Correspondence between ISO 9001:2000, ISO 13485:2003 and the US Quality System Regulation

Modified by Steve Howarth from a matrix prepared by Ed Kimmelman

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
1 Scope **1.1 General** This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements. NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.	**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)*	**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. … **(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 Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 1-301-443-6597, FAX 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.	The scope sections of each document set out their objectives. For the ISO, the objective is to harmonize regulation around the world. As a result an attempt was made by FDA during the revision of the GMPs, while the 1996 version of ISO 13485 was being developed, to incorporate the requirements that were included in that version of the Standard. While the agency could not revise the format of the regulation to follow that of the Standard, the requirements were included. This section of the regulation contains some additional regulatory issues that are not appropriate for ISO 13485:2003.

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1.2 Application All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.	**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.*	**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 nonimplementation 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.	Basically, the applicability guidance for the two documents is the same in both documents. In essence, they allow for the exclusion from the QMS requirements associated with activities not performed by the organization. ISO 13485:2003 explicitly limits those exclusions to those associated with product realization. Because of this approach, it will be necessary for registrars to explain in detail the scope of any certificates of compliance with ISO 13485:2003. They will have to spell out clearly any exclusions.

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2 Normative reference The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards. ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*.	**2 Normative reference** *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*		Note: As of 9/15/05, ISO 9000:2005 has canceled and replaced ISO 9000:2000.
3 Terms and definitions For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply. The following terms, used in this edition of ISO 9001 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 9001:1994, 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”.	**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.*	**820.3 Definitions.** (a) Act means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to the regulations in this part.	ISO 13485:2003 spells out clearly the new meanings of the words “supplier” and “organization”
	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*		I was not able to find the regulatory definition of this item, even though the definition in ISO 13485:2003 were probably taken from a regulatory source.

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	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*		I was not able to find the regulatory definition of this item, even though the definition in ISO 13485:2003 were probably taken from a regulatory source.
	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.*		I was not able to find the regulatory definition of this item, even though the definition in ISO 13485:2003 were probably taken from a regulatory source.
	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.	The regulatory definition is a bit broader, as it covers products that have not, as yet, been placed on the market, but have been released for distribution. This would mean that a lot of product that has been released for distribution could be included in the activities associated with a customer complaint, even though no part of the lot has reached the customer.
	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.*	[**21CFR §812.3(d)** Implant means a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also “implants” for purposes of this part.]	The definition in ISO 13485:2003 includes explicitly eye implants. It is unclear how the FDA treats these products.
		(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.	There is no corresponding term defined in ISO 13485:2003
		(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.	There is no corresponding term defined in ISO 13485:2003
		(e) Design history file (DHF) means a compilation of records which describes the design history of a finished device.	There is no corresponding term defined in ISO 13485:2003

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	3.6 labelling *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 "labelling" as "information supplied by the manufacturer."*	**[Federal Food, Drug, and Cosmetics Act, Section 201]:** (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article. (k) The "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package or such article, or is easily legible through the outside container or wrapper.	The definition in the regulation is a bit more detailed, but the definition in ISO 13485:2003 should cover all that is covered in the definitions of "label" and "labeling" in the regulation.
	(ISO 13485:2003, 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 from 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.	(f) Design input means the physical and performance requirements of a device that are used as a basis for device design.	The definition of "design and development inputs" in ISO 13485:2003 is actually incorporated into the requirements section. It is also a bit more explicit.
	(ISO 13485:2003, 7.3.3) Design and development outputs 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. *NOTE Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.*	(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.	The definition of "design and development outputs" in ISO 13485:2003 is actually incorporated into the requirements section. It is also a bit more explicit. While the regulation doesn't explicitly include examples of design output, it is clear that FDA considers items like the product and component specifications, manufacturing procedures, engineering drawings, and logbooks are part of the design output.

