ISO – 13485 (2003)	FDA QSR 21 CFR 820
Introduction **0.1 General** This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation, and servicing of medical devices, and the design, development, and provision of related services. It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement. It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products. The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed, and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation. There is a wide variety of medical devices, and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.	**Subpart A** **General Provisions** Note the ISO focus on enhancement of Customer Requirements, a Process Approach to the development of a Quality Management system, and Data Analysis as an input into Improvement/Maintenance System.

0.2 Process approach This International Standard is based on a process approach to quality management. Any activity that receives inputs and converts them to outputs can be considered as a process. For an organization to function effectively, it has to identify and manage numerous linked processes. Often the output from one process directly forms the input to the next. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach."	

0.3 Relationship with other standards **0.3.1 Relationship with ISO 9001** While this is a stand-alone standard, it is based on ISO 9001. Those clauses or subclauses that are quoted directly and unchanged from ISO 9001 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B (of the standard). Where the text of this International Standard is not identical to the text of ISO 9001, the sentence or indent containing that text as a whole is shown in italics (in blue italics for electronic versions). The nature and reasons for the text changes are noted in Annex B (of the standard). Font differences are not maintained in this matrix.	NOTE: QSR was harmonized to ISO 9001:1994 and is similar to ISO 13485:1996.
0.3.2 Relationship with ISO/TR 14969 ISO/TR 14969 is a Technical Report intended to provide guidance for the implementation of ISO 13485.	

0.4 Compatibility with other management systems This International Standard follows the format of ISO 9001 for the convenience of users in the medical device community. This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.	

ISO – 13485 (2003)	FDA QSR 21 CFR 820
1 Scope **1.1 General** This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001 (see Annex B).	

ISO – 13485 (2003)	FDA QSR 21 CFR 820
1 Scope **1.2 Application** All requirements of this International Standard are specific to organizations providing medical devices, regardless of the type or size of the organization. If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls [see 4.2.2 a) and 7.3]. If any requirement(s) in Clause 7 of this International Standard is (are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system [see 4.2.2 a)]. The processes required by this International Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system [see 4.1 a)]. In this International Standard, the terms "if appropriate" and "where appropriate" are used several times. When a requirement is qualified by either of these phrases, it is deemed to be "appropriate" unless the organization can document a justification otherwise. A requirement is considered "appropriate" if it is necessary in order for — the product to meet specified requirements, and/or — the organization to carry out corrective action.	**Sec. 820.1** **Scope** (a) Applicability. (1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in Sec. 820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter. (2) The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

	(3) In this regulation the term "where appropriate" is used several times. When a requirement is qualified by "where appropriate", it is deemed to be "appropriate" unless the manufacturer can document justification otherwise. A requirement is "appropriate" if non-implementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action. (b) Limitations The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event that it is impossible to comply with all applicable regulations, both in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.

2 Normative references The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2000*, Quality management systems—Fundamentals and vocabulary*	(c) Authority. Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action. (d) Foreign manufacturers If a manufacturer who offers devices for import into the United States refuses to permit or allow the completion of a Food and Drug Administration (FDA) inspection of the foreign facility for the purpose of determining compliance with this part, it shall appear for purposes of section 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act. (e) Exemptions or variances (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in Sec. 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological

	Health, Division of small Manufacturers Assistance, (HFZ-220), 1350 Piccard Drive, Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 1-301-443-6597, FAX 1-301-443-8818. (2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

3 Terms and definitions For the purposes of this *document*, the terms and definitions given in ISO 9000 apply, *together with the following*. The following terms, used in this edition of *ISO 13485* to describe the supply chain, have been changed to reflect the vocabulary currently used: supplier---------->organization---------->customer The term "organization" replaces the term "supplier" used in ISO 13485:1996, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor." Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service." Wherever requirements are specified as applying to "medical devices," the requirements apply equally to related services as supplied by the organization. The following definitions should be regarded as generic, as definitions provided in national regulations can differ slightly and take precedence.	**Sec. 820 3.3** Definitions. (a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (sects. 201-903, 52 Stat, 1040 et seq., as amended (21 U.S.C. 321-394)).
3.1 Active implantable medical device: active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.	All definitions in section 201 of the act shall apply to the regulations in this part.
3.2 Active medical device: medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.	

