment in which the medical device is manufactured, assembled and packaged. If applicable, these additional controls should be outlined in documented procedures.

You should be aware that sterilization processes validated and controlled in accordance with the requirements of existing International Standards should not be assumed to be effective in inactivating the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy (BSE), and Creutzfeld-Jakob disease. Specific recommendations have been produced in certain countries or regions for the processing of materials which are potentially contaminated with these agents (for additional information, see ISO 22442 series).

The sterile barrier system, its protective packaging and the associated packaging processes are of critical importance for the maintenance of sterility of sterile product up to the point of use. The packaging processes have to be validated and controlled. Additional information is provided by ISO 11607-1, ISO 11607-2 and ISO/TS 16775.

Process validation of sterile barrier systems demonstrates reproducibility, control and capability of the process to consistently producing sterile barrier systems meeting the established specifications. Process validation is not the only critical activity to assure maintenance of sterility up to the point of use. It is equally important to validate sterile barrier systems to demonstrate that stability requirements are met over the entire shelf life and sterile barrier integrity is maintained through the hazards of the specified transportation, distribution and handling.

Any failures or deviations encountered during process validation should be investigated. The determined root causes should be documented as well as conclusions and any corrections or corrective action.

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7.5.8 Identification

The organization shall document procedures for product identification and identify product by suitable means throughout product realization.

The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed.

If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.

The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

Intent

This section defines the requirements for product identification. This includes requirements for a documented procedure for product identification and product status during production. It also adds a specific requirement that any unique device identification introduced by applicable regulatory requirements is included in your QMS.

Guidance

Identification of product, such as raw materials, components and medical devices, is important for a number of reasons, including:

- controlling material throughout manufacture;
- demonstrating product source, status and safety requirements;
- permitting traceability; and
- facilitating fault diagnosis in the event of quality problems.

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Identification of product can be achieved by marking, tagging, or specifying a physical location for the product or its container. For example, on visually identical parts, if the functional characteristics are different, then different colors could be used. For bulk product or product from continuous processes, the identification could be by marking of batches or well-defined lots and accompanying documents.

It is usual for medical devices to be identified by a batch/lot/serial number. The extent to which raw materials and components need to be identified and related to the medical device batch/lot or serial number can depend upon a number of factors such as:

- raw materials involved;
- type of medical device;
- effect of failure of the medical device or components, or raw materials used therein;
- specified requirements;
- traceability, if necessary;
- design and development input;
- regulatory requirements; and
- software configuration management.

Any marking materials used for product identification, if applied to medical devices or components, should not have a deleterious effect on the safety or performance of the medical device.

Where software is a medical device, traceability can be achieved through electronic means using configuration management of the version, the various date/time stamps and comments on the code.

Status identification can include indication of:

- the state of the product in its lifecycle, such as "awaiting inspection." In a call center service, the status of messages taken could initially be "message received". On passing the message on to the customer, the status could change to "message delivered";
- the product status relative to conformity, such as:
  - accepted as fully meeting requirements,
  - accepted with identified nonconformities under concession,
  - awaiting further processing (e.g., awaiting sterilization),

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- on hold awaiting further analysis/ decision, or
- rejected as unsatisfactory.

The incorporation of unique device identification in your QMS can facilitate the use of Unique Device Identification (UDI) as required by applicable regulatory requirements. The UDI system seeks to improve the identification of medical devices by making it possible to identify a medical device rapidly and definitively along with some key attributes that affect its safety and performance during use. It can also facilitate more accurate reporting of reportable events as well as the ability to take appropriate and better-focused corrective action. The applicable regulatory requirements could outline the formation of the UDI code including; compilation, content, nomenclature and format. You should be aware of other regulations or guidance provided in the country or region where your product is marketed.

7.5.9 Traceability

7.5.9.1 General

The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5).

7.5.9.2 Particular requirements for implantable medical devices

The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.

The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection.

Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5).

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Intent

This section describes the requirements for traceability of product throughout product realization and distribution.

Guidance

Traceability is knowledge of where product came from or to where it was delivered. Using identification of product by batch/lot/serial number or electronic means permits traceability in two directions: forward to customers and backward to raw materials, components and processes used in manufacturing. The former is important if it is necessary to track medical devices to the user (e.g. patients or hospitals), and the latter enables investigation of quality problems and feedback for the prevention of nonconforming product.

Applicable regulatory requirements require traceability of some components (e.g., critical components of life supporting or life sustaining devices). Traceability can be conducted using lot numbers, tags, bar codes, serialization, certificates of analysis, or in the case of software, configuration management. It can be achieved by retaining appropriate records showing the identification for the product, including records of the inspection or test throughout production and service provision. The traceability methods and extent of traceability should be based on the risk associated with the product, appropriate to your organization and described in relevant documentation. Product traceability involves the ability to trace the history, application or location of a product or activity by means of recorded identification. Traceability is typically required when there is a need to trace a nonconformity back to its source and to determine the location of the remainder of the affected batch. Additional information regarding the use of configuration management as a means to maintain identification and traceability is available in ISO 10007.

Written agreements should be in place with importers or distributors who make available the medical devices to various markets and customers, such that traceability is maintained throughout the supply chain of the product.

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A traceability system for implantable medical devices is essential because it might not be possible to inspect the medical device while it is in use. Traceability can, therefore, avoid unnecessary explanation of implanted medical devices by precisely identifying those implants which incorporated a critical component subsequently identified to be faulty, or for which some process control has subsequently been shown to be inadequate. Regulatory requirements for certain higher risk implants can require additional traceability beyond your organization's possession, and your QMS should take account of these as appropriate. In addition, applicable regulatory requirements could require additional labelling material be provided (e.g., provision of information to be given to the patient).

Your organization can achieve traceability by each individual product having an identifier (e.g. serial number, date code, batch code, lot number) unique to the source of operation. Separate identifiers could be required for changes in operative personnel, changes in raw materials, changes in tooling, new or different machine set-ups, changes in process methods, etc. Traceability identifiers should appear on applicable inspection and stock records (see 4.2.4).

There can be situations where traceability requires identification of the specific personnel involved in each phase of medical device processing or delivery. A sequence of individuals could perform successive service functions, each of which is to be traceable. The recording of identification evidence through signatures on serially numbered documents is an example. Each individual's identification evidence should be unique and traceable.

7.5.10 Customer property

The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).

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Intent

This section outlines requirements pertinent to any customer property under the control of your organization.

Guidance

Your organization needs to consider how customer property will be managed and if there is a need for specific contingency actions to ensure the continuity of production or service provision. Your organization should identify responsibilities in relation to property and other assets owned by customers and under the control of your organization, in order to protect the property.

Examples of such property can include:

- measuring equipment provided for measurement purposes,
- raw materials or components supplied for inclusion in product (including packaging materials),
- product supplied for repair, maintenance or upgrading,
- product supplied for further processing (such as sterilization or testing),
- product from third parties that interfaces with and is supplied with your organization's product,
- intellectual property (including specifications, drawings, and proprietary information).

Confidential health information is considered customer property (see guidance for 4.2.5). Some examples of measures that you might adopt to protect your customers' or suppliers' intellectual property or personal data are:

- a specific location or file to store intellectual data including drawings, patent information, performance and sales results;
- password protection of computer files and added security features such as multifactor authentication, data encryption, firewalls;
- a policy requiring customer or supplier specifications and data be deleted at the end of a project; or
- restricting access to information to specific and qualified individuals.

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7.5.11 Preservation of product

The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device.

The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:

a) designing and constructing suitable packaging and shipping containers;
b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.

If special conditions are required, they shall be controlled and recorded (see 4.2.5).

Intent

This section describes requirements for ensuring product is preserved in a way that product requirements will continue to be met for its usable life.

Guidance

Consideration should be given to the various types of delivery and variations in environmental conditions which might be encountered.

Your organization's method for handling product could need to consider providing equipment (such as anti-static wrist straps, gloves and protective clothing) and transportation units (such as pallets, containers, conveyors, vessels, tanks, rigging, pipelines and vehicles). This is necessary so that damage, deterioration or contamination due to vibration, shock, abrasion, corrosion, temperature variation, electrostatic discharge, radiation or any other conditions occurring during handling and storage can be prevented. Maintenance of handling equipment is another factor to be considered.

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Packaging materials and the packaging processes should provide adequate protection against damage to product. During storage and transportation up to the point of use, the packaging materials and transport and storage conditions of medical devices (see also 7.3.3) are intended to provide appropriate protection against damage, deterioration or contamination.

