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FDA PROPOSED QUALITY MANAGEMENT SYSTEM REGULATION (QMSR) EXPERT ANALYSIS PART 2: UNDERSTANDING PROPOSED 21 CFR 820.35 - RECORDS

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About MEDIcept

MEDIcept strives to provide our clients with proven, trusted, and cost-effective solutions. We are an international consulting firm specializing in medical device, IVD, combination product, and biotechnology Regulatory, Quality, Clinical, Auditing, and Educational Services. Since 1996, we have worked with thousands of companies to solve their most critical FDA, global regulatory authority, and ISO issues. Our integrated solutions are rooted in our direct experience and span all stages of the product life.

Our staff includes former FDA and Notified Body personnel and industry experts with an in-depth functional knowledge of medical devices, IVDs, combination products, and biotechnology. Compliance requires the navigation of a complex maze of requirements. MEDIcept can provide state-of-the-art interpretation of those regulations, guidance documents, and standards and provides our client with the information they need to comply safely and cost-effectively.

We use our expertise to quickly identify the root cause, coalesce corrective actions, and provide easy to understand structured solutions or recommended improvements. Since we know corrective action implementation is where many projects fail, we do not just write an action list. We make sure all stakeholders understand why the solutions were chosen and why they are needed. We work hand-in-hand with clients to implement the solutions, so the solutions have been culturally absorbed when the project is done.

MEDIcept is committed to providing our clients with what they need. We are committed to quality deliverables because we value our clients' time and resources. This is why 90% of our clients come back to us repeatedly to solve new issues and recommend us to their colleagues.

U.S. FDA Proposed QMSR HOW TO SUBMIT COMMENTS

You may submit comments on the proposed regulation as follows:

Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 24, 2022. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 24, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Submitting electronic comments: Federal eRulemaking Portal - https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

On February 23, 2022, the U.S. FDA published the Draft Proposed Rulemaking for the new "Quality Management System Regulation" (QMSR) with public comments due by May 24, 2022. It is imperative that the entire industry thoroughly understand the new Proposal and any nuances. Further, it is important that everyone avail themselves of the opportunity to submit comments to the FDA before the due date.

This White Paper is Part 2 of a planned series of technical analyses to help inform any interested parties. To understand any regulatory requirements or standards, the discussion must be grounded in a firm understanding of the requirements in conjunction with the terminology and definitions.

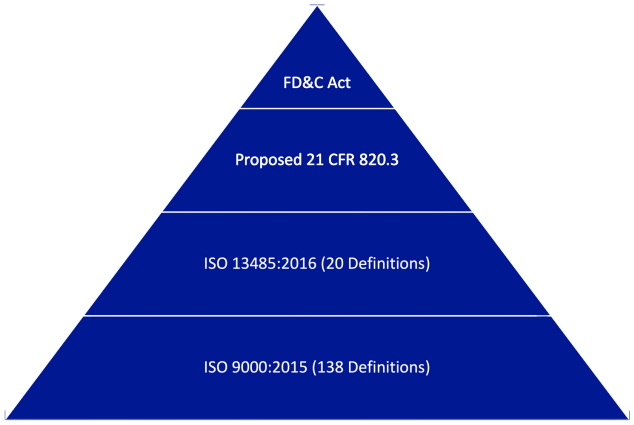
FDA proposes to incorporate by reference the international standard for device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016, *"Medical devices – Quality management systems – Requirements for regulatory purposes."* FDA also proposes additional requirements to align with existing provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act). Some of those additions and revisions are related to definitions and new Record requirements now found in the proposed **21 CFR 820.35, Records**.

Some requirements in the proposed **21 CFR 820.35 Records** are straightforward and understandable – other requirements as written may be exceptionally problematic, expensive to implement, and unintended by FDA. Any manufacturer obligated to comply with the Proposed QMSR, if not acutely aware of differences in terms/definitions between U.S. FDA regulations and ISO 13485:2016 in conjunction with the normative reference ISO 9000:2015 may be in for a rude awakening. Also, manufacturers must decide how they feel about eliminating the current *"21 CFR 820.180(c) Exceptions"* section.

Let us briefly discuss the content of **Part 1 of this White Paper Series - Understanding Definitions***. The 1996 version of 21 CFR 820.3 has twenty-nine (29) definitions/sub-definitions. ISO 13485:2016 contains a total of twenty (20) definitions. However, everyone must realize that ISO 13485:2016 also has one Normative Reference, ISO 9000:2015 *"Quality management systems – Fundamentals and vocabulary."* For ISO standards, a normative reference means that the entire normative standard is subsumed into the base standard.

This means that ISO 9000:2015 in its entirety, all one hundred thirty-eight (138) definitions, are a part of ISO 13485:2016 except where definitions have been redefined within ISO 13485:2016. Therefore, by incorporating ISO 13485:2016, the FDA will require ISO 9000:2015 unless redefined.

This accumulation of incorporation by reference will require people to understand both ISO 13485:2016 and ISO 9000:2015, in addition to understanding the revisions added by the newly Proposed QMSR in the context of the FD&C Act.



