AAMI Quality Systems White Paper

Comparison of 21 CFR Part 820 to ISO 13485:2016

February 2017, Updated February 2018

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A. ISO 13485:2016—What is it?

ANSI/AAMI/ISO 13485:2016, *Medical devices—Quality management systems—Requirements for regulatory purposes*, specifies requirements for a Quality Management System when an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

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 may 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.

Note that this 2016 revision to ISO 13485 supersedes and replaces the 2003 revision of ISO 13485. Medical device manufacturers that were conforming to the 2003 revision of this standard must achieve conformance to the 2016 revision no later than 3 years after the March 2016 publication of ISO 13485:2016.

B. Significant concept differences between the 21 CFR 820 and ISO 13485:2016

Product realization: Product realization is a set of interrelated processes that support the design and development, manufacturing, installation, and servicing of finished goods that meet customer requirements and intended purposes. These interrelated processes must be consistent with other processes of the Quality Management System, such as those related to resource management or measurement analysis and improvement. A key requirement for Planning of product realization is that the organization must document one or more processes for risk management in product realization. Records of risk management activities must be maintained.

Risk management: The Standard is very specific on using risk management to make decisions on activities related to Quality Systems or product realization processes when the effect of the process or situation could have an effect on the medical device safety or performance.

Definition of product: The Standard defines product as the "result of a process" with a note that there are four generic product categories:

- Services (e.g., transport)
- Software (e.g., computer program, dictionary)
- Hardware (e.g., engine mechanical part)
- Processed materials (e.g., lubricant)

The concept of product must be considered when determining the applicability of the clauses of the Standard.

C. Importance of ISO 13485 to medical device manufacturers

Compliance with ISO 13485 is often seen as the first step in achieving compliance with European regulatory requirements. The conformity of Medical Devices and In-vitro Diagnostic Medical Device according to European Union (EU) Regulations—**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices**—must be assessed before sale is permitted. The preferred method to prove conformity is the certification of the Quality Management System according ISO 13485 by a Notified Body. The result of a positive assessment is the certificate of conformity allowing the Conformité Européenne (CE) mark and the permission to sell the medical device in the European Economic Area (EEA). Compliance to ISO 13485:2016 is also supportive of other regulatory body requirements for Quality Management Systems. Finally, ISO 13485:2016 is included as part of the MDSAP Audit Model (2017-01-06 MDSAP AU P0002.004).

D. Comparing different Quality Management Systems standards and regulations

Comparing which standards/regulations?	Use these references
1. ISO 13485:2003 to ISO 13485:2016	1. Annex A of ISO 13485:2016 (page 27)
2. ISO 13485:2016 to ISO 9001:2015	2. Annex B of ISO 13485:2016 (page 31)
3. ISO 13485:2003 to 21 CFR Part 820	3. AAMI Compendium, 3rd edition (Table 3.1)
4. ISO 13485:2016 to 21 CFR Part 820	4. This AAMI white paper (Table 1)

E. Table 1—Additional information

Note that in several key ISO 13485:2016 clauses in Table 1 (Design Controls and CAPA, for example), the authors have included an estimate of resources that would be required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard. These estimates are provided as initial assumptions only and it is recommended that each organization should conduct a directed analysis to determine actual resources that would be required for a specific Quality Management System.

Estimate of effort to update existing 21 CFR Part 820 QS Management System components to align with ISO 13485:2016	Level	Examples
Minor updates required to existing documents	Minor	Clause 8.2.6: New requirement to document test equipment used
Major updates to existing documents or new documents required	Moderate	Clauses 7.3.7: Design Validation plans required

