PART II: EXPLORING THE RELATIONSHIP BETWEEN ISO 13485:2016 AND THE US FDA QUALITY SYSTEM REGULATION

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Author: **Robert Ruff**, Executive Director, NSF International
Researcher: **Samuel Brown**, Research Associate, NSF International

This tool clarifies the corresponding relationships between ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes clauses and the US FDA Quality System Regulation. Use this tool to ensure your quality management system meets applicable requirements of both ISO 13485:2016 and US FDA.

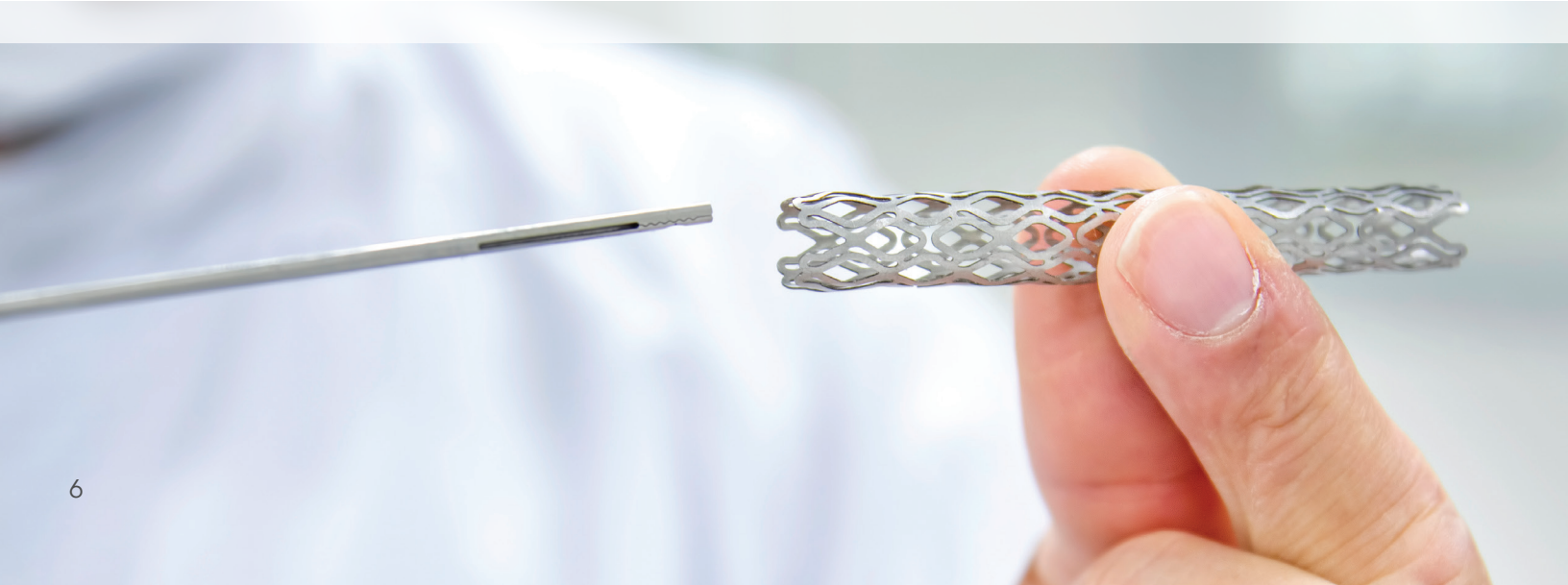
ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
1 Scope	**820.1 Scope**	
4.1.1 Quality management system, General requirements	**820.5 Quality system**	No significant difference in requirements.
4.1.2 Quality Management System	**820.5 Quality system**	Although 21 CFR § 820.5 is not explicit with respect to applying a risk based approach to the control of quality management system processes, the concept is explicit in the Preamble to the regulation (e.g. comment 4). 21 CFR § 820 provides the manufacturer the flexibility to determine necessary controls (throughout its quality management system) commensurate with risk.
4.1.3 Quality Management System	**820.20 Management Responsibility 820.70 Production and process controls** **820.100 Corrective and preventive action** **820.180 Records, General requirements** **820.181 Device master record** **820.184 Device history record** **820.186 Quality system record**	No significant difference in requirements.
4.1.4 Quality Management System	**820.40(b) Document controls, Document changes** **820.70(b) Production and process controls, Production and process changes**	No significant difference in requirements.

