REGULATORY COMPLIANCE ASSOCIATES® INC

Wellness for Business®

# Correspondence Between ISO 13485:2016 and 21 CFR Part 820 QMS Requirements

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| **4 Quality Management System**<br><br>**4.1 General Requirements**<br><br>**4.1.1** The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.<br><br>The organization shall establish, implement, and maintain any requirement, procedure, activity, or arrangement required to be documented by this International Standard or applicable regulatory requirements.<br><br>The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.<br><br>**NOTE**. Roles undertaken by the organization can include manufacturer, authorized representative, importer, or distributor.<br><br>**4.1.2** The organization shall:<br><br>**a)** determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization;<br><br>**b)** apply a risk based approach to the control of the appropriate processes needed for the quality management system;<br><br>**c)** determine the sequence and interaction of these processes.<br><br>**4.1.3** For each quality management system process, the organization shall:<br><br>**a)** determine criteria and methods needed to ensure that both the operation and control of these processes are effective;<br><br>**b)** ensure the availability of resources and information necessary to support the operation and monitoring of these processes;<br><br>**c)** implement actions necessary to achieve planned results and maintain the effectiveness of these processes;<br><br>**d)** monitor, measure as appropriate, and analyze these processes; | **Subpart A--General Provisions**<br><br>**Sec. 820.5 Quality System.**<br><br>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.<br><br>**Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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.<br><br>**(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.<br><br>**(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.<br><br>**(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.<br><br>**(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><br>**(i)** Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and<br><br>**(ii)** Reporting on the performance of the quality system to management with executive responsibility for review.<br><br>**(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. |

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| **e)** establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see **4.2.5**).<br><br>**4.1.4** The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be:<br><br>**a)** evaluated for their impact on the quality management system;<br><br>**b)** evaluated for their impact on the medical devices produced under this quality management system;<br><br>**c)** controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.<br><br>**4.1.5** When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.<br><br>**4.1.6** The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.<br><br>The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.<br><br>Records of such activities shall be maintained (see 4.2.5). | The dates and results of quality system reviews shall be documented.<br><br>**(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.<br><br>**(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><br>**4.2.1 General**<br><br>The quality management system documentation (see 4.2.4) shall include:<br><br>**a)** documented statements of a quality policy and quality objectives;<br><br>**b)** a quality manual; | **Subpart A—General Provisions**<br><br>**Sec. 820.5 Quality System.**<br><br>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.<br><br>**Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.** |

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| **c)** documented procedures and records required by this International Standard;<br><br>**d)** documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;<br><br>**e)** other documentation specified by applicable regulatory requirements. | **(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.<br><br>**(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.<br><br>**Subpart D--Document Controls**<br><br>**Sec. 820.40 Document Controls.**<br><br>Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:<br><br>**(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.<br><br>**(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. |
| **4.2.2 Quality Manual**<br><br>The organization shall document a quality manual that includes:<br><br>**a)** the scope of the quality management system, including details of and justification for any exclusion or non-application;<br><br>**b)** the documented procedures for the quality management system, or reference to them;<br><br>**c)** a description of the interaction between the processes of the quality management system. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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.<br><br>**(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. |

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| The quality manual shall outline the structure of the documentation used in the quality management system. | **(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.<br><br>**(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.<br><br>**(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. |
| **4.2.3 Medical Device File**<br><br>For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.<br><br>The content of the file(s) shall include, but is not limited to:<br><br>**a)** general description of the medical device, intended use/purpose, and labelling, including any instructions for use;<br><br>**b)** specifications for product;<br><br>**c)** specifications or procedures for manufacturing, packaging, storage, handling and distribution;<br><br>**d)** procedures for measuring and monitoring; as appropriate, requirements for installation;<br><br>**e)** as appropriate, procedures for servicing. | **Subpart M--Records**<br><br>**Sec. 820.181 Device Master Record.**<br><br>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><br>**(a)** Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;<br><br>**(b)** Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;<br><br>**(c)** Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;<br><br>**(d)** Packaging and labeling specifications, including methods and processes used; and<br><br>**(e)** Installation, maintenance, and servicing procedures and methods.<br><br>**Subpart K--Labeling and Packaging Control**<br><br>**Sec. 820.120 Device Labeling.**<br><br>Each manufacturer shall establish and maintain procedures to control labeling activities.<br><br>**(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. |

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| | **(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.<br><br>**(c) Labeling Storage**. Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mix-ups.<br><br>**(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.<br><br>**(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.<br><br>**Sec. 820.130 Device Packaging.**<br><br>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.<br><br>**Subpart L--Handling, Storage, Distribution, and Installation**<br><br>**Sec. 820.140 Handling.**<br>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.<br><br>**Sec. 820.150 Storage.**<br><br>(a) 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.<br><br>**(b)** Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.<br><br>**Sec. 820.160 Distribution.**<br><br>**(a)** Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that |

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| | 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.<br><br>**(b)** Each manufacturer shall maintain distribution records which include or refer to the location of:<br><br>**(1)** The name and address of the initial consignee;<br><br>**(2)** The identification and quantity of devices shipped;<br><br>**(3)** The date shipped; and<br><br>**(4)** Any control number(s) used.<br><br>**Sec. 820.170 Installation.**<br><br>**(a)** 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.<br><br>**(b)** 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.<br><br>**Subpart M--Records**<br><br>**Sec. 820.180 General Requirements.**<br><br>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.<br><br>**(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. |

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| | **(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.<br><br>**(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.<br><br>**Subpart N--Servicing**<br><br>**Sec. 820.200 Servicing.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with 820.100.<br><br>**(c)** 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.<br><br>**(d)** Service reports shall be documented and shall include:<br><br>**(1)** The name of the device serviced;<br><br>**(2)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br><br>**(3)** The date of service;<br><br>**(4)** The individual(s) servicing the device;<br><br>**(5)** The service performed; and<br><br>**(6)** The test and inspection data. |