Table 1—Comparison of 21 CFR Part 820 to ISO 13485:2016

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
N/A	0.1 Introduction, general 0.2 Clarification of concepts 0.3 Process approach 0.4 Relationship with ISO 9001 0.5 Compatibility with other management systems	Section 0.1 addresses: • Its potential application by suppliers to medical device manufacturers • How to use the Standard to meet any quality management system requirements from regulatory jurisdictions and the expected work by the organization • Action required by the organizations related to the standard definitions and potential for national and regional differences in definitions • The complimentary nature of the quality system requirements and the technical requirements for products • The strategic determination of an adoption of a Quality Management System (QMS) and influencers Section 0.2 describes common term or phrase utilization including: • As appropriate • Product • Risk • Shall, should, may, and can Explanations of the meaning of "as appropriate" in the Standard are similar to "where appropriate" in the Regulation with the Standard including the necessity to manage risk and comply with applicable regulatory requirements if a requirement is deemed appropriate. Section 0.3 explains the process approach. The Regulation has no similar explanation. Section 0.4 explains its relationship with ISO 9001 and references ISO 9000:2015 with regard to the fundamentals of Quality Systems. The Regulation does not reference these standards, although it does use some terms and concepts that appear in these standards. Section 0.5 addresses compatibility with management systems for other types of activities. The Regulation does not. ISO 13485:2016 places an emphasis on the on the lifecycle of the medical device.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.1 Scope (a) Applicability (b) Alignment with other regulations (c) Authority (d) Foreign manufacturers (e) Exemptions or variances	1 Scope 2 Normative references	The Regulation addresses exemptions, applicability to foreign manufacturers, and the authority under which the Regulation was promulgated. The Regulation also addresses possible conflicts between compliance with the Regulation and with other FDA regulations. The Standard addresses regulatory exclusions from design controls (based on scope of operations). The Standard includes: • Distribution in the scope, and although not in this section of the Regulation, is covered in subpart L • Provision of associated activities (e.g., technical support); this is not specifically called out in the Regulation • Applies the Standard to medical devices and associated services • Specifically states that the processes in the Standard are the responsibility of the organization regardless of whether or not they perform the process an ace accounted for in the organizations QMS by monitoring, maintaining and controlling the processes The Regulation and Standard BOTH address: • Exclusions and exceptions, however the Regulation is very specific to the types of products where the Regulation is applicable • How design and development controls can be excluded from a QMS • Actions to take when determining that a specific part of the requirements is not applicable
820.3 Definitions	3 Terms and definitions	The Standard: • Relies on ISO900:2015, GHTF documents, and additional or changed definitions within the standard • Includes definition for advisory notice which is in the 803 section of the CFR There are numerous differences between terms and definitions in the CFR and the standard. Two significant definitions are those of manufacturer and product. Significant definitions that are only in the CFR or the Standard: • In the Standard are definitions of: clinical evaluation, importer, life-cycle, medical device, post-market surveillance. • In the CFR are definitions of: control number, establish, finished device.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.5 Quality system	4 Quality management system 4.1 General requirements 4.1.1	The Regulation and the Standard specify that manufacturers or organizations have flexibility in structuring their Quality System according to their device type, organization size and structure, needs, and situation that meets the requirements of the standard or the Quality System regs. Both require maintenance of the effectiveness of the Quality System. The regulation terminology is Quality System, the standard terminology is Quality Management System. The standard requires that the organization documents the role(s) undertaken by the organization under the applicable regulatory requirements.
N/A	4.1 General requirements 4.1.2	The Standard requires the organization to determine the processes needed for the QMS and the application of those processes throughout the organization based on the role undertaken by the organization. A risk-based approach must be applied to control the appropriate processes needed for the QMS and documentation of the sequence and interactions of the QMS processes is required.
N/A	4.1 General requirements 4.1.3	The Standard requires that for each QMS process, the organization must: • Determine criteria and methods required to make sure that the operation and control of the processes are effective • Ensure that there are adequate resources and information necessary to support operation and monitoring of the processes • Implement actions required to achieved planned results and maintain the effectiveness of the processes • Monitor, measure, as appropriate, and analyze the processes • Establish and maintain records that demonstrate conformance to the Standard and compliance with applicable regulatory requirements.
N/A	4.1 General requirements 4.1.4	The Standard requires that the organization manages the QMS processes according to the Standard and applicable regulatory requirements. Changes made to the processes must be controlled as required by the Standard and applicable regulatory requirements and evaluated for: • Impact on QMS • Impacted on the medical devices produced under the QMS

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N/A	4.1 General requirements 4.1.5	The Standard requires that when an organization outsources any process that affects product conformity to requirements, it must monitor and ensure control over that process. The organization retains responsibility for conformance of that outsourced process to the Standard, the customer, and applicable regulatory requirements. The controls are proportionate to the risk involved and the ability of the external party to meet the requirements (according to 7.4). Written quality agreements are required.