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
4.1.5 QMS General Requirements	**820.50 Purchasing controls**	ISO 13485:2016 specifies written quality agreements between the organization and suppliers. 21 CFR § 820 requires "...purchased or otherwise received product" to be included in the Purchasing Controls procedures. ISO 13485:2016 limits its requirement to purchased product.
4.1.6 QMS General Requirements	**820.70(i) Production and process controls, Automated processes**	No significant difference in requirements.
4.2 Documentation Requirements		
4.2.1 General	**820.20(a) Management responsibility, Quality policy** **820.20(e) Management responsibility, Quality system procedures**	21 CFR § 820 specifies an outline of the structure of the documentation used in the quality system, where appropriate. ISO 13485:2016 specifies a Quality Manual that includes an outline of the structure of the documentation used in the quality management system.
4.2.2 Quality Manual	**820.20(e) Management responsibility, Quality system procedures**	21 CFR § 820 does not specify a Quality Manual. 21 CFR § 820 specifies an outline of the structure of the documentation used in the quality system, where appropriate. ISO 13485:2016 specifies a Quality Manual that includes an outline of the structure of the documentation used in the quality management system.
4.2.3 Medical device file	**820.181 Device master record**	No significant difference in requirements.
4.2.4 Control of Documents	**820.40 Document controls** **820.180 Records, General requirements** **820.180(b) Records, General requirements, Record retention period**	21 CFR § 820 specifies the documentation of the date and signature of the individual(s) approving the document. 21 CFR § 820 specifies that approved changes be communicated to appropriate personnel in a timely manner. 21 CFR § 820 specifies, "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." ISO 13485:2016 specifies documented procedures to "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"

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
4.2.5 Control of records	**820.180 Records, General requirements** **820.180(a) Records, General requirements, Confidentiality** **820.180(b) Records, General requirements, Record retention period** **820.186, Quality system record**	21 CFR § 820 requires records to be readily available for review and copying by FDA employees designated to perform inspections. 21 CFR § 820 specifies records stored in automated data processing systems must be backed up. 21 CFR § 820 specifies the explicit requirements allowing the manufacturer to mark records as confidential to aid FDA in determining publicly releasable information under provisions of the Freedom of Information Act (FOIA). ISO 13485:2016 specifies that the organization shall document procedures to define the controls needed for (amongst other things) the security of records and the protection of confidential health information. While ISO 13485:2016 does not specify a requirement for a Quality System Record (QSR), there are requirements for the various documents and procedures that are included (or referred to the location of) within the QSR.
5 Management responsibility		
5.1 Management commitment	**820.20(a) Management responsibility, Quality policy** **820.20(b)(3) Management responsibility, Organization, Management representative** **820.20(c) Management responsibility, Management review**	ISO 13485:2016 explicitly requires top management to communicate to the organization the importance of meeting customer and applicable regulatory requirements.
5.2 Customer focus	**820.5 Quality system** **820.20(b)(3) Management responsibility, Organization, Management representative**	No significant difference in requirements.
5.3 Quality Policy	**820.20(a) Management responsibility, Quality policy**	ISO 13485:2016 specifies additional detail relative to the quality policy; for example: 5.3 b) and e).
5.4 Planning		
5.4.1 Quality Objectives	**820.20(a) Management responsibility, Quality policy**	ISO 13485:2016 specifically requires quality objectives to be measurable.
5.4.2 Quality Management System Planning	**820.20(d) Management responsibility, Quality planning**	ISO 13485:2016 specifies in 5.4.2 "Top management shall ensure that: …b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented."

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
5.5 Responsibility, authority and communication		
5.5.1 Responsibility and Authority	**820.20(b)(1) Management responsibility, Organization, Responsibility and authority**	No significant difference in requirements.
5.5.2 Management Representative	**820.20(b)(3) Management responsibility, Organization, Management representative**	ISO 13485:2016 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.
5.5.3 Internal communication	**820.20(b)(3) Management responsibility, Organization, Management representative**	Although 21 CFR § 820 is explicit in terms of reporting on the performance of the quality system to management with executive responsibility, it is less explicit relative to other appropriate internal communication processes specified in ISO 13485:2016.
5.6 Management Review		
5.6.1 General	**820.20(c) Management responsibility, Management review**	ISO 13485:2016 specifies: (1) assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and objectives; and (2) specific requirements for management review input and output.
5.6.2 Review Input	**820.20(c) Management responsibility, Management review**	21 CFR § 820 is not explicit in terms of management review input.
5.6.3 Review Output	**820.20(c) Management responsibility, Management review**	21 CFR § 820 is not explicit in terms of management review output.
6 Resource management		