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| **4.2.4 Control of Documents**<br><br>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in **4.2.5**.<br><br>A documented procedure shall define the controls needed to:<br><br>**a)** review and approve documents for adequacy prior to issue;<br><br>**b)** review, update as necessary and re-approve documents;<br><br>**c)** ensure that the current revision status of and changes to documents are identified;<br><br>**d)** ensure that relevant versions of applicable documents are available at points of use;<br><br>**e)** ensure that documents remain legible and readily identifiable;<br><br>**f)** ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;<br><br>**g)** prevent deterioration or loss of documents;<br><br>**h)** prevent the unintended use of obsolete documents and apply suitable identification to them.<br><br>The organization shall ensure that changes to documents are reviewed and approved either by the original approving function, or another designated function that has access to pertinent background information upon which to base its decisions.<br><br>The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable regulatory requirements. | **Subpart D--Document Controls**<br><br>**Sec. 820.40 Document Controls.**<br><br>Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:<br><br>**(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.<br><br>**(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. |

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| **4.2.5 Control of Records**<br><br>Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.<br><br>The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.<br><br>The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.<br><br>Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.<br><br>The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization. | **Subpart M--Records**<br><br>**Sec. 820.180 General Requirements.**<br><br>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.<br><br>**(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.<br><br>**(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.<br><br>**(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.<br><br>**Subpart M--Records**<br><br>**Sec. 820.181 Device Master Record.**<br><br>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><br>**(a)** Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;<br><br>**(b)** Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications; |

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| | **(c)** Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;<br><br>**(d)** Packaging and labeling specifications, including methods and processes used; and<br><br>**(e)** Installation, maintenance, and servicing procedures and methods.<br><br>**Subpart M--Records**<br><br>**Sec. 820.184 Device History Record.**<br><br>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><br>**(a)** The dates of manufacture;<br><br>**(b)** The quantity manufactured;<br><br>**(c)** The quantity released for distribution;<br><br>**(d)** The acceptance records which demonstrate the device is manufactured in accordance with the DMR;<br><br>**(e)** The primary identification label and labeling used for each production unit; and<br><br>**(f)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.<br><br>**Subpart M--Records**<br><br>**Sec. 820.186 Quality System Record.**<br><br>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. |

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| **5 Management Responsibility**<br><br>**5.1 Management Commitment**<br><br>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:<br><br>**a)** communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;<br><br>**b)** establishing the quality policy;<br><br>**c)** ensuring that quality objectives are established;<br><br>**d)** conducting management reviews;<br><br>**e)** ensuring the availability of resources. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility**<br><br>**(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.<br><br>**(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.<br><br>**(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.<br><br>**(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.<br><br>**(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><br>**(i)** Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and<br><br>**(ii)** Reporting on the performance of the quality system to management with executive responsibility for review.<br><br>**(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.<br><br>**(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. |

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| | **(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. |
| **5.2 Customer Focus**<br><br>Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met. | No specific equivalent in 21 CFR Part 820 related to "Customer Focus." |
| **5.3 Quality Policy**<br><br>Top management shall ensure that the quality policy:<br><br>**a)** is applicable to the purpose of the organization;<br><br>**b)** includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;<br><br>**c)** provides a framework for establishing and reviewing quality objectives;<br><br>**d)** is communicated and understood within the organization;<br><br>**e)** is reviewed for continuing suitability. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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. |
| **5.4 Planning**<br><br>**5.4.1 Quality Objectives**<br><br>Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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.<br><br>**(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**<br><br>Top management shall ensure that:<br><br>a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives;<br><br>b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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. |

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| **5.5 Responsibility, Authority, and Communication**<br><br>**5.5.1 Responsibility and Authority**<br><br>Top management shall ensure that responsibilities and authorities are defined, documented, and communicated within the organization. Top management shall document the interrelation of all personnel who manage, perform, and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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.<br><br>**(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. |
| **5.5.2 Management Representative**<br><br>Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:<br><br>**a)** ensuring that processes needed for the quality management system are documented;<br><br>**b)** reporting to top management on the effectiveness of the quality management system and any need for improvement;<br><br>**c)** ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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.<br><br>**(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><br>**(i)** Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and<br><br>**(ii)** Reporting on the performance of the quality system to management with executive responsibility for review. |
| **5.5.3 Internal Communication**<br><br>Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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.<br><br>**(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. |

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| **5.6 Management Review**<br><br>**5.6.1 General**<br><br>The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.<br><br>Records from management reviews shall be maintained (see 4.2.5). | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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. |
| **5.6.2 Review Input**<br><br>The input to management review shall include, but is not limited to, information arising from:<br><br>**a)** feedback;<br><br>**b)** complaint handling;<br><br>**c)** reporting to regulatory authorities;<br><br>**d)** audits;<br><br>**e)** monitoring and measurement of processes;<br><br>**f)** monitoring and measurement of product;<br><br>**g)** corrective action;<br><br>**h)** preventive action;<br><br>**i)** follow-up actions from previous management reviews;<br><br>**j)** changes that could affect the quality management system;<br><br>**k)** recommendations for improvement;<br><br>**l)** applicable new or revised regulatory requirements. | **Subpart B--Quality System Requirements**<br><br>**Sec. Management Responsibility.**<br><br>**(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. |
| **5.6.3 Review Output**<br><br>The output from management review shall be recorded (see **4.2.5**) and include the input reviewed and any decisions and actions related to:<br><br>**a)** improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility**<br><br>**(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. |

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| **b)** improvement of product related to customer requirements;<br><br>**c)** changes needed to respond to applicable new or revised regulatory requirements;<br><br>**d)** resource needs. | The dates and results of quality system reviews shall be documented. |
| **6 Resource Management**<br><br>**6.1 Provision of Resources**<br>The organization shall determine and provide the resources needed to:<br><br>**a)** implement the quality management system and to maintain its effectiveness;<br><br>**b)** meet applicable regulatory and customer requirements. | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility**<br><br>**(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.<br><br>**(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.<br><br>**(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.<br><br>**Sec. 820.25 Personnel.**<br><br>**(a) 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. |
| **6.2 Human Resources**<br><br>Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.<br><br>The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.<br><br>The organization shall:<br><br>**a)** determine the necessary competence for personnel performing work affecting product quality;<br><br>**b)** provide training or take other actions to achieve or maintain the necessary competence;<br><br>**c)** evaluate the effectiveness of the actions taken; | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.25 Personnel.**<br><br>**(a) 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.<br><br>**(b) 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><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. |