820.20 Management responsibility	5.1 Management commitment	The Regulation states that management with executive responsibility is responsible for: • Quality policy • Appointment and documentation of management representative • Management review of the Quality System The Standard states that top management is responsible for: • Communication of the importance of meeting customer and regulatory requirements • Quality policy • Ensuring quality objectives are established • Management reviews • Availability of resources Specifics on each topic are further discussed in the individual clauses of both the Regulation and the Standard.
N/A	5.2 Customer focus	The Standard requires that top management ensure that customer requirements and applicable regulatory requirements are determined and met.
820.20(a) Quality policy	5.3 Quality policy	The Regulation and the Standard require a quality policy that is communicated and understood by the organization. The Standard specifies criteria of a quality policy, including review for continued suitability.
820.20(b) Organization	5.5.1 Responsibility and authority	The Regulation specifies the establishment of an organizational structure. The Standard requires that top management documents the interrelation of all personnel who perform work that could impact quality and ensure independence and authority necessary to perform that work.
820.20(b)(1) Responsibility and authority	5.5.1 Responsibility and authority	The requirements of the Regulation and the Standard are similar. No significant differences.
820.20(b)(2) Resources	5.1 Management commitment 6.1 Provision of resources	The requirements of the Regulation and Standard are similar.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.20(b)(3) Management representative	5.5.2 Management representative	The requirements for appointment of, documentation of, and responsibilities of a management representative are similar. The Regulation requires the management representative to report on the "performance" of the Quality System. The Standard requires the management representative to report on the effectiveness of the QMS and any need for improvement. The Standard also has an additional requirement for promotion of awareness of regulatory and QMS requirements throughout the organization.
820.20(c) Management review	5.1 Management commitment 5.6 Management review 5.6.1 General 5.6.2 Review input 5.6.3 Review output	Requirements to conduct periodic management reviews are similar. The Regulation specifies conducting management reviews with sufficient frequency and specifies the documentation of the date of the review and the results. Compliance to the standard requires that specific topics are covered during management reviews including monitoring and measurement of processes in addition to products, CAPA, assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. The Standard requires specific review output documentation related to improvements required to maintain all aspects of the QMS and its processes, improvement to product related to customer requirements, and changes due to changes in regulatory requirements and resource needs.
820.20(d) Quality planning	5.4.2 Quality management system planning	Requirements of the Regulation and Standard for quality planning are similar. The Regulation has specific requirements on how to define the quality plan and requirements to establish how the requirement for quality will be met. The Standard requires that quality objectives, including those required to meet regulatory and product requirements, are established within relevant functions and levels of the organization. The quality objectives must be measureable and link to quality policy. Top management is responsible for making sure that quality planning is performed to meet the quality objectives and the general aspects of the QMS and to make sure that changes to the system are planned, and implemented without negative impact.
N/A	5.5.3 Internal communication	The Standard requires that top management ensures appropriate communication processes are established for communication of the effectiveness of the QMS. This is not specifically stated within the Regulation.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.20(e) Quality system procedures	4.2 Documentation requirements 4.2.1 General 4.2.2 Quality manual	The Regulation requires establishment of procedures and instructions and an outline of the structure of the documentation used in the Quality System, but does not require a quality manual. The Standard requires QMS documentation including quality policy and objectives, a quality manual, documented procedures and records that the standard requires, documents and records required by the organization to effectively plan, operate and control processes, and other documents required by regulatory requirements. The Standard also requires that the quality manual includes the scope of the QMS as well as details and justifications of exclusions or non-application; documented or referenced procedures the QMS; a description of how the QMS processes interact , and an outline of the structure of the quality manual system documents.
820.22 Quality audit	8.2.4 Internal audit	Requirements of the Regulation and the Standard for quality audits are similar. The Regulation includes specific requirements for management having responsibility for the area audited to review the audit reports and specific requirements to document the dates of the quality audit. The Standard specifically requires a planned audit program that considers status and importance of the processes and areas under audit, as well as results of previous audits. The Standard also requires that the audit criteria, scope, interval and methods are defined and documented. The Standard includes specifics related to the audit report to include identification of the processes and areas audited and the conclusions. The Standard includes specific requirements that management responsible for the audited area ensure corrections and corrective actions be taken without undue delay and any follow-up activities include verification of the actions taken and reporting verification results.
820.25 Personnel (a) General	6.2 Human resources, general	Requirements of the Regulation and the Standard for personnel are similar. The Standard references establishing competence, providing needed training, and ensuring awareness of personnel.

