Overview: Proposed Rule Quality Management System Regulation

FDA Small Business Regulatory Education for Industry (REdI)

June 9, 2022

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Learning Objectives

- Discuss the proposed amendment to 21 CFR Part 820: Quality Management System Regulation (QMSR)
- Review ISO 13485:2016 and discuss rationale for its incorporation by reference into proposed rule
- Identify changes in proposed QMSR

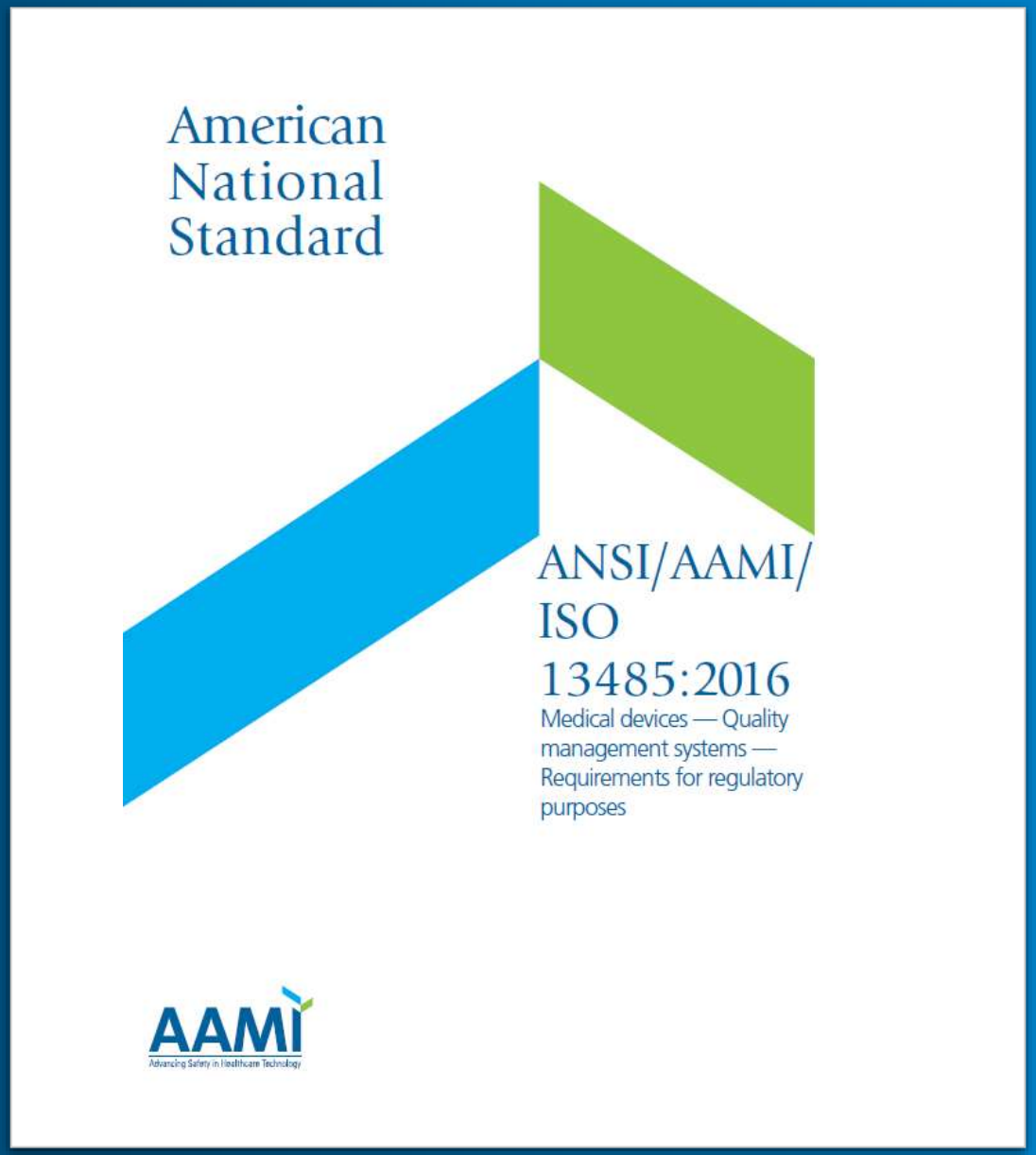
Proposed Quality Management System Regulation (QMSR)