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| **d)** ensure that its personnel are aware of the relevance and importance of their activities and how<br><br>**e)** they contribute to the achievement of the quality objectives;<br><br>**f)** maintain appropriate records of education, training, skills and experience (see 4.2.5).<br><br>NOTE. The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided. | **(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.<br><br>**Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(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. |
| **6.3 Infrastructure**<br><br>The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product.<br><br>Infrastructure includes, as appropriate:<br><br>**a)** buildings, workspace and associated utilities;<br><br>**b)** process equipment (both hardware and software);<br><br>**c)** supporting services (such as transport, communication, or information systems).<br><br>The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect<br>product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.<br><br>Records of such maintenance shall be maintained (see **4.2.5**). | **Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls**<br><br>**(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.<br><br>**(f) Buildings.** Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling.<br><br>**(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><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><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><br>**(3) Adjustment.** Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted |

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| | on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.<br><br>**(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.<br><br>**(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. |
| **6.4 Work Environment and Contamination Control**<br><br>**6.4.1 Work Environment**<br><br>The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.<br><br>If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment.<br><br>The organization shall:<br><br>**a)** document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;<br><br>**b)** ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.<br><br>NOTE. Further information can be found in ISO 14644 and ISO 14698. | **Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(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.<br><br>**(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.<br><br>**(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.<br><br>**(f) Buildings.** Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling. |
| **6.4.2 Contamination Control**<br><br>As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. | **Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(e) Contamination Control.** Each manufacturer shall establish and maintain procedures to prevent contamination of |

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| For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes. | equipment or product by substances that could reasonably be expected to have an adverse effect on product quality. |
| **7 Product Realization**<br><br>**7.1 Planning of Product Realization**<br><br>The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.<br><br>The organization shall document one or more processes for risk management in product realization.<br>Records of risk management activities shall be maintained (see 4.2.5).<br><br>In planning product realization, the organization shall determine the following, as appropriate:<br><br>**a)** quality objectives and requirements for the product;<br><br>**b)** the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment;<br><br>**c)** required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;<br><br>**d)** records needed to provide evidence that the realization processes and resulting product meet requirements (see **4.2.5**).<br><br>**e)** The output of this planning shall be documented in a form suitable for the organization's method of operations.<br><br>NOTE. Further information can be found in ISO 14971. | **Subpart C—Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(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.<br><br>**Subpart H--Acceptance Activities**<br><br>**Sec. 820.80 Receiving, In-Process, and Finished Device Acceptance.**<br><br>**(a) General.** Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.<br><br>**(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.<br><br>**(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><br>**(1)** The activities required in the DMR are completed;<br><br>**(2)** the associated data and documentation is reviewed;<br><br>**(3)** the release is authorized by the signature of a designated individual(s); and<br><br>**(4)** the authorization is dated.<br><br>**(e) Acceptance Records.** Each manufacturer shall document acceptance activities required by this part. These records shall include:<br><br>**(1)** The acceptance activities performed; |

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| | **(2)** the dates acceptance activities are performed;<br><br>**(3)** the results;<br><br>**(4)** the signature of the individual(s) conducting the acceptance activities; and<br><br>**(5)** where appropriate the equipment used. These records shall be part of the DHR.<br><br>**Subpart L--Handling, Storage, Distribution, and Installation**<br><br>**Sec. 820.140 Handling.**<br><br>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.<br><br>**Sec. 820.150 Storage.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.<br><br>**Sec. 820.160 Distribution.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall maintain distribution records which include or refer to the location of:<br><br>**(1)** The name and address of the initial consignee;<br><br>**(2)** The identification and quantity of devices shipped;<br><br>**(3)** The date shipped; and<br><br>**(4)** Any control number(s) used. |

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| | **Subpart M--Records**<br><br>**Sec. 820.180 General Requirements.**<br><br>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.<br><br>**(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.<br><br>**(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.<br><br>**(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.<br><br>**Sec. 820.184 Device History Record.**<br><br>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><br>**(a)** The dates of manufacture;<br><br>**(b)** The quantity manufactured;<br><br>**(c)** The quantity released for distribution; |

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| | **(d)** The acceptance records which demonstrate the device is manufactured in accordance with the DMR;<br><br>**(e)** The primary identification label and labeling used for each production unit; and<br><br>**(f)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.<br><br>**Sec. 820.186 Quality System Record.**<br><br>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.<br><br>**Subpart N--Servicing**<br><br>**Sec. 820.200 Servicing.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with 820.100.<br><br>**(c)** 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.<br><br>**(d)** Service reports shall be documented and shall include:<br><br>**(1)** The name of the device serviced;<br><br>**(2)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br><br>**(3)** The date of service;<br><br>**(4)** The individual(s) servicing the device;<br><br>**(5)** The service performed; and<br><br>**(6)** The test and inspection data. |

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| **7.2 Customer-Related Processes**<br><br>**7.2.1 Determination of Requirements Related to Product**<br><br>The organization shall determine:<br><br>**a)** requirements specified by the customer, including the requirements for delivery and post-delivery activities;<br><br>**b)** requirements not stated by the customer but necessary for specified or intended use, as known;<br><br>**c)** applicable regulatory requirements related to the product;<br><br>**d)** any user training needed to ensure specified performance and safe use of the medical device;<br><br>**e)** any additional requirements determined by the organization. | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Inputs**<br><br>**(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. |
| **7.2.2 Review of Requirements Related to Product**<br><br>The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:<br><br>**a)** product requirements are defined and documented;<br><br>**b)** contract or order requirements differing from those previously expressed are resolved;<br><br>**c)** applicable regulatory requirements are met;<br><br>**d)** any user training identified in accordance with 7.2.1 is available or planned to be available;<br><br>**e)** the organization has the ability to meet the defined requirements.<br><br>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5).<br>When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.<br><br>When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Inputs**<br><br>**(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.<br><br>**(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.<br><br>**(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 |