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820.25(b) Training	6.2. Human resources, general	Requirements of the Regulation and Standard are similar. The Regulation has additional requirements to make personnel aware of the device defects that could result from improper job performance, and to make personnel who perform verification and validation activities aware of defects and errors they may encounter in performing their jobs. The Regulation specifies requirement of procedures for identifying training needs. The Standard specifies requirements for documenting the process to establish competency, provide training and ensure personnel awareness. The Standard requires a documented risk-based evaluation of the effectiveness of the training actions taken. The Standard expands the training needs to include employee awareness of how their activities contribute to the achievement of quality objectives.
N/A	7.2 Customer-related processes 7.2.1 Determination of requirements related to product	The Standard requires that 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.
N/A	7.2 Customer-related processes 7.2.2 Review of requirements related to product	The Standard requires that the organization reviews the requirements related to product 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 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, and; 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.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
N/A	7.2 Customer-related processes 7.2.3 Communication	The Standard requires that the organization plans and documents arrangements for communicating with customers related to: product information; inquiries, contracts or order handling; customer feedback and complaints; and, advisory notices. The Standard requires that the organization communicates with regulatory authorities in accordance with applicable regulatory requirements.
820.30 Design controls (a) General	7.3 Design and development 7.3.1 General	The Regulation requires design and development procedures for design of Class III, Class II, and certain Class I devices in order to ensure that specified design requirements are met. The Standard requires that the organization shall document procedures for design and development of product. The definition of product in 3.15 is "result of a process." Note 1 to this definition lists 4 generic product categories: services, software, hardware, processed materials. Refer to previous information on exclusion of design and development requirements (820.1 and Clauses 1 & 2).
820.30(b) Design and development planning	7.3.2 Design and development planning Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor**	The requirements for design and development planning are similar between the Regulation and the Standard. The Regulation requires interfaces between groups or activities that provide or result in input to the design and development process be identified in the plan. The Standard requires that the documented design and development plans include: 7.3.2 a) The design and development stages; 7.3.2 b) the review(s) needed at each design and development stage; 7.3.2 c) the verification, validation and design transfer activities that are appropriate at each design and development stage; 7.3.2 d) the responsibilities and authorities for design and development; 7.3.2 e) the methods to ensure traceability of design and development outputs to design and development inputs; 7.3.2 f) the resources needed, including necessary competence of personnel. Comments: Design and development planning procedures should be reviewed to ensure adequate compliance with 7.3.2(c), 7.3.2(e), and 7.3.2(f), which are not explicitly required in the Regulation.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.30(c) Design input	7.3.3 Design and development inputs Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	The requirements for design inputs are similar. The Regulation includes explicit requirement that the design input address the intended use of the device and the needs of the user and patient and that design input requirements are approved with a dated approval, this requirement is in the Standard in the general area of 4.2.4 Control of documents. The Regulation also requires that the *procedure* includes a *mechanism* for addressing incomplete, ambiguous or conflicting requirements, not required in the Standard. The Standard requires that design and development inputs include: 7.3.3 a) functional, performance, usability and safety requirements, according to intended use; 7.3.3 b) applicable regulatory requirements and standards; 7.3.3 c) applicable output(s) of risk management; 7.3.3 d) as appropriate, information derived from previous similar designs; 7.3.3 e) other requirements essential for design and development of the product and processes. The Standard requires that product requirements are able to be verified or validated. The Standard also refers the users to IEC 62366-1, *Medical devices—Part 1: Application of usability engineering to medical devices*. Comments: Design and development inputs procedures should be reviewed to ensure adequate compliance with 7.3.3(a), 7.3.3(b), and 7.3.3(c), 7.3.3(d), and 7.3.3(e), which are not explicitly required in the Regulation.
820.30(d) Design output	7.3.4 Design and development outputs Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor**	Requirements for design output are similar. The Regulation requires that design outputs are documented, reviewed and approved prior to release with a dated signature. The Standard requires that design outputs shall: 7.3.4 a) meet the input requirements for design and development; 7.3.4 b) provide appropriate information for purchasing, production and service provision; 7.3.4 c) contain or reference product acceptance criteria; 7.3.4 d) specify the characteristics of the product that are essential for its safe and proper use. The Standard also requires the outputs of design and development are in a form suitable for verification against the design and development inputs and are approved before release.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
		The requirement identification of essential design outputs is slightly different between the Regulation and the Standard. The Regulation requires that outputs essential to the proper functioning of the device are identified. The Standard requires that the design and development outputs specify the characteristics of the product that are essential for its safe and proper use. Comments: Design and development outputs procedures should be reviewed to ensure adequate compliance with 7.3.4(b), which is not explicitly required in the Regulation.
820.30(e) Design review	7.3.5 Design and development review Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor**	Requirements for design review are similar. The Regulation requires the use of an independent reviewer, and also that 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). The Standard requires that design and development reviews: 7.3.5 a) evaluate the ability of the results of design and development to meet requirements; 7.3.5 b) identify and propose necessary actions. Comments: Design and development review procedures should be reviewed to ensure adequate compliance with 7.3.5(b), which is not explicitly required in the Regulation.
820.30(f) Design verification	7.3.6 Design and development verification Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	Requirements for design verification are similar. The Regulation includes specific documentation requirements, specifically that 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 design history file (DHF). The Standard requires planned and documented arrangements for design verification. The plans must include methods, acceptance criteria, and, as appropriate, statistical techniques. The Standard also requires that when the intended use of a medical device requires that it is connected to, or is interfaced with, other medical device(s), the verification includes confirmation that the design outputs meet design inputs in that configuration. Comments: Design and development verification procedures should be reviewed to ensure adequate compliance with 7.3.6.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.30(g) Design validation	7.3.7 Design and development validation Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Moderate**	Requirements for design validation are similar. Both require that the design validation is conducted on representative product. Representative product includes initial production units, batches or their equivalent. The Standard goes further to require that the rationale for the choice of product for design validation be documented. The Regulation has additional requirements for risk analysis and software validation and includes specific documentation requirements, specifically that 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 design history file (DHF). The Standard requires that design and development validation is planned and has documented arrangements to ensure that the product can meet the requirements of the application or intended use. The validation plans must also include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. The Standard requires that as part of design validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. Similar to design and development verification the Standard requires that 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. The Standard requires that validation is completed prior to release for use of the product to the customer. Because of this, and the requirement for Clinical or performance evaluations be part of design and development validation, the standard states that a medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. Records of the results and conclusions of the validation and necessary actions shall be maintained (see 4.2.4 and 4.2.5). The requirement for Clinical Evaluation/Performance Evaluation is very different from the Regulation, but not different from what is done for FDA submissions.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.30(h) Design transfer	7.3.8 Design and development transfer Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	Requirements for design transfer are similar for transition of design outputs to production specifications. The Standard also requires that the procedures for design transfer 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. Recorded results and conclusions of the transfer is also a requirement of the Standard. Comments: Design and development transfer procedures should be reviewed to ensure adequate compliance with 7.3.8, and specifically with "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," which are not explicitly required in the Regulation.
820.30(i) Design changes	7.3.9 Control of design and development changes Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	Requirements for design changes are similar. The Standard requires that the organization determines the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. The Standard also requires that review of design and development changes includes 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.
820.30(j) Design history file	7.3.10 Design and development files Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	The Standard has a general requirement for maintaining design and development files as follows: 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 Regulation explicitly identifies the Design History File (DHF) as the compilation of records which describes the design history of a finished device. There may be country specific requirements the design records. For example, the EU Medical Device Directive requires a Technical File or Design Dossier.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.40 Document controls	4.2 Documentation requirements 4.2.1 General 4.2.4 Control of documents Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	Requirements are similar for documents and control of changes, including having procedure(s). The Regulation requires specific document change records, which include a description of the change to the document, identification of the affected documents and the signature of the approving individual, the date of approval and the date the change becomes effective. The Regulation also requires that approved changes are communicated to the appropriate personnel in a timely manner. The Standard has additional requirements for control of documents of "external origin," and for the protection of confidential health information. The Standard includes requirements for prevention of loss or deterioration and legibility and identifiability of documents. The Standard also requires that a defined period of retention for at least one copy of obsolete documents are retained is documented. This period for retention of the 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, or as specified by regulatory requirements.
820.50 Purchasing controls (a) Evaluation of suppliers, contractors and consultants	7.4.1 Purchasing process Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	Requirements for evaluation of suppliers are similar. The Regulation has an explicit requirement to evaluate, select, and control contractors and consultants. The level of control is based on the evaluation performed and documented. The Standard requires that supplier evaluation and selection criteria is based on; the suppliers ability to provide product that meets the organizations requirements; performance of the supplier; effect of the purchased product on the quality of the medical device; and be proportionate to the risk associated with the medical device. The Standard also requires that the suppliers are monitored and re-evaluated, including monitoring the performance of the suppliers in meeting requirements for purchased product. This monitoring output is to be used as input into the supplier re-evaluation process.

