# US FDA QUALITY SYSTEM REGULATION VERSUS ISO 13485:2016 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

# NSF INTERNATIONAL 21 CFR § 820 & ISO 13485:2016 ALIGNMENT CHART

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

| 21 CFR § 820 | US FDA QUALITY SYSTEM REGULATION | ISO 13485:2016 | SPECIFIC DIFFERENCES |
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| **820.1 Scope** | | **1 Scope** | |
| **820.5 Quality System** | Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part. | **4.1.1 Quality management system, General requirements** | No significant difference in requirements. |
| **820.20(a) Quality Policy** | Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization. | **5.3 Quality Policy**<br>**5.4.1 Quality Objectives** | ISO 13485:2016 specifies additional detail relative to quality policy. For example: 5.3 b), 5.3 e). ISO 13485:2016 specifically requires the quality objectives to be measurable. |
| **820.20(b) Organization** | Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part. | **5.5.1 Responsibility and Authority** | No significant difference in requirements. |
| **820.20(b)(1) Responsibility and Authority** | Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks. | **5.5.1 Responsibility and Authority** | No significant difference in requirements. |
| **820.20(b)(2) Resources** | Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part. | **6.1 Provision of Resources** | No significant difference in requirements. |
| **820.20(b)(3) Management Representative** | Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:<br>(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and<br>(ii) Reporting on the performance of the quality system to management with executive responsibility for review. | **5.5.2 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. |

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| **820.20(c) Management Review** | Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented. | **5.6 Management Review**<br>**5.6.1 General**<br>**5.6.2 Review Input**<br>**5.6.3 Review Output** | ISO 13485:2016 specifies: (1) assessing opportunities for improvement and the need for changes to the QMS; and (2) specific requirements for management review input and output. |
| **820.20(d) Quality Planning** | Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met. | **5.4.2 Quality Management System Planning** | ISO 13485:2016 specifies 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. |
| **820.20(e) Quality System Procedures** | Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate. | **4.2 Documentation Requirements**<br>**4.2.1 General**<br>**4.2.2 Quality Manual** | 21 CFR § 820 specifies an outline of the structure of the documentation used in the quality system; and ISO 13485:2016 specifies a Quality Manual. |
| **820.22 Quality Audit** | Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented. | **8.2.4 Internal 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.<br>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;<br>ISO 13485:2016 also specifies the verification of the actions taken and reports of the verification results. |
| **820.25(a) Personnel, General** | Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed | **6.1 Provision of Resources**<br>**6.2 Human Resources** | No significant difference in requirements. |
| **820.25(b) Personnel, Training** | Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.<br>(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.<br>(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions. | **6.2 Human Resources**<br>**6.4.1(b) Work Environment** | ISO 13485:2016 specifies more detail than 21 CFR § 820 and addresses "competence" as opposed to training (e.g. competence via education, skills, experience).<br>21 CFR § 820 specifies requirements for: (1) personnel performing verification and validation activities, and (2) 21 CFR § 820 states that personnel shall be made aware of device defects which may occur from improper performance of their jobs. |

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| **820.30(a) Design Controls, General** | (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.<br>(2) The following class I devices are subject to design controls:<br>(i) Devices automated with computer software; and<br>(ii) The devices listed in the following chart.<br>Section Device<br>868.6810 Catheter, Tracheobronchial Suction.<br>878.4460 Glove, Surgeon's.<br>880.6760 Restraint, Protective.<br>892.5650 System, Applicator, Radionuclide, Manual.<br>892.5740 Source, Radionuclide Teletherapy. | **7.3.1 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). |
| **820.30(b) Design and Development Planning** | Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves. | **7.3.2 Design and development planning** | 21 CFR § 820 requires documented design plans.<br>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) - f) during design and development planning. |
| **820.30(c) Design Input** | Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented. | **7.3.3 Design and development inputs** | 21 CFR § 820 specifies the documentation of the date and signature of the individual(s) approving the design inputs.<br>ISO 13485:2016 specifies specific inputs; including applicable output(s) of risk management. |
| **820.30(d) Design Output** | Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented. | **7.3.4 Design and development outputs** | ISO 13485:2016 specifies "b) provide appropriate information for purchasing, production and service provision." |

