53.	820.120(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.	7.5.1 Control of production and service provision 6.3 Infrastructure 7.5.11 Preservation of the product	**7.5.1** *Control of production and service provision* Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: ... e) implementation of defined operations for labelling and packaging; ... **6.3** *Infrastructure* The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained (see 4.2.5). **7.5.11** *Preservation of product* The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution.	The QS Regulation requires more information.	No significant difference

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).		
54.	820.120(e) Control Number	Where a control number is required by 820.65, that control number shall be on or shall accompany the device through distribution.	7.5.8 Identification 7.5.9 Traceability	**7.5.8** *Identification* If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. **7.5.9** *Traceability* **7.5.9.2** *Particular requirements for implantable medical devices* The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.	The QS Regulation calls out specific control number requirements (see 820.65).	The standard supports a unique device identification system were necessary based on regulatory requirements as well as specific traceability for implanted medical devices.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
55.	820.130 Device Packaging	Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.	7.5.1 Control of production and service provision 7.5.11 Preservation of product	**7.5.1** *Control of production and service provision* Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: ... e) implementation of defined operations for labelling and packaging; ... **7.5.11** *Preservation of product* The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).	No significant difference.	No significant difference.

56.	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.	7.5.11 Preservation of product 6.3 Infrastructure	**7.5.11** *Preservation of product* The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5). **6.3** *Infrastructure* The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.	No significant difference.	No significant difference.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				Records of such maintenance shall be maintained (see 4.2.5).		
57.	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.	7.5.11 Preservation of product	**7.5.11** *Preservation of product* **7.5.** The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).	The QS Regulations has a provision for stock rotation.	No significant difference.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
58.	820.150 Storage(b)	Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.	7.5.11 Preservation of product	**7.5.11** *Preservation of product* The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).	The QS Regulation requires procedures for authorizing receipt from and dispatch to storage and stock rooms.	No significant difference.
59.	820.160 Distribution(a)	Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.	7.5.11 Preservation of product 7.1 Planning of product realization 7.2 Customer Related processes	**7.5.11** *Preservation of product* The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device **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. ... c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;	The QS Regulation is explicit on the prohibition and distribution of expired or deteriorated devices.	No significant difference.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. **7.2** *Customer Related processes* **7.2.1** *Determination of requirements related to 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, as known; c) applicable regulatory requirements related to the product; d) any user training needed to ensure specified performance and safe use of the medical device; e) any additional requirements determined by the organization. **7.2.2** *Review of requirements related to product* The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: a) product requirements are defined and documented; b) contract or order requirements differing from those previously expressed are resolved;		

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
				c) applicable regulatory requirements are met; d) any user training identified in accordance with 7.2.1 is available or planned to be available; e) 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 4.2.5). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.		

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
60.	820.160 Distribution(b)	(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.	7.5.9 Traceability	**7.5.9** *Traceability* The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5). **7.5.9.2** The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements. The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5).	The QS Regulations requires distribution records to the initial consignee for all devices and documentation requirements.	The standard allows the organization to define the extent of traceability in accordance with the regulatory requirements.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
61.	820.170 Installation (a.b)	Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device. (b) The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.	7.5.3 Installation activities	**7.5.3** *Installation activities* The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5).	No significant difference.	No significant difference.
62.	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 the U.S. 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 U.S. FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.	4.2.5 Control of records	**4.2.5** *Control of records* Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements. Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.	No significant difference.	No significant difference.

	21 CFR 820	Requirement	ISO 13485:2016	Requirement	U.S. FDA Quality System considerations	ISO 13485:2016 considerations
63.	820.180(a) Confidentiality	Records deemed confidential by the manufacturer may be marked to aid the U.S. FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.	4.2.5 Control of records	**4.2.5** *Control of records* …The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements…	This is a specific requirement related to confidentiality for the U.S. FDA.	There are no requirements for releasing potentially proprietary information.
64.	820.180(b) Record Retention Period	All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.	4.2.4 Control of documents 4.2.5 Control of records	**4.2.4** *Control of Documents* The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable regulatory requirements. **4.2.5** *Control of Records* The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.	No significant difference.	No significant difference.