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ASQ Medical Device Division – Proposed FDA QMSR changes
DOCKET NUMBER: FDA-2021-N-0507

Comments may conflict with each other showing the different opinions that this change creates.

Clause/Page	Comment from proposed QMSR	Proposed change / Comments /Recommendations
III Background, A. Introduction / 10122, first column at the top	In determining whether to participate in MDSAP and which FDA specific provisions were needed for the United States, FDA conducted a thorough review and comparison of ISO 13485 and part 820 and concluded that very few FDA-specific requirements needed to be added to this audit model, demonstrating not only the similarities between the current part 820 and ISO 13485, but the comprehensive QMS approach provided by ISO 13485.	If this is the case, then why does the FDA need to make changes to part 820 to incorporate ISO 13485 by reference? Why not just update those sections of 820 they feel need to be a bit more harmonized without infringing on the copyright of ISO 13485? By updating the US CFR by reference to ISO 13485 the FDA is relinquishing its responsibility to an organization that is not responsible for the protection of US Citizens. Only the FDA is responsible for the protection of US Citizens, not ISO.
III Background, B Need for Regulation/ 10122, middle column first paragraph	Currently, device manufacturers registered with the FDA must comply with the current part 820. In addition to the current part 820, registered manufacturers in many other jurisdictions and domestic manufacturers that export devices must comply with ISO 13485, which is substantially similar to the current part 820. As a result, there is redundant effort for some manufacturers in complying with both the current part 820 and ISO 13485. The redundancy of effort to comply with two substantially similar requirements creates inefficiency.	This is not a true statement. Most companies write SOPs covering both the FDA regulation and ISO 13485 because they are very much similar in nature. Plus, the fact that the FDA is saying they are similar does not create inefficiencies. What creates inefficiencies is the reporting of complaints, vigilance, UDI databases, recalls, submissions. Inefficacies are not related to following the basic quality system regulation and or quality standard. The inefficiency will come to play when 820 references ISO 13485:2016 and then the ISO standard is updated. Now a company must comply with both an outdated standard and the new standard if they distribute outside the US. Ref Part 51.1 Policy (f). Like the Preamble to 820 (FR Vol 61, No 195) FDA should follow that as their reference to ISO 13485 as they did with ISO 9001:1994 and not include it in the revised regulation. Regulation is law, Standards are not.

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III Background, B Need for the Regulation/ 10122, middle column last paragraph	Although the requirements under the current part 820 are effective and very similar to those in ISO 13485, incorporating ISO 13485 by reference would further the Agency's goals for regulatory simplicity and global harmonization and should reduce burdens on regulated industry, thereby providing patients more efficient access to necessary devices (Ref. 9).	If the current part 820 is effective and "**very**" similar to ISO 13485, then it's counterintuitive to say 820 needs to be updated to reference ISO 13485. It's not the QMS that makes it easier to access efficient necessary devices for patients, it's the submission process. That needs to be harmonized. If an organization has a cleared 510(k), they should not have to write a technical file for the EU or other countries and vice versa. The focus of the FDA should be to harmonize the submission process as the QMS is already harmonized. The FDA should keep the review process but allow for different types of submissions meeting the pre-submission requirements. There should be no need to write several documents that say the same thing, but in different formats.
B. Definitions / Page 10125, middle column	We are retaining the majority of the definition of ''rework''; however, we are proposing to remove the term ''device master record (DMR)'' (§ 820.3(j)) from the regulation. The device master record is not a term used in ISO 13485 and so this definition does not need to be retained.	This is not a true statement as ISO 13485 defines the content of medical device file (aka DMR) per ISO 13485:2016 4.2.3. Every major device manufacturer uses the term DMR. Removing this term is not value adding and a waste of time as companies would need to update SOPs that cover both. At the least, Clause 820.45 should include clarification that the Medical Device File means the combination of the historical "DHF and DMR". The same for the historical "DHR" or batch record, which is not addressed in the proposed Regulation change.
C. Incorporation by Reference (Proposed § 820.7) / 10126, first column, 2nd paragraph	While we recognize that adopting ISO 13485 could seem like a significant change, the current part 820 and ISO 13485 are substantially similar, and this effort promotes international harmonization.	Again, the FDA is stating that part 820 and ISO 13485:20-16 are "substantially similar", but it is counterintuitive to say there needs to be change to harmonize. The FDA should find verbiage that is not "infringing" upon quality terms that are "similar" to ISO 13485 so device manufactures that only distribute in the US are not forced to comply with an ISO standard.