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| **820.30(e) Design Review** | Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF). | **7.3.5 Design and development review** | 21 CFR § 820 specifies design reviews include "individual(s) who does not have direct responsibility for the design stage being reviewed".<br>ISO 13485:2016 specifies that reviews will "identify and propose necessary actions". |
| **820.30(f) Design Verification** | Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF. | **7.3.6 Design and development verification** | ISO 13485:2016 specifies requirements for verification of connectivity or interfaces with other medical devices as applicable.<br>21 CFR § 820 specifies that the individual(s) performing the verification and the date of the activity be documented. |
| **820.30(g) Design Validation** | Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses A1:D91 shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF. | **7.3.7 Design and development validation** | ISO 13485:2016 specifies requirements for validation of the device while connected to or interfaced with other medical devices as applicable.<br>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 to 21 CFR § 820 - but is expected as discussed in the preamble comment 65.<br>21 CFR § 820 specifies additional documentation requirements such as the documentation (within the DHF) of the date and individuals performing the validation. |
| **820.30(h) Design Transfer** | Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications. | **7.3.8 Design and development transfer** | 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. Comment 86 of the QSR Preamble 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." |

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| **820.30(i) Design Changes** | Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation. | **7.3.9 Control of design and development changes** | 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." |
| **820.30(j) Design History File** | Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part. | **7.3.10 Design and development files** | No significant difference in requirements. |
| **820.40 Document Controls** | Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following: | **4.2.4 Control of documents**<br>**4.2.5 Control of records** | No significant difference in requirements. |
| **820.40(a) Document approval and distribution** | Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use. | **4.2.4 Control of documents**<br>**4.2.5 Control of records** | 21 CFR § 820 specifies the documentation of the date and signature of the individual(s) approving the document.<br>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." |
| **820.40(b) Document Changes** | Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective. | **4.2.4 Control of documents** | 21 CFR § 820 specifies that approved changes be communicated to appropriate personnel in a timely manner.<br>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." |

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| **820.50 Purchasing Controls** | Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements. | **4.1.5 QMS General Requirements**<br>**7.4.1 Purchasing process** | ISO 13485:2016 specifies written quality agreements between the organization and suppliers.<br>21 CFR § 820 requires "... purchased or otherwise received product" to be included in the Purchasing Controls procedures.<br>ISO 13485:2016 limits its requirement to purchased product. |
| **820.50(a) Evaluation of Suppliers, Contractors, and Consultants** | Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:<br>(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.<br>(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.<br>(3) Establish and maintain records of acceptable suppliers, contractors, and consultants. | **7.4.1 Purchasing process** | 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 QSR Preamble discusses this requirement.<br>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. |
| **820.50(b) Purchasing Data** | Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with 820.40. | **7.4.2 Purchasing information** | ISO 13485:2016 specifies "The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier."<br>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)." |
| **820.60 Identification** | Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups. | **7.5.8 Identification** | 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. |
| **820.65 Traceability** | Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR. | **7.5.9 Traceability**<br>**7.5.9.1 General** | ISO 13485:2016 requires procedures for traceability based on regulatory requirements.<br>21 CFR § 820 specifies the types of devices that require traceability. |