Your organization needs to provide suitable storage facilities, considering not only physical security but also environmental conditions (e.g. temperature and humidity). It can be appropriate to check product periodically in storage to detect possible deterioration. Consideration could need to be given to administrative procedures for product expiration dates, stock rotation and lot segregation.

Examples of preservation measures include the maintaining of:

- dust- and static-free conditions for semiconductors,
- temperature/humidity controls,
- hygienic conditions for manufacturing,
- protection for fragile product, and
- protection against the elements (e.g. wind, water flooding, extreme sunlight).

The identification of product with a limited shelf life or expiration date, or product which requires special protection during storage and transport, is important to ensure that such product is not used if the shelf life or expiration date has been exceeded. Your organization therefore should define product shelf life applicable under specified storage conditions.

7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

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As necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5);
b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5);
c) have identification in order to determine its calibration status;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

The organization shall perform calibration or verification in accordance with documented procedures.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.5).

The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. 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 including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

NOTE Further information can be found in ISO 10012.

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Intent

This section includes the requirements for calibration of measuring and monitoring equipment. In addition, requirements for validation of software used in monitoring and measurement are described.

Guidance

It is very important to understand the concepts of monitoring and measurement:

- Monitoring is supervising, checking or observing over a period of time, and
- Measurement is determining a quantity, magnitude, or dimension, by using measuring equipment.

The calibration of monitoring and measurement equipment needs to be traceable to the appropriate national or international standards. For example, a reference instrument used to calibrate your measuring device needs to be calibrated by an accredited organization or against a certified instrument. In some cases, this may not be possible. For example, in a case where a special tool is developed that is verified with an internal developed standard, such internally developed standards need to be identified, authorized and be traceable to the initial product specification with the appropriate validation.

The calibration needs to be performed for the measuring or monitoring ranges relevant to those being measured or monitored routinely throughout product realization. For example, when the routine measurements are made in the pH range of 10-12, it is not acceptable for a pH meter to be calibrated for a pH range of 4-7.

The requirements refer explicitly to monitoring and measuring equipment, including test software. It is helpful to approach the subject of control of monitoring and measuring equipment from the perspective that measuring is itself a process involving materials, equipment and procedures. The intent of the requirements is to give your organization confidence in the monitoring and measuring equipment that it uses to ensure that product meets customer and applicable regulatory requirements.

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Statistical methods are important in showing which monitoring and measuring equipment are used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

The requirements of this section are also applied by your organization when demonstrating the conformity of product to the specified requirements. This can involve measurements subsequent to production and inspection of product (e.g. during handling, storage, packaging, preservation, delivery or servicing).

Documented procedures should include details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Some monitoring and measuring equipment are not used for purposes that affect the quality of the product, including service, provided by your organization. As a result, the following examples are not necessarily part of your organization's QMS:

- instruments that are used to provide an indication only (e.g. a pressure gauge used only to determine the existence of line pressure), but are not used to control the actual manufacturing process, or a pressure gauge on a fire extinguisher or on a sprinkler system;
- instruments that are associated with business administration and are not used in product realization (e.g. clocks to control working times, thermostats to control operator comfort); and
- instruments that can be attached to process equipment, but are not used for process control.

Some monitoring and measuring equipment require an initial calibration or certification but need not be included in the control programme. Your organization may periodically verify the legibility of markings, but there is not a need for a calibration interval. Examples of such equipment are:

- mercury-in-glass thermometers,
- steel rulers, and
- laboratory volumetric measurement glassware that is not exposed to processes or environments which might affect its calibration.

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Monitoring and measuring materials intended to provide a qualitative reference should be stored and maintained in a location which does not compromise the integrity of the material.

Software applications for monitoring and measuring product or processes should be validated. Examples include software used for:

- measuring product on a coordinate measuring machine,
- software analysing the sterilization process parameters and determining whether the process meets the process requirements,
- software determining the regurgitation rate of a prosthetic heart valve based on the dynamic measurement of the flow.

Additional information regarding the management of monitoring and measuring equipment is available in ISO 10012.

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8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:

a) demonstrate conformity of product;
b) ensure conformity of the quality management system;
c) maintain the effectiveness of the quality management system.

This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.

Intent

This section gives general requirements to plan and implement processes related to measurement, analysis and improvement. A note from the previous edition of ISO 13485 regarding the need for procedures for the implementation and control of the application of statistical techniques is incorporated in the normative text.

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Guidance

Your organization needs to plan and implement the requirements of this section. Figure 4 illustrates four typical phases that can be used to plan, implement and maintain effective processes. The four phases identified are:

1) Planning.
2) Measurement and analysis within and across data sources.
3) Improvement.
4) Input to management.

Documented procedures, requirements and records should be maintained by your organization to ensure and demonstrate the effective planning, operation and control of the processes. Documented evidence of decisions and actions taken will be a part of the QMS.

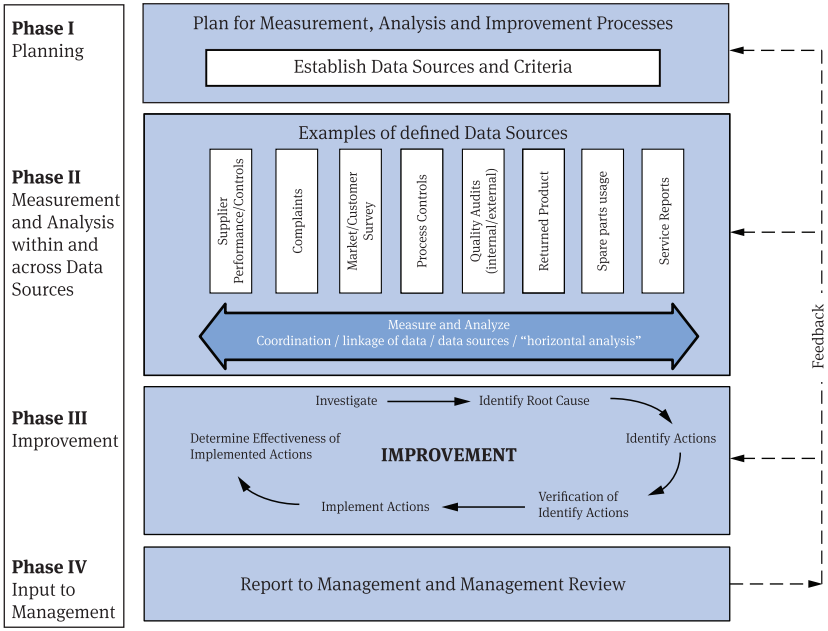

Figure 4 — Processes for measurement, analysis and improvement

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Planning (Phase I) involves identifying and specifying methods and associated resources in order to meet specific objectives for effective monitoring and measurement of your organization's QMS processes. The planning phase should be aligned with your organization's overall business planning processes and include consideration of the medical device's intended use, markets and users, as well as regulatory requirements in order to identify the necessary monitoring and measurement activities.

The planning phase should ensure the following:

- identification of relevant internal and external data sources that are indicators of process and product performance;
- provision for adequate resources that could include technical experts, testing laboratories, data management, infrastructure, or training;
- establishment of responsibilities and authorities to enable the necessary actions;
- definition of requirements for each identified data source, including limits, acceptance criteria, escalation criteria and mechanisms for reporting of nonconformities or potential nonconformities;
- analysis of data elements within data sources;
- coordination and analysis of data across data sources.

Where new data sources need to be established, your organization should confirm that they have been identified and their criteria defined. Your organization should identify and document relevant data sources and data elements both internal and external to your organization. Data elements can provide information regarding nonconformities, potential nonconformities and the effectiveness of the established processes.

Escalation criteria used for initiating the improvement process can be called action levels, trigger points, or threshold levels. Escalation criteria should be documented in an appropriate procedure and would likely include certain generic action levels as well as specific action levels resulting from risk management activities. In particular, criteria should be established for immediate escalation. For example, an incident alleging a death or serious injury should be escalated to the improvement phase for immediate action. For new technology and existing technologies with new intended uses/applications,

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initial escalation criteria could be difficult to define for the monitoring process. Therefore, your organization should plan for resources to analyze information in order to confirm initial assumptions and establish or revise escalation criteria.

Phase II is the measurement and analysis within and across data sources. Your organization should review the processes critical to the operations with regard to quality and regulatory requirements and select relevant data sources to measure, analyze and facilitate improvement as necessary. In addition, periodic review by top management is done to review these improvements are being done to ensure the suitability, adequacy and effectiveness of the QMS.