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820.50(b) Purchasing data	7.4.2 Purchasing information Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor**	Requirements for purchasing data in the Regulation and purchasing information in the Standard are similar. The Regulation and the Standard require that manufacturers pursue an agreement with suppliers to provide notification of any changes to the product or service. The Standard requires that the documented purchasing information includes requirements for product acceptance, procedures, processes and equipment, requirements for qualification of supplier personnel and QMS requirements. The Standard also requires that the organization must ensure the adequacy of the specified purchasing requirements prior to communicating to the supplier. The Standard also requires that if traceability is required, based on 7.5.9, then the traceability follows through to relevant purchasing documentation.
820.60 Identification	7.5.8 Identification	Requirements for identification are similar. The Standard explicitly addresses identification of returned devices. The Standard also requires that if required by regulatory requirements, that the organization documents a system to assign **U**nique **D**evice **I**dentification to the medical device.
820.65 Traceability	7.4.2 Purchasing information 7.5.9.1 Traceability, general 7.5.9.2 Particular requirements for implantable medical devices	The Regulation has traceability requirements for life supporting, life sustaining, and implantable devices through distribution to the initial consignee (820.160). It achieves general traceability of devices through Device History Records. The Standard explicitly requires traceability records for components, materials, and conditions for the work environment used, if they could cause the medical device to not satisfy its specified safety and performance requirements. The Standard has additional traceability requirements for implantable medical devices for traceability beyond distributors or distribution services. This traceability includes maintaining the name and address of the shipping package consignee. The Standard requires that if traceability is required, based on 7.5.9, then the traceability follows through to relevant purchasing documentation (7.4.2).
N/A	7.5.10 Customer property	The Standard requires that the organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product while it is under the organizations control or being used by the organization. If customers product is lost, damaged, or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records. The Regulation has no corresponding requirement related to customer property.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.70 Production and process controls (a) General (b) Production and process changes	7.1 Planning of product realization 7.5.1 Control of production and service provision 4.2.4 Control of documents Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	Requirements for developing, controlling and monitoring production processes are similar. The Regulation explicitly requires verification or validation of changes to specifications, methods, processes and procedures. The Regulation also requires compliance with specified reference standards or codes and the approval of processes and process equipment. The Standard requires that the organization establishes one or more processes for risk management in product realization and that records arising from risk management shall be maintained (see 4.2.5). The Standard references ISO 14971 for further information. The Standard covers change control of documented production and process procedures in 4.2.4 Control of Documents. Comments: Standard requires qualification of "infrastructure."
820.70(c) Environmental control	6.4.1 Work environment	Requirements for documenting environmental requirements for the work environment are similar between the Regulation and the Standard. The Regulation requires periodical inspections of the environmental system. The Standard requires procedures for monitoring and controlling the work environment and refers to ISO 14644, *Cleanrooms and associated controlled environments*, and ISO 14698, *Cleanrooms and associated controlled environments—Bio contamination control*.
820.70(d) Personnel	6.4.1 (a) and (b)	The requirements in the Regulation and Standard are similar.
820.70(e) Contamination control	6.4.2 Contamination control	The Regulation requires procedures to prevent contamination of equipment of product by substances that could reasonably be expected to have an adverse effect on product quality. The Standard requires that the organization has planned and documented arrangements for contaminated or potentially contaminated product to prevent contamination of the work environment, personnel or product. The Standard requires that the organization documents requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging process for sterile medical devices.
820.70(f) Buildings	6.3 Infrastructure 7.5.1 Control of production and service provision Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Moderate**	The Regulation requirements for buildings and the Standard requirements for infrastructure, which includes buildings, are similar. The Standard requires qualification of infrastructure. The Standard specifies that infrastructure requirements shall also include requirements to prevent product mix-up and ensure orderly product handling.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.70(g) Equipment	6.3 Infrastructure 7.5.1 Control of production and service provision Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	The Regulation requirements for equipment and The Standard requirements for infrastructure, which includes equipment are similar. The Regulation has additional requirements for adherence to maintenance schedules, periodic inspections to ensure that maintenance is being performed as scheduled, and making equipment adjustment limitations readily available to personnel making adjustments. The Standard has an additional requirement pertaining to supporting services such as transport, communication, or information systems.
820.70(h) Manufacturing material	7.5.2 Cleanliness of product Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2 016 Standard: **Minor**	The Regulation requirements for manufacturing materials and The Standard requirements for cleanliness of product are similar. The Standard includes a provision for documented requirements for product which cannot be cleaned prior to sterilization or use, but its cleanliness is of significance in use and when product is supplied to be used non-sterile and its cleanliness is of significance in use. The Standard also list two situations where product is cleaned prior to sterilization where the requirements for documented work environment in 6.4.1 are not required, prior to the cleaning.
