

Technical Information Report

AAMI TIR102: 2019

U.S. FDA 21 CFR mapping
to the applicable regulatory
requirement references in
ISO 13485:2016 Quality
Management Systems

U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016 Quality Management Systems

Approved 30 August 2019 by
AAMI

Abstract: This document provides a mapping of the US FDA 21 CFR requirements to the "regulatory requirements" references in ISO 13485:2016. This mapping is intended to be a tool for US industry to help identify the regulatory requirements from the US medical device regulations to be addressed through an ISO 13485 quality management system.

Keywords: quality systems, regulations, 21 CFR 820, medical devices

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Application of Quality Systems to Medical Devices Working Group

This technical information report (TIR) was developed and approved by the AAMI Medical Device Wireless Committee.

At the time this document was published, the **AAMI Application of Quality Systems to Medical Devices Working Group** had the following members:

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the TIR. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE—This foreword does not contain provisions of the AAMI TIR102, *U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016 Quality Management Systems* (AAMI TIR102:2019), but it does provide important information about the development and intended use of the document.

Introduction

This Technical Information Report (TIR) is intended to demonstrate alignment of regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device.

This TIR is a comparison of the requirements of 21 CFR 820 and ANSI/AAMI/ISO 13485:2016. Within this TIR, 21 CFR 820 may be referred to as the Quality System (QS) Regulation. In addition, ANSI/AAMI/ISO 13485:2016 may be referred to as ISO 13485:2016 or the standard.

AAMI Quality Management working group (AAMI QM/WG 01) has completed an analysis to identify differences between the requirements of 21 CFR 820 and the clauses of ISO 13485:2016, as well as some key considerations in the evolution of global quality management system for the medical device industry.

U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016, Quality management systems

1 Scope

This document is a comparison of requirements between 21 CFR 820 and ANSI/AAMI/ISO 13485:2016 that demonstrates similarities, highlights differences, and discusses key considerations for medical device manufacturers. It is not a word-for-word literal identification of differences; thus, the reader must be familiar with quality management system requirements along with the statutory definitions to apply this report.

This document provides the basis for interpretation of the associated requirements and applicable U.S. FDA rules. Users must be aware that this analysis provides a comparison of the QS Regulation and the standard only. It is not inclusive of all global regulatory requirements applicable to medical device quality systems.

The comparison covers all parts of 21 CFR 820 including appropriate references to the Preamble to the QS Regulation and ANSI/AAMI/ISO 13485:2016. Other standards or parts of the U.S. regulations may be referenced but are not explicitly included in this report.

2 Using this technical information report

This document was produced by AAMI QM/WG 01 comprised of representatives from the medical device sector. For the proper use of this TIR, readers should have full understanding of both 21 CFR 820 and ISO 13485:2016. Although the information contained in this document has been carefully considered, it is up to the individual organization to ensure compliance with all regulatory requirements. This document is intended for manufacturers and it is expected that the reader is familiar with regulatory quality management system requirements and definitions within the medical devices sector and regulations. It is intended for informational purposes and it is not intended to be used to assess or audit compliance with regulatory requirements.

- The working group has listed the primary and some secondary core references, not all referenced sections of the standard or QS Regulation are listed.
- The users of this document should keep in mind that a quality management system is a set of interrelated processes. Since both the QS Regulation and ISO 13485:2016 require the organization to define the interrelationships of quality management system, the user should keep in mind that there may be additional linkages connections that an organization must consider as you define your quality management system.

The Key Considerations section discusses notable differences between the QS Regulation and ISO 13485:2016. This part also includes narrative relative to any systemic differences between the U.S. FDA QS Regulation and ISO 13485:2016, which may have impact beyond a specific section.

The second section of the TIR consists of two mapping tables: 21 CFR 820 to ISO 13485:2016; and ISO 13485:2016 to 21 CFR 820. The mapping is provided in two directions purposefully. When evaluating the two quality management systems, the full intent and similarities can only be determined by comparing in both directions. Therefore, both tables should be reviewed in their entirety.

An example of this is 21 CFR 820 supplier controls compared to ISO 13485:2016 outsourced suppliers and purchasing controls and the need for quality agreements. While there are no incongruities among the requirements for the quality management systems, there may be some verbiage or directed differences. This difference may not have been noticed reviewing the requirements in only one direction. The requirements of both the QS Regulation and ISO 13485:2016 require quality agreements and allow a risk-based approach to meet this requirement (i.e. contracts, purchase orders, drawings, or specifications). The requirements of both the QS Regulation and ISO 13485:2016 can be met with flexible risk-based solutions and fulfill the obligation of both quality management systems.

