

Refs	Requirements	What to look for and how	Compl	Auditor notes and evidence
		<i>considered?</i>		
4.2.3 820.40(b)	Are document changes reviewed and approved by the same function that performed the original review and approval (unless specifically designated otherwise)? Are change records maintained, including description of the change, identification of the affected documents, approval signatures and date, and when the change becomes effective?	Is there a clearly stated requirement that changes to documents must be reviewed and approved by the same function that issued the original document, or by another, explicitly designated function? Is it implemented? Are changes in documents (mostly product and process specifications) backed by design change and/or process change records, such as engineering change notices? How is it defined/documented when document changes become effective?		

4.2.4 Control of Records

4.2.4	Is there a documented procedure for the identification, storage, protection, retrieval, retention, and disposition of records?	Are there documented instructions how to identify, organize, store, protect, and retrieve records? Are storage locations for records defined?		
4.2.4 820.180(b)	Are retention periods for records defined? Are records retained for at least the period of time equivalent to the expected life of the device, and no less than 2 years?	Is a retention period defined for each type of record? How is this period determined? Is the retention period at least two years or equivalent to the lifetime of the device, whichever is greater? Are regulatory requirements considered?		
4.2.4 820.180	Are records organized and maintained to ensure that they remain legible, readily identifiable and retrievable, and to prevent deterioration and loss? Are records accessible to the regulatory inspections? Are electronic records backed up?	Are records stored in dry, clean locations to minimize deterioration? Is there a system for organizing the records? Are boxes, drawers, binders holding records properly identified? Are records easily retrievable (not by asking for retrieval of specific records)? Are records kept in a location that is accessible to regulatory inspections? Are electronic records backed up? Are there specific schedules, instructions, etc. for backing up data? Where are the back-up media (tapes, disks, etc.) kept?		
4.2.4 820.181	For each type of device, is there a Device Master Record (DMR) including, or referring to appropriate device specifications, production process specifications, quality assurance procedures, packaging and labeling specifications, and installation, maintenance and servicing procedures and methods?	How is the DMR organized? Is it a file containing the actual specifications documents, or is it a list referring to these documents and their locations? Is the DMR complete, e.g., includes all required categories of documents? Who decides, and how, which documents are included in the DMR? Are all documents included in the DMR correctly identified, reviewed, approved and otherwise controlled? Are the DMR documents the same		

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