820.70(i) Automated processes	7.5.6 Validation of processes for production and service provision 4 Quality management system 4.1.6	Requirements are similar between the Regulation and the Standard. The Regulation includes specific documentation requirements. The Regulation includes production software and Quality System software. The Standard covers this requirement in 4.1.6. The Standard states that the level of software validation is "proportionate" to the risk associated with the software including the effect on the ability of the product to conform to specifications. In 4.1.6 the Standard requires that a procedure is documented for the validation of the application of computer software used in the Quality Management System. Such software is validated prior to initial use and, as appropriate, after changes to the software or its application. The specific approach and activities associates with the original validation and revalidation is proportionate to the risk associated with the use of the software.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.72 Inspection, measuring and test equipment	7.6 Control of monitoring and measuring devices	The Regulation requirements for inspection, measuring and test equipment, including the use of standards for calibration or documented methods when no standards exist, of monitoring and measuring devices are similar to the Standard requirements. The Standard requires that the measuring equipment be safeguarded from adjustments that would invalidate measurement results. The Standard has more detailed requirements for assessing the impact of out-of-calibration equipment on product, and addresses software validation requirements when used in monitoring and measurement applications, proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. The Standard also refers to ISO 10012, *Measurement management systems—Requirements for measurement processes and measuring equipment*. The Regulation requires specific requirements for calibration records, and that the records be displayed on or near each piece of equipment or be readily available to personnel using the equipment.
820.75 Process validation	7.5.6 Validation of processes for production and service provision Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Moderate**	Requirements for process validation are similar. The Regulation has additional explicit requirements for monitoring, controlling, and documenting validated processes during routine production and having qualified operators perform validated processes. The Regulation requires procedures for monitoring and controlling validated processes to ensure that specified requirements continue to be met. The Standard lists specific items that shall be contained within validation procedures 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.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
N/A	7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems	The Standard requires documented procedures for the validation of processes for sterilization and sterile barrier systems, that they are validated prior to use and following product or process changes, as appropriate. The Standard also requires records of the results and conclusions of validation and any necessary actons. The Standard refers to ISO 11607-1, P*ackaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems*, and ISO 11607-2, *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes*.
820.80 Receiving, in-process, and finished device acceptance (a) General (b) Receiving acceptance activities (c) In-process acceptance activities (d) Final acceptance activities	7.1 (c) Planning of product realization 7.4.3 Verification of purchased product 7.5.10 Customer property 8.2.6 Monitoring and measurement of product Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	**General:** The Regulation requires a procedure be established and maintained for acceptance activities including inspections, tests or other verification activities. Both the Regulation and the Standard require, as applicable, identification of of equipment used for acceptance (measurement) activities **Receiving activities:** The Regulation requires procedures for acceptance of incoming product. This includes inspection testing, or otherwise some verification that the incoming product is conforming to specified requirements. Acceptance or rejection must be documented. The Standard requires that this incoming product verification is based on the supplier evaluation results and proportionate to the risks associated with the purchased product. The Standard requires that when the organization becomes aware of any changes to purchased product, the organization shall determine whether these changes affect the product realization process or the medical device **In process acceptance activities:** The Regulation requires devices to be controlled until the required inspections, tests or other verification activities are complete, or necessary approvals are received and documented. The Standard requires that the organization monitors and measures the characteristics of the product to verify that product requirements are met at applicable stages or product realization in accordance with planned and documented arrangements and procedures. **Final acceptance activities:** The Regulation has requirements that procedures for finished device acceptance to ensure that each production run, lot or batch of finished devices meets acceptance criteria. The Regulation also requires that finished devices be held in quarantine or otherwise adequacy controlled until released. In addition to several other requirements, the Regulation requires dated authorization of release by designated individual(s). The Standard explicitly requires satisfactory completion of all planned and documented arrangements before product release and service delivery. **Customer property:** The Standard also specifically addresses the care and control of customer property; the Regulation has no corresponding requirement.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.80(e) Acceptance records	7.1 (d) Planning of product realization 8.2.6 Monitoring and measurement of product Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor to Moderate**	Requirements are similar. The Regulation has specific requirements for completion and documentation, review, and approval of acceptance activities within the DHR prior to release of a finished device. Both require the documentation of the individual responsible for release of the product.
820.86 Acceptance status	7.5.8 Identification	Requirements for identifying product acceptance status (Regulation) throughout the manufacturing, packaging, labeling, installation and servicing, of the product and product status identification throughout product realization (Standard) are similar. The Standard has reference to UDI requirements (see 820.60 Identification).
820.90 Nonconforming product (a) Control of nonconforming product (b) Nonconformity review and disposition	8.3 Control of nonconforming product 8.3.1 General 8.3.2 Actions in response to nonconforming product detected before delivery 8.3.3 Actions in response to nonconforming product detected after delivery Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor**	**General:** The Regulation and the Standard requirements for control of nonconforming product are similar. Both require that product that does not conform to specified requirements are identified and controlled. Both require document procedure(s) to define the controls, identification, segregation, evaluation and disposition of the nonconforming product. The Regulation requires notification of the person or organization responsible for the nonconformance. The Standard requires notification of any external party responsible for the nonconformity. The Standard specifically requires that the procedure includes related responsibilities and authorities for the activities. The Regulation requires that the procedures define the responsibility for the review and authority for the disposition of the product. Both require records of the activities and outcomes of investigations and rationale for decisions. **Nonconformity identified before delivery:** The Standard describes how an organization can deal with nonconforming product detected before delivery in 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 Standard requires that concession can only occur if justification is provided, approval is obtained and applicable regulatory requirements are met. Both the Standard and the Regulation require record of use of nonconforming product, including justification and the signature of the person authorizing its use.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