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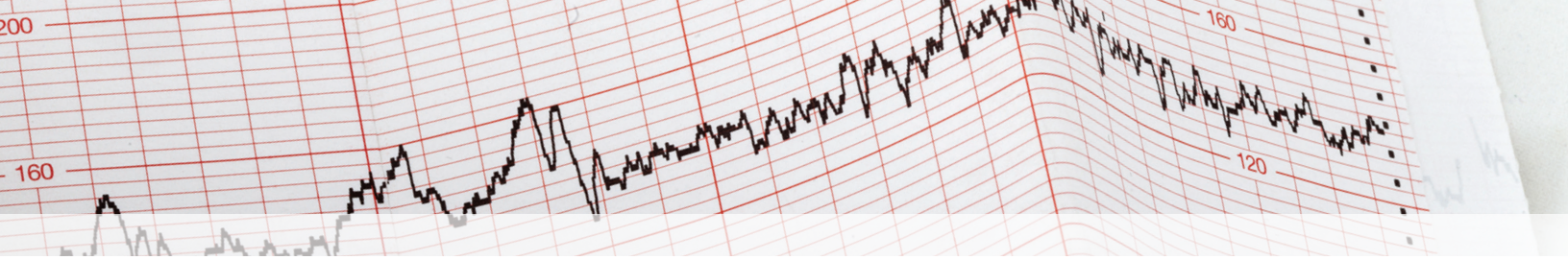
| **820.70(a) Production and Process Controls, General** | Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:<br>(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;<br>(2) Monitoring and control of process parameters and component and device characteristics during production;<br>(3) Compliance with specified reference standards or codes;<br>(4) The approval of processes and process equipment; and<br>(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples. | **7.5.1 Control of Production and Service Provision** | In this clause, ISO 13485:2016 specifies requirement that may align with other 21 CFR § 820.70 requirements beyond 21 CR 820.70(a). For example, in clause 7.5.1, ISO 13485:2016 specifies "b) qualification of infrastructure"; whereas, this requirement appears in "820.70(f) Buildings" of 21 CFR § 820. |
| **820.70(b) Production and Process Changes** | Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40. | **4.1.4 Quality Management System** | No significant difference in requirements. |
| **820.70(c) Environmental Control** | Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed. | **6.4.1 Work environment** | No significant difference in requirements. |
| **820.70(d) Personnel** | Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual. | **6.4.1 Work environment** | No significant difference in requirements. |



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| **820.70(e) Contamination Control** | Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality. | **6.4.2 Contamination control** | ISO 13485:2016's specified requirements are "as appropriate" unless relative to sterile medical devices. However, as stated in ISO 13485:2016 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.<br>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. |
| **820.70(f) Buildings** | Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling. | **6.3 Infrastructure** | No significant difference in requirements. |
| **820.70(g) Equipment** | Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.<br>(1) Maintenance schedule. Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.<br>(2) Inspection. Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.<br>(3) Adjustment. Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments. | **6.3 Infrastructure**<br>**7.5.1 Control of production and service provision** | 21 CFR § 820 specifies specific activities relative to the maintenance schedules, periodic inspections to assure adherence to equipment maintenance schedules, and posting of inherent limitations or allowable tolerances.<br>21 CFR § 820 also requires the documentation of dates and individuals conducting specified activities. |
| **820.70(h) Manufacturing Material** | Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented. | **7.5.2 Cleanliness of Product** | ISO 13485:2016 specifies conditions that would require documentation of cleanliness requirements. |

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| **820.70(i) Automated Processes** | When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented. | **4.1.6 QMS General Requirements**<br>**7.5.6 Validation of processes for production and service provision**<br>**7.6 Control of monitoring and measuring equipment** | No significant difference in requirements. |
| **820.72(a) Control of Inspection, Measuring, and Test Equipment** | Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented. | **7.6 Control of monitoring and measuring equipment** | No significant difference in requirements. |
| **820.72(b) Calibration** | Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.<br>(1) Calibration standards. Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.<br>(2) Calibration records. The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment. | **7.6 Control of monitoring and measuring equipment** | 21 CFR § 820 specifies specific documentation requirements including: "The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date..." |
| **820.75(a) Process Validation** | Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented. | **7.5.6 Validation of processes for production and service provision**<br>**7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems** | 21 CFR § 820 specifies the documentation of the date and signature of the individual(s) approving the validation. |