3.3 Advisory notice: notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in — the use of a medical device, — the modification of a medical device, — the return of the medical device to the organization that supplied it, or — the destruction of a medical device. NOTE—Issue of an advisory notice might be required to comply with national or regional regulations.	
3.4 Customer complaint: written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, or performance of a medical device that has been placed on the market.	(b) *Complaint* means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.
3.5 Implantable medical device: medical device intended — to be totally or partially introduced into the human body or a natural orifice, or — to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention. NOTE—This definition applies to implantable medical devices other than active implantable medical devices.	
3.6 Labeling: written, printed, or graphic matter — affixed to a medical device or any of its containers or wrappers, or — accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents. NOTE—Some regional and national regulations refer to “labeling” as	

"information supplied by the manufacturer."	
3.7 Medical device: any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of — diagnosis, prevention, monitoring, treatment, or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of, or compensation for an injury, — investigation, replacement, modification, or support of the anatomy or of a physiological process, — supporting or sustaining life, — control of conception, — disinfection of medical devices, — providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means. NOTE—This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [15].	(l) *Finished device* means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.
3.8 Sterile medical device: category of medical device intended to meet the requirements for sterility. NOTE—The requirements for sterility of a medical device might be subject to national or regional regulations or standards.	
	(c) *Component* means any raw material, substance, piece, part, software, firmware, labeling or assembly which is intended to be included as part of the finished, packaged, and labeled device.

	(d) *Control number* means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.
	(e) *Design history file (DHF)* means a compilation of records which describes the design history of a finished device.
	(f) *Design input* means the physical and performance requirements of a device that are used as a basis for device design.
	(g) *Design output* means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.
	(h) *Design review* means a documented comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.
	(i) *Device history record (DHR)* means a compilation of records containing the production history of a finished device.
	(j) *Device master record (DMR)* means a compilation of records containing the procedures and specifications for a finished device.
	(k) *Establish* means define, document (in writing or electronically), and implement.
	(m) *Lot* or *batch* means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.
	(n) *Management with executive responsibility* means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.
	(o) *Manufacturer* means any person who designs, manufacturers, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing,

	repacking, or specification development, and initial distributors of foreign entities performing these functions.
	(p) *Manufacturing material* means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.
	(q) *Nonconformity* means the non-fulfillment of a specified requirement.
	(r) *Product* means components, manufacturing materials, in-process devices, and returned devices.
	(s) *Quality* means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.
	(t) *Quality audit* means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.
	(u) *Quality policy* means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.
	(v) *Quality system* means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
	(w) *Remanufacturer* means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.
	(x) *Rework* means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.
	(y) *Specification* means any requirement with which a product, process, service, or other activity must conform.

	(z) *Validation* means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
	(1) *Process validation* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.
	(2) *Design validation* means establishing by objective evidence that device specifications conform with user needs and intended use(s).
	(aa) *Verification* means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
4 Quality Management System **4.1 General Requirements** The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyze these processes, and f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system (see 8.5.1). NOTE: Processes needed for the quality management system referred to above should include processes for management activities, provision of	**Subpart A – General Provisions** **Section 820.5 Quality System** Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

resources, product realization and measurement.	

ISO – 13485 (2003)	FDA QSR 21 CFR 820
4 Quality Management System **4.2 Documentation Requirements** **4.2.1 General** The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, e) records required by this International Standard (see 4.2.4), and f) any other documentation specified by national or regional regulations. Where this International Standard specifies that a requirement, procedure, activity, or special arrangement be "documented", it shall, in addition, be implemented and maintained. For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing.	**Sec. 820.40.Subpart B – Quality System Requirements** **Section 820.20 Management Responsibility** (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. **Subpart M – Records** **Section.820.181 Device Master Record** Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with Sec.820.40. The DMR for each type of device shall include, or refer to the location of, the following information: (a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications; (b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications; (c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used; (d) Packaging and labeling specifications, including methods and processes used; and (e) Installation, maintenance, and servicing procedures, and methods.