		Nonconformity identified after delivery: The Standard requires that when the organization becomes aware of nonconforming product identified after delivery or use has started that they take action appropriate to the effects or potential effects of the nonconformity. The Standard also requires that procedures be established for issuing advisory notices in accordance with applicable regulatory requirements. Records for all activities are required to be maintained.
820.90 Nonconforming product (2) rework	8.3.4 Rework	The Regulation and the Standard are similar in the requirements for performance and documentation of rework of product, including evaluation of any adverse effect of the rework on the product. The Standard requires that procedures for rework undergo the same review and approval as the original procedure.
820.100 Corrective and preventive action (a) procedures (1) data analysis (2) investigation (3) identification of actions (4) verification or validation of CAPA actions (5) implement changes (6) communicate (7) management review (b) records	8.4 Analysis of data 8.5 Improvement 8.5.2 Corrective action 8.5.3 Preventive action Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Moderate**	**General:** The Standard requires that the organization identifies and implements changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the QMS as well as medical device safety and performance through the use of the quality policy and objectives, audit results, analysis of data, corrective actions, preventive actions and management review. **Procedures and records:** The Regulation and the Standard are similar in procedural requirements and records. **Analysis of data:** The Standard focuses on all data available from, at a minimum, feedback, conformity to product requirements, characteristics and trends of processes and product, including opportunities for improvement, suppliers, audits, and service reports, as appropriate. If analysis of data shows that the QMS is not suitable, adequate or effective, the organization shall use this data as input for improvement (8.5). The Regulation requires analysis of similar areas for identification of existing or potential causes of nonconforming product or other quality products. Both the Regulation and the Standard require appropriate statistical techniques are included in the procedures and utilized.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.100 Corrective and preventive action *(continued from previous page)*		**Corrective and preventive action:** The Regulation and the Standard are similar in requirements for review, investigation of causes, determination of required actions to prevent recurrence or occurrence, implementing actions, verification or validation that the actions are effective and do not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device and reviewing the effectiveness of the corrective or preventive action taken The Regulation includes specific procedural requirements. The Standard requires that any corrective action be taken without undue delay and that corrective actions are proportionate to the effects of the nonconformities encountered. The Standard requires that preventive action taken is proportionate to the effects of potential problems. **Communication:** The Regulation requires dissemination of information related to quality problems to those directly responsible for assuring the quality of the product or the prevention of such problems. The Regulation also requires relevant information of identified quality problems, as well as CAPA actions be submitted for management review.
820.120 Device labeling	7.5 Production and service provision 7.5.1 (e) Control of production and service provision Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor**	Both the Regulation and the Standard have similar requirements for production controls of labeling operations. The Regulation has requirements for label integrity, inspection, storage, operations, and control numbers, which are more explicit and detailed than the Standard. The Regulation requires a specific, documented label release prior to use of the label.
820.130 Device packaging	7.5 Production and service provision 7.5.1 (e) Control of production and service provision 7.5.11 Preservation of product Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Moderate**	The Regulation requires that packaging and shipping containers be designed to protect devices during customary conditions of processing, storage, handling and distribution. The Standard requires implementation of defined operations for packaging (7.5.1). The Standard requires that the organization shall protect product from alteration, contamination or damage when exposed to expected conditions during processing, handling and distribution. The Standard also requires that suitable packaging and shipping containers are designed and constructed and requirements for special conditions be documented if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.140 Handling 820.150 Storage	4.2.3 Medical device file 7.1 Planning of product realization 7.5.11 Preservation of product	Requirements for handling and storage in the Regulation and preservation of product in the Standard are similar. The Standard requires that the medical device file includes specifications for storage and handling and that in the planning of product realization, plans for handling and storage are developed. The Regulation specifically addresses stock rotation for product that may deteriorate over time, as well as procedures that describe the methods of authorizing receipt from and dispatch to storage areas and stock rooms.
820.160 Distribution	4.2.3 Medical device file 7.1 Planning of product realization process 7.5.9.2 Particular requirements for implantable medical devices	The Standard requires that the medical device file includes specifications for distribution and that in the planning of product realization, plans for distribution are developed. The Regulation requires distribution procedures and records of distribution. The Procedures must cover: • Control and distribution of finished devices to ensure that only those devices approved for release are distributed • Review of purchase orders to ensure that ambiguities and errors are resolved before devices are released for distribution • Processes to ensure that when a products quality or fitness for use deteriorates over time, expired devices, or devices deteriorated beyond acceptable fitness for are not distributed The Standard specifically requires distribution records for implantable devices through to the name and address of shipping package consignee. Purchase orders and contracts are covered in the Standard under 7.2 Customer related processes. The Regulation requires distribution records which include or reference: the name and address of initial consignee; identification and quantity of devices shipped, date shipped, and any control numbers used.