Examples of data sources can be, but are not restricted to:

- regulatory requirements,
- previous management reviews,
- information on supplier performance or controls,
- complaints,
- reports of adverse events,
- process controls,
- monitoring or measurement of product,
- quality audits (internal/external),
- product recall,
- spare parts usage,
- service reports,
- returned product,
- market/customer surveys,
- scientific literature,
- media sources,
- product realization activities (design, purchasing, production and service and customer information),
- risk management, and
- other post market documentation.

When an issue is identified in data sources, it is also important that your organization identifies and reviews related information from other data sources including information from external data sources.

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During Phase III, acceptance criteria should be based on system, product and process specifications or requirements which are typically identified during design and development activities. This includes the structure of your QMS, development and maintenance of processes for production, delivery, servicing, installation, and distribution.

Moving on to Phase IV, the involvement of management at appropriate levels in actions taken, such as review or approval, in response to nonconformities or potential nonconformities should be established. Your top management should ensure that measurement criteria are defined for identified data sources and communicated across your organization.

As a check on the effectiveness of the processes defined, your organization should regularly review the outputs of processes, make improvements or adjustments as needed and share information from the review/improvement with top management. Documented evidence of the reviews and actions taken are a part of your QMS.

The use of statistical methods can be beneficial to your organization in a wide range of circumstances, including data collection, analysis and application. These techniques are useful for demonstrating process capability, as well as product conformity to specified requirements. They assist in deciding what data to obtain, and in making the best use of the data to gain a better understanding of customer requirements and expectations.

Additional details are found in the GHTF/SG3/N18 document and information regarding statistical techniques is available in ISO/TR 10017.

8.2 Monitoring and measurement

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented.

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The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

If applicable regulatory requirements require the organization to gain specific experience from post-production activities, the review of this experience shall form part of the feedback process.

Intent

This section gives specific requirements on gathering and monitoring information regarding whether your organization is meeting customer requirements. This information is a source for data analysis (see section 8.4). In addition, this section outlines a new requirement to document the procedure for obtaining and using feedback information from production and post-production activities including a requirement to use feedback information as input into risk management for monitoring and maintaining product requirements in product realization and improvement processes.

Guidance

Data collected from production and post-production activities can reveal a previously unforeseen hazardous situation or modify the estimation of the severity or occurrence of harm. Your organization should review the risk management file for the medical device and update it as necessary to maintain its currency. This review can occur on an ad-hoc or periodical basis depending on the significance of the collected data and their effect on the overall benefit/risk ratio of the medical device.

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8.2.2 Complaint handling

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.

These procedures shall include at a minimum requirements and responsibilities for:

a) receiving and recording information;
b) evaluating information to determine if the feedback constitutes a complaint;
c) investigating complaints;
d) determining the need to report the information to the appropriate regulatory authorities;
e) handling of complaint-related product;
f) determining the need to initiate corrections or corrective actions.

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.

Complaint handling records shall be maintained (see 4.2.5).

Intent

This section sets out the general requirement for establishing and maintaining a complaint handling process and includes a number of items the associated documented procedures need to address including the content of a complaint handling file and what to do with complaints. It also provides new requirements to document such as:

i) timely complaint handling according to applicable regulatory requirements,
ii) why a complaint was not investigated, and
iii) correction or corrective action resulting from the complaint.

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Guidance

Complaints can come from several different sources. Some examples are users, healthcare providers, distributors, suppliers, published literature, general public or regulatory authorities.

There needs to be an initial recorded review and evaluation of the complaints to determine if the feedback received is a complaint as defined in 3.4 of ISO 13485. It is important to note that this evaluation is not the same as a complaint investigation. The evaluation is performed to determine whether the information is truly a complaint or not and to determine whether the complaint needs to be investigated or not. If the evaluation decision is that it is not a complaint, the justification has to be recorded. Any customer reports received by your organization should be evaluated. Customer service requests and warranty claims are the most common external indications of product deficiency that might be subject to correction or corrective action to prevent recurrence of the problem. Your organizations could also consider other functions or departments within your organization to be customers. In this case, internal complaints can be treated as customer complaints and processed accordingly.

A separate determination is made to establish whether an investigation is necessary. For similar complaints, duplicative investigations are not necessary. In cases where an investigation would be duplicative, a reference to the original investigation is an acceptable justification for not conducting a second investigation. This information need not be duplicated in the investigation report if the complaint and investigation report can be properly identified and tied together. This information is basic information essential to any complaint investigation.

There are certain situations where the required information for a complaint cannot be obtained, or obtained in a timely manner. In these situations, the organization should provide documented support of reasonable efforts made to obtain the information. This will be acceptable if a reasonable and good faith effort was made. For example, a single phone call to a hospital would not be a reasonable, serious and committed effort to obtain information, but perhaps three attempts at different times of the day over several days could be a good faith effort. The effort to obtain complaint information should be proportionate with the risk associated with the complaint.

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A third evaluation is completed to determine if the complaint represents a reportable adverse event as outlined in section 8.2.3 of the standard. Your organization should formally designate a person(s) (by role or position) to collect and coordinate all written and oral customer complaints about medical devices. This person(s) should have the authority to ensure immediate review of any complaint, particularly those relating to injury, death or any hazard. In evaluating the complaint, your organization should consider whether the medical device:

- fails to conform to its specification, or
- conforms with its specifications but nevertheless causes problems in use.

For instance, a complaint with a medical device conforming to its specifications could be caused by an issue with an output of the design and development process incorporated into the product specification. Complaints related to handling can, for example, indicate inadequate instructions for use.

The investigation of a complaint can determine that activities performed by an external provider for your organization could be involved. The external party can be a separate legal entity (e.g. a supplier or representative/agent), but can also be, for example, within another division or the head office of your organization. Whoever the other party is, arrangements have to be such that there is two-way communication of whatever information is needed to properly investigate and resolve the complaint. This will normally be provided for in the contract or quality agreement with the external party.

The documented complaints system should cover the following:

- establishing responsibility for operating the system;
- evaluating the complaint;
- creating records and statistical summaries to enable the major causes of complaints to be determined;
- taking any corrective action;
- segregating and disposing of customer returns and faulty stock (special attention might need to be given to decontamination);
- filing of customer correspondence and other relevant records (the retention time for these should be defined).

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The records of complaint investigations should contain enough information to show that the complaint was properly reviewed, for example, a determination of whether or not:

- there was an actual medical device failure to perform per specifications,
- the medical device was being used to treat or diagnose a patient,
- death, injury or illness was involved, or
- there was any relationship between the medical device and the reported incident or adverse event.

An investigation record typically includes:

- name of the medical device;
- date the complaint was received;
- UDI, medical device nomenclature or control number used;
- name and address of the complainant;
- nature of the complaint;
- summary of the investigation to include but not limited to records or testing performed such as:
  - review of manufacturing records to include batch records as defined in 7.5.1 of the standard,
  - review of production non-conformities associated with the product,
  - testing of returned product or similar product,
  - evaluation of any applicable changes for impact on the product,
  - any other activity performed as part of the investigation;
- results of the investigation;
- correction(s) made;
- corrective action taken;
- justification if no action is taken;
- dates of the investigation;
- name of the investigators;
- if applicable, report to regulatory authority; and
- reply (if any) to the complainant.

A complaint investigation record could contain information that is considered confidential personal health information. As such, the storage and handling of these records should be appropriately addressed by procedures documented within the organization (see 4.2.5) to meet the applicable regulatory requirements.

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Complaints should be considered for review and update of risk management activities. For example, new hazards or failure modes can be identified through product complaints or customer feedback. As another example, complaint rate could increase or the severity of a complaint could differ from what was documented in the risk management file. As such, the risk management documents should be updated in a timely manner to evaluate the need for risk control measures to be taken. While the identification of a new hazard or failure mode might not lead to exceeding the risk acceptability criteria for your organization to take immediate actions, the trending and updating is important for monitoring purposes.

8.2.3 Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities shall be maintained (see 4.2.5).

Intent

This is a new section for the requirement to document procedure(s) to report complaints that meet reporting criteria of an adverse event to regulatory authorities or to issue advisory notices following the receipt of a complaint of an adverse event. It adds the requirement for maintaining records of reporting to regulatory authorities.