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
6.1 Provision of Resources	**820.20(b)(2) Management responsibility, Organization, Resources**	No significant difference in requirements.
6.2 Human Resources	**820.25(a) Personnel, General** **820.25(b) Personnel, Training** **820.70(b)(1) Process validation**	ISO 13485:2016 specifies more detail than 21 CFR § 820 and addresses "competence" as opposed to training (e.g. competence via education, training, skills, experience). 21 CFR § 820 specifies requirements for personnel performing verification and validation activities. 21 CFR § 820 specifically states that personnel shall be made aware of device defects which may occur from improper performance of their jobs.
6.3 Infrastructure	**820.70(a) Production and process controls, General** **820.70(c) Production and process controls, Environmental control** **820.70(f) Production and process controls, Buildings** **820.70(g) Production and process controls, Equipment** **820.70(i) Production and process controls, Automated processes** **820.140 Handling** **820.150 Storage** **820.160(a) Distribution**	No significant difference in requirements.
6.4 Work environment and contamination control		

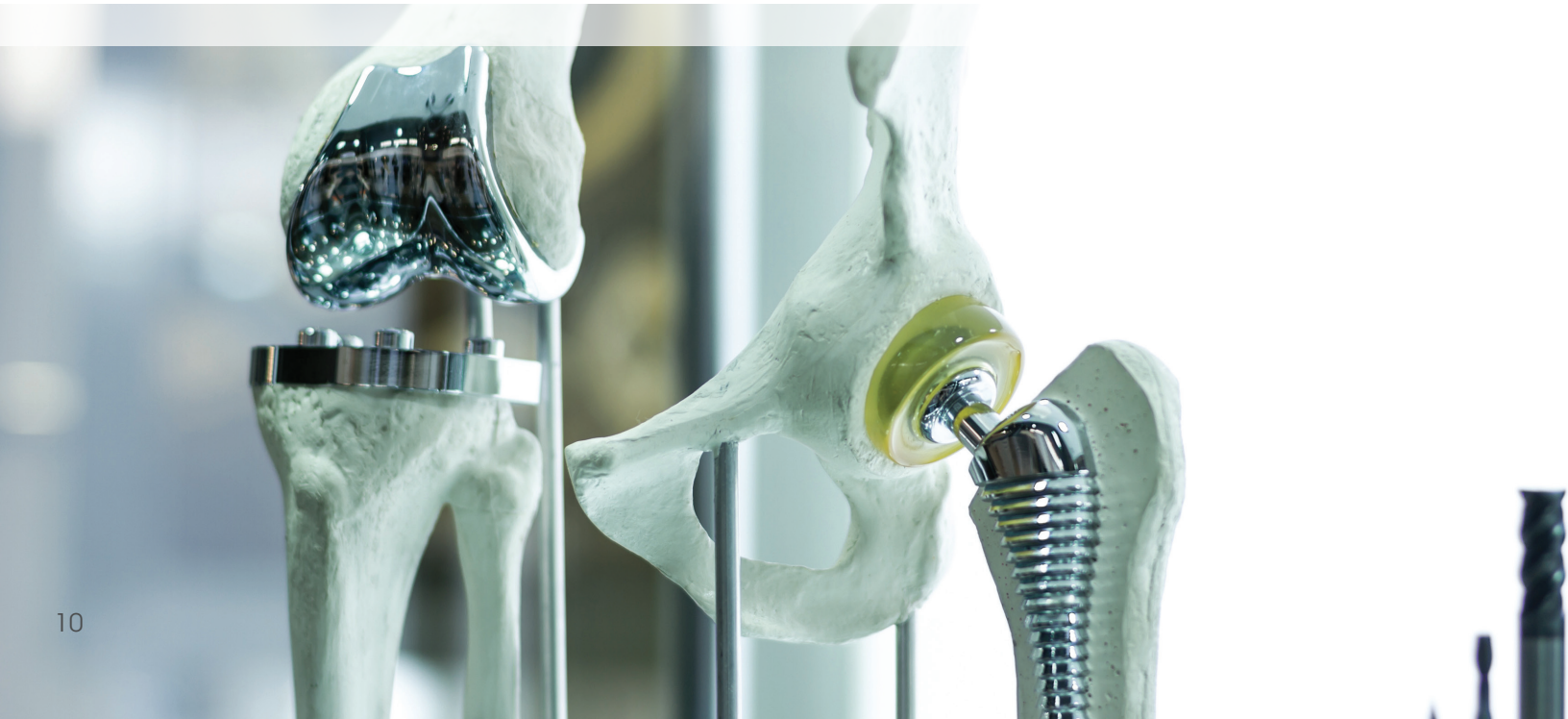


ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
6.4.1 Work environment	**6.4.1 Work environment** **820.70(c) Production and process controls, Environmental control** **820.70(d) Production and process controls, Personnel** **820.70(e) Production and process controls, Contamination control**	No significant difference in requirements.
6.4.2 Contamination control	**820.70(c) Production and process controls, Environmental control** **820.70(d) Production and process controls, Personnel** **820.70(e) Production and process controls, Contamination control**	ISO 13485:2016 clause 6.4.2 specifies requirements are "as appropriate" unless relative to sterile medical devices. However, as stated in ISO 13485:2016 clause 0.2 Clarification of concepts, when a requirement is qualified by the phrase "as appropriate", it is deemed to be appropriate unless the organization can justify otherwise. For sterile devices, ISO 13485:2016 specifies "...the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes." 21 CFR § 820 is not this specific.
7. Product Realization		