820.170 Installation	4.2.3 Medical device file 7.5.3 Installation activities 7.5.8 Identification	In general, the Regulation and Standard are similar. The Regulation requires test procedures, where appropriate, for installation. The Standard requires that the Medical device file includes requirements or installation, as applicable. The Standard requires that if the agreed customer requirements allow installation of the medical device to be performed by an external party other than the manufacturers, or its supplier, then the organization shall provide documented requirements for the medical device installation and verification of installation. The addition of "agreed customer requirements" is different than the Regulation. The Standard requires that the product status is maintained through installation.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.180 Records, general requirements	4.2.5 Control of records	The regulation and standard have similar requirements for record legibility and storage. The Regulation specifically requires back up of records stored in data processing systems. The Regulation also requires manufacturers to make records available to company officials and FDA employees. The Standard has no corresponding requirement.
820.180(a) Confidentiality	4.2.5 Control of records	The Regulation has a provision for manufacturers to mark records during an inspection to identify those containing confidential information. The Standard requires that the organization define and implements methods for protecting confidential health information contained in records in accordance with applicable regulatory requirements.
820.180(b) Record retention period	4.2.5 Control of records	Requirements for retention of documents and records are similar.
820.180(c) Exceptions	N/A	The Regulation exempts reports of internal audits, supplier audits, and management reviews from review during FDA inspections. The Standard has no comparable exemptions.
820.181 Device master record	4.2.1 Documentation requirements, general 4.2.3 Medical device file Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Minor**	Requirements are similar for maintaining a record or file for each type or model of device which includes procedures and specifications for production processes, packaging, labeling and quality assurance. The Regulation assigns the name "Device Master Record" to these records/files. The standard assigns the name Medical device file. The Regulation and the Standard have slightly different requirements for the documents included or referenced to maintain the product throughout its lifecycle. The Device Master Record and Medical device file can be the same series of documents, once the requirements from both the regulation and the Standard are incorporated.
820.184 Device history record	7.5.1 Control of production and service provision	The Regulation and the Standard have similar requirements for maintaining records of production history for each medical device, batch of medical devices. The Regulation assigns the name "Device History Record" to these records. In addition, the Standard includes explicit requirements for documenting sterilization processes for each sterilization batch. The Regulation has no comparable explicit requirement; however, the expectation is that sterilization processes batches will be documented. The Regulation requires that the Device History Record includes the primary identification label and labeling used for each production unit, as well as the dates of manufacture, the quantity manufacture, the quantity released for distribution and the acceptance records.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
820.186 Quality system record		The Standard does not require a Quality System record (QSR) but does require the types of records and documents that could be kept in the QSR.
820.198 Complaint files	8.2.2 Complaint handling Effort required to update existing 21 CFR Part 820 Quality System procedures and resultant processes to meet the ISO 13485:2016 Standard: **Moderate**	The requirements for complaint handling activities are similar. In addition, the Regulation requires that certain complaints be investigated and that complaints reportable under 21 CFR Part 803 be identified. The Regulation's record-keeping requirements are more stringent. The Standard requires that the documented procedures include timely complaint handling in accordance with applicable regulatory requirements. It also requires that the procedure includes requirements and responsibilities for: • Determining the need to report complaint information to the appropriate regulatory authorities • Handling of complaint related product • Determining the need to initiate corrections or corrective actions The Standard also requires that if an investigation determine activities outside the organization contributed to the complaint, relevant information must be exchanged between the organization and the external party involved.
820.200 Servicing	7.5.4 Servicing activities 8.4 Analysis of data	Requirements are similar. Both require Service records to be analyzed to determine if they meet the definition of a compliant. In addition, the Regulation has more detailed requirements for information to be included in service records.
820.250 Statistical techniques	8.1 Measurement, analysis, and improvement, general	Requirements are similar. In addition, the Regulation requires establishing procedures for using statistical techniques and sampling methods, and for basing sampling plans on valid statistical rationale.
N/A	8.2 Monitoring and measurement 8.2.1 Feedback	The Standard requires that that as part of measuring the effectiveness of the QMS, the organization gathers and monitors information related to whether or not the organization has met the customer requirements. Method(s) used must be documented. There must be a procedure for the feedback process and it shall ensure that data from production as well as post-production activities are gathered as part of the feedback process. The information gathered from the feedback process must be considered as potential input for risk management, monitoring and maintaining product requirements as well as the product realization or improvement process. If there are regulatory requirements for gaining specific experience from post-production activities, this information must be part of the feedback process.

21 CFR Part 820 Quality System Regulation sections ("the Regulation")	ISO 13485:2016 clause(s) ("the Standard")	Similarities, significant differences, and key requirements
21 CFR Part 820 does not cover this topic; however, other areas of the CFR include requirements for these activities.	8.2 Monitoring and measurement 8.2.3 Reporting to regulatory authorities	The Standard requires that if applicable regulatory requirements require notification of complaints related to specific criteria, or the issuance of advisory notices, then the organization must have a documented procedure(s) for notification to the appropriate authorities, and maintain records of such reporting.
N/A	8.2 Monitoring and measurement 8.2.5 Monitoring and measurement of processes	The Standard requires that the organization applies suitable methods for monitoring and, as appropriate measuring the QMS processes. The methods chosen are required to demonstrate the ability of the processes to achieved planned results. When they are not achieved, correction and corrective action must be taken, as appropriate.