Guidance

Regulatory requirements can place requirements on your organization to monitor the use of your medical devices and to inform regulatory authorities of certain defined experience in use. Illness and injury are frequently defined by applicable regulations. In addition, your organization can issue advisory

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notices on medical devices when certain criteria are met. Your organization has to document the appropriate procedures to issue such notices in accordance with the applicable regulatory requirements.

8.2.4 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system:

a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;
b) is effectively implemented and maintained.

The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

NOTE Further information can be found in ISO 19011.

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Intent

This section instructs your organization to perform internal audits and provides criteria for some requirements of the internal audit program. This section adds a requirement for the internal audit to determine that applicable regulatory requirements have been effectively implemented and maintained.

Guidance

The requirements contained in this section are for an internal audit and review of your QMS to verify conformity with the requirements of ISO 13485 and compliance with applicable regulatory requirements. The review and evaluations these requirements are focused. During internal audit, your organization should review your procedures to ensure adequacy with regard to conformity with ISO 13485 and compliance with the applicable regulatory requirements and determine whether the procedures are effectively implemented. In contrast, management review is a broader review of your organization to ensure that the quality policy is implemented, the organization is working toward meeting quality objectives and the QMS is suitable, adequate and effective.

Your organization needs to understand that conducting effective internal audits is crucial to the effective operation of the QMS. Using the feedback provided by such audits and other information sources, such as complaints and service records, your organization closes the feedback loop to provide assurance that the processes used to realize your product is operating in a state of control.

Planning of the internal audit program should permit changes in the emphasis and intervals based on associated risk. For example, a major change to a product or process could necessitate a focused audit in a particular area or set of requirements. To support this, your organization could, for instance, conduct a focused audit of the design and development process for a particular product.

The results of audits are usually stated in a written report (see 4.2.5) which indicates the deficiencies found. Avoiding undue delay is usually accomplished by including appropriate target dates for responding to audit findings. The information arising from internal audits are communicated and used as an input to management review (see 5.6.2).

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A series of limited, well-defined audits can be as effective as one single comprehensive audit. This approach to auditing can be operated flexibly to give special or repeat attention to any areas of weakness or of other concern.

In addition to the periodic internal audits, a special internal audit can be initiated for the following purposes:

- when verifying that your QMS continues to meet specified requirements and is being implemented, if required, within the framework of a contractual relationship;
- when undergoing significant changes in functional areas (e.g. reorganizations or procedural revisions);
- when investigating safety, performance or reliability of the product which are, or which are suspected to be, in jeopardy due to nonconformities;
- when verifying that required corrective actions have been taken and have been effective.

Internal audits can be partially or fully subcontracted to qualified auditors. For information and details relating to auditor competences further information can be found in ISO 17021-3.

8.2.5 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

Intent

This section instructs your organization to monitor and measure its QMS processes to ensure they produce the intended results.

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Guidance

When determining suitable methods, it is advisable that your organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their effect on the conformity to product requirements and on the suitability, adequacy and effectiveness of your QMS.

Once data sources, data elements and acceptance criteria have been specified, as part of the planning process, your organization is required to perform measurement, monitoring and analysis processes to determine conformity or nonconformity. Software used in measurement, monitoring and analysis, whether purchased (off-the-shelf) or custom developed, has to be validated for its intended use.

For the purpose of this guidance, measurement is a set of operations to determine a value of a data element (i.e. quantity, quality). Data collected from the measurement of product, process and QMS are acquired throughout the life-cycle of product. Your organization should define the frequency of taking measurements, together with the necessary associated precision and accuracy required. Your organization should also ensure that the data collected is current and relevant.

Monitoring is the systematic and regular collection of a measurement. Your organization should define during the planning phase what, when and how data should be monitored. The data should be defined such that it can be analyzed for further action. The monitoring of data can be continuous or periodic, depending on the type of data source and elements. The monitoring processes should be periodically reviewed for their continued suitability. Measurement data should be retained as a quality record. Your organization should maintain data in a form that is retrievable, suitable for analysis and meets both QMS and regulatory requirements.

An example of incorporating a feedback process could be that a customer survey conducted by the marketing department indicated that there was a general dissatisfaction with the packaging of a particular product. When investigated further (within and across other data sources) and reviewed with other data from complaints, returned product and service reports, it became evident that

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there was a potential for misuse, unsafe use, or damage to the medical device as a result of the current packaging configuration. As the result of this analysis, escalation to the improvement phase (Phase III in Figure 4) for corrective action should be considered.

8.2.6 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.

Evidence of conformity with the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to perform measurement activities.

Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed.

For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.

Intent

This section instructs your organization to monitor and measure product to ensure it conforms to specifications. The requirement from the previous edition of ISO 13485 related to active implantable and implantable devices has been incorporated into a new general requirement that is applicable to all medical devices.

Guidance

In-process inspection and testing includes all such activities between the acceptance of incoming materials and submission of the medical device for final inspection. The results of in-process inspection and testing can be used

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both for process control and for the early identification of nonconforming product. Purchased product is verified under the provisions of ISO 13485, 7.4.3.

Final inspection involves activities (examination, inspection, measurement or test) upon which the final release of product is based. Records of previously performed inspection and testing results can also be reviewed.

The specified requirements forming the basis of final inspection and test should include all designated release criteria. These should be directly related to the type of medical device involved and its intended use. Final inspection and testing should provide objective evidence of conformity with all designated release criteria that have not been confirmed through previous inspection and testing. Final testing can include, if practical, testing under simulated or actual conditions of use, and using medical devices selected from a lot or batch.

In the case of medical devices that are assembled or installed at the user's premises, any additional inspection and testing should be carried out after completion of assembly/installation. In such cases, the inspection and testing activities might not be carried out by your organization, but your organization should ensure the availability of all necessary information about the inspection and test procedure and the results expected.

When selecting measurement methods for ensuring that product conforms to requirements and when considering customer requirements, your organization should consider the following:

- product characteristics, which then determine the types of measurement, suitable measurement means, the accuracy required and skills needed;
- equipment, software and tools required;
- location of suitable measurement points in the realization process sequence;
- characteristics to be measured at each point and the documentation and acceptance criteria to be used;
- customer-established points for observation or verification of selected characteristics of the product;
- inspections or testing required to be observed or performed by regulatory authorities;

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- timing and manner in which your organization intends, or is required by the customer or regulatory authorities, to engage qualified third parties to perform activities within the QMS;
- qualification of people, materials, product, processes and the QMS;
- final inspection to confirm that verification activities have been completed and accepted; and
- records of the results of product measurements needed.

Your organization's inspection and test records should facilitate assessment of in-process and finished product having fulfilled the requirements for quality.

As applicable, records of monitoring and measurements can:
- identify the inspection/test procedure(s) and revision level used,
- identify the test equipment used,
- include test data,
- be signed and dated by the person responsible for the inspection or test,
- clearly identify the number of product examined and the number of product accepted, and
- record the disposition of any product failing inspection or test, and the reasons for failure.

For implantable medical devices in addition to inspection and test records, your organization should record the identity of personnel performing any inspection or testing to facilitate failure investigation, and corrective or preventive actions.

8.3 Control of nonconforming product

8.3.1 General

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product.

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The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5).

Intent

This section outlines requirements for your organization on identifying and controlling nonconforming product. This section adds a new requirement to document a procedure to define controls, responsibilities and authorities to identify, document, segregate, evaluate and dispose of nonconforming product. Additionally, this section adds a new requirement to evaluate nonconforming product to determine if an investigation or notification of any external party responsible for the nonconformity are necessary.

Guidance

Your organization is responsible for the implementation and maintenance of your QMS to enable you to consistently provide medical devices meeting customer and regulatory requirements. Nonconformity is the failure to fulfil a requirement. It is important to understand that requirements being reviewed for conformity can relate to product, process or QMS.

When a nonconformity is identified, your organization will determine the significance, the associated risk and the potential for recurrence. Once these have been determined your organization can decide the nonconformity has little associated risk or is unlikely to recur. In such cases, your organization could decide only to carry out a correction.

Should the nonconformity recur within your QMS, during manufacture or after the medical device has been delivered to a customer, it is an indication that improvement action(s) could be needed. In either case, a corrective action

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should be carried out with the aim to prevent recurrence. The corrective action can be as simple as training to establish competency or as complex as redesigning the manufacturing process.

Action taken to eliminate observed nonconformities within the scope of a single QMS (regardless of whether the action is taken at more than one site or facility operating within that QMS) would be considered corrective action. However, similar action applied within another QMS (regardless of whether it is the same site, facility, or organization) that has not yet experienced these nonconformities, would likely be considered preventive action. Regardless of how you categorize the action, this would be evidence of the application of a risk-based approach.