7.1 Planning of product realization	**820.20(d) Management responsibility, Quality planning** **820.30 Design controls** **820.50 Purchasing controls** **820.70 Production and process controls** **820.72 Inspection, measuring, and test equipment** **820.60 Identification** **820.65 Traceability** **820.75 Process validation** **820.170 Installation** **820.180 Records, General requirements** **820.200 Servicing**	With the exception of 820.30(g), 21 CFR § 820 is not explicit with respect to applying a risk based approach to the planning and control of quality management system processes. However, the concept is explicit in the Preamble to the regulation (e.g. comments 4, 13, 31, 81, 83, 115, 121, 159, 161). 21 CFR § 820 provides the manufacturer the flexibility to determine necessary controls (throughout its quality management system) commensurate with risk.
7.2 Customer-related processes		

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
7.2.1 Determination of requirements related to product	**820.30(c) Design controls, Design input** **820.160(a) Distribution**	ISO 13485:2016 is more explicit than 21 CFR § 820 relative to the determination of requirements related to product. However, appropriate compliance with 820.160(a) and where appropriate, 820.30(c) should address the specified requirements of ISO 13485:2016 clause 7.2.1.
7.2.2 Review of requirements related to product	**820.30(e) Design controls, Design review** **820.30(i) Design controls, Design changes** **820.40 Document controls** **820.160(a) Distribution**	ISO 13485:2016 is more explicit than 21 CFR § 820 relative to the review of requirements related to product. However, appropriate compliance with 820.40, 820.160(a) and where appropriate, 820.30(e) and 820.30(i), should address the specified requirements of ISO 13485:2016 clause 7.2.2.
7.2.3 Communication	**820.160 Distribution** **820.198 Complaint files**	ISO 13485:2016 is more explicit than 21 CFR § 820 relative to communicating with customers. However, appropriate compliance with 820.160 and 820.198 should address the specified requirements of ISO 13485:2016 clause 7.2.3.
7.3 Design and development		
7.3.1 General	**820.30(a) Design controls, General**	21 CFR § 820 specifies exclusions from design control requirements based on the risk of the device (i.e. class I devices other than those cited in 820.30(a)).
7.3.2 Design and development planning	**820.30(b) Design controls, Design and development planning**	21 CFR § 820 requires documented design plans. ISO 13485:2016 does not require a documented design and development plan, but does require the documentation of information specified in 7.3.2 a) through f) during design and development planning.
7.3.3 Design and development inputs	**820.30(c) Design controls, Design input**	21 CFR § 820 specifies the documentation of the date and signature of the individual(s) approving the design inputs. ISO 13485:2016 specifies specific inputs; including applicable output(s) of risk management.