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D. Proposed Requirement for a Quality Management System (Proposed § 820.10) / 10126, 3rd column, 2nd paragraph	We also propose to clarify that Clause 7.3 Design and Development applies only to the manufacturers of the class I devices that are listed in this provision in addition to all manufacturers of class II and III devices. This retains the scope of current § 820.30(a). We are not proposing to modify which devices are subject to these requirements and are only revising this provision to reflect the location of similar requirements in ISO 13485. We also note that this is consistent with clause 1 of ISO 13485, which recognizes that there may be exclusions by the regulatory authority from the Design and Development requirement and directs the manufacturer to document such in its justification for exclusion.	If the FDA intends to "harmonize" with ISO 13485 then all class I devices need to follow design controls. We are not proposing that but noting it. The exclusion that ISO and FDA have are different in that the FDA is saying the only Class I devices that need to follow design controls are listed under 820.30(a) (2). If a manufacturer makes (has design responsibility for) any type of Class I device under ISO 13485, it needs to follow design controls. Exclusion means that the company does not do design controls. For instance, they are just a relabeler.
F. Proposed Supplementary Provisions (Proposed Subpart B) / 10127, 1st column, 2nd paragraph	FDA notes that the current part 820 contains requirements for record types that are not specifically identified in ISO 13485, such as, quality system record, device master record, design history file, and device history record. We are not proposing to retain separate requirements for these record types as we believe the elements that comprise those records are largely required to be documented by other ISO 13485 Clauses, such as Clause 4.2 and its subclauses.	DMR has already been covered above, but ISO calls it a Medical Device File under 4.2.3. DHF is covered under ISO 13485 7.3.10. DHR is covered under **note** in 7.5.1 (batch record is sometimes used by a pharmaceutical company that makes devices) and ISO refers to several Quality documents within given sub-clauses like management review, purchasing controls, CAPA, etc. So, to eliminate terms that major device manufacturers are currently using is not value added. Many major and small device manufacturers use the terms DHF, quality records, etc.
2. Proposed Controls for Device Labeling and Packaging (Proposed § 820.45) / 10127, 3rd column	If this rule is finalized as proposed, regulated industry must meet the requirements in ISO 13485 7.5.1 and the proposed § 820.45.	ISO 13485 7.5.1 is already being followed per 820 Subpart G Production and Process Controls. This change only clarifies what should be required. Labeling is poorly represented in ISO 13485:2016.