FDA published the proposed amendment to 21 CFR Part 820: **Quality Management System Regulation (QMSR)** on February 24, 2022

www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments

Revisions to Part 820 replace most of the existing regulation with an incorporation by reference (IBR) to the 2016 edition of International Organization for Standardization (ISO) 13485 - *Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*

Comment period closed on May 24, 2022



ISO 13485: 2016

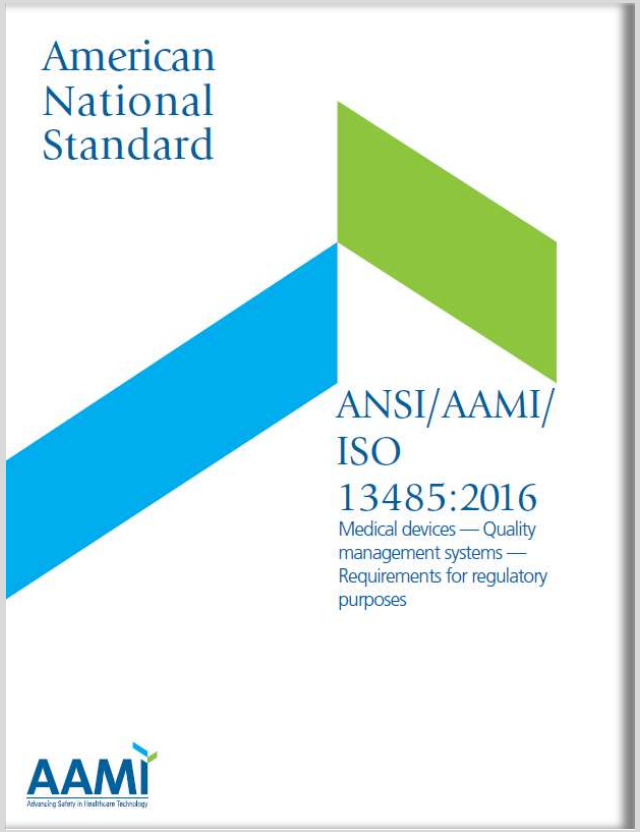
Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

Establishes requirements for a Quality Management System (QMS) that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including:

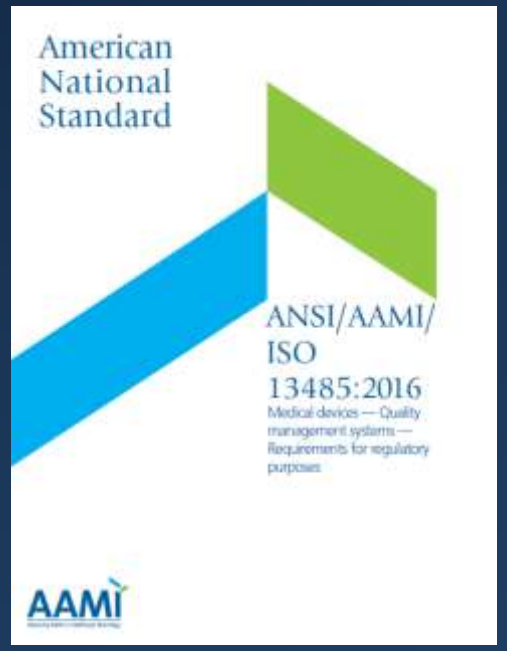
- design and development
- production
- storage
- distribution
- installation
- servicing and
- final decommission/disposal of medical devices

Rationale for Utilization of ISO 13485: 2016

- Regulatory expectations for a QMS have evolved
- Used by many other countries
- Lessons learned through current and previous FDA programs utilizing ISO 13485 demonstrated feasibility
- Requirements are substantively similar between the current part 820 and ISO 13485:2016



Benefits of ISO 13485: 2016



- Modernized QMS principles
- Greater integration of risk management activities
- Globally harmonized requirements
  - Standard used by many other Regulatory Authorities
  - Many global manufacturers already comply with ISO 13485

Goals of Proposed Quality Management System Regulation

- Simplify and Streamline the Regulation
- Reduce burden on manufacturers
- Keep country specific requirements at a minimum
- Maintain a similar level of assurance in a manufacturer's quality management system

Overview of Proposed Quality Management System Regulation

- Withdraws most of the requirements in the current part 820
  - Retains the scope and a number of the definitions from the current part 820
- Incorporates by reference ISO 13485:2016
  - Minimal called out provisions to ensure consistency with other applicable FDA requirements
    - Includes definitions, clarifying concepts, and requirements
- Includes conforming edits to Part 4 (cGMPs for combination products)
  - Does not impact the CGMP requirements for combination products