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
7.3.4 Design and development outputs	**820.30(d) Design controls, Design output**	ISO 13485:2016 specifies "b) provide appropriate information for purchasing, production and service provision…" Comment 76 of the Preamble to 21 CFR § 820 states "The [design] output includes the device, its labeling and packaging, associated specifications and drawings, and production and quality assurance specifications and procedures."
7.3.5 Design and development review	**820.30(e) Design controls, Design review**	21 CFR § 820 specifies design reviews include "individual(s) who does not have direct responsibility for the design stage being reviewed…" ISO 13485:2016 specifies that reviews will "identify and propose necessary actions."
7.3.6 Design and development verification	**820.30(f) Design controls, Design verification**	ISO 13485:2016 specifies requirements for verification of connectivity or interfaces with other medical devices as applicable. 21 CFR § 820 specifies that the individual(s) performing the verification and the date of the activity be documented.
7.3.7 Design and development validation	**820.30(g) Design controls, Design validation**	ISO 13485:2016 specifies requirements for validation of the device while connected to or interfaced with other medical devices as applicable. ISO 13485:2016 specifies "the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements," which is not explicit in 21 CFR § 820, but is expected as discussed in Preamble comment 65. 21 CFR § 820 specifies additional documentation requirements such as the date and individual(s) performing the validation.
7.3.8 Design and development transfer	**820.30(h) Design controls, Design transfer**	ISO 13485:2016 specifies "that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements." While this is not explicitly stated in 21 CFR § 820, it is the expectation of design verification activities as well as design transfer activities. Preamble comment 86 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."
7.3.9 Control of design and development changes	**820.30(i) Design controls, Design changes**	ISO 13485:2016 specifies additional requirements. For example ISO 13485:2016 specifies (1) "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"; and, (2) "The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device."
7.3.10 Design and development files	**820.30(j) Design controls, Design history file**	No significant difference in requirements.
7.4 Purchasing		

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
7.4.1 Purchasing process	**820.50 Purchasing** **820.50 Purchasing, Evaluation of suppliers, contractors, and consultants**	ISO 13485:2016 clause 4.1.5 specifies written quality agreements between the organization and suppliers. 21 CFR § 820 requires "...purchased or otherwise received product" to be included in the Purchasing Controls procedures. ISO 13485:2016 limits its requirement to purchased product. ISO 13485:2016 specifies purchasing criteria to be "…d) proportionate to the risk associated with the medical device." Although not explicitly stated in 21 CFR § 820, comment 115 of the Preamble to 21 CFR § 820 discusses this requirement. ISO 13485:2016 specifies requirements relative to the re-evaluation of suppliers. Although not explicitly stated in 21 CFR § 820, comment 105 of the Preamble discusses this requirement.
7.4.2 Purchasing information	**820.50(b) Purchasing, Purchasing data**	ISO 13485:2016 specifies, "The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier." ISO 13485:2016 specifies, "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)."
7.4.3 Verification of purchased product	**820.80(a) Receiving, in-process, and finished device acceptance, General** **820.80(b) Receiving, in-process, and finished device acceptance, Receiving acceptance activities**	No significant difference in requirements.
7.5 Production and service provision		