In these tables where the requirements of the regulation and standard are considered equivalent “No significant difference” will be noted. Where differences are noted, close consideration should be given to the specific details of the requirements considering the organization’s unique quality system and products.

3 Key considerations

When developing the mapping tables, certain topics emerged that warranted further discussion. This section provides a high-level summary of those topics.

3.1 Definitions

The analysis of the QS Regulation and ISO 13485:2016 identified differences in terminology requirements; however, use and expectations of terms have evolved to become more similar in meaning and application. These similarities are further demonstrated through review of the Preamble to the QS Regulation and other guidance.

Definitions are integral to the interpretation of the QS Regulation and ISO 13485:2016. There are definitions that are specific to the QS Regulation, those that are specific to ISO 13485:2016, and those that are found in both. In some cases, there are slight differences that may lead to a different interpretation of similar requirements. Therefore, to appropriately use this document an understanding of the definitions in both documents is fundamental.

For example, the definition of product in the QS Regulation does not include services, however, the QS Regulation with the Preamble uses the combined term product and services. As compared to the definition in ISO 13485:2016 which explains the four product categories and includes services. Therefore, if the organization is not familiar with the definition in ISO 13485:2016 or the Preamble, it may lead to the wrong interpretation that services are not covered.

3.2 Training and Competence

The term training has evolved to mean establishing competence through education, training, skills and experience as defined in ISO 13485:2016 as required in 6.2. The U.S. FDA requirements are not explicit for making resources decisions in 21 CFR 820. However, the U.S. FDA expectation is further explained in Comment 59 of the Preamble to QS Regulation, “...a manufacturer must ensure that persons assigned to particular functions...possess the necessary education, background, training, and experience to perform their functions correctly,” demonstrating that both quality management systems expect competency as a requirement.

3.3 Approvals vs. Signature

In several locations within ISO 13485:2016, the requirement for an approval is identified. This parallel requirement within the QS Regulations is more specific and outlines the need for a signature and date to meet the legal precedence of what evidence is required for approval, while Response 94 within the Preamble to the Quality System Regulations (QSR) further describes what constitutes a signature. While a signature and date would provide objective evidence for approval, the need for approval as stated in ISO 13485:2016 does not specifically require a signature. Therefore, to meet legal/statutory requirements, all approvals identified within ISO 13485:2016 will require a signature and date.

3.4 Risk Management/Risk-based

Risk management activities should be integrated throughout a manufacturer’s Quality Management System (QMS) and address the lifecycle of a medical device. ISO 13485:2016 clearly outlines the expectations for risk management activities and risk-based approach to controls within QMS processes to occur throughout the QMS in various clauses of the standard. This is much more prescriptive than the QS Regulation. Risk terminology may differ; however, expectations are similar between the QS Regulation and ISO 13485:2016, with ISO 13485:2016 being more explicit with risk management principles throughout the QMS.

While the QS Regulation only mentions the requirements for ‘risk analysis’ in the design validation requirements in 21 CFR 820.30(g), the expectations for risk management are outlined throughout the Preamble to the QS Regulation (see Table 1).

For example, Comment 159 of the Preamble states that the U.S. “FDA agrees that the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered... the U.S. FDA does expect the manufacturer to develop procedures for assessing the risk, the actions that need to be taken for different levels of risk, and how to correct or prevent the problem from recurring, depending on that risk assessment.” While not specified in the requirements of Corrective and Preventive Action (CAPA) (21 CFR 820.100), there is an expectation that a risk-based approach is integrated throughout the Corrective and Preventive Action system.

For additional examples, Table 1 below highlights each section of the QS Regulation and the relevant Preamble comments related to risk-based decisions or risk management processes (for example see ISO 14971).

Table 1: QS Regulation and risk-related Preamble comments

21 CFR Reference	Section	Preamble comment
820.1	Scope	4, 13
820.30	Design Controls	81, 83
820.50	Purchasing Controls	99, 115
820.65	Traceability	121
820.70	Production and Process Controls	31
820.90	Nonconforming Products	161
820.100	Corrective and Preventive	159
820.200	Servicing	200

The terminology used in the QS Regulation is only one component of the risk management process as it includes risk analysis, risk evaluation, risk control, and production and post-production information collection and review. Although the terminology in the QS Regulation is not encompassing of the entire risk management process, the expectation is that full risk management activities occur across the entire medical device lifecycle.