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VI. Proposed Effective Date and Implementation Strategy / 10128, 1st column top	FDA inspections will not result in the issuance of certificates of conformance to ISO 13485, nor is FDA developing a certification program for ISO 13485. In addition, manufacturers with a certificate of conformance to ISO 13485 are not exempt from FDA inspections.	We agree that FDA should not accept ISO certification. Many companies get the certification, but their history shows that they have been issued warning letters by the FDA for the very things the ISO Certificate indicates are in place. If ISO certification is truly the future state, then it should be clearly stated by the Agency. If that is the case, then ISO certification should lower the risk profile of companies and they should get a pass when it comes to routine audits. FDA already does this with companies that have MDSAP certification, so why not use the same approach?
§ 820.10 Requirements for a quality management system. / 10133, 3rd paragraph	A manufacturer subject to this part as described by § 820.1(a) must: (a) *Document. Document* a quality management system that complies with the requirements of ISO 13485 (incorporated by reference, see § 820.7) and this part;	For a company that only distributes product in the US, why should they have to comply with an ISO Standard? They should not be forced to comply with a standard. Part 51 incorporation by Reference should not apply to quality systems as it does for other ISO standards related to risk management, biocompatibility, sterile barrier packaging, etc. The requirements for the QMS should strictly be governed by the FDA and not the ISO organization that is not even located in the US. There will be additional cost burdens on small companies to comply with the requirements of ISO 13485 (such as purchasing the standard). The FDA should update the sections of 820 to harmonize with the ISO standard using their own verbiage.
§ 820.10 Requirements for a quality management system. / 10133, 3rd paragraph	(1) For Clause 7.5.8 in ISO 13485, Identification, the manufacturer must document a system to assign unique device identification to the medical device in accordance with the requirements of part 830.	This is already covered in the definition of UDI per 820.3 (cc) and by reference to the UDI regulation 830. Additional requirements are covered under 820.120, that states *Each manufacturer shall establish and maintain procedures to control labeling activities. (b)…. the correct unique device identifier (UDI) or universal product code (UPC).*
§ 820.10 Requirements for a quality management system. / 10133, 3rd paragraph	(2) For Clause 7.5.9.1 in ISO 13485, Traceability—General, the manufacturer must document procedures for traceability in accordance with the requirements of part 821, if applicable.	This is requirement is already covered under both 820.65 and part 821.

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§ 820.10 Requirements for a quality management system. / 10133, 3rd paragraph	(3) For Clause 8.2.3 in ISO 13485, Reporting to regulatory authorities, the manufacturer must notify FDA of complaints that meet the reporting criteria of part 803 of this chapter.	This requirement is already covered under 820.198 (a) (3) and part 803.
§ 820.10 Requirements for a quality management system. / 10133, 3rd paragraph	(4) For Clauses 7.2.3, 8.2.3, and 8.3.3, advisory notices shall be handled in accordance with the requirements of part 806.	This requirement is already covered by 806 and Part 7. There is no need for there to be a reference to ISO 13485 for a company that is only distributing in the US.
§ 820.10 Requirements for a quality management system. / 10133, 8rd paragraph	(c) *Design and Development.* Manufacturers of class II, class III, and those class I devices listed below must comply with the requirements in Design and Development, Clause 7.3 and its Subclauses in ISO 13485.	ISO does not include an independent reviewer for design controls, and this is a step backwards. Since most companies distribute product in the US and OUS, they have already incorporated an independent reviewer for design controls. The current design control requirements in 820 are superior to those in 13485. When 13485:2016 was revised it was brought in line with 820, except for the independent reviewer. ISO adopted the term Design and Development Files)
General	*"FDA is proposing to incorporate by reference the current 2016 version of ISO 13485. Any future revisions to this standard would need to be evaluated to determine the impact of the changes and whether this rule, if finalized, should be amended."*	It would be helpful if the FDA were to draw up a plan and communicate how the revised ISO 13485 changes would be assessed, and amendments handled without much delay. Plans for handling future changes to the ISO 13485 need to be part of the current QMSR activity.
VI. Proposed Effective Date and Implementation Strategy	*FDA proposes that any final rule based on this proposal become effective 1 year after the date of publication of the final rule in the* ***Federal Register****. This approach is intended to provide adequate time for manufacturers to make any changes necessary to comply with the requirements of ISO 13485.*	It may involve lot of work to establish a requirement for risk management to occur throughout a QMS and total product life-cycle risk management system, which may lead to a one-year timeline to implement a new QMSR being insufficient for some organizations. This should be a three-year timeline, similar to the implementation of current ISO standards. 1 year for gap, 1 year for implementation, 1 year for steady state.... 2-3 years is reasonable.