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<tr><th>ISO 13485:2016</th><th>US FDA Quality System Regulation<br>(QSR - 21 CFR 820)</th></tr>
<tr><td></td><td>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).</td></tr>
<tr><td>7.2.3 Communication<br><br>The organization shall plan and document arrangements for communicating with customers in relation to:<br><br>a) product information;<br><br>b) enquiries, contracts or order handling, including amendments;<br><br>c) customer feedback, including complaints;<br><br>d) advisory notices.<br><br>The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.</td><td>Refer to Subpart M—Records, Sec. 820.198 Complaint Files.</td></tr>
<tr><td>7.3 Design and Development<br><br>7.3.1 General<br><br>The organization shall document procedures for design and development.</td><td>Subpart C--Design Controls<br><br>Sec. 820.30 Design Controls.<br><br>(a) General.<br><br>(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><br>(2) The following class I devices are subject to design controls:<br><br>(i) Devices automated with computer software; and<br><br>(ii) The devices listed in the following chart.<br><br><table><tr><th>Section</th><th>Device</th></tr><tr><td>868.6810</td><td>Catheter, Tracheobronchial Suction.</td></tr><tr><td>878.4460</td><td>Glove, Surgeon's.</td></tr><tr><td>880.6760</td><td>Restraint, Protective.</td></tr><tr><td>892.5650</td><td>System, Applicator, Radionuclide, Manual.</td></tr><tr><td>892.5740</td><td>Source, Radionuclide Teletherapy.</td></tr></table></td></tr>
<tr><td>7.3.2 Design and Development Planning<br><br>The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses.<br><br>During design and development planning, the organization shall document:</td><td>Subpart C--Design Controls<br><br>Sec. 820.30 Design Controls.<br><br>(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</td></tr>
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| **a)** the design and development stages;<br><br>**b)** the review(s) needed at each design and development stage;<br><br>**c)** the verification, validation, and design transfer activities that are appropriate at each design and development stage;<br><br>**d)** the responsibilities and authorities for design and development;<br><br>**e)** the methods to ensure traceability of design and development outputs to design and development inputs;<br><br>**f)** the resources needed, including necessary competence of personnel. | result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves. |
| **7.3.3 Design and Development Inputs**<br><br>Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include:<br><br>**a)** functional, performance, usability and safety requirements, according to the intended use;<br><br>**b)** applicable regulatory requirements and standards;<br><br>**c)** applicable output(s) of risk management;<br><br>**d)** as appropriate, information derived from previous similar designs;<br><br>**e)** other requirements essential for design and development of the product and processes.<br><br>These inputs shall be reviewed for adequacy and approved.<br><br>Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.<br><br>NOTE. Further information can be found in IEC 62366–1. | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(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. |
| **7.3.4 Design and Development Outputs**<br><br>Design and development outputs shall:<br><br>**a)** meet the input requirements for design and development;<br><br>**b)** provide appropriate information for purchasing, production and service provision;<br><br>**c)** contain or reference product acceptance criteria; | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(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. |

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| **d)** specify the characteristics of the product that are essential for its safe and proper use.<br><br>The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release.<br><br>Records of the design and development outputs shall be maintained (see **4.2.5**). | 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. |
| **7.3.5 Design and Development Review**<br><br>At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to:<br><br>**a)** evaluate the ability of the results of design and development to meet requirements;<br><br>**b)** identify and propose necessary actions.<br><br>Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.<br><br>Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5). | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(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). |
| **7.3.6 Design and Development Verification**<br><br>Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.<br><br>The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.<br><br>If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.<br><br>Records of the results and conclusions of the verification and necessary actions shall be maintained<br>(see 4.2.4 and 4.2.5). | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(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. |
| **7.3.7 Design and Development Validation**<br><br>Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(g) Design Validation.** Each manufacturer shall establish and maintain procedures for validating the device design. Design |

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| The organization shall document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.<br><br>Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5).<br><br>As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements.<br><br>A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.<br><br>If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.<br><br>Validation shall be completed prior to release for use of the product to the customer. Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4 and 4.2.5). | validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF. |
| **7.3.8 Design and Development Transfer**<br><br>The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.<br><br>Results and conclusions of the transfer shall be recorded (see 4.2.5). | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(h) Design Transfer.** Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications. |
| **7.3.9 Control of Design and Development Changes**<br><br>The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety, and applicable regulatory requirements for the medical device and its intended use.<br><br>Design and development changes shall be identified. Before implementation, the changes shall be:<br><br>**a)** reviewed;<br><br>**b)** verified; | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(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. |

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| **c)** validated, as appropriate;<br><br>**d)** approved.<br><br>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.<br><br>Records of changes, their review, and any necessary actions shall be maintained (see 4.2.5). | |
| **7.3.10 Design and Development Files**<br><br>The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes. | **Subpart C--Design Controls**<br><br>**Sec. 820.30 Design Controls.**<br><br>**(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. |
| **7.4 Purchasing**<br><br>**7.4.1 Purchasing Process**<br><br>The organization shall document procedures (see **4.2.4)** to ensure that purchased product conforms to specified purchasing information.<br><br>The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:<br><br>**a)** based on the supplier's ability to provide product that meets the organization's requirements;<br><br>**b)** based on the performance of the supplier;<br><br>**c)** based on the effect of the purchased product on the quality of the medical device;<br><br>**d)** proportionate to the risk associated with the medical device.<br><br>The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.<br><br>Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. | **Subpart E—Purchasing Controls**<br><br>**Sec. 820.50 Purchasing Controls.**<br><br>Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.<br><br>**(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><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><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><br>**(3)** Establish and maintain records of acceptable suppliers, contractors, and consultants.<br><br>**(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 |