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| **820.75(b) Process Validation** | Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.<br>(1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).<br>(2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented. | **8.2.5 Monitoring and measurement of processes** | ISO 13485:2016 clause 8.2.5 specifies the expectations for monitoring and measurement of processes.<br>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. |
| **820.75(c) Process Validation** | When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented. | **4.1.4 QMS General Requirements**<br>**7.5.6 Validation of processes for production and service provision**<br>**8.2.5 Monitoring and measurement of processes** | No significant difference in requirements. |
| **820.80(a) Receiving, in-process, and finished device acceptance, General** | Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities. | **7.1 Planning of product realization**<br>**8.2.6 Monitoring and measurement of product** | No significant difference in requirements. |
| **820.80(b) Receiving Acceptance Activities** | Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented. | **7.4.3 Verification of purchased product** | No significant difference in requirements. |
| **820.80(c) In-Process Acceptance Activities** | Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented. | **7.5.10 Customer property**<br>**8.2.6 Monitoring and measurement of product** | No significant difference in requirements. |
| **820.80(d) Final Acceptance Activities** | Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:<br>(1) The activities required in the DMR are completed;<br>(2) the associated data and documentation is reviewed;<br>(3) the release is authorized by the signature of a designated individual(s); and<br>(4) the authorization is dated. | **7.5.10 Customer property**<br>**8.2.6 Monitoring and measurement of product** | 21 CFR § 820 specifies "Finished devices shall be held in quarantine or otherwise adequately controlled until released". |

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| **820.80(e) Acceptance Records** | Each manufacturer shall document acceptance activities required by this part. These records shall include:<br>(1) The acceptance activities performed;<br>(2) the dates acceptance activities are performed;<br>(3) the results;<br>(4) the signature of the individual(s) conducting the acceptance activities; and<br>(5) where appropriate the equipment used. These records shall be part of the DHR. | **4.2.5 Control of records**<br>**7.1 Planning of product realization**<br>**8.2.6 Monitoring and measurement of product** | Although both require records, 21 CFR § 820 specifies specific record content requirements. |
| **820.86 Acceptance status** | Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed. | **7.5.8 Identification** | No significant difference in requirements. |
| **820.90(a) Control of Nonconforming Product** | Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented. | **8.3 Control of nonconforming product**<br>**8.3.1 General** | Standard Clause 8.3.3 specifies requirements for nonconforming product detected after delivery. |
| **820.90(b) Nonconformity Review and Disposition** | 1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.<br>(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR. | **8.3.2 Actions in response to nonconforming product detected before delivery**<br>**8.3.3 Actions in response to nonconforming product detected after delivery**<br>**8.3.4 Rework** | No significant difference in requirements. |

| 21 CFR § 820 | US FDA QUALITY SYSTEM REGULATION | ISO 13485:2016 | SPECIFIC DIFFERENCES |
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| **820.100(a) Corrective and Preventive Action** | Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:<br>(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;<br>(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;<br>(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;<br>(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;<br>(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;<br>(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; and<br>(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. | **8.4 Analysis of data**<br>**8.5 Improvement**<br>**8.5.1 General**<br>**8.5.2 Corrective Action**<br>**8.5.3 Preventive Action** | 21 CFR § 820 specifies "(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device."<br>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."<br>ISO 13485:2016 contains specific clauses relative to "corrective action" and "preventive action".<br>ISO 13485:2016 requires corrective action to be taken "without undue delay." |
| **820.100(b) Corrective and Preventive Action** | All activities required under this section, and their results, shall be documented. | **8.5.2 Corrective Action**<br>**8.5.3 Preventive Action** | No significant difference in requirements. |
| **820.120 Device Labeling** | Each manufacturer shall establish and maintain procedures to control labeling activities. | **7.5.1 Control of production and service provision** | No significant difference in requirements. |
| **820.120(a) Label Integrity** | Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use. | **7.5.1 Control of production and service provision**<br>**7.5.11 Preservation of product** | ISO 13485:2016 does not prescribe specific requirements for labeling other than stating that production controls shall include "implementation of defined operations for labelling and packaging."<br>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 throughout the product's production, packaging, distribution and storage channels; and environments. |