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	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].*	[**Federal Food, Drug, and Cosmetics Act, Section 201**: (h) The term "device (…) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.]	No significant difference.
	(ISO 13485:2003, 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).*	(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.	The definition of "design and development review" in ISO 13485:2003 is actually incorporated into the requirements section. Otherwise there is no significant difference.
	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*		
		(i) Device history record (DHR) means a compilation of records containing the production history of a finished device.	There is no corresponding term defined in ISO 13485:2003
		(j) Device master record (DMR) means a compilation of records containing the procedures and specifications for a finished device.	There is no corresponding term defined in ISO 13485:2003

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		(k) Establish means define, document (in writing or electronically), and implement.	There is no corresponding term defined in ISO 13485:2003
		(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.	There is no corresponding term defined in ISO 13485:2003
		(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.	There is no corresponding term defined in ISO 13485:2003
	(ISO 9000:2005, 3.2.7) top management – person or group of people who directs and controls an organization at the highest level.	(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.	The intent of both definitions is the same.
		(o) Manufacturer means any person who designs, manufactures, 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.	There is no corresponding term defined in ISO 13485:2003
		(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.	There is no corresponding term defined in ISO 13485:2003
	(ISO 9000:2005, 3.6.2) nonconformity – non-fulfilment of a requirement.	(q) Nonconformity means the nonfulfillment of a specified requirement.	Identical
	(ISO 9000:2005, 3.4.2) product – the result of a process **NOTE 1** There are four generic product categories, as follows: — Services (e.g., transport); — Software (e.g., computer program, dictionary); — Hardware (e.g., engine mechanical part); — Processed materials (e.g., lubricant). …	(r) Product means components, manufacturing materials, in- process devices, finished devices, and returned devices.	The definition in ISO 13485:2003 more clearly reflects the process approach of this document. The definition in ISO 13485:2003 is a bit more detailed.
	(ISO 9000:2005, 3.1.1) quality – degree to which a set of inherent characteristics fulfils requirements.	(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.	No significant difference. The definition in the regulation reflects the objective of the regulation, which is the assurance of product safety and effectiveness.

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	(ISO 9000:2005, 3.9.1) audit – systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled…	(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.	The definition in the regulation imposes the requirement related to defined intervals, and includes activities that occur after the audit is actually performed.
	(ISO 9000:2005, 3.2.4) quality policy – overall intentions and direction of an organization related to quality as formally expressed by top management.	(u) Quality policy means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.	No significant difference.
	(ISO 9000:2005, 3.2.2) system – set of interrelated or interacting elements.	(v) Quality system means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.	The definition in the regulation is more instructive, but is consistent with the intent of ISO 13485:2003.
		(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.	There is no corresponding term defined in ISO 13485:2003
	(ISO 9000:2005, 3.6.7) rework – action on a nonconforming product to make it conform to the requirements. NOTE Unlike rework, repair can affect or change parts of the nonconforming product.	(x) Rework means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.	No significant difference.
	(ISO 9000:2005, 3.7.3) specification – document stating requirements. NOTE A specification can be related to activities (e.g., procedure document, process specification and test specification), or products (e.g., product specification, performance specification and drawing).	(y) Specification means any requirement with which a product, process, service, or other activity must conform.	The regulation requires documentation of specifications.
	(ISO 9000:2005, 3.8.5) validation – confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. NOTE 1 The term "validated" is used to designate the corresponding status. NOTE 2 The use conditions for validation can be real or simulated.	(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).	No significant difference, but neither definition is very informative. The regulatory definition is more detailed in that it breaks out and defines "process validation" and "design validation". Normally, validation is performed on the final product or process for manufacturing, monitoring, testing, and supporting the product.
	(ISO 9000:2005, 3.8.4) verification – confirmation, through the provision of objective evidence that specified requirements have been fulfilled. NOTE 1 The term "verified" is used to designate the corresponding status. NOTE 2 Confirmation can comprise activities such as — Performing alternative calculations, — Comparing a new design specification with a similar proven design specification, — Undertaking tests and demonstrations, and — Reviewing documents prior to issue.	(aa) Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.	No significant difference. ISO 13485:2003 is more detailed.