The Difference in ISO Definitions versus U.S. Definition of "Record"

In U.S. legal terms from 44 U.S. Code § 3301, the definition of "record" *"includes all recorded information, regardless of form or characteristics."* In U.S. legal requirements, the biggest and broadest term is "Records" under which there are many types of records to include documents (i.e., specifications, policies, procedures), whereas ISO 9000:2015 defines "Record" more narrowly as a subset of "Document" in clause 3.8.10 as:

3.8.10
record
document (3.8.5) stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize *traceability* (3.6.13) and to provide evidence of *verification* (3.8.12), *preventative action* (3.12.1) and *corrective action* (3.12.2).

Note 2 to entry: Generally records need not be under revision control.

Note 2 in ISO 9000:2015 starts pulling in some of the nuances/differences between the U.S. definition and the ISO definition of "Record" when it states, ***"generally records need not be under revision control."*** Typically, a "Document" is under revision control to often include a signature (written or electronic) and date, whereas a "Record" does not. Within ISO, control of a "Record" focuses on retrievability and does not normally require a signature and date. To help us understand these nuances better we also need to understand two additional ISO definitions – "Document" and "Documented Information."

3.8.5
document
information (3.8.2) and the medium on which it is contained

EXAMPLE - *Record* (3.8.10), *specification* (3.8.7), procedure document, drawing, report, standard.

Note 1 to entry: The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or combination thereof.

Note 2 to entry: A set of documents, for example specifications and records, is frequently called "documentation."

Note 3 to entry: Some *requirements* (3.6.4) (e.g. the requirement to be readable) relate to all types of documents. However, there can be different requirements for specifications (e.g. the requirement to be revision controlled) and for records (e.g. the requirement to be retrievable).

3.8.6
documented information
information (3.8.2) required to be controlled and maintained by an *organization* (3.2.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

- The *management system* (3.5.3), including related processes (3.4.1);
- Information created in order for the organization to operate (documentation);
- Evidence of results achieved (*records* (3.8.10)).

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

So why is the definition of "Record" a concern?

The FDA proposed QMSR in 21 CFR 820.35 Records states,

"§ 820.35 Control of records.
In addition to the requirements of Clause 4.2.5 in ISO 13485 (incorporated by reference, see § 820.7), Control of Records, the ***manufacturer must obtain the signature for each individual who approved or re-approved the record, and the date of such approval***, on that record and include the below information in certain records as follows ..."

ISO 13485:2016 Clause 4.2.5 "Control of records" does NOT require signatures and dates. It only requires:

"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*** ... Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

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."

The ISO terms "Document" or "Documented Information" take on the broader term/definition requiring revisions controls versus the similar but different U.S. legal definition of "Record."

Inherently, this will cause a conflict for manufacturers who market internationally across different legal jurisdictions that utilize ISO 13485:2016 Clause 2 "Normative references," which lists ISO 9000:2015 for medical device and IVD regulatory requirements. Enforcement of these legal requirements for a "Record" may therefore be different as to which jurisdiction and regulatory auditor is assessing a manufacturer's Quality Management System. This is contrary to the stated intent of the FDA's Proposed QMSR.

The current FDA 21 CFR 820 Quality System regulation issued back in 1996 very carefully navigated these differences by explicitly stating where a "Record" as defined by U.S. law needed a signature and date within specific sections of the current 21 CFR 820 versus placing the requirements for any signature and date in the general controls of "Records" found in 21 CFR 820.180 General Requirements.

Any additional requirements for specific signatures or dates beyond those required within ISO 13485:2016 must be carefully crafted, different than the general manner

within “21 CFR 820.35 Records” section used in the Proposed QMSR to maintain the goal and purpose of global harmonization/ convergence. Requiring signatures and dates on all “Records” as defined by FDA will be overly burdensome and expensive, especially for electronic systems that would require software changes and new software validations.

What about the FDA “Exceptions” for FDA review of certain records?

The current FDA Quality System regulation in 21 CFR 820.180(c) states:

“(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.”

The proposed QMSR eliminates these “Exceptions.” In the proposed rulemaking FDA has also committed to revising the “Medical Device Guide to Inspection,” known currently as “Quality System Inspection Technique (QSIT).” If the proposed requirements remain unchanged, the proposal states that the FDA will now be able to review Quality/Internal Audits, Management Reviews, and Supplier Audits similar to other regulatory auditors like Notified Bodies and MDSAP Auditing Organizations.

Manufacturers must determine how important this issue is to them and inform the Agency via their comments.

Additional “Record” requirements

Every manufacturer should carefully read the additional remaining requirements. While the requirements are not new and exist practically verbatim in the current 21 CFR 820 Quality System regulation, consideration should be given as to whether all these particular U.S. requirements are necessary.

The elimination of country-specific requirements, where possible, would further the global convergence efforts and allow manufacturers more efficiency in establishing a single Quality Management System for global regulators.

**Visit https://www.medicept.com/news/ for a copy of Part 1 of this White Paper Series - Understanding Definitions.*