| 21 CFR § 820 | US FDA QUALITY SYSTEM REGULATION | ISO 13485:2016 | SPECIFIC DIFFERENCES |
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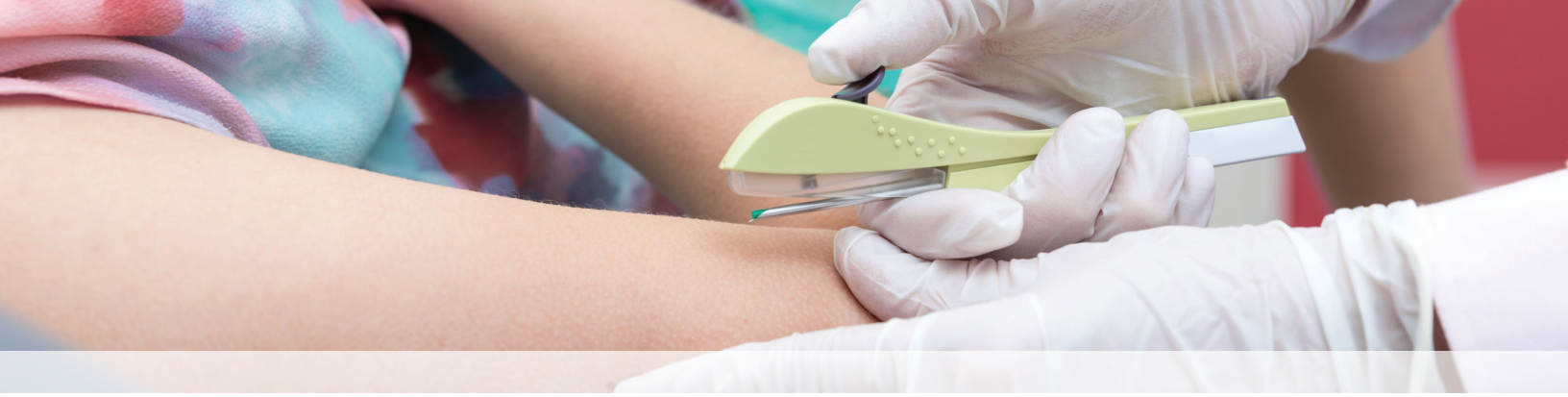
| **820.120(b) Labeling Inspection** | Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or universal product code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR. | **7.4.3 Verification of purchased product**<br>**7.5.1 Control of production and service provision**<br>**8.2.6 Monitoring and measurement of product** | ISO 13485:2016 does not prescribe specific requirements for labeling other than stating that production controls shall include "implementation of defined operations for labelling and packaging" and does not specifically address the inspection of labels. However, 8.2.6 Monitoring and measurement of product and 7.4.3 Verification of purchased products should account for the additional activities cited in 21 CFR § 820.120(b). |
| **820.120(c) Labeling Storage** | Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mix-ups. | **6.4.1 Work environment**<br>**7.5.1 Control of production and service provision** | ISO 13485:2016 does not prescribe specific requirements for labeling other than stating that production controls shall include "implementation of defined operations for labelling and packaging" and does not specifically address the labeling storage requirements cited in 21 CFR § 820. |
| **820.120(d) Labeling Operations** | Each manufacturer shall control labeling and packaging operations to prevent labeling mix-ups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR. | **7.5.1 Control of production and service provision**<br>**4.2.3 Medical device file** | 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. |
| **820.120(e) Control Number** | Where a control number is required by 820.65, that control number shall be on or shall accompany the device through distribution. | **7.5.8 Identification**<br>**7.5.9.2 Particular requirements for implantable medical devices** | ISO 13485:2016 does not require control numbers, although it does specify requirements for UDI (when required) and traceability for implantable medical devices. |
| **820.130 Device Packaging** | Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution. | **7.3 Design and development**<br>**7.5.1 Control of production and service provision**<br>**7.5.11 Preservation of product** | No significant difference in requirements. |
| **820.140 Handling** | Each manufacturer shall establish and maintain procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling. | **7.5.11 Preservation of product** | 21 CFR § 820 specifies procedures must include provisions to assure "mix-ups" do not occur. |
| **820.150(a) Storage** | Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate. | **7.5.11 Preservation of product** | ISO 13485:2016 does not specify a provision for stock rotation. |
| **820.150(b) Storage** | Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms. | | ISO 13485:2016 does not specify a comparable requirement. |