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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 continual improvement 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. NOTE: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.	**4 Quality management system** **4.1 General requirements** *The organization shall establish, document, implement and maintain a quality management system and maintain 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 analyse 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 resources, product realization and measurement.	**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.	No significant differences

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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, and e) records required by this International Standard (see 4.2.4). NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. NOTE 2 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 3 The documentation can be in any form or type of medium.	**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 management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing.* NOTE *1* The extent of the quality management system documentation can differ from one organization to another due to a) the size of the 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.		The ISO13485 standard lists the required quality management system documentation in this clause, while the QSR indicates the documentation requirements in the various sections throughout the regulation. There is no significant difference in the documentation requirements for the two documents, except as indicated below. The QSR implicitly recognizes that the extent of quality management system documentation will reflect the size and complexity of the organization. It also implicitly recognizes that some documentation may not be needed due to the expertise (either through training, education, or experience) of the personnel. This text is included in ISO 13485:2003 in order to accommodate the definition of "establish" in the QSR.
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 exclusion (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.	**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 exclusion 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.*		The QSR has no requirement for a Quality Manual. Such a manual would still be helpful in explaining the nature and extent of the quality management system to an FDA investigator during an inspection. It would also be useful in the training of personnel with regard to the quality management system of the organization and their place within that system. The Quality Manual could be used as the repository of some of the individual quality management system documentation required by the QSR (e.g., the organizational structure and interrelationships, the highest level procedures in a small organization dealing with items like document control, recordkeeping, training)

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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 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.	**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 another designated function which has access to pertinent background information upon which to base its decisions.* *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.*	**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 all 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 requirements are essentially the same, except that the QSR has the specific requirement to communicate changes to documents to the affected personnel. ISO 13485:2003 requires the organization to define a retention period for obsolete documents.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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.	**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.*	**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. (a) Confidentiality. Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter. (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. (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.	No significant differences in the general requirements associated with control of records, except that the QSR contains requirements for communications with FDA.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
		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 Installation, maintenance, and servicing procedures and methods.	The QSR requires the establishment of a Device Master Record (DMR). The DMR may be a separate file of documents and records, or it may be document containing references to the various elements of the DMR. ISO 13485:2003 has no requirement for such a file even though it requires the individual documents and records that would be contained within that file.
		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.	The QSR requires the establishment of a Device History Record (DHR) for each lot of devices or unit manufactured. The DHR may be a separate file containing the records, or may be document that references the location of these records. ISO 13485:2003 does not require the establishment of such a file, even though it requires the individual records that would be contained with that file.
		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.	The QSR requires the establishment of a Quality System Record, which may be a separate file containing the required documents or a document referencing the required contents. ISO 13485:2003 does not require the establishment of such a file, even though it does requirement the establishment of the various documents that would be included in that file.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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 continually improving 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.	**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 purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.*	**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.	No significant differences in management responsibilities; the QSR spells some of them out in subsequent sections of the regulation.
5.2 Customer focus Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).	**5.2 Customer focus** *Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1).*		ISO 13485:2003 has a distinct focus on meeting customer requirements in addition to meeting regulatory requirements. The QSR is entirely focused on meeting those requirements that have as their objective the design, manufacture, distribution, and support of safe and effective medical devices. ISO 13485:2003 will include requirements for determining customer requirements during the entire product realization process, while the QSR will include requirements that identify product and process requirements that are focused on ensuring safe and effective medical devices.
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 continually improve 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.	**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* *a) management system,* b) provides a framework for establishing and reviewing quality objectives, c) is communicated and understood within the organization, and d) e) is reviewed for continuing suitability.	**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.	No significant differences

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
5.4 Planning **5.4.1 Quality objectives** Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	**5.4 Planning** **5.4.1 Quality objectives** Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	**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.	No significant differences
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.	**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.	**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. **(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. **(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.	The QSR contains the prescriptive requirements for a quality plan and quality system procedures. It is not clear what the FDA is looking for when they ask for a quality plan. It seems to be combination of a high level quality planning document, containing policy and key objectives, with a mandate to drive those objectives down into the organization, and a set of high level procedures that illustrate how that plan will be met. Both the QSR and ISO 13485:2003 require the establishment of these kinds of procedures; only the QSR gives them special standing as quality system procedures.
5.5 Responsibility, authority and communication **5.5.1 Responsibility and authority** Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.	**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 as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).*	**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.	No significant differences