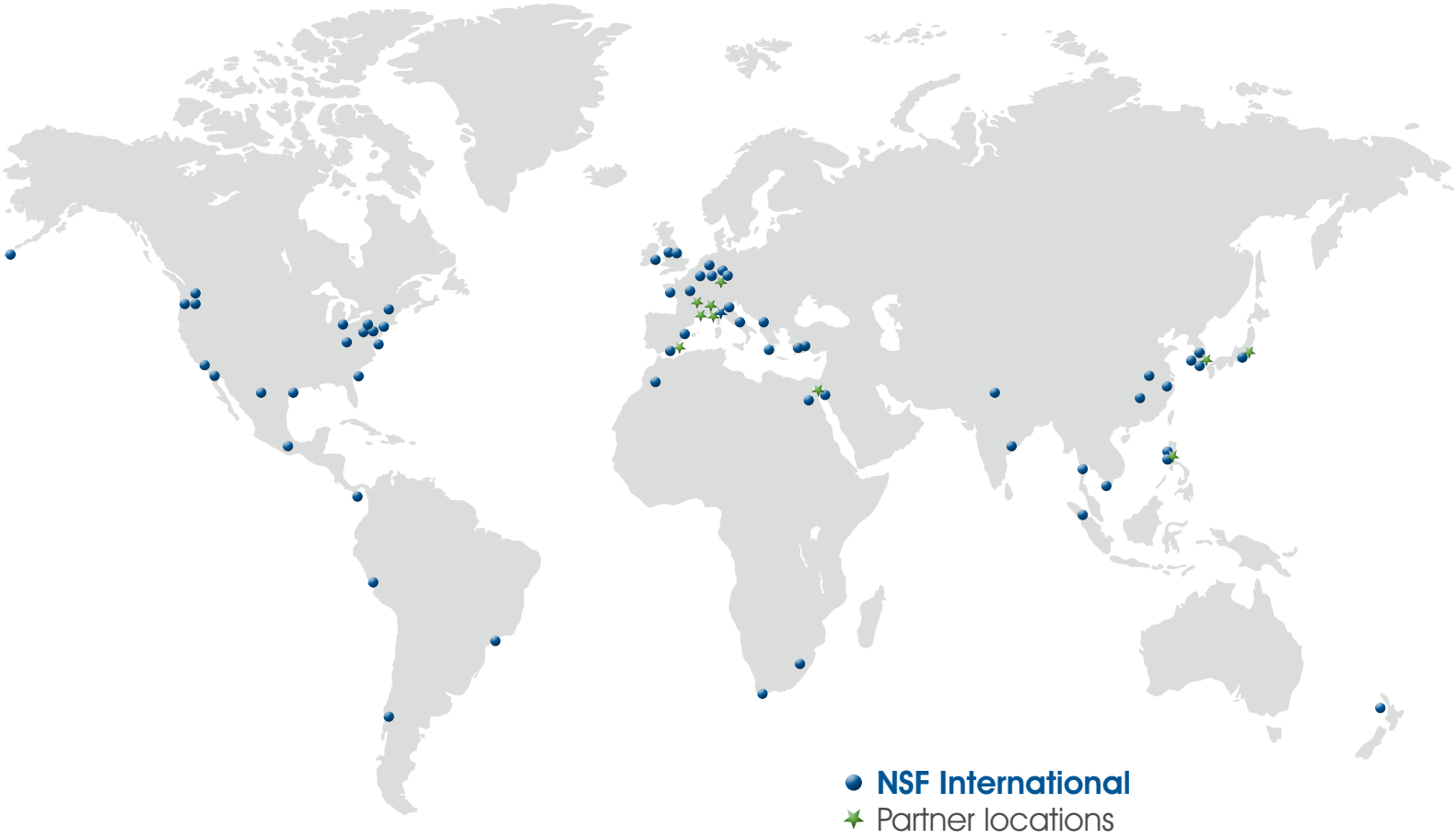
ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
7.5.1 Control of Production and Service Provision	**820.30 Design controls** **820.70(a) Production and process controls, General** **820.70(f) Production and process controls, Buildings** **820.72 Inspection, measuring, and test equipment** **820.75(b) Process validation** **820.80 Receiving, in-process, and finished device acceptance** **820.100(a) Corrective and preventive action** **820.120 (a)–(d) Device labeling** **820.130 Device packaging** **820.160 Distribution** **820.170 Installation** **820.184 Device history record** **820.200 Servicing**	21 CFR § 820.184 specifies additional Device History Record (DHR) content beyond that specified in ISO 13485:2016 clause 7.5.1: (a) The dates of manufacture; (d) The acceptance records which demonstrate the device is manufactured in accordance with the Device Master Record (DMR); (e) The primary identification label and labeling used for each production unit; and (f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.) ISO 13485:2016 does not prescribe specific requirements for labeling other than stating that production controls shall include "implementation of defined operations for labeling and packaging." 21 CFR § 820 provides specific detail relative to label integrity. However, ISO 13485:2016 requires preservation of product as well as design verification and design validation which would include confirming label integrity through the product's lifecycle, including production, packaging, distribution and storage channels, and environments. ISO 13485:2016 does not specifically address the inspection of labels. However, 8.2.6 Monitoring and measurement of product and 7.4.3 Verification of purchased product should account for the additional activities cited in 21 CFR § 820.120(b). ISO 13485:2016 does not prescribe specific requirements for labeling storage requirements cited in 21 CFR § 820. ISO 13485:2016 does not prescribe specific requirements for documenting labels and labeling used for each production unit, lot, or batch in a specific file/record.
7.5.2 Cleanliness of Product	**820.70(d) Production and process controls, Personnel** **820.70(e) Production and process controls, Contamination control** **820.70(h) Production and process controls, Manufacturing material**	ISO 13485:2016 specifies conditions that would require documentation of cleanliness requirements. ISO 13485:2016 clause 7.5.2 states "If product is cleaned in accordance with [7.5.2] a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process."
7.5.3 Installation activities	**820.170 Installation**	No significant difference in requirements
7.5.4 Servicing activities	**820.200 Servicing**	ISO 13485:2016 requires analysis to determine if service activities carried out by the organization or its supplier represent a complaint. 21 CFR § 820 provides a specific type of service event that must automatically be considered a complaint (i.e. service reports relative to a 21 CFR § 803 medical device reporting). ISO 13485:2016's requirement for use of appropriate statistical techniques relative to record analysis is found in clause 8.1. 21 CFR § 820 specifies specific content requirements relative to service reports.