| 21 CFR § 820 | US FDA QUALITY SYSTEM REGULATION | ISO 13485:2016 | SPECIFIC DIFFERENCES |
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| **820.160(a) Distribution** | Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed. | **7.2.1 Determination of requirements related to product**<br>**7.2.2 Review of requirements related to product**<br>**7.5.1 Control of production and service provision** | 21 CFR § 820 specifies explicit provisions relative to the prohibition of the distribution of expired or deteriorated devices. |
| **820.160(b) Distribution** | Each manufacturer shall maintain distribution records which include or refer to the location of:<br>(1) The name and address of the initial consignee;<br>(2) The identification and quantity of devices shipped;<br>(3) The date shipped; and<br>(4) Any control number(s) used. | **7.5.9.2 Particular requirements for implantable medical devices** | ISO 13485:2016 specifies provisions for maintaining distribution records for implantable medical devices.<br>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. |
| **820.170(a) Installation** | Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device. | **7.5.3 Installation activities** | No significant difference in requirements. |
| **820.170(b) Installation** | The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation. | **7.5.3 Installation activities** | No significant difference in requirements. |
| **820.180 General Requirements** | All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up. | **4.2.5 Control of records** | 21 CFR § 820 requires records to be readily available for review and copying by FDA employees designated to perform inspections.<br>21 CFR § 820 specifies records stored in automated data processing systems must be backed up. |

| 21 CFR § 820 | US FDA QUALITY SYSTEM REGULATION | ISO 13485:2016 | SPECIFIC DIFFERENCES |
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| **820.180(a) Confidentiality** | Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter. | **4.2.5 Control of records** | 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).<br>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. |
| **820.180(b) Record Retention Period** | All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. | **4.2.4 Control of documents**<br>**4.2.5 Control of records** | No significant difference in requirements. |
| **820.180(c) Exceptions** | This section does not apply to the reports required by 820.20(c) Management review, 820.22 Quality audits, and supplier audit reports used to meet the requirements of 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken. | | ISO 13485:2016 does not specify a comparable requirement. |
| **820.181 Device Master Record** | Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with 820.40. The DMR for each type of device shall include, or refer to the location of, the following information:<br>(a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;<br>(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;<br>(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;<br>(d) Packaging and labeling specifications, including methods and processes used; and<br>(e) Installation, maintenance, and servicing procedures and methods. | **4.2.3 Medical device file** | No significant difference in requirements. |

| 21 CFR § 820 | US FDA QUALITY SYSTEM REGULATION | ISO 13485:2016 | SPECIFIC DIFFERENCES |
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| **820.184 Device History Record** | Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:<br>(a) The dates of manufacture;<br>(b) The quantity manufactured;<br>(c) The quantity released for distribution;<br>(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;<br>(e) The primary identification label and labeling used for each production unit; and<br>(f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used. | **7.5.1 Control of production and service provision** | 21 CFR § 820 specifies additional DHR content beyond that specified in ISO 13485:2016. (e.g. (a) The dates of manufacture;...<br>(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;<br>(e) The primary identification label and labeling used for each production unit; and<br>(f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.) |
| **820.186 Quality System Record** | Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by 820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with 820.40. | **4.2.5 Control of records** | While ISO 13485:2016 does not specify a requirement for a QSR, there are requirements for the various documents and procedures that are included (or referred to the location of) within the QSR. |
| **820.198(a) Complaint Files** | Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:<br>(1) All complaints are processed in a uniform and timely manner;<br>(2) Oral complaints are documented upon receipt; and<br>(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. | **8.2.2 Complaint handling** | No significant difference in requirements.<br>However, the definition of "complaint" in 3.4 of ISO 13485:2016 includes the term "usability" – not included in the definition of the term contained in 21 CFR § 820.3(c).<br>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.<br>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." |
| **820.198(b) Complaint Files** | Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. | **8.2.2 Complaint handling** | 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. |