NOTE 1 – The extent of the quality management system documentation can differ from one organization to another due to a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. NOTE 2 – The documentation can be in any form or type of medium.	
4 Quality Management System **4.2 Documentation Requirements** **4.2.2 Quality Manual** The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions and/or non-application (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	**Subpart M – Records** **Section 820.186 Quality System Record** Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by Sec. 820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with Sec. 820.40/

ISO – 13485 (2003)	FDA QSR 21 CFR 820
4 Quality Management System **4.2 Documentation Requirements** **4.2.3 Control of Documents** Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed a) to review and approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or by another designated function that has access to pertinent background information upon which to base its decisions.	**Subpart D- Document Controls** **Section 820.40 Document Controls** Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following: (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 obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use. (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.

The organization shall define the period for which at least one copy of obsolete controlled 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 4.2.4), or as specified by relevant regulatory requirements.	

ISO – 13485 (2003)	FDA QSR 21 CFR 820
4 Quality Management System **4.2 Documentation Requirements** **4.2.4 Control of Records** Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.	**Subpart M – Records** **Section. 820.180 General Requirements** All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up. (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. **Section. 820.184 Device History Record** Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information: (a) The dates of manufacture; (b) The quantity manufactured; (c) The quantity released for distribution; (d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR; (e) The primary identification label and labeling used for each production unit; and (f) Any device identification(s) and control number(s) used.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
No ISO Equivalent	**Subpart M – Records** **Section. 820.180 General Requirements** (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 or this chapter. (c) *Exceptions.* This section does not apply to the reports required by Sec. 820.20(c) Management review, Sec.820.22 Quality audits, and supplier audit reports used to meet the requirements of Sec.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.

5 Management Responsibility **5.1 Management Commitment** Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. NOTE – For the purpose of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.	**No QSR Equivalent**
5.2 Customer Focus Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1).	**No QSR Equivalent**

5 Management Responsibilities **5.3 Quality Policy** Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	**Subpart B – Quality System Requirements** **820.20 Management Responsibility** (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 **5.4.1 Quality Objectives** Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1a], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	**No QSR Equivalent**

5.4 Planning **5.4.2 Quality Management System Planning** Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	**No QSR Equivalent**
5 Management Responsibilities **5.5 Responsibility, Authority, and Communication** **5.5.1 Responsibility and Authority** Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. Top management shall establish 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. NOTE – National or regional regulations might require the nomination of specific persons responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).	**Subpart B – Quality System Requirements** **Section.820.20 Management Responsibility** (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. (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
5.5 Responsibility, Authority, and Communication **5.5.2 Management Representative** Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of regulatory and customer requirements throughout the organization. NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	**Subpart B – Quality System Requirements** **820.20 Management Responsibility** (b) *Organization.* (3) *Management representative.* Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for: (i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and (ii) Reporting on the performance of the quality system to management with executive responsibility for review.
5 Management Responsibilities **5.5 Responsibility, Authority, and Communication** **5.5.3 Internal Communication** 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.	**No QSR Equivalent**

ISO – 13485 (2003)	FDA QSR 21 CFR 820
5.6 Management Review **5.6.1 General** Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).	**Subpart B – Quality System Requirements** **Section 820.20 Management Responsibility** (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 Management Responsibilities **5.6 Management Review** **5.6.2 Review input** The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, g) recommendations for improvement, and h) new or revised regulatory requirements.	**No QSR Equivalent**

5.6 Management Review **5.6.3 Review Output** The output from the management review shall include any decisions and actions related to a) improvements needed to maintain the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	**No QSR Equivalent**