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| Records of the results of evaluation, selection, monitoring, and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5). | the quality of a finished device. Purchasing data shall be approved in accordance with 820.40. |
| **7.4.2 Purchasing Information**<br><br>Purchasing information shall describe or reference the product to be purchased, including as appropriate:<br><br>**a)** product specifications;<br><br>**b)** requirements for product acceptance, procedures, processes and equipment;<br><br>**c)** requirements for qualification of supplier personnel;<br><br>**d)** quality management system requirements.<br><br>The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier.<br><br>Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.<br><br>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). | **Subpart E--Purchasing Controls**<br><br>**Sec. 820.50 Purchasing Controls.**<br><br>**(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. |
| **7.4.3 Verification of Purchased Product**<br><br>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.<br><br>When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.<br><br>When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information.<br><br>Records of the verification shall be maintained (see 4.2.5). | **Subpart H--Acceptance Activities**<br><br>**Sec. 820.80 Receiving, In-Process, and Finished Device Acceptance.**<br><br>**(a) General.** Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.<br><br>**(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.<br><br>**Subpart E--Purchasing Controls**<br><br>**Sec. 820.50 Purchasing Controls.**<br><br>Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements. |

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| | **(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. |
| **7.5 Production and Service Provision**<br><br>**7.5.1 Control of Production and Service Provision**<br><br>Production and service provision shall be planned, carried out, monitored. and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to:<br><br>**a)** documentation of procedures and methods for the control of production (see 4.2.4);<br><br>**b)** qualification of infrastructure;<br><br>**c)** implementation of monitoring and measurement of process parameters and product characteristics;<br><br>**d)** availability and use of monitoring and measuring equipment;<br><br>**e)** implementation of defined operations for labelling and packaging;<br><br>**f)** implementation of product release, delivery and post-delivery activities.<br><br>The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved. | **Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(a) 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><br>**(1)** Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;<br><br>**(2)** Monitoring and control of process parameters and component and device characteristics during production;<br><br>**(3)** Compliance with specified reference standards or codes;<br><br>**(4)** The approval of processes and process equipment; and<br><br>**(5)** Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.<br><br>**Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(a) 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><br>**(1)** Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production; |

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| | **(2)** Monitoring and control of process parameters and component and device characteristics during production;<br><br>**(3)** Compliance with specified reference standards or codes;<br><br>**(4)** The approval of processes and process equipment; and<br><br>**(5)** Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.<br><br>**(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.<br><br>**(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><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><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><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. |
| **7.5.2 Cleanliness of Product**<br><br>The organization shall document requirements for cleanliness of product or contamination control of product if:<br><br>**a)** product is cleaned by the organization prior to sterilization or its use;<br>**b)** product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use;<br><br>**c)** product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; | **Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(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. |

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| **d)** product is supplied to be used non-sterile, and its cleanliness is of significance in use;<br><br>**e)** process agents are to be removed from product during manufacture.<br><br>If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process. | **(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.<br><br>**(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. |
| **7.5.3 Installation Activities**<br><br>The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate.<br><br>If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation.<br><br>Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5). | **Subpart L--Handling, Storage, Distribution, and Installation**<br><br>**Sec. 820.170 Installation.**<br><br>**(a)** 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.<br><br>**(b)** 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. |
| **7.5.4 Servicing Activities**<br><br>If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met.<br><br>The organization shall analyze records of servicing activities carried out by the organization or its supplier:<br><br>**a)** to determine if the information is to be handled as a complaint;<br><br>**b)** as appropriate, for input to the improvement process.<br><br>Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5). | **Subpart N—Servicing**<br><br>**Sec. 820.200 Servicing.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with 820.100.<br><br>**(c)** 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.<br><br>**(d)** Service reports shall be documented and shall include:<br><br>**(1)** The name of the device serviced; |

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| | **(2)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br><br>**(3)** The date of service;<br><br>**(4)** The individual(s) servicing the device;<br><br>**(5)** The service performed; and<br><br>**(6)** The test and inspection data. |
| **7.5.5 Particular Requirements for Sterile Medical Devices**<br><br>The organization shall maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices. | 21 CFR Part 820 does not specifically address sterilization controls. |
| **7.5.6 Validation of Processes for Production and Service Provision**<br><br>The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.<br><br>Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes, including:<br><br>**a)** defined criteria for review and approval of the processes;<br><br>**b)** equipment qualification and qualification of personnel;<br><br>**c)** use of specific methods, procedures and acceptance criteria;<br><br>**d)** as appropriate, statistical techniques with rationale for sample sizes;<br><br>**e)** requirements for records (see **4.2.5**);<br><br>**f)** revalidation, including criteria for revalidation;<br><br>**g)** approval of changes to the processes.<br><br>The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and | **Subpart G—Production and Process Controls**<br><br>**Sec. 820.75 Process Validation**<br><br>**(a)** 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.<br><br>**(b)** 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><br>**(1)** Each manufacturer shall ensure that validated processes are performed by qualified individual(s).<br><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.<br><br>**(c)** When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.<br><br>**Subpart G—Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(a) General.** Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device |

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| activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.<br><br>Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5). | 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><br>**(1)** Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;<br><br>**(2)** Monitoring and control of process parameters and component and device characteristics during production;<br><br>**(3)** Compliance with specified reference standards or codes;<br><br>**(4)** The approval of processes and process equipment; and<br><br>**(5)** Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.<br><br>**(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.<br><br>**(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><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><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><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.<br><br>**(i) Automated Processes.** When computers or automated data processing systems are used as part of production or the |

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| | 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. |
| **7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems**<br><br>The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems.<br><br>Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate.<br><br>Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).<br><br>NOTE. Further information can be found in ISO 11607-1 and ISO 11607-2. | 21 CFR Part 820 does not specifically address sterilization controls. |
| **7.5.8 Identification**<br><br>The organization shall document procedures for product identification and identify product by suitable means throughout product realization.<br><br>The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used, or installed.<br><br>If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.<br><br>The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product. | **Subpart F--Identification and Traceability**<br><br>**Sec. 820.60 Identification.**<br><br>Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups.<br><br>**Subpart H—Acceptance Activities**<br><br>**Sec. 820.86 Acceptance Status.**<br><br>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.<br><br>**Subpart K--Labeling and Packaging Control**<br><br>**Sec. 820.120 Device Labeling.**<br><br>Each manufacturer shall establish and maintain procedures to control labeling activities.<br><br>**(a) Label Integrity.** Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of |