3.5 CAPA vs. Improvement Process

The concept of CAPA has progressed and been refined within both ISO 13485:2016 and ISO 9001 over the past two decades. “Corrective Action and Preventive Action (CAPA), when published in the QS Regulation in 1996, was based off the early CAPA concept found in both ISO 13485:2016 and ISO 9001, and is detailed as a combined concept of analysis, corrective action, and preventive action in a single section (820.100). The ISO concept of CAPA has progressed and been refined to separate out important aspects of these two critical processes, and in 8.5 of ISO 13485:2016, it is clearly stated that “when planned results are not achieved, correction and corrective action shall be taken, as appropriate”, thereby allowing a defined process without necessarily escalating to the Improvement Process.

At this escalated risk level within the Improvement Process, the only difference in the ISO requirements between Corrective Action and Preventive Actions is the need to prevent “undue delay” related to Corrective Action.

For example, current quality practices allow the manufacturer to handle corrections and corrective actions for lower risk issues at a lower level, justified by using appropriate risk-based and statistical methodology. Escalation is not necessary for corrections. This allows manufacturers to focus effort and resources to the higher risk issues where there is higher expectation of depth and breadth of investigation, resulting actions, and formal effectiveness checks.

3.6 Additional Resources

3.6.1 Modernization of the standard and harmonization with the QSR

Users must keep in mind that the QS Regulation was written in 1996 and, over time, understanding of the intent and application of the regulation have evolved resulting in similarities in terminology becoming more apparent and aligned. There are additional resources available to help with the interpretation and implementation of ISO 13485:2016 and 21 CFR 820. ISO has published ISO 13485:2016, *Medical devices – A Practical Guide*, to provide users with examples of best practices and guidance on ways to meet requirements. The handbook is intended to guide organizations in the development, implementation and maintenance of their quality management system in accordance with ISO 13485:2016.

The U.S. FDA has several additional resources to help in the understanding and implementation of 21 CFR 820 including some of the links below:

- <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>
- <https://www.fda.gov/Training/CDRHLearn/default.htm>
- <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>
- <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm>

There are multiple guidance documents that have been published by the Global Harmonization Task Force (GHTF) and are available on the International Medical Device Regulators Forum (IMDRF) website that may also be of interest (www.imdrf.org). These include:

- GHTF/SG3/N19:2012, *Nonconformity Grading System for Regulatory Purposes and Information Exchange*
- GHTF/SG3/N18:2010, *Guidance on Corrective Action and Preventive Action and related QMS processes*
- GHTF/SG3/N17:2008, *Guidance on the Control of Products and Services Obtained from Suppliers*
- GHTF/SG3/N15R8, *Risk Management Principles and Activities within a QMS*
- GHTF/SG3/N99-10:2004, *Process Validation Guidance*

For all these resources, it is important to read the Preamble and Introduction sections because they often provide additional information regarding the intent behind the requirements and can help in the interpretation of those requirements.

Table 2: Comparison from 21 CFR 820 to ISO 13485:2016

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
1.	820.5 Quality System	Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.	4.1.1 Quality management system, General requirements	4.1.1 <i>Quality management system, General requirements</i> 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.	No significant difference.	No significant difference.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
2.	820.20(a) Quality Policy	Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.	5.3 Quality Policy 5.4.1 Quality Objectives	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. 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.	The QS Regulation provides additional details on the requirements for a quality policy.	The standard requires the quality objectives to be measurable and has additional detail relative to the quality policy.
3.	820.20(b) Organization	Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.	5.5.1 Responsibility and Authority	5.5.1 Responsibility and Authority Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.	No significant difference.	No significant difference.
4.	820.20(b)(1) Responsibility and Authority	Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.	5.5.1 Responsibility and Authority	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.	No significant difference.	No significant difference.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
5.	820.20(b)(2) Resources	Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.	6.1 Provision of Resources	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.	No significant difference.	The standard defines that the organization's resources should be reviewed specifically in reference to customer requirements".
6.	820.20(b)(3) Management Representative	Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for: (i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and (ii) Reporting on the performance of the quality system to management with executive responsibility for review.	5.5.2 Management Representative	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.	No significant difference.	The Standard has an additional requirement for promotion of awareness of regulatory and Quality Management System requirements throughout the organization. The standard specifies the management representative has responsibility and authority to ensure the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.
7.	820.20(c) Management Review	Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.	5.6 Management Review 5.6.1 General 5.6.2 Review Input 5.6.3 Review Output 5.1 Management Commitment	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. 5.6.2 Review input The input to management review shall include, but is not limited to, information arising from:	The QS Regulation specifies the documentation of the date of the review and the results (see Approvals vs. Signature in section 2).	No significant difference considering QS Regulation with Preamble. The standard has more specific detail about the requirement including what specifically should be a part of the review input and output. Compliance to the standard requires that specific topics are covered during management review. The Standard requires specific documentation related to maintaining all aspects of the Quality Management System.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				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. 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; c) changes needed to respond to applicable new or revised regulatory requirements; d) resource needs. 5.1 Management Commitment Top management shall provide evidence of its commitment to the development and implementation of the quality management		

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				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.		

