Navigating the Quality Management System Regulation

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Quality Management System Regulation

- Part 1: Overview of the Quality Management System Regulation

- **Part 2: Navigating the Quality Management System Regulation**

Learning Objectives

- Discuss purpose and scope of the Quality Management System Regulation (QMSR)
- Review key requirements of the QMSR
  - Include referencing ISO 13485:2016 and Clause 3 of ISO 9000:2015
- Compare the 1996 and 2024 Part 820 regulations
- Identify ways to adapt to regulatory changes

ISO = International Organization for Standardization

QMSR: Purpose and Scope

Purpose of QMSR

Ensure ability to consistently manufacture devices that meet applicable requirements and specifications

Provide a framework for achieving quality

Assure that finished devices will be safe and effective

Assure that finished devices comply with FD&C Act

Scope of QMSR

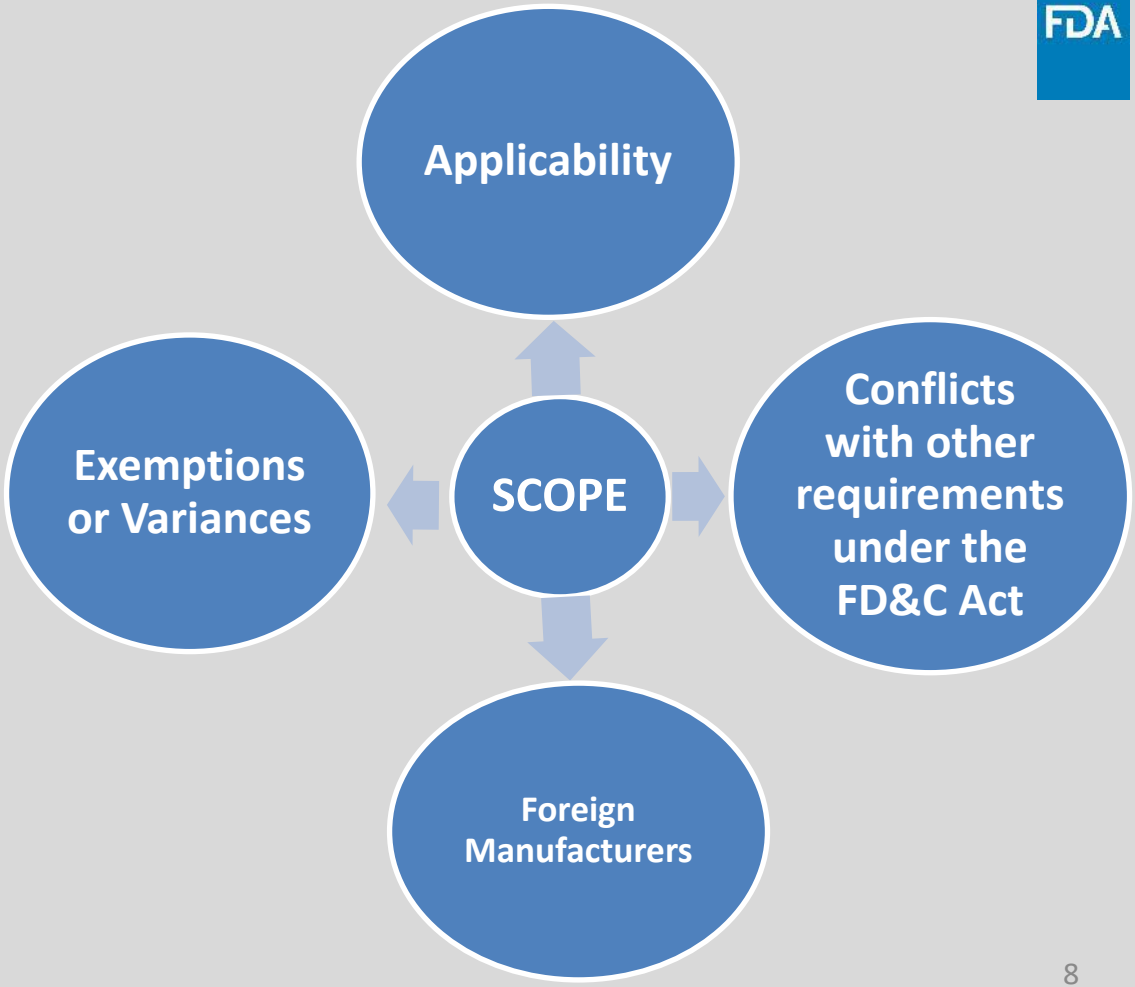
- Governs methods used in, and facilities and controls used for all finished devices intended for humans