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| | processing, storage, handling, distribution, and where appropriate use.<br><br>**(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.<br><br>**(c) Labeling Storage.** Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mix-ups.<br><br>**(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.<br><br>**(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.<br><br>**Sec. 820.130 Device Packaging.**<br><br>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.<br><br>**Subpart L--Handling, Storage, Distribution, and Installation**<br><br>**Sec. 820.140 Handling.**<br><br>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.<br><br>**Sec. 820.150 Storage.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms. |

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| | **Sec. 820.160 Distribution.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall maintain distribution records which include or refer to the location of:<br><br>**(1)** The name and address of the initial consignee;<br><br>**(2)** The identification and quantity of devices shipped;<br><br>**(3)** The date shipped; and<br><br>**(4)** Any control number(s) used.<br><br>**Sec. 820.170 Installation.**<br><br>**(a)** 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.<br><br>**(b)** 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.<br><br>**Subpart M—Records**<br><br>**Sec. 820.184 Device History Record.**<br><br>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><br>**(a)** The dates of manufacture;<br><br>**(b)** The quantity manufactured; |

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| | **(c)** The quantity released for distribution;<br><br>**(d)** The acceptance records which demonstrate the device is manufactured in accordance with the DMR;<br><br>**(e)** The primary identification label and labeling used for each production unit; and<br><br>**(f)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.<br><br>**Subpart N--Servicing**<br><br>**Sec. 820.200 Servicing.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with 820.100.<br><br>**(c)** 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.<br><br>**(d)** Service reports shall be documented and shall include:<br><br>**(1)** The name of the device serviced;<br><br>**(2)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br><br>**(3)** The date of service;<br><br>**(4)** The individual(s) servicing the device;<br><br>**(5)** The service performed; and<br><br>**(6)** The test and inspection data. |
| **7.5.9 Traceability**<br><br>**7.5.9.1 General**<br><br>The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5). | **Subpart F--Identification and Traceability=**<br><br>**Sec. 820.65 Traceability**<br><br>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 |

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| | 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. |
| **7.5.9.2 Particular Requirements for Implantable Medical Devices**<br><br>The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.<br><br>The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection.<br><br>Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5). | 21 CFR Part 820 does not specifically address implantable Medical Devices<br><br>**Subpart H—Acceptance Activities**<br><br>**Sec. 820.80 Receiving, In-Process, and Finished Device Acceptance**<br><br>**(e) Acceptance Records.** Each manufacturer shall document acceptance activities required by this part. These records shall include:<br><br>**(1)** The acceptance activities performed;<br><br>**(2)** the dates acceptance activities are performed;<br><br>**(3)** the results;<br><br>**(4)** the signature of the individual(s) conducting the acceptance activities; and<br><br>**(5)** where appropriate the equipment used. These records shall be part of the DHR. |
| **7.5.10 Customer Property**<br><br>The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5). | 21 CFR Part 820 does not have an equivalent "Customer Property" provision. |
| **7.5.11 Preservation of Product**<br><br>The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device.<br><br>The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:<br><br>**a)** designing and constructing suitable packaging and shipping containers; | **Subpart K--Labeling and Packaging Control**<br><br>**Sec. 820.120 Device Labeling.**<br><br>Each manufacturer shall establish and maintain procedures to control labeling activities.<br><br>**(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.<br><br>**(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, |

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| b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.<br><br>If special conditions are required, they shall be controlled and recorded (see 4.2.5). | 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.<br><br>**(c) Labeling Storage.** Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mix-ups.<br><br>**(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.<br><br>**(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.<br><br>**Sec. 820.130 Device Packaging.**<br><br>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.<br><br>**Subpart L—Handling, Storage, Distribution, and Installation**<br><br>**Sec. 820.140 Handling.**<br><br>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.<br><br>**Sec. 820.150 Storage.**<br><br>**(a)** 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.<br><br>**(b)** Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.<br><br>**Sec. 820.160 Distribution.**<br><br>**(a)** 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 |

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| | deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.<br><br>**(b)** Each manufacturer shall maintain distribution records which include or refer to the location of:<br><br>**(1)** The name and address of the initial consignee;<br><br>**(2)** The identification and quantity of devices shipped;<br><br>**(3)** The date shipped; and<br><br>**(4)** Any control number(s) used.<br><br>**Sec. 820.170 Installation.**<br><br>**(a)** 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.<br><br>**(b)** 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.<br><br>**Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(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. |
| **7.6 Control of Monitoring and Measuring Equipment**<br><br>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.<br><br>The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. | **Subpart G--Production and Process Controls**<br><br>**Sec. 820.72 Inspection, Measuring, and Test Equipment.**<br><br>**(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, |

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| As necessary to ensure valid results, measuring equipment shall:<br><br>**a)** be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5);<br><br>**b)** be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5);<br><br>**c)** have identification in order to determine its calibration status;<br><br>**d)** be safeguarded from adjustments that would invalidate the measurement result;<br><br>**e)** be protected from damage and deterioration during handling, maintenance and storage.<br><br>The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected.<br><br>Records of the results of calibration and verification shall be maintained (see 4.2.5).<br><br>The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.<br><br>The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).<br><br>NOTE. Further information can be found in ISO 10012. | 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.<br><br>**(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><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><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. |
| **8 Measurement, Analysis, and Improvement**<br><br>**8.1 General** | **Subpart O--Statistical Techniques**<br><br>**Sec. 820.250 Statistical Techniques.**<br><br>**(a)** Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques |

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| The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed to:<br><br>**a)** demonstrate conformity of product;<br><br>**b)** ensure conformity of the quality management system;<br><br>**c)** maintain the effectiveness of the quality management system.<br><br>This shall include determination of appropriate methods, including statistical techniques, and the extent of their use. | required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.<br><br>**(b)** 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. |
| **8.2 Monitoring and measurement**<br><br>**8.2.1 Feedback**<br><br>As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented.<br><br>The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities.<br><br>The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.<br><br>If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process. | **Subpart M – Records**<br><br>**Sec. 820.198 Complaint Files.**<br><br>**(a)** 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><br>**(1)** All complaints are processed in a uniform and timely manner;<br><br>**(2)** Oral complaints are documented upon receipt; and<br><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.<br><br>**(b)** 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.<br><br>**(c)** 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.<br><br>**(d)** 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><br>**(1)** Whether the device failed to meet specifications; |