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
8.	820.20(d) Quality Planning	Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.	5.4.2 Quality Management System Planning 4.1 QMS General Requirements	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. 4.1 QMS 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.	No significant difference.	The standard has more specific detail with the link to 4.1.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
9.	820.20(e)	820.20(e) Quality system procedures. Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.	4.2.1 Documentation Requirements General 4.2.2 Quality Manual	4.2.1 Documentation requirements 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. 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.	The QS Regulation specifies an outline of the structure of the documentation.	The standard specifies a Quality Manual.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
10.	820.22	820.22 Quality Audit Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.	8.2.4 Internal audits 5.6.2 Review Input	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.	The QS Regulation specifies the date of the audit and the audit report.	No significant differences.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				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.		

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
11.	820.25(a) Personnel, General	Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.	6.1 Provision of Resources 6.2 Human Resources	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. 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; 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.	No significant difference.	The standard has more specific detail.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
12.	820.25(b) Personnel, Training	Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented. (1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs. (2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.	6.2 Human Resources 6.4.1(b) Work Environment	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; 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. 6.4.1(b) Work Environment The organization shall: ... 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.	The QS Regulation states that personnel should be aware of device defects.	The standard has more specific requirements and applies a risk-based approach in training and effectiveness of the actions taken.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations												
13.	820.30(a) Design Controls, General	(1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. (2) The following class I devices are subject to design controls: (i) Devices automated with computer software; and (ii) The devices listed in the following chart. <table><tr><td>Section number</td><td>Device description</td></tr><tr><td>868.6810</td><td>Catheter, Tracheobronchial Suction</td></tr><tr><td>878.4460</td><td>Glove, Surgeon's</td></tr><tr><td>880.6760</td><td>Restraint, Protective</td></tr><tr><td>892.5650</td><td>System, Applicator, Radionuclide, Manual</td></tr><tr><td>892.5740</td><td>Source, Radionuclide Teletherapy</td></tr></table>	Section number	Device description	868.6810	Catheter, Tracheobronchial Suction	878.4460	Glove, Surgeon's	880.6760	Restraint, Protective	892.5650	System, Applicator, Radionuclide, Manual	892.5740	Source, Radionuclide Teletherapy	1.0 Scope 7.3.1 General	1.0 Scope 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 to this International Standard reflect any exclusion of design and development controls. 7.3.1 General The organization shall document procedures for design and development.	No significant difference.	The scope of the standard allows for exclusions of design and development if allowed per the regulations and justified.
Section number	Device description																	
868.6810	Catheter, Tracheobronchial Suction																	
878.4460	Glove, Surgeon's																	
880.6760	Restraint, Protective																	
892.5650	System, Applicator, Radionuclide, Manual																	
892.5740	Source, Radionuclide Teletherapy																	

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
14.	820.30(b) Design and Development Planning	Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.	7.3.2 Design and development planning	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.	The QS Regulation requires documented design plans, updates, and interfaces between different groups related to the design project. The design plans required by the QS Regulation are specific to the design project not general procedures for design and development planning.	No significant difference considering QS Regulation with Preamble.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
15.	820.30(c) Design Input	Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.	7.3.3 Design and development inputs	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.	The QS Regulation requires the date and signature of the individual approving the design inputs from user and patient (see Approvals vs. Signature discussion).	The standard provides requirements on specific inputs, and has a more direct link to risk management, and usability.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
16.	820.30(d) Design Output	Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.	7.3.4 Design and development outputs	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	The QS Regulation expects a signature (see Approvals vs. Signature discussion).	No significant difference considering QS Regulation, definitions and Preamble.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
17.	820.30(e) Design Review	Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (DHF).	7.3.5 Design and development review 7.3.10 Design and Development files	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 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.	The QS Regulation specifically requires an "individual(s) who does not have direct responsibility for the design stage being reviewed" to be a part of the design review process.	The standard requires that reviews should "identify and propose necessary actions".