| 21 CFR § 820 | US FDA QUALITY SYSTEM REGULATION | ISO 13485:2016 | SPECIFIC DIFFERENCES |
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| **820.198(c) Complaint Files** | Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. | **8.2.2 Complaint handling** | 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. |
| **820.198(d) Complaint Files** | Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:<br>(1) Whether the device failed to meet specifications;<br>(2) Whether the device was being used for treatment or diagnosis; and<br>(3) The relationship, if any, of the device to the reported incident or adverse event. | **8.2.3 Reporting to regulatory authorities** | 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. |
| **820.198(e) Complaint Files** | When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:<br>(1) The name of the device;<br>(2) The date the complaint was received;<br>(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br>(4) The name, address, and phone number of the complainant;<br>(5) The nature and details of the complaint;<br>(6) The dates and results of the investigation;<br>(7) Any corrective action taken; and<br>(8) Any reply to the complainant. | **8.2.2 Complaint handling**<br>**7.2.3 Communication** | 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. |
| **820.198(f) Complaint Files** | When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. | | ISO 13485:2016 does not specify a comparable requirement. Although ISO 13485:2016 does not discuss where records may be located, clause 4.2.5 requires "The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records ... Records shall remain legible, readily identifiable, and retrievable." |
| **820.198(g) Complaint Files** | If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:<br>(1) A location in the United States where the manufacturer's records are regularly kept; or<br>(2) The location of the initial distributor. | | ISO 13485:2016 does not specify a comparable requirement. Although ISO 13485:2016 does not discuss where records may be located, 4.2.5 requires "The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records ... Records shall remain legible, readily identifiable, and *retrievable*." |