Activities	
Design	Manufacture
Packaging	Labeling
Storage	Installation
Servicing	

QMSR: Requirements

QMSR Requirements

820.1 Scope



QMSR Requirements

820.3 Definitions

Requirements specify that:

- Definitions in ISO 13485:2016 and Clause 3 of ISO 9000:2015
  - Apply, except as specified in paragraph (b) of this section
  - Do not affect meaning of similar terms defined
- The 5 terms defined also apply and are either not used or not defined in ISO 13485 and Clause 3 of ISO 9000

QMSR Requirements

820.3 Definitions

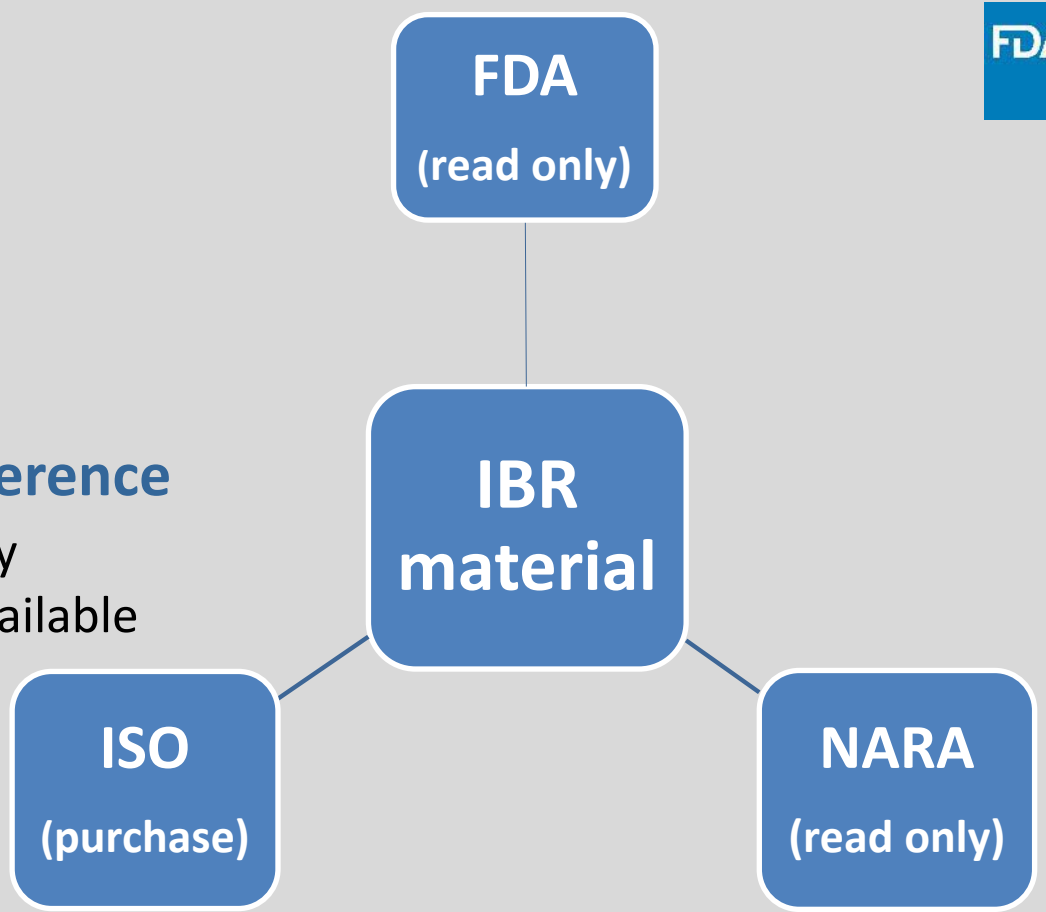
Requirements specify that:

- All definitions in section 201 of FD&C Act apply
- The 5 terms defined apply and supersede definitions for correlating terms in ISO 13485:2016 and Clause 3 of ISO 9000:2015

QMSR Requirements

820.7 Incorporation by reference

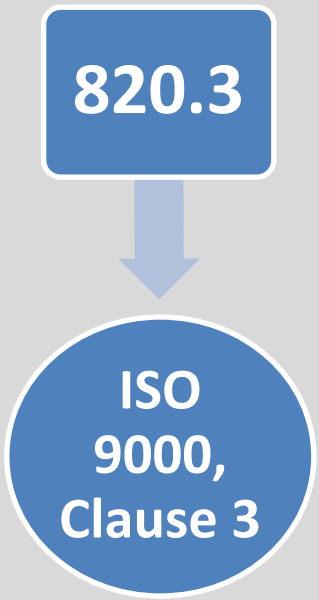
— All approved incorporation by reference (IBR) material is available

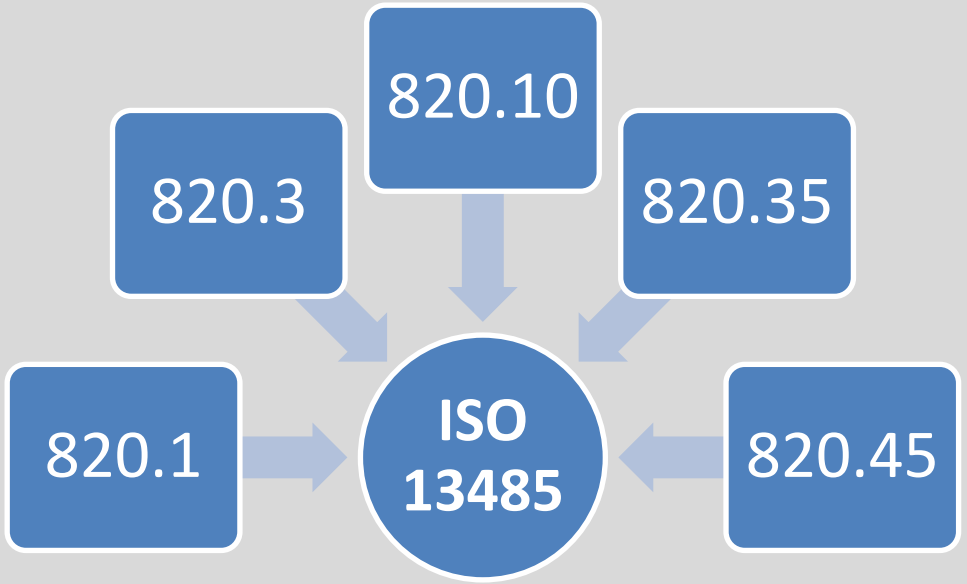


NARA = National Archives and Records Administration

QMSR Requirements

820.7 Incorporation by reference





QMSR Requirements

820.10 Requirements for a quality management system

Specifies requirements for:

- Documenting a quality management system
- Complying with other applicable regulatory requirements:

21 CFR Part	Title
830	Unique Device Identification (UDI)
821	Medical Device Tracking Requirements
803	Medical Device Reporting
806	Medical Devices; Reports of Corrections and Removals

QMSR Requirements

820.10 Requirements for a quality management system

Specifies requirements for:

- Complying with Design and Development requirements of Clause 7.3 in ISO 13485:2016
- Complying with requirements in Traceability for Implantable devices, Clause 7.5.9.2 in ISO 13485:2016

QMSR Requirements

820.10 Requirements for a quality management system

Specifies:

- That an adulterated device, as well as the person responsible for the adulteration, is subject to regulatory action

QMSR Requirements

820.35 Control of records

Specifies requirements:

- For specific information to be included in these records:
  - Complaints
  - Servicing activities
  - For each medical device or batch of medical device, including UDI
  - Confidential

QMSR Requirements

820.45 Device labeling and packaging controls

Specifies requirements for:

- Documenting and maintaining procedures for labeling and packaging
- Examining labeling and packaging for accuracy prior to release or storage