People in your organization need to be empowered with the authority and responsibility to report nonconformities at any stage of a process in order to ensure timely detection and disposition of nonconformities.

Top management of your organization should ensure the establishment of an effective process to provide for review and disposition of identified nonconformities.

Nonconforming product includes nonconforming product occurring in your organization's own facilities as well as to nonconforming product received or delivered by your organization.

Procedures established and maintained by your organization should have the following purposes:

- to determine which product is involved in the nonconformity (e.g. what production time interval, production machines or product) and the quantity of product involved;
- to identify the nonconforming product to make sure that it can be distinguished from the conforming product;
- to document the existence and source of the nonconformity;
- to evaluate the nature of the nonconformity;
- to consider the alternatives for the disposition of the nonconforming product;
- to decide upon and record what disposition should be made;

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- to control (e.g. by physical segregation) the subsequent processing of the nonconforming product consistent with the disposition decision; and
- to notify others who might be affected by the nonconformity including, if appropriate, the customer.

When a nonconformity is determined, your organization should determine the need for correction as well as corrective action. Correction refers to scrap, repair, rework, or adjustment and relates to eliminating a nonconformity, whereas the corrective action relates to the elimination of the cause of nonconformity (see 8.5.2).

If nonconforming product is to be used, accepted or released, your organization could decide to do so either by correcting the nonconforming product and then re-evaluating it, or by using the product as is.

Information concerning nonconforming product should be provided to all appropriate personnel, so that action is taken, if necessary, to identify and correct the cause of the nonconformity and prevent recurrence (see 8.5). Information concerning nonconforming product might require the review and updating of risk management activities.

For any returned product for which there is a risk of contamination (e.g. microbiological, viral, chemical, radioactive), consideration should be given to regulatory requirements for hazardous materials.

Control should be established over the disposal of nonconforming product designated as scrap to ensure that it:

- is clearly identified with its status,
- cannot be confused with conforming product,
- cannot re-enter the production system, and
- is disposed of safely.

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8.3.2 Actions in response to nonconforming product detected before delivery

The organization shall deal with nonconforming product by one or more of the following ways:

a) taking action to eliminate the detected nonconformity;
b) taking action to preclude its original intended use or application;
c) authorizing its use, release or acceptance under concession.

The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5).

Intent

This new section heading has been introduced to separate the requirements what to do when nonconforming product is detected before delivery.

Guidance

In the course of your organization's operations, nonconforming outputs could be identified after any verification, validation, inspection or test is carried out. ISO 13485 requires your organization to have a process to deal with any nonconforming output.

The methods and techniques your organization uses for controlling nonconforming outputs and retaining appropriate documented information, should be appropriate for your organization. Use of formal nonconformity reports, or customer complaint forms, etc., can facilitate keeping track of what action was taken. This documented information does not need to be complex but needs to be detailed and descriptive.

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Some customers might require notification of any nonconforming output and approve what steps should be taken. If this is the case, it will be necessary to notify the customer following detection of the nonconforming output. You might wish to include information concerning the steps you propose taking along with the notification.

If your organization chooses to use, accept or release nonconforming product when nonconformity exists, your organization has made a concession. When concessions are made, your organization cannot give up regulatory responsibilities for medical devices and related services and each concession should be reviewed to ensure that the nonconformity does not conflict with applicable regulatory requirements. The identity of the person(s) within your organization who authorizes each concession is maintained in a record, and this record should include information documenting that regulatory requirements have been fully met.

8.3.3 Actions in response to nonconforming product detected after delivery

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.5).

The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5).

Intent

This new section has been introduced to separate the requirements on what to do when nonconforming product is detected after delivery.

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Guidance

The procedures for dealing with nonconformities discovered in product which has already been shipped can include taking such actions as:

- withdrawing product from sale,
- withdrawing product from distribution,
- giving advice to customers (this can take the form of checks to be carried out before use, providing additional guidance on the use of the product or the replacement of certain product including software or components/assemblies), or
- requesting the physical return or destruction of product.

The nature and seriousness of the hazard associated with the nonconformity along with the intended use of the medical device and the potential for patient injury or failure to meet regulatory requirements will determine the urgency and extent of the action and whether it will be necessary to issue an advisory notice and to report to regulatory authorities. Regulatory requirements can specify that advisory notices are reported to designated regulatory authorities. Depending on the risks, there could be a need to involve the applicable regulatory bodies and to make the public aware of the problem.

A service organization will likely detect nonconformities while or after the service is provided. It is not possible to correct processes to provide services in the same way a tangible product can be handled. However, it is possible to initiate a corrective action so that the service provision can be revised to reduce the probability of recurrence of the problem.

The procedures for generating, authorizing and issuing an advisory notice should specify:

- the arrangements which enable the procedure to be activated, even in the absence of key personnel;
- the authority to initiate action, and the method of determining the affected product;
- the system for determining the disposition of returned product (e.g. rework, repackage, scrap); and

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- the communication system (which includes the necessity to report to local or national authorities), the points of contact and the methods of communication between your organization and regulatory authorities and customers.

Actions taken when nonconforming product is detected after delivery or use has started is sometimes referred to as "product recall." Because the term "recall" has different definitions in different national or regional jurisdictions, its use in ISO 13485 has been avoided when describing such activities.

An advisory notice should provide:

- a description of the medical device and model designation;
- the serial numbers, UDI, or other identification (for instance batch or lot numbers) of the medical devices concerned;
- the reason for the issue of the notice;
- any advice regarding possible hazards; and
- any consequent actions to be taken.

If a medical device is returned to your organization, the progress of agreed corrections should be monitored and, if appropriate, the quantities of product physically returned to your organization or scrapped locally or corrected locally should be reconciled. In certain regulatory jurisdictions, it could be necessary to communicate with regulatory authorities in accordance with applicable regulatory requirements (see 8.2.3).

8.3.4 Rework

The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure.

After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

Records of rework shall be maintained (see 4.2.5).

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Intent

The new section separates the requirements related to rework of nonconforming product to conformance with specification.

Guidance

The clause requires that a determination of any adverse effect of the rework upon product is made, whether there is repeated rework or not. The intent is that such a determination is made with any rework, given the potential harmful effect rework could have on product. Having the same review and approval also means using the same verification/validation process as would be applied to product that has not undergone rework.

8.4 Analysis of data

The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:

a) feedback;
b) conformity to product requirements;
c) characteristics and trends of processes and product including opportunities for improvement;
d) suppliers;
e) audits;
f) service reports, as appropriate.

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If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5.

Records of the results of analyses shall be maintained (see 4.2.5).

Intent

The subclause instructs your organization to analyse multiple sources of data to determine whether your QMS is suitable for your organization, adequate for the operations being conducted and operates effectively.

New requirements expand the scope of existing documented procedures to determine the adequacy of your QMS (added to determination of suitable and effective); the use of appropriate methods and statistical techniques to demonstrate suitability, adequacy, and effectiveness of your QMS; and new bullets added to use audit and service report information as new quality data sources. Additionally, a new requirement that describes when analysis of data shows that your QMS is not suitable, adequate or effective then the analysis is to be used as input to the improvement process describe in section 8.5.

Guidance

For this guidance, analysis is a systematic review and evaluation of data from measurements to derive a conclusion. Information from GHTF/SG3/N18, titled Quality management system — Medical devices — Guidance on corrective action and preventive action and related QMS processes, has been incorporated into this handbook.

Your organization needs to have documented procedures for the analysis of data against criteria developed during planning. Analysis is performed to identify nonconformity or potential nonconformity or identify areas where further investigation should be initiated. In addition, analysis is used to

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demonstrate the suitability, adequacy and effectiveness of your QMS processes as well as ensuring product meets customer and regulatory requirements. Analysis can be performed utilizing analytical tools, a team of experts, process owners or independent reviewers. The results of the analysis should be recorded.

After it is determined what will be measured, statistical techniques should be identified to understand variability and thereby guide your organization to maintain or improve effectiveness and efficiency. These techniques also facilitate better use of available data to assist in decision making. Statistical techniques assist in identifying, measuring, analyzing, interpreting and modelling variability.

For the analysis of nonconformity, appropriate statistical and non-statistical techniques can be applied. Examples of statistical techniques are:

- Statistical Process Control (SPC) charts,
- Pareto analysis,
- Data trending,
- Linear and non-linear regression analysis,
- Experimental design (DOE — Design of Experiments) and analysis of variance, and
- Graphical methods (histograms, scatter plots, etc.).