| 21 CFR § 820 | US FDA QUALITY SYSTEM REGULATION | ISO 13485:2016 | SPECIFIC DIFFERENCES |
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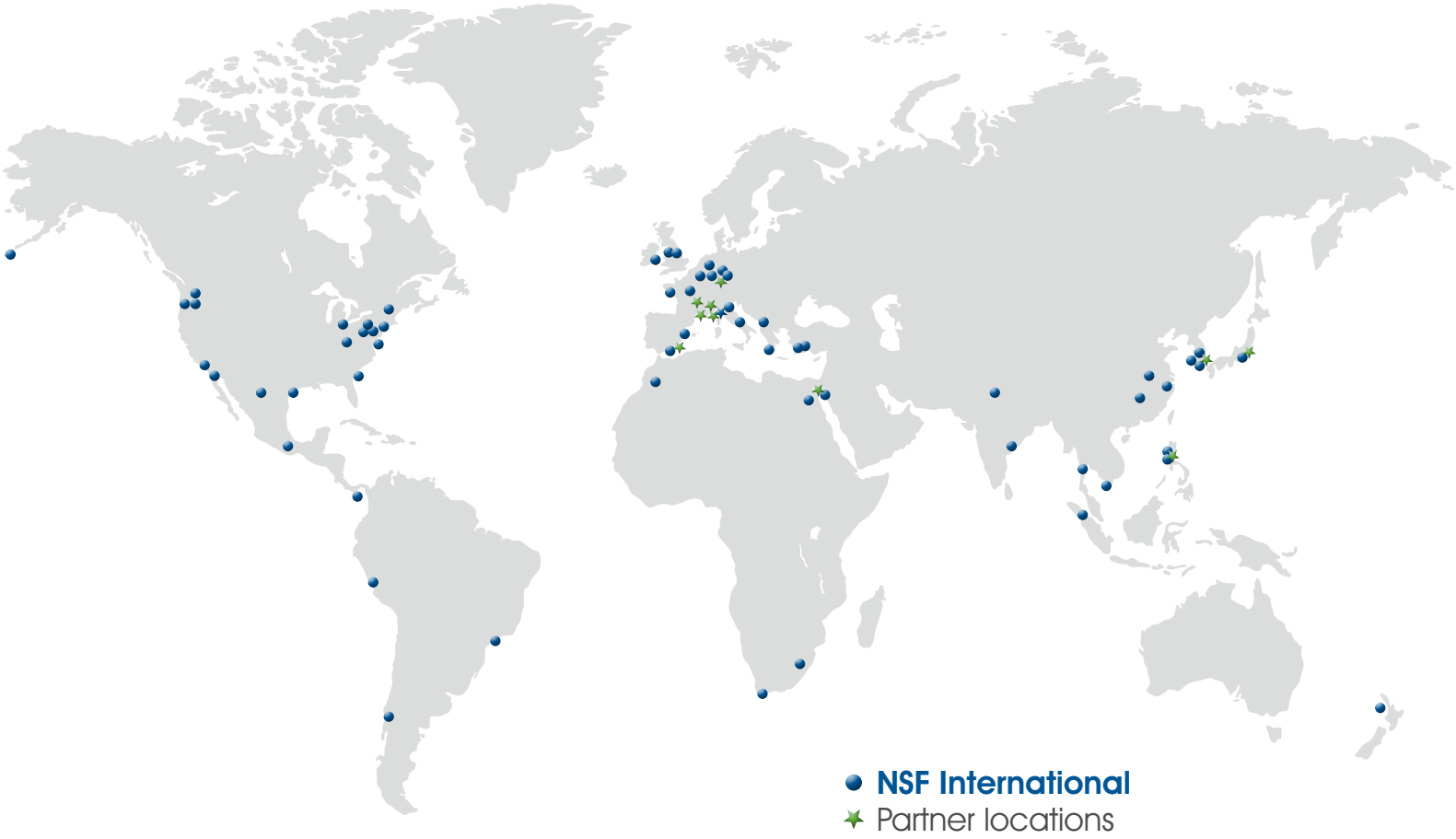
| **820.200(a) Servicing** | Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements. | **7.5.4 Servicing activities** | No significant difference in requirements. |
| **820.200(b) Servicing** | Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with 820.100. | **7.5.4 Servicing activities**<br>**8.1 Measurement, analysis, and improvement, General** | ISO 13485:2016's requirement for use of appropriate statistical techniques is found in 8.1. |
| **820.200(d) Servicing** | Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of 820.198. | **7.5.4 Servicing activities** | ISO 13485:2016 requires analysis to determine if service activities carried out by the organization or its supplier represent a complaint.<br>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 reportable events). |
| **820.200(e) Servicing** | Service reports shall be documented and shall include:<br>(1) The name of the device serviced;<br>(2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br>(3) The date of service;<br>(4) The individual(s) servicing the device;<br>(5) The service performed; and<br>(6) The test and inspection data. | **7.5.4 Servicing activities** | 21 CFR § 820 specifies specific content requirements relative to service reports. |
| **820.250(a) Statistical Techniques** | Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics. | **8.1 Measurement, analysis and improvement, General** | 21 CFR § 820 requires documented procedures for identifying valid statistical techniques.<br>ISO 13485:2016 requires the organization to plan for and determine appropriate statistical techniques and the extent of their use. |
| **820.250(b) Statistical Techniques** | Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented. | **7.5.6 Validation of processes for production and service provision**<br>**8.1 Measurement, analysis and improvement, General** | 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. |

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LMD-776-0418