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
7.5.5 Particular requirements for sterile medical devices	**820.75(b)(2) Process validation**	Reference to process validation relative to sterilization is not explicit in 21 CFR § 820. However, Preamble comment 143 specifically references sterilization as a process requiring validation. 21 CFR § 820.75(b)(2) requires the documentation of records associated with validated processes.
7.5.6 Validation of processes for production and service provision	**820.75(a) & (c) Process validation** **820.70(i) Production and process controls, Automated processes** **820.250(b) Statistical techniques**	21 CFR § 820 specifies the documentation of the date and signature of the individual(s) approving the validation. 21 CFR § 820 specifies specific detail with respect to sampling plans including establishing and maintaining procedures to ensure sampling methods are adequate for their intended use and to ensure when changes occur the sampling plans are reviewed.
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems	**820.75(a) Process validation**	Reference to process validation relative to sterilization and sterile barrier systems is not explicit in 21 CFR § 820. However, Preamble comment 143 specifically references sterilization as a process requiring validation. Sterile barrier systems must be validated during design validation (820.30) and sterile barrier packaging processes require process validation (820.75(a)) as results cannot be fully verified by subsequent inspection and test.
7.5.8 Identification	**820.60 Identification** **820.86 Acceptance status** **820.120(e) Device labeling, Control number**	ISO 13485:2016 specifies more detailed requirements including the documentation of procedures to ensure medical devices returned to the organization are identified and distinguished from conforming product. ISO 13485:2016 does not require control numbers, although it does specify requirements for unique device identification (UDI) when required and traceability for implantable medical devices.
7.5.9 Traceability		
7.5.9.1 General	**820.65 Traceability**	ISO 13485:2016 requires procedures for traceability based on regulatory requirements. 21 CFR § 820 specifies the types of devices that require traceability.