ISO – 13485 (2003)	FDA QSR 21 CFR 820
6 Resource Management **6.1 Provision of Resources** The organization shall determine and provide the resources needed a) to implement the quality management system and to maintain its effectiveness, and b) to meet regulatory and customer requirements.	**Subpart B – Quality System Requirements** **Section 820.20 Management Responsibility** (b) *Organization.* (2) *Resources.* Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.
6 Resource Management **6.2 Human Resources** **6.2.1 General** Personnel performing work affecting product quality should be competent on the basis of appropriate education, training, skills, and experience.	**Subpart B – Quality System Requirements** **Section.820.25 Personnel** (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
6 Resource Management **6.2 Human Resources** **6.2.2 Competence, Awareness, and Training** The organization shall a) determine the necessary competence for personnel performing work affecting product quality b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills, and experience (see 4.2.4). NOTE – National or regional regulations might require the organization to establish documented procedures for identifying training needs.	**Subpart B – Quality System Requirements** **Section 820.25 Personnel** (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. (1) As part of their training, personnel shall be made aware of device defects that may occur from the improper performance of their specific jobs. (2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
6 Resource Management **6.3 Infrastructure** The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication). The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained (see 4.2.4).	**Subpart G – Production and Process Controls** **Section 820.70 Production and Process Controls** (f) *Buildings.* Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling. (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. (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. (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. (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
6 Resource Management **6.4 Work Environment** The organization shall determine and manage the work environment needed to achieve conformity to product requirements. The following requirements apply. a) The organization shall establish documented requirements for health, cleanliness, and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1). b) If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1). c) The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)]. d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment, or personnel (see 7.5.3.1).	**Subpart G – Production and Process Controls** **Section 820.70 Production and Process Controls** (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. (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.1 Planning of Product Realization** 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 (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations. The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.4). NOTE 1 - A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.	**Subpart B – Quality System Requirements** **Section.820.20 Management Responsibility** (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820

NOTE 2 - The organization may also apply the requirements given in 7.3 to the development of product realization processes. NOTE 3 – See ISO 14971 for guidance related to risk management	
7 Product Realization **7.2 Customer-related Processes** **7.2.1 Determination of requirements related to the product** The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.2 Customer-related Processes** **7.2.2 Review of requirements Related to the Product** The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a 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 a) product requirements are defined and documented, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	**Subpart L – Handling, Storage, Distribution, and Installation** **Section.820.160 Distribution** (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. (b) Each manufacturer shall maintain distribution records which include or refer to the location of: (1) The name and address of the initial consignee; (2) The identification and quantity of devices shipped; (3) The date shipped; and (4) Any control number(s) used.

7 Product Realization **7.2 Customer-related Processes** **7.2.3 Customer Communication** The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, c) customer feedback, including customer complaints, and d) advisory notices (see 8.5.1).	**No QSR Equivalent**

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.3 Design and Development** **7.3.1 Design and Development Planning** The organization shall establish documented procedures for design and development. The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be documented and updated, as appropriate, as the design and development progresses (see 4.2.3). NOTE – Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.	**Subpart C – Design Controls** **Section.820.30 Design Controls** (a) *General.* (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. (2) The following class I devices are subject to design controls: (i) Devices automated with computer software; and (ii) The devices listed in the following chart. **Section** | **Device** 868.6810 | Catheter, Tracheobronchial Suction 878.4460 | Glove, Surgeon's 880.6760 | Restraint, Protective 892.5650 | System, Applicator, Radionuclide, Manual 892.5740 | Source, Radionuclide Teletherapy (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.3 Customer-related Processes** **7.3.2 Design and Development Inputs** Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional, performance, and safety requirements, according to the intended use, b) applicable statutory and regulatory requirements, c) where applicable, information derived form previous similar designs, d) other requirements essential for design and development, and e) output(s) of risk management (see 7.1). These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous and not in conflict with each other.	**Subpart C – Design Controls** **Section.820.30 Design Controls** (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.3 Customer-related Processes** **7.3.3 Design and Development Outputs** The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production, and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use. Records of the design and development outputs shall be maintained (see 4.2.4). NOTE – Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.	**Subpart C – Design Controls** **Section.820.30 Design Controls** (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.3 Customer-related Processes** **7.3.4 Design and Development Review** At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel (see 5.5.1 and 6.2.1). Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	**Subpart C – Design Controls** **Section.820.30 Design Controls** (e) *Design reviews.* 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 Product Realization **7.3 Customer-related Processes** **7.3.5 Design and Development Verification** Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).	**Subpart C – Design Controls** **Section 820.30 Design Controls** (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 Product Realization **7.3 Customer-related Processes** **7.3.6 Design and Development Validation** Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4). As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations (see NOTE 2). NOTE 1 – If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer. NOTE 2 – Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.	**Subpart C – Design Controls** **Section 820.30 Design Controls** (g) *Design Validation.* Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.
No ISO Equivalent	**Subpart C – Design Controls** **Section.820.30 Design Controls** (h) *Design Transfer.* Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.3 Customer-related Processes** **7.3.7 Control of Design and Development Changes** Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	**Subpart C – Design Controls** **Section 820.30 Design Controls** (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.
No ISO Equivalent	**Subpart C – Design Controls** **Section.820.30 Design Controls** (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 approval design plan and the requirements of this part.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.4 Purchasing** **7.4.1 Purchasing Process** The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	**Subpart E – Purchasing Controls** **Section 820.50 Purchasing Controls** Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements. (a) *Evaluation of suppliers, contractors, and consultants.* Each manufacturer shall establish and maintain the requirements, including quality requirements that must be met by suppliers, contractors, and consultants. Each manufacturer shall: (1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented. (2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors and consultants, based on the evaluation results. (3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.4 Purchasing** **7.4.2 Purchasing Information** Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information – i.e. documents (see 4.2.3) and records (see 4.2.4).	**Subpart E – Purchasing Controls** **Section 820.50 Purchasing Controls** (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 Section 820.40.
7 Product Realization **7.4 Purchasing** **7.4.3 Verification of Purchased Product** The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.4).	**Subpart H – Acceptance Activities** **Section.820.80 Receiving, in-process, and finished device acceptance** (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.5 Production and Service Provision** **7.5.1 Control of Production and Service Provision** **7.5.1.1 General Requirements** The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, f) the implementation of release, delivery and post-delivery activities, and g) the implementation of defined operations for labeling and packaging. The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved. NOTE – A batch can be a single medical device.	**Subpart G – Production and Process Controls** **Section.820.70 Production and Process Controls** (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: (1)Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production; (2)Monitoring and control of process parameters and component and device characteristics during production; (3)Compliance with specified reference standards or codes; (4)The approval of processes and process equipment; and (5)Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples. **Subpart G – Production and Process Controls** **Section.820.70 Production and Process Controls** (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 Sec.820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with Sec.820.40.