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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 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.	**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 *(see 8.5)*, 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.	**820.20 Management responsibility** **(a) 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.	No significant differences, except the requirements in ISO 13485:2003 reflect the focus on meeting customer requirements.
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.	**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.	**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.	No significant differences; the QSR implicitly requires the necessary communication processes that make for successful interrelationships
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).	**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).	**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.	No significant differences.
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, and g) recommendations for improvement.	**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*		The requirements for review input that are spelled out in ISO 13485:2003 are logical and would be expected by an FDA investigator during an inspection that focused on management responsibilities.
5.6.3 Review output The output from the management review shall include any decisions and actions related to a) the effectiveness of the quality management system and its processes b) improvement of product related to customer requirements, and c) resource needs.	**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.		The requirements for review output that are spelled out in ISO 13485:2003 are logical and would be expected by an FDA investigator during an inspection that focused on management responsibilities.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
6 Resource management **6.1 Provision of resources** The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	**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*	**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.	No significant differences, especially since ISO 13485:2003 includes the requirement to meet regulatory requirements.
6.2 Human resources **6.2.1 General** Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. **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).	**6.2 Human resources** **6.2.1 General** Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. **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.*	**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. **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. **(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 which 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.	No significant differences.
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).	**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).*	**820.70 Production and process control** **(f) Buildings.** Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, 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.	The intent of the two documents is consistent; the QSR contains a number of specific requirements related to the creation of maintenance schedules, inspections and adjustment of equipment, and manufacturing materials.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements.	**6.4 Work environment** The organization shall determine and manage the work environment needed to achieve conformity to product requirements. *The following requirements shall 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).*	**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. **(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.	The intent of both documents is consistent; ISO 13485 specifically calls for control of used product to prevent contamination of other product, the manufacturing environment or personnel.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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. 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. NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.	**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. 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.*	**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.	The QSR doesn't specifically recognize the concept of product realization, even though it includes requirements related to essentially all of the processes associated with product realization. The QSR also requires, either implicitly or explicitly, in various sections planning associated with these requirements. ISO 13485:2003 recognizes the fact that risk management is a process that shall be conducted throughout the product realization process, while the QSR refers to risk management only in the section related to design validation. FDA, however, recognizes the wisdom of the ISO 13485:2003 risk management requirements will seek records associated with risk management consistent with the requirements set out in ISO 13485:2003.
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.	**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.		The closest the QSR gets to determining customer requirements related to the product is in 820.30(c) design inputs. The customer requirements referred to in clause 7.2 of ISO 13485:2003 refer to those requirements associated with getting the product to the customer. This includes items associated with order handling and what were referred to in early versions of ISO 9001 as contract review. These are not part of the focus of the QSR.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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, 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.	**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.		
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.	**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 *(see 8.2.1), and* *d) advisory notices (see 8.5.1).*		