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| | **(2)** Whether the device was being used for treatment or diagnosis; and<br><br>**(3)** The relationship, if any, of the device to the reported incident or adverse event.<br><br>**(e)** 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><br>**(1)** The name of the device;<br><br>**(2)** The date the complaint was received;<br><br>**(3)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br><br>**(4)** The name, address, and phone number of the complainant;<br><br>**(5)** The nature and details of the complaint;<br><br>**(6)** The dates and results of the investigation;<br><br>**(7)** Any corrective action taken; and<br><br>**(8)** Any reply to the complainant.<br><br>**(f)** 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.<br><br>**(g)** 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><br>**(1)** A location in the United States where the manufacturer's records are regularly kept; or<br><br>**(2)** The location of the initial distributor. |
| **8.2.2 Complaint Handling**<br><br>The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.<br><br>These procedures shall include at a minimum requirements and responsibilities for:<br><br>**a)** receiving and recording information; | **Subpart M – Records**<br><br>**Sec. 820.198 Complaint Files.**<br><br>**(a)** 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><br>**(1)** All complaints are processed in a uniform and timely manner; |

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| **b)** evaluating information to determine if the feedback constitutes a complaint;<br><br>**c)** investigating complaints;<br><br>**d)** determining the need to report the information to the appropriate regulatory authorities;<br><br>**e)** handling of complaint-related product;<br><br>**f)** determining the need to initiate corrections or corrective actions.<br><br>If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.<br><br>If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved. Complaint handling records shall be maintained (see 4.2.5). | **(2)** Oral complaints are documented upon receipt; and<br><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.<br><br>**(b)** 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.<br><br>**(c)** 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.<br><br>**(d)** 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><br>**(1)** Whether the device failed to meet specifications;<br><br>**(2)** Whether the device was being used for treatment or diagnosis; and<br><br>**(3)** The relationship, if any, of the device to the reported incident or adverse event.<br><br>**(e)** 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><br>**(1)** The name of the device;<br><br>**(2)** The date the complaint was received;<br><br>**(3)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br><br>**(4)** The name, address, and phone number of the complainant;<br><br>**(5)** The nature and details of the complaint;<br><br>**(6)** The dates and results of the investigation; |

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| | **(7)** Any corrective action taken; and<br><br>**(8)** Any reply to the complainant.<br><br>**(f)** 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.<br><br>**(g)** 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><br>**(1)** A location in the United States where the manufacturer's records are regularly kept; or<br><br>**(2)** The location of the initial distributor. |
| **8.2.3 Reporting to Regulatory Authorities**<br><br>If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities.<br><br>Records of reporting to regulatory authorities shall be maintained (see 4.2.5). | **Subpart M – Records**<br><br>**Sec. 820.198 Complaint Files.**<br><br>**(a)** 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><br>**(1)** All complaints are processed in a uniform and timely manner;<br><br>**(2)** Oral complaints are documented upon receipt; and<br><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.<br><br>**(b)** 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.<br><br>**(c)** 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.<br><br>**(d)** 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 |

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| | 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><br>**(1)** Whether the device failed to meet specifications;<br><br>**(2)** Whether the device was being used for treatment or diagnosis; and<br><br>**(3)** The relationship, if any, of the device to the reported incident or adverse event.<br><br>**(e)** 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><br>**(1)** The name of the device;<br><br>**(2)** The date the complaint was received;<br><br>**(3)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br><br>**(4)** The name, address, and phone number of the complainant;<br><br>**(5)** The nature and details of the complaint;<br><br>**(6)** The dates and results of the investigation;<br><br>**(7)** Any corrective action taken; and<br><br>**(8)** Any reply to the complainant.<br><br>**(f)** 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.<br><br>**(g)** 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><br>**(1)** A location in the United States where the manufacturer's records are regularly kept; or<br><br>**(2)** The location of the initial distributor. |
| **8.2.4 Internal Audit**<br><br>The organization shall conduct internal audits at planned intervals to determine whether the quality management system: | **Subpart B--Quality System Requirements**<br><br>**Sec. 820.22 Quality Audit.**<br><br>Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in |

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| **a)** conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;<br><br>**b)** is effectively implemented and maintained.<br><br>The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.<br><br>An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.<br><br>Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5).<br><br>The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.<br><br>NOTE. Further information can be found in ISO 19011. | 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. |
| **8.2.5 Monitoring and Measurement of Processes**<br><br>The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. | **Subpart G--Production and Process Controls**<br><br>**Sec. 820.70 Production and Process Controls.**<br><br>**(a) 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><br>**(1)** Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;<br><br>**(2)** Monitoring and control of process parameters and component and device characteristics during production;<br><br>**(3)** Compliance with specified reference standards or codes;<br><br>**(4)** The approval of processes and process equipment; and |

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| | **(5)** Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.<br><br>**Subpart O--Statistical Techniques**<br><br>**Sec. 820.250 Statistical Techniques.**<br><br>**(a)** 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.<br><br>**(b)** 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. |
| **8.2.6 Monitoring and Measurement of Product**<br><br>The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.<br><br>Evidence of conformity to the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see **4.2.5**). As appropriate, records shall identify the test equipment used to perform measurement activities.<br><br>Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed.<br><br>For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing. | **Subpart H--Acceptance Activities**<br><br>**Sec. 820.80 Receiving, In-Process, and Finished Device Acceptance.**<br><br>**(a) General.** Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.<br><br>**(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.<br><br>**(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.<br><br>**(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><br>**(1)** The activities required in the DMR are completed;<br><br>**(2)** the associated data and documentation is reviewed;<br><br>**(3)** the release is authorized by the signature of a designated individual(s); and |