QMSR Requirements

820.45 Device labeling and packaging controls

Specifies requirements for:

- Documenting release of labeling for use per Clause 4.2.5 of ISO 13485:2016
- Establishing and maintaining labeling and packaging operations to prevent mix-ups:
  - Document results of labeling inspection per Clause 4.2.5 of ISO 13485

Navigating QMSR Requirements

Familiarize	• Familiarize yourself with FDA regulations and applicable standards
Conduct	• Conduct Gap Analysis
Implement	• Implement robust documentation
Foster	• Foster a Culture of Compliance

Comparing the 1996 and 2024 Part 820 regulations

1996 and 2024 Part 820 Regulations

	1996 Regulation	2024 Regulation
Title	Quality System Regulation (QS Reg)	Quality Management System Regulation (QMSR)
Issued Date	October 7, 1996	February 2, 2024
Effective Date	June 1, 1997	February 2, 2026

Comparing Part 820 Requirements

1996 Regulation	2024 Regulation
Subpart A-General Provisions 820.1, 820.3, 820.5	substantively similar and incorporation by reference (IBR)
Subpart B-Quality System Requirements 820.20, 820.22, 820.25	IBR
Subpart C-Design Controls 820.30	substantively similar and IBR
Subpart D-Document Controls 820.40	IBR with regulatory requirements also set forth in section 820.35
Subpart E-Purchasing Controls 820.50	IBR

Comparing Part 820 Requirements

1996 Regulation	2024 Regulation
Subpart F-Identification and Traceability 820.60, 820.65	IBR with links to other regulations
Subpart G-Production and Process Controls 820.70, 820.72, 820.75	IBR
Subpart H-Acceptance Activities 820.80, 820.86	IBR
Subpart I-Nonconforming Product 820.90	IBR
Subpart J-Corrective and Preventive Action 820.100	IBR

Comparing Part 820 Requirements

1996 Regulation	2024 Regulation
Subpart K-Labeling and Packaging Control 820.120, 820.130	IBR with regulatory requirements also set forth in section 820.45
Subpart L-Handling, Storage, Distribution, and Installation 820.140, 820.150, 820.160, 820.170	IBR
Subpart M-Records 820.180, 820.181, 820.184, 820.186, 820.198	IBR with regulatory requirements also set forth in section 820.35 and links to other regulations
Subpart N-Servicing 820.200	IBR with regulatory requirements also set forth in section 820.35
Subpart O- Statistical Techniques 820.250	IBR

Ways to Adapt to Regulatory Changes

Ways to Adapt to Regulatory Changes

- Identify and understand regulatory changes
- Conduct gap analysis
- Identify differences
- Revise processes and procedures to incorporate changes

Ways to Adapt to Regulatory Changes

- Train employees on revised processes and procedures
- Implement new processes and procedures
- Monitor implementation of revised processes and procedures

Resources

Slide Number	Cited Resource	URL
1	Final Rule: Medical Devices; Quality System Regulation Amendments	www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments#sectno-reference-820.3
5	ISO 13485: 2016- Medical Devices- Quality management systems- Requirements for regulatory purposes	ibr.ansi.org/Standards/iso1.aspx
11	21 CFR 4: Regulation of Combination Products	www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-4
12	ISO 9000: 2015-Quality management systems- Fundamentals and vocabulary	www.iso.org/obp/ui#iso:std:iso:9000:ed-4:v1:en

Summary

- The Quality Management System Regulation (QMSR) specifies requirements that provide assurance that devices are safe and effective
- The QMSR incorporates by reference ISO 13485:2016 and Clause 3 of ISO 9000:2015 standards
- All definitions in Section 201 of the FD&C Act and QMSR supersede correlating definitions in ISO 13485 and Clause 3 of ISO 9000

Industry Education

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2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

CDRH Learn

Device Advice

Email DICE

Your Call to Action

- Embrace continuous efforts of harmonization
- Familiarize yourself with: 2024 Final Rule; QMSR; ISO 13485:2016; and Clause 3 of ISO 9000:2015
- Conduct gap analysis of your current procedures to identify any gaps in meeting regulatory requirements
- Engage in continuous training on implementing the QMSR


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