Structure of the Proposed QMSR

820.1 Scope.

820.3 Definitions.

820.7 Incorporation by reference.

820.10 Requirements for a quality management system.

820.15 Clarification of concepts.

820.35 Control of records.

820.45 Device labeling and packaging controls.

Definitions

(§820.3)

Withdraw

- Establish

Retain

- *Act*----> **FD&C Act**
- *Management with executive responsibility*----> **Top Management**
- *Process Validation*-----> **Validation of processes**
- Finished device
- HCT/P
- Design validation
- Remanufacturer
- Nonconformity
- Verification
- Component

Definitions (cont.)

(§820.3)

Retain with modification

- Rework: removing the reference to device master record (DMR)
- Product: retaining, but adding ‘service’ to the definition

Clarify/Supersede

- *Medical device*---> **Device**
- *Labelling*---> **Labeling**
- Manufacturer

Add

- Customer
- Process agent

Linkages/ Applicable Regulatory Requirements

(§820.10)

- Document a QMS
- Requirement to comply with other linked/applicable requirements:
  - 21 CFR Part 830: Unique Device Identification Requirements (Clause 7.5.8)
  - 21 CFR Part 821: Traceability Requirements, if applicable (Clause 7.5.9)
  - 21 CFR Part 803: Reporting to Regulatory Authorities (Clause 8.2.3)
  - 21 CFR Part 806, Advisory Notices (Clauses 7.2.3, 8.2.3, 8.3.3)
- Applicability of Design and Development activities
- Traceability
  - Add a requirement to ensure that devices that support or sustain life, comply with the traceability requirements, in addition to just implantable devices as outlined in Clause 7.5.9.2

Clarification of Concepts

(§820.15)

Organization

- Clarify the term to also include the meaning of the term manufacturer as defined in the proposed §820.3

Safety and Performance

- Where safety and performance is used, it shall be construed to mean the same as “safety and effectiveness”

Validation of processes

- Clarify the term as used in ISO 13485 to refer to “process validation” as defined in the current Part 820

Control of Records

(§820.35)

- Signature and date requirements for records
- Information required by 21 CFR Part 803, complaint and servicing activities
- Documentation required to meet Unique Device Identification (UDI) requirements of 21 CFR Part 830
- Confidentiality of records FDA receives

Must meet these requirements in addition to those in Clause 4.2.5

Controls for Device Labeling and Packaging

(§820.45)

- Proposes to retain requirements from QS reg as ISO 13485 fails to provide additional requirements
- ISO 13485 lacks specific requirements to address labeling inspection activities
- Intended to strengthen controls for labeling and packaging operations

Must meet these requirements in addition to those in Clause 7.5.1(e)

Proposed QMSR Key Considerations

- Does not modify which establishments or products are subject to part 820
- Incorporates the 2016 version of ISO 13485
  - Any future changes to the standard would need to be evaluated
- Proposes a transition period
- ISO 13485: 2016 standard available in the ANSI Incorporated by Reference (IBR) Portal
  - https://ibr.ansi.org/
- FDA will retain our inspectional authority
  - FDA inspections **will not result** in the issuance of certificates of conformance to ISO 13485:2016
  - Manufacturers with a certificate of conformance to ISO 13485:2016 are not exempt from FDA inspections
  - FDA **will not require** ISO 13485 certificates

FDA Implementation Activities

- Updating technology systems
- Training of personnel
- Replacing current inspection model, Quality System Inspection Technique (QSIT)
- Revise [and/or develop] relevant regulations, policies, procedures and other documents impacted by this rulemaking
  - Compliance Program Guidance Manual (CPGM)
  - Guidance Documents
- Education and Communication

Knowledge Check #1

The proposed QMSR replaces most of the existing regulation by incorporating by reference ISO13485:2016

1. True
2. False

Knowledge Check #2

Identify the benefit of incorporating ISO13485:2016 by reference?

1. Requirements are very similar to the current part 820 Quality System Regulation
2. It is globally harmonized and widely in use
3. It has modernized QMS principles
4. All of the above

Summary

- FDA issued a proposed rule to amend Part 820
- The proposed rule will incorporate by reference ISO13485:2016
- The change will further harmonize global regulatory requirements for QMS
- The benefits of this change include simplified and streamlined regulatory requirements and less burden while maintaining a similar level of assurance in a firm's quality management system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