Non-statistical techniques are for example:

- Management reviews,
- Results from quality meetings,
- Safety committees (internal/external),
- Failure Mode and Effect Analysis (FMEA), and
- Fault Tree Analysis (FTA).

Analysis will likely occur at several different points of time or organizational levels. For example, a certain amount of analysis and possible failure investigation (e.g. where there is evidence of a nonconformity) could occur for each data source.

In addition to the analysis within the data sources, there should also be a level of analysis across data sources to determine the extent and significance

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of nonconformity or potential nonconformity. The linkage of data from different data sources could be referred to as horizontal analysis. The horizontal analysis may:

- determine that the action proposed from the data source analysis is appropriate without further progress into improvement; or
- provide additional information warranting progress into improvement, regardless of whether the data source analysis escalated the nonconformity or potential nonconformity.

The outcome of measurement and analysis leads to different scenarios as shown in Figure 5.

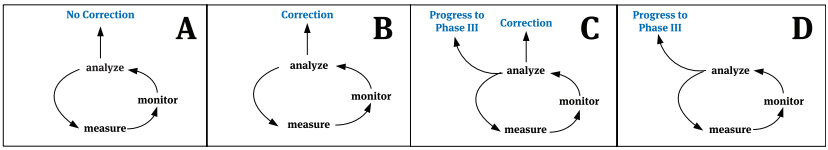

Figure 5 — Outcomes of measurement and analysis

The following tables provide more details to support the use of Figure 5. Each scenario is described with an example showing the different outcome of measurement and analysis.

Basic example	The documentation requirements in a design and development procedure were not followed. The missing documentation involves changing to a different supplier of an electronic board. The requirement is to document the supplier name and supplier number in the research report.

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Scenario A	No correction required, continue measurement and monitoring. The decision is made not to take any correction nor escalate the handling of the nonconformity to improvement (Phase III in Figure 4).	
Example		
	Nonconformity	The supplier number was not included in the research report (however, the supplier name is documented).
	Key Results of Measurement and Analysis	Analysis indicates that the procedure is adequate and well known to the users of the research procedure. Following a review of the issue this appears to be a one-time oversight. The intent of the requirement is for convenience only.
	Conclusion	No initial correction — It is not necessary to update the research report, as the supplier is documented by name, hence traceability is maintained. Do not escalate to improvement (Phase III).

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Scenario B	Correction required, continue measurement and monitoring. The decision is made to perform a correction but not to escalate the handling of the nonconformity to improvement (see Phase III in section 8.1).	
Example		
	Nonconformity	The supplier name and number was not included in the research report.
	Key Results of Measurement and Analysis	Analysis indicates that the procedure is adequate and well known to the users of the research procedure. Following a review of the issue this appears to be a one-time oversight. The intent of the requirement is to ensure traceability to the supplier and this could be lost if the research report is not updated.
	Conclusion	Take an initial correction to update the research report with the supplier name and number. Do not escalate to improvement (Phase III).

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<table>
<tr><td>Scenario C</td><td colspan="2">Correction and escalation to further investigation under the improvement phase.

The decision is made to perform an initial correction. However, there is a need for escalation to improvement (Phase III in section 8.1) to investigate further as a result of the analysis performed in order to determine appropriate corrective action.</td></tr>
<tr><td rowspan="3">Example</td><td>Nonconformity</td><td>The supplier name and number was not included in the research report.</td></tr>
<tr><td>Key Results of Measurement and Analysis</td><td>Analysis indicates that the procedure may not be adequate and it is not well known to the users of the research procedure. The issue has been identified in multiple reports.

In some cases, traceability to the supplier could be established via other means, and in other cases it could not.</td></tr>
<tr><td>Conclusion</td><td>Take an initial correction to update the research report with the supplier name and number (in the cases where the supplier could be identified).

Escalate to improvement (Phase III) for corrective action.</td></tr>
</table>

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Scenario D	Escalation for further investigation under the improvement phase. The decision is made that there is not enough information at this time to determine the required action. Therefore, the investigation is escalated to improvement (Phase III in section 8.1).	
Example		
	Nonconformity	The supplier name and number was not included in the research report.
	Key Results of Measurement and Analysis	Analysis indicates that the procedure may not be adequate and it is not well known to the users of the research procedure. The issue has been identified in multiple reports. Traceability to the supplier could not be established via other means in any of the cases.
	Conclusion	No initial correction — The supplier is not known so an initial correction cannot be taken at this time. Escalate to improvement (Phase III) for corrective action.

Documented procedures should clearly delineate and define when escalation to improvement (Phase III in section 8.1) is required.

Your organization could have a functional group or process surrounding some of their main data sources (e.g. complaint handling, handling of nonconformities, material review boards, or change management process). Within such a group or process, certain activities described in Figure 5 can be implemented without escalation.

Your organization could have predefined events that, due to the significance of the risk, will be escalated directly to improvement without any delay.

When no correction is implemented, or correction is initiated within a group or process that does not necessitate escalation, there needs to be monitoring and analysis of the data source (e.g. trending) to determine if escalation to improvement is necessary based on accumulated information. Whenever an issue is escalated to improvement (Phase III), any information gained (from

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investigation or identified action taken) should be an input to the improvement activities.

8.5 Improvement

8.5.1 General

The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review.

Intent

The section covers changes to product, process or QMS to maintain the suitability, adequacy and effectiveness of the QMS. The requirement has been expanded explicitly to include requiring that changes be made to the QMS, processes or product ensure the safety and performance of a medical device. Additionally, the requirement to use information from post-market surveillance (as well as other sources) to identify changes to QMS, process or product is added.

Guidance

The improvement phase of a corrective action process or preventive action process is designed to eliminate or mitigate a nonconformity or potential nonconformity.

The improvement activities depend on the specific nonconformity or potential nonconformity. Any previous data from measurement and analysis (Phase II) should be utilized as input to the improvement (Phase III) process (see section 8.1).

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The improvement phase and the activities described in Figure 6 needs to be documented. Improvement generally involves the following activities that the organization would take sequentially or sometimes simultaneously:

- Investigate — thorough investigation of the reported nonconformity.
- Identify cause — in-depth analysis to determine cause or causes.
- Identify actions — identification of appropriate actions to resolve issue.
- Verify — complete any required verification or validation of identified actions.
- Implement — take identified actions, and
- Check effectiveness — confirm that implemented actions have resolved issue.

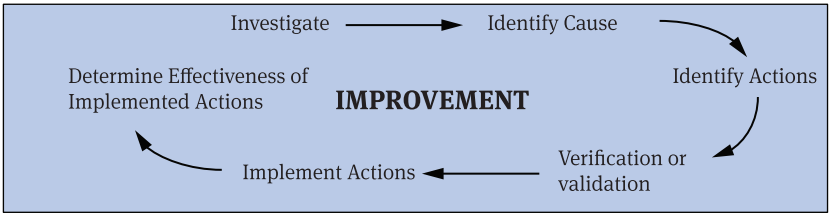

Figure 6 — Phase III — Improvement

The purpose of investigation is to determine the root cause of existing or potential nonconformities, whenever possible, and to provide recommendations of solutions. The magnitude/scope of the investigation should be commensurate with the determined risk of the nonconformity.

Good practice shows that a documented plan should be in place prior to conducting the investigation. The plan should include:

- Description of the nonconformity expressed as a problem statement.
- Scope of the investigation.
- Investigation team and their responsibilities.
- Description of activities to be performed.
- Resources.
- Methods and tools, and
- Timeframe.

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From the information obtained throughout the process the problem statement should be reviewed and refined as appropriate.

The investigation should:

- Determine the extent of the nonconformity or potential nonconformity.
- Acknowledge that there are likely to be several causes of an event, hence the investigation should not cease prematurely.
- Require that symptoms be distinguished from root causes and advocate the treatment of root causes rather than just the symptoms.
- Require that an end point be defined for the investigation as an overly exhaustive investigation may unduly delay the correction of non-conformity or unnecessarily incur additional cost. [For example, if removal of the causes identified so far will correct 80 % of the effects then it is likely that the significant causes have been identified (Pareto rule)].
- Take into account the output of relevant risk management activities; and
- Agree on the form of evidence. For example, evidence should support:
  - the seriousness of the event,
  - the likelihood of occurrence of the event, and
  - the significance of the consequences flowing from the event.