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§ 820.10 Requirements for a quality management system.	*A manufacturer subject to this part as described by § 820.1(a) must:* This section specifies that the company's Quality System complies to ISO 13485:2016. This cost is approximately $200. This also include the requirement to purchase ISO 9000:2015 Definitions, which costs approximately $200.	If this is mandatory to comply, then the annual registration cost should be reduced by the equivalent amount during the first year required for implementation.
VI. Proposed Effective Date and Implementation Strategy	FDA proposes that any final rule based on this proposal become effective 1 year after the date of publication of the final rule in the Federal Register	This section specifies that the company's Quality System complies to ISO 13485:2016. However, FDA has not offered any assistance to companies with this transition. This would be a great opportunity for Regulatory Education for Industry (REdI) to offer free training, very similar to the annual conference.
I.A	"Such harmonization should provide patients more efficient access to necessary devices, leading to improvement of life quality of the consumers."	This is pretty vague at best. FDA should elaborate on how this promotes and protects Public Health.
VII	The annualized costs savings of medical device establishments are estimated at approximately $533 million at a 7 percent discount rate, and approximately $439 million at a 3 percent discount rate.	Cost savings would be negatable in the near term, and minor in the long term based on standardization.

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Current 820.180 (c)	"(c) Exceptions. This section does not apply to the reports required by § 820.20(c) Management review, § 820.22 Quality audits, and supplier audit reports used to meet the requirements of § 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken."	We would like clarification on whether FDA would have access to internal audits, supplier audits, and management review material as it is permitted under ISO 13485. Today, these documents are off limits to FDA's inspectors for encouraging manufacturers to improve their quality management systems. We are concerned if this long-standing FDA policy would change after the 21 CFR 820 amendment is finalized. This is what we believe FDA's position has been in the past and want to be assured this will continue: "FDA believes that refraining from routinely reviewing these reports may help ensure that the audits are complete and candid and of maximum use to the manufacturer." (FR 61(195):52613; October 7, 1996) "FDA recognizes that quality audits of suppliers have a significant and demonstrated value as a management tool for corrective action, quality improvement, and overall assurance of component and service quality, and does not seek to undermine their value." (FR 61(195):52625) "[FDA] believes that the disclosure of the audit reports themselves would be counterproductive to the intent of the quality system." (FR 61(195):52637).
New 820.35	Propose to include signature and date requirements for records subject to Clause 4.2.5 of ISO 13485	Instead of requiring signature and date, it should be considered that the records should be ALCOA (attributable, legible, contemporaneous, original, and accurate) Calling out the date directly: 04/01/02 vs 02/01/04 (US vs EU style), would be too prescriptive… The assumption is that initials = signature. Digital signature = signature. Thinking inspection sheets where each line is initialed once completed. FDA should provide additional detail to better define the requirements for record dating.
1. Proposal for Control of Records (Proposed § 820.35)	The whole section is non-value added as all this is already coved within the regulation.	This appears to be redundant information and should just reference the current Regulations for UDI and Labeling.

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E. Incorporation by Reference	FDA is proposing to incorporate by reference the current 2016 version of ISO 13485.	The parts incorporated by reference to ISO 13485:2016 include NOTEs. NOTEs in ISO standards are intended for promoting readers' understanding of the respective sections and not for compliance, but we are not certain how FDA intends to use the NOTEs. FDA should not use the NOTEs as requirements. In addition, there are other elements that are NOT applicable and should NOT be included i.e., "0.5 Compatibility with other management systems"
Overall	Overall	The proposed changes will improve the ability of all Medical Device professionals to speak the same language and not need to switch back and forth (ISO/EU/FDA). Long-term, we see this as a beneficial effort to improve standardization and will improve on imported medical devices' compliance with QMS standards. Moving toward more Risk Management and Risk-based Thinking is viewed as a positive step.

End of Document/Jim Shore/23 May 2022