7.5.1.2 Control of production and service provision – Specific Requirements **7.5.1.2.1 Cleanliness of product and contamination control** The organization shall establish documented requirements for cleanliness of product if a) product is cleaned by the organization prior to sterilization and/or its use, or b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or c) product is supplied to be used non-sterile and its cleanliness is of significance in use, or d) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process.	**Subpart G – Production and Process Controls** **Section.820.70 Production and Process Controls** (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. (h) *Manufacturing Material.* Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.
7.5.1.2.2 Installation activities If appropriate, the organization shall establish documented requirements, which contain acceptance criteria for installing and verifying the installation of the medical device. If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, the organization shall provide documented requirements for installation and verification. Records of installation and verification performed by the organization or its authorized agent shall be maintained (see 4.2.4).	**Section 820.170 Installation** (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. (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.

7.5.1.2.3 Servicing activities If servicing is a specified requirement, the organization shall establish documented procedures, work instructions, and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements. Records of servicing activities carried out by the organization shall be maintained (see 4.2.4). NOTE—Servicing can include, for example, repair and maintenance.	**Subpart N – Servicing** **Section.820.200 Servicing** (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. (b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with Sec.820.100. (c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 or 804 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of Sec.820.198. (d) Service reports shall be documented and shall include: (1) The name of the device serviced; (2) Any device identification(s) and control number(s) used; (3) The date of service; (4) The individual(s) servicing the device; (5) The service performed; and (6) The test and inspection data
7.5.1.3 Particular requirements for sterile medical devices The organization shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch (see 4.2.4). Sterilization records shall be traceable to each production batch of medical devices (see 7.5.1.1).	

ISO – 13485 (2003)	FDA QSR 21 CFR 820
No ISO Equivalent	**Subpart G – Production and Process Controls** **Section.820.70 Production and Process Controls** (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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.5 Production and Service Provision** **7.5.2 Validation of Processes for Production and Service Provision** **7.5.2.1 General Requirements** The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use. Records of validation shall be recorded (see 4.2.4)	**Subpart G – Production and Process Controls** **Section.820.75 Process Validation** (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. (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. (1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s). (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. (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.