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
7.3 Design and development	**7.3 Design and development**	**820.30 Design controls**	The overall objectives of the two documents related to design control planning are consistent. The QSR limits the applicability of design controls to more high risk medical devices, while ISO 13485:2003 applies them to all medical devices.
7.3.1 Design and development planning	**7.3.1 Design and development planning**	**(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.	
	The organization shall establish documented procedures for design and development.	(2) The following class I devices are subject to design controls:	
The organization shall plan and control the design and development of product.	The organization shall plan and control the design and development of product.	(i) Devices automated with computer software; and	
During the design and development planning, the organization shall determine	During the design and development planning, the organization shall determine	(ii) The devices listed in the following chart.	
a) the design and development stages,	a) the design and development stages,	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) the review, verification and validation that are appropriate to each design and development stage, and	*b) the review, verification, validation and design transfer activities (see Note) that are appropriate at each design and development stage, and*		
c) the responsibilities and authorities for design and development.	c) the responsibilities and authorities for design and development.	**(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 organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	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.	
Planning output shall be updated as appropriate, as the design and development progresses (see 4.2.3).	*Planning output shall be documented, and updated as appropriate, as the design and development progresses (see 4.2.3).*	**(h) Design transfer.** Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.	
	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.	**(j) Design history file.** Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.	While ISO 13485:2003 requires the creation of design control documentation and records, the QSR requires the establishment of a Design History File which either contains or refers to all the documents and records associated with the application of the design control processes to a particular product.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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 and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development. These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	**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 from 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.	**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.	No significant differences.
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.	**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.*	**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.	The intent of the two documents is consistent, with the QSR containing specific requirements associated with the approval and release of design outputs.
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. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	**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).	**820.30 Design controls** **(e) Design review.** Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).	The intent of the two documents is consistent, with ISO 13485:2003 illustrating in more detail the objectives of the design review and the QSR including prescriptive design review process requirements not contained in ISO 13485:2003.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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).	**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).	**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.	The intent of the two documents is consistent, with the QSR including prescriptive design verification process requirements not contained in ISO 13485:2003.
7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements (7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, 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)	**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 (see Note 1).* 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.*	**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.	The intent of the two documents is consistent. The QSR seems to indicate that risk analysis is a design validation process. This is not consistent with the teachings of ISO 14971:2000 which calls for risk management activities throughout the product realization process. ISO 13485:2003 addresses a scenario not addressed by the QSR (e.g., where final assembly of the medical device is accomplished on delivery to the customer) The QSR contains a number of design validation process requirements not included in ISO 13485:2003.
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).	**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).	**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.	ISO 13485:2003 contains requirements related to the effect of design changes on product already delivered and records of design changes that do not appear in the QSR.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
7.4 Purchasing **7.4.1Purchasing process** The organization shall 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).	**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).	**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.	No significant differences.
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.	**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).*	**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 Sec. 820.40.	The intent of both documents is consistent. ISO 13485:2003 contains a requirement associated with the organization ensuring the adequacy of purchasing requirements prior to communicating them to the supplier. The QSR contains a requirement that the organization obtain, where possible the agreement of the supplier to notify the organization of changes to the product or service so that the organization can assess the potential effect on the quality of the medical device.
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.	**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).*	**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 contains requirements related to the scenario where the organization seeks to verify purchased product at the supplier's location.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
7.5 Production and service provision **7.5.1 Control of production and service provision** 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 work instructions, 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, and f) the implementation of release, delivery and post-delivery activities.	**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 labelling 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.* ***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.* ***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*	**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. **(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. **(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. **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	The intent of both documents is consistent with each of the documents providing details of control or the types of processes that must be controlled in a way that supplements each other. It is suggested that the sections be read together in order to get a complete list of processes and process controls that are to be included in the quality management system

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	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). ***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.* ***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).*	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. **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.	
7.5.2 Validation of processes for production and service provision 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.	**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 maintained (see 4.2.4)* ***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 of each sterilization process shall be maintained (see 4.2.4).*	**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. **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.	No significant differences. The QSR contains a number of prescriptive requirements associated with documentation of validation activities. There are no specific requirements related to process validation of sterilization processes in the QSR.

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7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4). NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.	**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)].* ***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.* ***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.*	**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. **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. **820.80 Receiving, in-process, and finished device acceptance** **(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. **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.	ISO13485:2003 addresses the identification and traceability of product returned to the organization in order to ensure it is distinguished from normal product. ISO 13485:2003 includes some general requirements associated with traceability not found in the QSR. The requirements for implantable and active implantable devices found in both documents are supplementary and all must be incorporated into the quality management system of an organization supplying such medical devices. The QSR contains a number of prescriptive requirements associated with the records of acceptance status.
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.	**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.*		Aside from the general controls to be exerted by the organization over purchased product, the QSR does not specifically address the issue of care to be exercised over customer property when it is being held or processed by the organization.