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
18.	820.30(f) Design Verification	Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.	7.3.6 Design and development verification 7.3.10 Design and development files	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. 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.	The QS Regulation requires that the individual performing the verification activities are documented including the date of the activity (see Approvals vs. Signature – Section 2).	The standard requires verification plans and discusses requirements for verification of connectivity with other medical devices.

19.	820.30(g) Design Validation	Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.	7.3.7 Design and development validation 7.3.10 design and development files	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. 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). 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	The QS Regulation expressly calls out the requirement for risk analysis and software validation (see Risk Management/Risk-based discussion).	The standard provides additional requirements to ensure connectivity with other medical devices (if applicable). The standard specifies risk management throughout the entire product realization. The standard also specifically states that "the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements".
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	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				file shall include, or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.		
20.	820.30(h) Design Transfer	Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.	7.3.8 Design and development transfer	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).	No significant difference considering QS Regulation with Preamble. While this is not explicitly stated in the regulation, Comment 86 of the Preamble to the QS Regulation states "The intent of the requirement was to ensure that all design specifications released to production have been approved, verified, and validated before they are implemented as part of the production process."	The standard has specific requirements.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
21.	820.30(i) Design Changes	Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.	7.3.9 Control of design and development changes	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).	No significant difference.	No significant difference.
22.	820.30(j) Design History File	Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.	7.3.10 Design and development files	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.	No significant difference.	No significant difference.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
23.	820.40 Document Controls	Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:	4.2.4 Control of documents 4.2.5 Control of records	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; 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... 4.2.5 Control of records Records shall be maintained to provide evidence of conformity to requirements and	QS Regulation requires a signature (see Approvals vs. Signature – Section 2).	The standard has separated out records and documents to highlight the differences in these document types.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				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....		
24.	820.40(a) Document approval and distribution 820.40(b) Document Changes	(a) Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use. (b) Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records	4.2.4 Control of documents 4.2.5 Control of records	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;	The QS Regulation provides additional documentation requirements to include a date and signature of the individual approving the document (see Approvals vs. Signature - Section 2). The QS Regulation specifically requires that approved changes to documents be reported in a timely manner and specific documentation requirements including signature (see Approvals vs. Signature – Section 2).	The standard provides additional discussion of requirements.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
		of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.		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... 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....		
25.	820.50 Purchasing Controls	Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.	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 QS Regulations separates the terms product and service. However, there is no significant difference when considering the QS Regulation and Preamble comment number 111, 113, 114.	The standard defines product to consider services.

26.	820.50(a) Evaluation of Suppliers, Contractors, and Consultants	Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall: (1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented. (2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results. (3) Establish and maintain records of acceptable suppliers, contractors, and consultants.	7.4.1 Purchasing process 7.4.3 Verification of purchased product	7.4.1 Purchasing process ... 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 organization's 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. 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). 7.4.3 Verification of purchased product 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 organization's requirements; b) based on the performance of the supplier;	No significant difference when considering the QS Regulations and the Preamble (115 and 105).	The standard is more explicit in these requirements.
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	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				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. 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).		

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
27.	820.50(b) Purchasing Data	Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with 820.40.	7.4.2 Purchasing information	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. 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).	No significant difference.	The standard is more explicit in these requirements.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
28.	820.60 Identification	Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups.	7.5.8 Identification 6.3 Infrastructure	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. 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....	No significant difference.	The standard is more explicit in these requirements.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
29.	820.65 Traceability	Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.	7.5.9 Traceability 7.5.1 Control of production and service provision	7.5.9 Traceability 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). 7.5.1 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: ... 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.	The QS Regulation specifies the types of products that require traceability to the initial consignee. 21 CFR 820 lays out requirements for traceability which is distinguished from requirements for tracking laid out in 21 CFR 821 Preamble.	No significant difference as the standard requires procedures for traceability based on regulatory requirements.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
30.	820.70(a) Production and Process Controls, General	Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include: (1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production; (2) Monitoring and control of process parameters and component and device characteristics during production; (3) Compliance with specified reference standards or codes; (4) The approval of processes and process equipment; and (5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.	7.5.1 Control of 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.	No significant difference.	The standard has specific requirements for planning.
31.	820.70(b) Production and Process Changes	Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be	4.1.4 General 4.2.4 Control of Documents	4.1.4 General The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable	No significant difference	No significant difference

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
		approved in accordance with 820.40.		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. 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; g) prevent deterioration or loss of documents;		