The investigation should include the collection of data to facilitate analysis and should build upon any analysis, evaluation and investigation that were previously performed. This will require the investigator to identify, define and further document the observed effects/non-conformity, or already determined causes, to ensure that the investigator understands the context and extent of the investigation. It could be necessary to:

- Review and clarify the information provided.
- Review any additional information available from a horizontal analysis.
- Consider whether this is a systemic issue/non-systemic issue.
- Gather additional evidence, if required.
- Interview process owners/operators or other parties involved.
- Review documents; and
- Inspect facilities or the environment of the event.

Previous investigations should be reviewed in order to determine if the event is a new problem or the recurrence of a previous problem where, for example,

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an ineffective solution was implemented. The following questions will assist in making the determination:

- Is the nonconformity from a single data source?
- Does the current nonconformity correlate with nonconformities from other data sources?
- Are multiple data sources identifying the same nonconformity?
- Do other nonconformities have an effect on the problem investigated here?

Many of the tools used in investigations rely upon a cause and effect relationship between an event and a symptom of that event. To ensure that causes are identified, not symptoms, the following should be considered:

- There is a clear description of a cause and its effect. The link between the cause and the undesirable outcome needs to be described.
- Each description of a cause describes the combined conditions that contribute to the undesired effect.

A failure to act is only considered a cause if there was a pre-existing requirement to act (e.g., a process step identifies an action that was not taken). The requirement to act could arise from a procedure, or may also arise from regulations, standards or guidelines for practice, or other reasonably expected actions.

Some of the more common tools and techniques include:

- Cause and effect diagrams.
- 5-Why's analysis.
- Pareto charting.
- Fishbone/Ishikawa cause and effect diagrams.
- Change analysis.
- Risk analysis techniques, or
- Is/Is Not.

The outcome of an investigation should include:

- Clearly defined problem statement.
- The information that was gathered, reviewed or evaluated.
- The results of the reviews/evaluations of the information.
- Identification of cause(s) or contributing factors; and
- Solutions to address the cause(s) or contributing factor(s).

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The cause or contributing factors of detected nonconformity or potential nonconformity should promptly be identified by your organization so that corrective action can be taken to prevent recurrence, or preventive action taken to prevent occurrence. The process to identify the cause should start with the output(s) of the investigation. The output of any analysis should be a clear statement of the most fundamental cause(s) resulting in the nonconformity.

When assessing relevant data, the following should be considered:

- Systematic generation of cause and effect conclusions supported by documented evidence.
- Evaluation of significant or underlying causes and their relationship to the problem.
- Identification of causes, not the symptoms; and
- Identification, if appropriate, more than one root cause.

Causes or contributing factors of nonconformities or potential nonconformities can include the following:

- Failure of, or malfunction of, incoming materials, processes, tools, equipment or facilities in which product is processed, stored or handled, including the equipment and systems therein.
- Inadequate or non-existent procedures and documentation.
- Non-compliance with procedures.
- Inadequate process control.
- Inadequate scheduling.
- Lack of training.
- Inadequate working conditions.
- Inadequate resources (human or material).
- (Inherent) process variability.

Management at different levels in your organization should be involved in each improvement action either through approval of the improvement steps or reporting. The Management Review is the overall mechanism for top management to ensure that the improvement process (and the QMS as a whole) is suitable, adequate and effective and identified improvement actions are taken to maintain the suitability, adequacy and effectiveness of the QMS.

Your organization should have a mechanism/procedure that expeditiously raises safety related issues or other high risk issues to management. These

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issues can be identified in the data sources, the improvement phase, or originate from other sources external to the QMS. In addition to this expeditious escalation mechanism, your organization should define management and personnel responsibilities (i.e. process owner) for the measurement, analysis and improvement processes to ensure that the processes and the actions being implemented are effective. For this purpose, there needs to be a mechanism for management at different levels to stay informed of the information or data from:

- The measurement and analysis activities from the individual data sources, or
- The investigations, actions, implementations, etc. from the improvement processes.

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered.

The organization shall document a procedure to define requirements for:

a) reviewing nonconformities (including complaints);
b) determining the causes of nonconformities;
c) evaluating the need for action to ensure that nonconformities do not recur;
d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
f) reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and action taken shall be maintained (see 4.2.5).

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Intent

This section requires your organization to follow up on actions taken for non-conformities (investigation and correction) by taking action to prevent the nonconformity from recurring and maintain records that include the results of investigation and actions taken.

There is a new requirement to take any necessary corrective action without undue delay along with the new requirement to document a procedure that, in addition to other previous requirements, defines requirements for:

- reviewing nonconformities (including all complaints, not just customer complaints);
- planning (in addition to documenting) action needed;
- verifying that a corrective action does not adversely affect the ability (of product, process or QMS) to meet applicable regulatory requirements, or a medical device's safety and performance.

Guidance

When the cause(s) have been determined, your organization has to identify and document the necessary corrective actions. These actions should be reviewed to ensure that all necessary actions are identified. The review can benefit from a cross functional approach.

As applicable, product disposition decisions have to be documented.

Corrective action should address systemic problems. For example, changing the procedure and training of personnel to the revised procedure might not by itself be appropriate or sufficient to address the systemic cause(s).

A list of action items should be documented. These can include:

- development of a detailed description of the implementation;
- review regulatory requirements (e.g. submissions, licensing, certifications);
- definition of roles and responsibilities for execution of action items;
- identification of the necessary resources (e.g. IT, infrastructure, work environment);
- verification or validation protocols of the action(s) with acceptance criteria;
- implementation schedule, including timelines;

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- identification of a method or data for the determination of effectiveness with acceptance criteria; and
- identification of the starting point of monitoring following the corrective action.

The degree of action taken should be dependent upon and related to the risk, size and nature of the problem and its effect on product quality. For example, the level of investigation to determine the cause of the nonconformity, the work done to determine and verify the appropriateness of action, and the level of documentation kept, would be far more extensive for a nonconformity relating to the failure of a medical device compared to a less serious nonconformity such as the failure to conduct an internal audit when scheduled.

Corrective action has to be implemented without undue delay. This again is related to the risk of the nonconformity. In other words, when the risk of an issue is high (severity is high or likelihood of occurrence is high) the action should be expedited and appropriate urgency to take this action drives a shorter time to implementation.

This edition of ISO 13485 makes the implementation of the risk-based approach a requirement throughout your QMS. To support this, you could consider the use of some standard number of days for investigation that would be based on risk. Fewer days for higher risk and more days for lower risk. The investigation task is one that could benefit from this risk-based approach. As far as the overall time your organization allows for completion of a corrective action, it is recommended that you allow that be determined by the action plan created after the completion of the investigation. This should be reviewed by the appropriate personnel in your organization to ensure there are no excessive delay and the limited resources of your organization are sufficient. If the risk is higher or you do not have the competency or sufficient resources, you can use this as a reason to escalate this to top management for further action. The bottom line is that your organization has to determine the delay in taking action that can be allowed in proportion to the risk.

Before the implementation of actions, your organization has to appropriately verify the identified action and approve their implementation in accordance

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with your change control process. In addition, validation could be required where process validation or re-validation is necessary, or where user needs or intended uses are changed and design validation will be required.

Verification activities are to ensure that all the elements of the proposed action (documentation, training or other activity) will satisfy the requirements of the proposed action. These activities should be performed by persons knowledgeable in the design and development or use of the product or process that is the subject of corrective action.

Validation activities generate data and information that confirm the likelihood of the effectiveness of the corrective action to eliminate the nonconformity or proposed nonconformity.

Examples of items to be considered when planning the verification/validation activities include:

- Does the action(s) eliminate the identified root cause(s)?
- Does the action(s) cover all affected product/processes?
- Does the action(s) adversely affect the final product?
- Is it possible to finalize the actions in a timely manner to a planned schedule (resources, materials/kits, logistics, communications, etc.)?
- Is the execution of the action commensurate with the degree of risk previously established?
- Are new risks or nonconformities derived from the action?

The following items could be considered at implementation:

- parties involved,
- necessary materials,
- processes to be implemented or changed,
- training needed to ensure competency,
- communications to ensure awareness,
- tools to be used,
- timelines for the implementation of the action,
- criteria to verify that the action is effective, and
- appropriate information to be recorded.