7.5.2.2 Particular requirements for sterile medical devices The organization shall establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use. Records of validation each sterilization process shall be maintained (see 4.2.4).	
7 Product Realization **7.5 Production and Service Provision** **7.5.3 Identification and Traceability** **7.5.3.1 Identification** The organization shall identify the product by suitable means throughout product realization and shall establish documented procedures for such product identification. The organization shall establish documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product [see 6.4 d)].	**Subpart F – Identification and Traceability** **Section 820.60 Identification** Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups.
7.5.3.2 Traceability **7.5.3.2.1 General** The organization shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3, and 8.5). Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4). NOTE—Configuration management is a means by which identification and traceability can be maintained.	**Subpart F – Identification and Traceability** **Section 820.65 Traceability** Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices In defining the records required for traceability, the organization shall include records of all components, materials, and work environment conditions, if these could cause the medical device not to satisfy its specified requirements. The organization shall require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4).	
7.5.3.3 Status identification The organization shall identify the product status with respect to monitoring and measurement requirements. The identification of product status shall be maintained throughout production, storage, installation, and servicing of the 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.	**Subpart H – Acceptance Activities** **Section 820.86 Acceptance Status** Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

7 Product Realization **7.5 Production and Service Provision** **7.5.4 Customer Property** The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4). NOTE - Customer property can include intellectual property or confidential health information.	**No QSR Equivalent**
7 Product Realization **7.5 Production and Service Provision** **7.5.5 Preservation of Product** The organization shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of a product. The organization shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded (see 4.2.4).	**Subpart L – Handling, Storage, Distribution, and Installation** **Section 820.140 Handling** Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do no occur during handling. **Section 820.150 Storage** (a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, 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. (b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

	Subpart L – Handling, Storage, Distribution, and Installation **Section 820.160 Distribution** (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. (b) Each manufacturer shall maintain distribution records which include or refer to the location of: (1) The name and address of the initial consignee; (2) The identification and quantity of devices shipped; (3) The date shipped; and (4) Any control number(s) used.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
No ISO Equivalent	**Subpart K – Labeling and Packaging Control** **Section 820.120 Device Labeling** Each manufacturer shall establish and maintain procedures to control labeling activities. (a) *Labeling 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. (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 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. (c) *Labeling Storage.* Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mixups. (d) *Labeling Operations.* Each manufacturer shall control labeling and packaging operations to prevent labeling mixups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR. (e) *Control Number.* Where a control number is required by Sec.820.65, that control number shall be on or shall accompany the device through distribution. **Section 820.130 Device Packaging** Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution

ISO – 13485 (2003)	FDA QSR 21 CFR 820
7 Product Realization **7.6 Control of Monitoring and Measuring Devices** The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1). The organization shall establish documented 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. Where necessary to ensure valid results, measuring equipment shall a) Be calibrated or verified at specified intervals, or prior use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded b) Be adjusted or re-adjusted as necessary; c) Be identified to enable the calibration status to be determined; d) Be safeguarded from adjustments that would invalidate the measurement result; e) Be protected from damage and deterioration during handling, maintenance and storage.	**Subpart G – Production and Process Controls** **Section 820.72 Inspection, Measuring, and Test Equipment** (a) *Control of Inspection, measuring, and test equipment.* Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented. (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. (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. (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.

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 on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE - See ISO 10012 for guidance related to measurement management systems

ISO – 13485 (2003)	FDA QSR 21 CFR 820
8 Measurement, Analysis and Improvement **8.1 General** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to maintain the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use. NOTE – National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.	**Subpart H – Acceptance Activities** **Section 820.80 Receiving, in-process, and finished device Acceptance** (a) *General.* Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities. **Subpart O – Statistical Techniques** **Section 820.250 Statistical Techniques** (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. (b) Sampling plans, when used, shall be written and based on 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.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
8 Measurement, Analysis and Improvement **8.2 Monitoring and Measurement** **8.2.1 Feedback** As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. The organization shall establish a documented procedure for a feedback system [see 7.2.3 c)] to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3). If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form part of the feedback system (see 8.5.1).	**Subpart M – Records** **Section 820.198 Complaint Files** (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: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting. (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. (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. (d) Any complaint that represents an event which must be reported to FDA under part 803 or 804 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 Sec. 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event.

Subpart M – Records
Section 820.198 Complaint Files

(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:
(1) The name of the device;
(2) The date the complaint was received;
(3) Any device identification(s) and control number(s) used;
(4) The name, address, and phone number of the complainant;
(5) The nature and details of the complaint;
(6) The dates and results of the investigation;
(7) Any corrective action taken; and
(8) Any reply to the complaint.