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7.5.5 Preservation of product The organization shall preserve 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.	**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).*	**820.120 Device labeling.** Each manufacturer shall establish and maintain procedures to control labeling activities. **(a) Label integrity.** Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use. **(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. **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. (c) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms. **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. **820.140 Handling.** Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling. **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	While the intent of the two documents is consistent, the QSR contains many prescriptive requirements related to label control and the handling, storage, packaging, preservation, and distribution of product not specifically called out in ISO 13485:2003.

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		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.	
7.6 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 processes 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 to 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. 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 10012-1 and ISO 10012-2 for guidance.	**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 to 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. 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.*	**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.	The intent of the two documents is consistent, with ISO 13485:2003 giving generalized guidance as to the control of monitoring and measuring devices and the QSR focusing more specifically on the process of calibration of such equipment.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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 continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	**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.*	**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 a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.	There is no one section of the QSR that corresponds to this clause of ISO 13485:2003. It is clear from a reading of the overall QSR that the objectives of this clause of ISO 13485:2003 and the QSR are consistent.
8.2 Monitoring and measurement **8.2.1 Customer satisfaction** As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	**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).*	**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	The QSR contains prescriptive requirements regarding the handling of complaints and other user input that would be useful in conducting corrective or preventive action. These requirements are not spelled out in detail in ISO 13485:2003, but compliance with the requirements set out in the QSR would satisfy the requirements of ISO 13485:2003.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
		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. (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 complainant. (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 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
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 and impartiality 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 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.	**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 and impartiality 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.*	**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.	No significant differences. Note that ISO 10011 has been superseded by ISO 19001.
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.	**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.	**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.	The intent of the two documents is consistent, even though the QSR is far more detailed and has a product focus.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
8.2.4 Monitoring and measurement of product 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). 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, unless otherwise approved by a relevant authority and, where applicable, by the customer.	**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.* ***8.2.4.2 Particular requirement 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*	**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. **(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. **(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. **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 a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.	The intent of the two documents is consistent, even though the QSR is far more detailed and prescriptive. The acceptance records requirements of the QSR would appear to satisfy the implantable and active implantable requirements of ISO 13485:2003.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
8.3 Control of nonconforming product	**8.3 Control of nonconforming product**	**820.90 Nonconforming product.**	The intent of the two documents is consistent.
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 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.	**(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.	The QSR provides more detail as to the items to be recorded in a nonconforming product situation. It explicitly addresses the subject of the need for an investigation in such a situation.
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 by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application.	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 the person(s) authorizing the concession shall be maintained (see 4.2.4).*	**(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.	
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, 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).	(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.	
When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	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.	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. *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).*		ISO 13485:2003 addresses the handling of already released product that is subject to a finding of nonconformity. ISO 13485:2003 provides requirements related to rework of non-conforming product.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
8.4 Analysis of data The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual 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) customer satisfaction (see 8.2.1), 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.	**8.4 Analysis of data** *The organization shall establish documented procedures to determine, collect and analyse 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 (see 8.2.1),* 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).*	**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 a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.	There is no one section of the QSR that corresponds directly with subclause 8.4 of ISO 13485:2003. Requirements for analysis of data related to various elements of the quality management systems is contained in a number of QSR sections. The intent of the two documents as it relates to analysis of data is consistent.
8.5 Improvement **8.5.1 Continual improvement** The organization shall continually improve the 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.	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.*	**820.20 Management responsibilities** **(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. **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	There is no one section of the QSR that corresponds directly with subclause 8.5.1 of ISO 13485:2003. The intent of the two documents as it relates to improvement of the quality management system through the use of corrective and preventive action is consistent. The requirements of the QSR are significantly more prescriptive related to the handling and documentation of complaints.

ISO 9001:2000	ISO 13485:2003	US Quality System Regulation (21 CFR 820)	Comments
		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. (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 complainant. (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.	

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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, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken. **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) records of the results of action taken (see 4.2.4), and e) reviewing preventive action taken.	**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 4.2.4), and* *f) reviewing the corrective action taken and its effectiveness.* **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*	**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; (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 disseminated 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.	The intent of the two documents is consistent. The requirements as set out by the QSR are more prescriptive.