Your organization has to gather data related to the effectiveness of the implemented action. Your organization needs to ensure that actions taken were

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effective and confirm there are no new issues or concerns. The following questions should be considered at appropriate times throughout the process and be revisited in the final review:

- Has the problem been comprehensively identified?
- Has the extent of the problem been identified (e.g. range of affected devices, patient outcome, process, production lines, operator)?
- Has the root cause/contributing factors of the problem been identified and addressed?
- Has the improvement action been defined, planned, documented, verified and implemented?

If your organization finds the actions are not effective, improvement activities have to be re-initiated. If your organization finds the actions create a new issue or a new nonconformity, then data gathering and analysis activities need to be initiated to consider further improvement.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.

The organization shall document a procedure to describe requirements for:

a) determining potential nonconformities and their causes;
b) evaluating the need for action to prevent occurrence of nonconformities;
c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

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Intent

The section requires your organization to investigate potential nonconformities and to take action to prevent the nonconformity from occurring and outlines new requirements that preventive actions shall be proportionate to the effects of potential problems and that your organization document a procedure that defines requirements for:

- planning and documenting preventive action needed and implementing the action;
- if appropriate, updating documentation that is affected by the action; and
- verifying that preventive action does not adversely affect the ability of product, process or QMS to meet applicable regulatory requirements or the medical device's safety and performance.

Records of the results of any investigation and action taken are maintained.

Guidance

Preventive action is taken when a potential nonconformity is identified as the result of an analysis of records and other relevant sources of information. The degree of preventive action taken should be dependent upon and related to the risk, size and nature of the problem and its potential effect(s) on product quality. Preventive actions can include changes to the product or a process. In such case, the requirements in Clause 7.3.9 on control of design and development changes; and 4.1.4 on control of process changes respectively apply.

Sources for information for initiating preventive actions may include:

- risk management processes,
- process measurements,
- statistical process control documents,
- identification of results that indicate a trend but not out-of-specification, or
- difficulties with suppliers (see 7.4.1).

Verification of a preventive action can be accomplished by introducing the conditions that would induce nonconformity and confirming that the nonconformity does not occur.

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Annex A — Guidance for small organizations

This section of this handbook is written particularly for a small organization that wishes to implement a suitable, adequate and effective QMS. For the purposes of this handbook, a small organization is not only a matter of the number of employees or size, but also the way it is managed. With only a few people involved, communications in a small organization can often be simple and more direct. Individuals are expected to undertake a wide variety of tasks within your organization. Decision making can be confined to a few people (or even one).

In a small organization, however, there can be challenges in implementing a suitable, adequate and effective QMS due to:

- minimal available resources;
- perceived costs involved in setting up and maintaining a QMS;
- lack of experience in understanding and applying the standard;
- lack of organizational knowledge and experience in apply the process approach and formalised risk-based decision making.

Much of the advice given in this annex of this handbook will also be relevant to medium and large organizations that can adapt techniques and improvements developed successfully elsewhere.

If you are a small organization's top manager, you should look at the time and money spent implementing a QMS in the same way as on any other investment. For the investment to be viable, you have to be able to achieve a return for the time and effort expended, through improvements in your organization's

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processes and marketability of your product. The return on your investment can also relate to your organization's ability to handling the risks associated with compliance with regulatory QMS requirements. Your decisions at the early stages of introducing/developing your QMS will have a major influence in these areas.

How to Start

The first step is to use this handbook to give yourself an understanding of what a QMS is and what its requirements are.

Since it is not the purpose of ISO 13485 to impose a totally new way of managing your organization, the next step is to look at what you are doing now and the results you are achieving. You will need to analyze which requirements of the standard your organization is already meeting and those it is not yet meeting.

Modifications will be required to align current practices to meet the requirements of ISO 13485.

More information and support

Some sources that you can use for advice are:

- industry or professional associations;
- quality associations;
- government departments, particularly those that specialize in small organization affairs and organization development units;
- Internet web pages including the ISO site (www.iso.org) and internet forums about quality;
- other organizations which already have a QMS in place;
- certification/registration bodies;
- standards development organizations;
- consultants;
- customers; or
- suppliers.

It is advisable to ask your customers if they have any requirements that you might need to consider for inclusion in your QMS.

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Going ahead

The next question is "How much can I do myself?" If you feel you are going to need assistance, the items in the bullets above can be used to identify possible sources and associated costs.

You will need to establish personnel and time resources available to you, since these will determine how much assistance you will need. There are many sources of assistance available, such as training courses, seminars, software packages and sometimes even financial support.

Before using external assistance, the key issue you and the top management of your organization need to recognize is that due to the specific nature of your product, processes, structure, and personnel. Your approach and your QMS should be unique to your organization to be suitable, adequate and effective. Consequently, you need to be wary of generic solutions that cannot be adequately adapted to your product, service, and organization, whether these are offered in a software package or by a consultant.

It is important, during the introduction, development, implementation and continuing certification phases of the QMS, that all employees in your organization are fully engaged to ensure effective utilization and operation of the QMS and to achieve maximum benefit for your organization's operations.

This can be achieved by ensuring all employees throughout the organization including top management, departmental leaders, junior staff, reception staff, and maintenance staff:

- have been fully briefed, including having the necessary understanding of the importance of having the QMS,
- have been correctly trained in the overall QMS and any specific requirements for them to undertake their roles and responsibilities,
- be aware that changes can be made to the QMS but these need to be controlled.

Top management has the responsibility to ensure adequate resources are provided for the correct operation of the QMS and if this is not done, the correct operation of the QMS can be compromised.

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Using internal resources

The section entitled *Guidance on what the standard means* will prove helpful here. You can use this section to identify what the standard requires and how these requirements relate to what your organization does. This comparison should identify the areas where you need to further develop your QMS. This section also includes examples that can be useful for small enterprises.

It is important to realize that there should be no reason for you to substantially change the way your organization is run. The standard sets out what needs to be done, but you have to decide how you are going to implement it. Changes that you make should result in an improvement for your organization.

Using external resources

Though not necessary, you might want to engage the services of external resources to guide you through the process of establishing, implementing or maintaining your QMS.

For example, an external resource could be hired for some or all the following activities:

- preliminary status survey or assessment,
- training,
- implementation,
- internal audits.

The selection of the external resource is an important step and should be carried out with rigorous scrutiny of qualifications, credentials, quality management-specific knowledge, experience and references.

The use of an external resource does not remove your responsibility for establishing, implementing and maintaining your QMS. Therefore, it is in your own interest that you and your staff are actively involved with the external resource throughout the entire period of engagement.

ISO/TC 176 has produced the standard ISO 10019:2005 *Guidelines for the selection of quality management system consultants and use of their services* to provide further advice on the use of consultants.

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What does Registration/Certification and Accreditation mean?

Registration/certification and accreditation are terms that have specific meanings. Certification can be regarded as the formal recognition by others that your QMS complies with a set of internationally agreed upon requirements. In some countries, a registered QMS is certified and the term "certification" is used instead of registration. For the sake of brevity, the terms certified and certifications are used in this section.

Certification is not a mandatory requirement of implementing ISO 13485, but could be required by some of your customers. Your decision regarding certification might also be influenced by your competitors' actions or by applicable regulatory requirements.

To obtain certification to ISO 13485, it is essential that your organization fully implement all applicable requirements as defined in the standard. A formal audit by a certification body (sometimes called a registrar) is required to provide this certification.

It is not necessary to conform to any additional requirements to achieve ISO 13485 certification. However, your customers or a specific regulator can require you to conform to additional requirements.

If you are considering certification, your first step is to research certification bodies to find out which of them are accredited in your sector [e.g. Nomenclature of Economic Activities (NACE) codes], what is offered, what the likely costs are and the requirements for the certification activities.

Accreditation is the formal recognition that a Certification Agency/Registrar has been approved to issue certificates typically by demonstrating compliance to ISO/IEC 17021 which is the standard assessed by accreditation bodies to assure the competence and rigour of accredited certification agency. Once accredited, the certification agency is permitted to issue certificates to companies who have undergone and successful passed a 3rd party audit by demonstrating compliance with ISO 13485.

Guidance contained in this handbook can be useful as background information for those representing QMS assessors, Conformity Assessment Bodies and regulatory enforcement bodies.

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ISO 13485:2016 – Medical devices – A practical guide is intended to help organizations in the medical devices sector implement the requirements of International Standard ISO 13485, thereby demonstrating their ability to provide products and related services in compliance with the laws and regulations of the medical devices industry.

Such organizations, which may be involved in one or more stages of the life cycle or supply chain of a medical device, include 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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