(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.

(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:
(1) A location in the United States where the manufacturer's records are regularly kept; or
(2) The location of the initial distributor.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
8 Measurement, Analysis and Improvement **8.2 Monitoring and Measurement** **8.2.2 Internal Audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that 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 (see 8.5.2). NOTE See ISO 19011 for guidance related to quality auditing.	**Subpart B – Quality System Requirements** **Sectiontion 820.22 Quality Audit** Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
8 Measurement, Analysis and Improvement **8.2 Monitoring and Measurement** **8.2.3 Monitoring and Measurement of Processes** The organization shall apply suitable methods for monitoring and, where applicable, 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, to ensure conformity of the product.	**Subpart G – Production and Process Controls** **Section 820.70 Production and Process Controls** (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: (2) Monitoring and control of process parameters and component and device characteristics during production

8 Measurement, Analysis and Improvement **8.2 Monitoring and Measurement** **8.2.4 Monitoring and Measurement of Product** **8.2.4.1 General requirements** 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 appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed.	**Subpart H – Acceptance Activities** **Section 820.80 Receiving, in-process, and finished device Acceptance** (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. (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: (1) The activities required in the DMR are completed; (2) The associated data and documentation is reviewed; (3) The release is authorized by the signature of a designated individual(s); and (4) The authorization is dated. (e) *Acceptance Records.* Each manufacturer shall document acceptance activities required by this part. These records shall include: (1) The acceptance activities performed; (2) the dates acceptance activities are performed; (3) the results; (4) the signature of the individual(s) conducting the acceptance activities; and (5) where appropriate the equipment used. These records shall be part of the DHR.
8.2.4.2 Particular requirements for active implantable medical devices and implantable medical devices The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.	

ISO – 13485 (2003)	FDA QSR 21 CFR 820
8 Measurement, Analysis and Improvement **8.3 Control of Nonconforming Product** 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 controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession; c) by taking action to preclude its original intended use or application. The organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of person(s) authorizing the concession shall be maintained (see 4.2.4). Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. 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.	**Subpart I – Nonconforming Product** **Section 820.90 Nonconforming Product** (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. (b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use. (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.

If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).	
8 Measurement, Analysis and Improvement **8.4 Analysis of Data** The organization shall establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) feedback, b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers. Records of the results of the analysis of data shall be maintained (see 4.2.4).	**Subpart J – Corrective and Preventive Action** **Section 820.100 Corrective and Preventive Action** (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (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;

8 Measurement, Analysis and Improvement **8.5 Improvement** **8.5.1 General** The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review. The organization shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1). If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4). If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.	**No QSR Equivalent**

ISO – 13485 (2003)	FDA QSR 21 CFR 820
8 Measurement, Analysis and Improvement **8.5 Improvement** **8.5.2 Corrective Action** The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, including, if appropriate, updating documentation (see 4.2), e) recording of the results of any investigation and of action taken (see 4.2.2), and f) reviewing corrective action taken and its effectiveness.	**Subpart J – Corrective and Preventive Action** **Section 820.100 Corrective and Preventive Action** (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (2) Investigating the cause of nonconformities relating to product, processes, and the quality system; (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; (6) Ensuring that information related to quality problems or nonconforming product is disseminating to those directly responsible for assuring the quality of such product or the prevention of such problems; and (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. (b) All activities required under this section, and their results, shall be documented.

ISO – 13485 (2003)	FDA QSR 21 CFR 820
8 Measurement, Analysis and Improvement **8.5 Improvement** **8.5.3 Preventive Action** The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) recording of the results of any investigations and of action taken (see 4.2.4), and e) reviewing preventive action taken and its effectiveness.	**Subpart J – Corrective and Preventive Action** **Section 820.100 Corrective and Preventive Action** (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (2) Investigating the cause of nonconformities relating to product, processes, and the quality system; (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; (6) Ensuring that information related to quality problems or nonconforming product is disseminating to those directly responsible for assuring the quality of such product or the prevention of such problems; and (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. (b) All activities required under this section, and their results, shall be documented.