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| | **(4)** the authorization is dated.<br><br>**(e) Acceptance Records.** Each manufacturer shall document acceptance activities required by this part. These records shall include:<br><br>**(1)** The acceptance activities performed;<br><br>**(2)** the dates acceptance activities are performed;<br><br>**(3)** the results;<br><br>**(4)** the signature of the individual(s) conducting the acceptance activities; and<br><br>**(5)** where appropriate the equipment used. These records shall be part of the DHR. |
| **8.3 Control of Nonconforming Product**<br><br>**8.3.1 General**<br><br>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product.<br><br>The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.<br><br>Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation, and the rationale for decisions shall be maintained (see 4.2.5). | **Subpart I--Nonconforming Product**<br><br>**Sec. 820.90 Nonconforming Product.**<br><br>**(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.<br><br>**(b) Nonconformity Review and Disposition.**<br><br>**(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><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><br>The organization shall deal with nonconforming product by one or more of the following ways: | **Subpart I--Nonconforming Product**<br><br>**Sec. 820.90 Nonconforming Product.** |

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| a) taking action to eliminate the detected nonconformity;<br><br>b) taking action to preclude its original intended use or application;<br><br>c) authorizing its use, release or acceptance under concession.<br><br>The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5). | **(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.<br><br>**(b) Nonconformity Review and Disposition.**<br><br>**(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><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. |
| **8.3.3 Actions in Response to Nonconforming Product detected after Delivery**<br><br>When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.5).<br><br>The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5). | **Subpart I--Nonconforming Product**<br><br>**Sec. 820.90 Nonconforming Product.**<br><br>**(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.<br><br>**(b) Nonconformity Review and Disposition.**<br><br>**(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><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 |

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| | 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. |
| **8.3.4 Rework**<br><br>The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure.<br><br>After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.<br><br>Records of rework shall be maintained (see 4.2.5). | **Subpart I--Nonconforming Product**<br><br>**Sec. 820.90 Nonconforming Product.**<br><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. |
| **8.4 Analysis of Data**<br><br>The organization shall document procedures to determine, collect, and analyze appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use.<br><br>The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:<br><br>**a)** feedback;<br><br>**b)** conformity to product requirements;<br><br>**c)** characteristics and trends of processes and product, including opportunities for improvement;<br><br>**d)** suppliers;<br><br>**e)** audits;<br><br>**f)** service reports, as appropriate.<br><br>If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5.<br><br>Records of the results of analyses shall be maintained (see 4.2.5). | **Subpart O--Statistical Techniques**<br><br>**Sec. 820.250 Statistical Techniques**<br><br>**(a)** 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.<br><br>**(b)** 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. |

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| **8.5 Improvement**<br><br>**8.5.1 General**<br><br>The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions, and management review. | **Subpart B – Quality System Requirements**<br><br>**Sec. 820.20 Management Responsibility.**<br><br>**(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.<br><br>**Subpart B – Quality System Requirements**<br><br>**Sec. 820.22 Quality Audit.**<br><br>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.<br><br>**Subpart M – Records**<br><br>**Sec. 820.198 Complaint Files.**<br><br>**(a)** 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><br>**(1)** All complaints are processed in a uniform and timely manner;<br><br>**(2)** Oral complaints are documented upon receipt; and<br><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.<br><br>**(b)** 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. |

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| | **(c)** 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.<br><br>**(d)** 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><br>**(1)** Whether the device failed to meet specifications;<br><br>**(2)** Whether the device was being used for treatment or diagnosis; and<br><br>**(3)** The relationship, if any, of the device to the reported incident or adverse event.<br><br>**(e)** 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><br>**(1)** The name of the device;<br><br>**(2)** The date the complaint was received;<br><br>**(3)** Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;<br><br>**(4)** The name, address, and phone number of the complainant;<br><br>**(5)** The nature and details of the complaint;<br><br>**(6)** The dates and results of the investigation;<br><br>**(7)** Any corrective action taken; and<br><br>**(8)** Any reply to the complainant.<br><br>**(f)** 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.<br><br>**(g)** 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: |

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| | **(1)** A location in the United States where the manufacturer's records are regularly kept; or<br><br>**(2)** The location of the initial distributor.<br><br>**Subpart J--Corrective and Preventive Action**<br><br>**Sec. 820.100 Corrective and Preventive Action.**<br><br>**(a)** Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:<br><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><br>**(2)** Investigating the cause of nonconformities relating to product, processes, and the quality system;<br><br>**(3)** Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;<br><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><br>**(5)** Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;<br><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><br>**(7)** Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.<br><br>**(b)** All activities required under this section, and their results, shall be documented. |
| **8.5.2 Corrective Action**<br><br>The organization shall take action to eliminate the cause of nonconformities in order to prevent<br>recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. | **Subpart J--Corrective and Preventive Action**<br><br>**Sec. 820.100 Corrective and Preventive Action**.<br><br>**(a)** Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: |

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| The organization shall document a procedure to define requirements for:<br><br>**a)** reviewing nonconformities (including complaints);<br><br>**b)** determining the causes of nonconformities;<br><br>**c)** evaluating the need for action to ensure that nonconformities do not recur;<br><br>**d)** planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;<br><br>**e)** verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;<br><br>**f)** reviewing the effectiveness of corrective action taken.<br><br>Records of the results of any investigation and of action taken shall be maintained (see 4.2.5). | **(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><br>**(2)** Investigating the cause of nonconformities relating to product, processes, and the quality system;<br><br>**(3)** Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;<br><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><br>**(5)** Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;<br><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><br>**(7)** Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.<br><br>**(b)** All activities required under this section, and their results, shall be documented. |
| **8.5.3 Preventive Action**<br><br>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. The organization shall document a procedure to describe requirements for:<br><br>**a)** determining potential nonconformities and their causes;<br>**b)** evaluating the need for action to prevent occurrence of nonconformities;<br><br>**c)** planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;<br><br>**d)** verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; | **Subpart J--Corrective and Preventive Action**<br><br>**Sec. 820.100 Corrective and Preventive Action.**<br><br>**(a)** Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:<br><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><br>**(2)** Investigating the cause of nonconformities relating to product, processes, and the quality system;<br><br>**(3)** Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; |

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| **e)** reviewing the effectiveness of the preventive action taken, as appropriate.<br><br>Records of the results of any investigations and of action taken shall be maintained (see 4.2.5). | **(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><br>**(5)** Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;<br><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><br>**(7)** Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.<br><br>**(b)** All activities required under this section, and their results, shall be documented. |