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
7.5.9.2 Particular requirements for implantable medical devices	**820.50 Purchasing controls** **820.160(b), 820.184**	ISO 13485:2016 specifies provisions for maintaining distribution records for implantable medical devices. 21 CFR § 820 specifies distribution records for all devices; and specifies specific additional information to be included (or referred to the location of) in the distribution records.
7.5.10 Customer property	**820.80(a)–(d) Receiving, in-process, and finished device acceptance**	21 CFR § 820 is not explicit with respect to "customer property". However, if the customer property is intended to be incorporated into the product, acceptance activities specified in 820.80 apply.
7.5.11 Preservation of product	**820.120(a) Device labeling, Label integrity** **820.130 Device packaging** **820.140 Handling** **820.150 Storage** **820.160 Distribution**	ISO 13485:2016 does not prescribe specific requirements for labeling other than stating that production controls shall include "implementation of defined operations for labeling and packaging." 21 CFR § 820 provides specific detail relative to label integrity. However, ISO 13485:2016 requires preservation of product as well as design verification and design validation which would include confirming label integrity through the product's lifecycle, including production, packaging, distribution and storage channels, and environments.. 820.150(a) specifies procedures must include provisions to assure "mix-ups" do not occur. ISO 13485:2016 does not specify a provision for stock rotation.
7.6 Control of monitoring and measuring equipment	**820.70(i) Production and process controls, Automated processes** **820.72 Inspection, measuring, and test equipment** **820.75(b) Process validation**	21 CFR § 820 specifies specific documentation requirements including: "The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date..."
8 Measurement, analysis and improvement		
8.1 General	**820.100 Corrective and preventive action** **820.250 Statistical techniques**	21 CFR § 820 specifies specific detail with respect to sampling plans including establishing and maintaining procedures to ensure sampling methods are adequate for their intended use and to ensure when changes occur the sampling plans are reviewed.
8.2 Monitoring and measurement		
8.2.1 Feedback	**820.80 Receiving, in-process, and finished device acceptance** **820.90 Nonconforming product** **820.100 Corrective and preventive action** **820.198 Complaint files**	ISO 13485:2016 explicitly specifies information gathered in the feedback process will serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
8.2.2 Complaint handling	**820.198 Complaint files**	No significant difference in requirements. However, the definition of "complaint" in 3.4 of ISO 13485:2016 includes the term "usability", which is not included in the definition of the term contained in 21 CFR § 820.3(c). The definition of "complaint" in 3.4 of ISO 13485:2016 also includes concerns "related to a service that affects the performance of such medical devices" as a potential source of complaints. ISO 13485:2016 defines the term "complaint" as "Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices." 21 CFR § 820 specifies that when no complaint investigation is made, the name of the individual responsible for the decision not to investigate must be documented and maintained. ISO 13485:2016 does not specify that an investigation is not necessary if such an investigation has already been performed for a similar complaint and another investigation is not necessary. Although ISO 13485:2016 requires complaint handling records to be maintained it does not provide the specific detail relative to records of complaint investigations that is specified in 21 CFR § 820.
8.2.3 Reporting to regulatory authorities	**820.198 Complaint files**	ISO 13485:2016 specifies regulatory reporting requirements must be met, but does not include the specific details of 21 CFR § 820 relative to the information to be documented and maintained; nor that complaints representing events that must be reported under 21 CFR § 803 be maintained in a separate portion of the complaint file.
8.2.4 Internal Audit	**820.22 Quality audit**	21 CFR § 820 specifies the date of the audit be documented and the audit reports must be reviewed by management having responsibility for the matters audited. ISO 13485:2016 explicitly specifies that an audit program be planned to take into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. ISO 13485:2016 specifies requirements for the management responsible for the area being audited to ensure that corrections and corrective actions are taken without undue delay; ISO 13485:2016 also specifies the verification of the actions taken and reports of the verification results.
8.2.5 Monitoring and measurement of processes	**820.70 Production and process controls** **820.75(b) Process validation**	Relative to validated processes, 21 CFR § 820 specifies that the monitoring and control methods and data, the date performed, and individual(s) performing the process or the major equipment be documented.
8.2.6 Monitoring and measurement of product	**820.80 Receiving, in-process, and finished device acceptance** **820.160 Distribution**	Although both require records, 21 CFR § 820 specifies specific record content requirements.

ISO 13485:2016	21 CFR § 820	SPECIFIC DIFFERENCES
8.3 Control of nonconforming product		
8.3.1 General	**820.90(a) Nonconforming product, Control of nonconforming product**	No significant difference in requirements.
8.3.2 Actions in response to nonconforming product detected before delivery	**820.90(b) Nonconforming product, Nonconformity review and disposition**	No significant difference in requirements.
8.3.3 Actions in response to nonconforming product detected after delivery	**820.90(b) Nonconforming product, Nonconformity review and disposition**	No significant difference in requirements.
8.3.4 Rework	**820.90(b)(2) Nonconforming product, Nonconformity review and disposition**	No significant difference in requirements.
8.4 Analysis of data	**820.100(a)(1) Corrective and preventive action**	No significant difference in requirements.
8.5 Improvement		
8.5.1 General	**20.30(i) Design controls, Design changes** **820.40(b) Document controls, Document changes** **820.70(b) Production and process controls, Production and process changes** **820.100(a) Corrective and preventive action**	No significant difference in requirements.
8.5.2 Corrective Action	**820.100 Corrective and preventive action**	ISO 13485:2016 contains specific clauses relative to "corrective action" (8.5.2) and "preventive action" (8.5.3). ISO 123485:2016 clause 8.5.2 requires corrective action to be taken "without undue delay". 21 CFR § 820 specifies "(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems;"
8.5.3 Preventive Action	**820.100 Corrective and preventive action**	ISO 13485:2016 contains specific clauses relative to "corrective action" (8.5.2) and "preventive action" (8.5.3).



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NSF INTERNATIONAL | MEDICAL DEVICES
2001 Pennsylvania Avenue NW, Suite 950 Washington, DC 20006 USA
T +1 202-822-1850 | **E** medicaldevices@nsf.org
www.nsf.org

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