Quality Management System Regulation (QMSR) – Risk Management, Risk-Based Approach, and Risk-Based Decisions

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Risk Management Activities

Source: Rev.1 engineering

Learning Objectives

- Define key risk terms
- Explain the role of risk management within the Quality Management System
- Identify Quality Management System Regulation (QMSR) requirements for risk management, risk-based approach, and risk-based decisions
- Review examples of risk documentation

Key Risk Terms

Key Risk Terms

- ***Risk***: combination of the probability of occurrence of harm and the severity of that harm

- ***Risk management:*** systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling and monitoring risk

ANSI/AAMI/ISO 13485:2016; SOURCE: ISO 14971:2007

Key Risk Terms

- FDA Response to Comment 32

"...ISO 13485 Clause 0.2 states that ‘‘when the term ‘risk’ is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.’’

Medical Devices; Quality System Regulation Amendments FR 89 7496 Final Rule (2024 Final Rule)

Key Risk Terms

- **Risk-based approach:** identifying risks and opportunities and focusing on preventing or reducing undesired effects

- **Risk-based decision:** making a specific decision based on risk assessment and other criteria

ANSI/AAMI/ISO 13485:2016; Medical Device, A Practical Guide

Role of Risk Management

Role of Risk Management

- Identify, assess, control, communicate and review device risks to the quality management system processes
- Provide reasonable assurance of safety and effectiveness
  - Throughout total product life cycle

Role of Risk Management

- Provide a framework for sound decision making-within a quality management system; for example:
  - Identifying design outputs that are essential for the proper functioning of the device
  - Continually updating based on postmarket surveillance data
  - Defining the extent of verification activities for purchased product
  - Defining the approach to quality management system software validation, or revalidation activities, in proportion to the risk associated with the use of the software

QMSR Requirements for Risk Management, Risk-Based Approach, and Risk-Based Decisions

QMSR Requirements: Risk Management, Risk-Based Approach, and Risk-Based Decisions

- Codified, Title 21 Code of Federal Regulations (CFR) 820.10(a)
  - Requirements for a quality management system
    - *Document.* Document a quality management system that complies with the applicable requirements of ISO 13485 (incorporated by reference, see § 820.7) and other appliable requirements of this part
- Incorporated By Reference to ISO 13485:2016, Medical devices- Quality management systems- Requirements for regulatory purposes
- Clarified in FDA response to Comments #19 and #27 of the 2024 Medical Devices; Quality System Regulation Amendments FR 89 7496 Final Rule (2024 Final Rule)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risk-Based Decisions

- FDA Response to Comment 19

"...although the integration of risk management principles throughout ISO 13485 does not represent a shift in philosophy, the explicit integration of risk management throughout the clauses of ISO 13485 more explicitly establishes a requirement for risk management to occur throughout a QMS and should help industry develop more effective total product lifecycle risk management systems...’’

Medical Devices; Quality System Regulation Amendments FR 89 7496 Final Rule (2024 Final Rule)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risk-Based Decision

- Quality Culture: FDA Response to Comment 27

- "...FDA expects medical device manufacturers, led by individuals with executive responsibilities, to embrace a culture of quality as a key component in ensuring the manufacture of safe and effective medical devices..."

- "A culture of quality meets regulatory requirements through a set of *behaviors, attitudes, activities ,and processes."*

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 4.1	General Requirements
Clause 6.2	Human Resources (NOTE, *for guidance and understanding*)
Clause 7.1	Planning of product realization
Clause 7.3	Design and Development
Clause 7.4	Purchasing

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 7.5	Production and service provision
Clause 7.6	Control of monitoring and measuring equipment
Clause 8.2	Monitoring and Measurement
Clause 8.3	Control of nonconforming product
Clause 8.5	Improvement

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 4.1	**General Requirements** • apply a risk-based approach to the control of the appropriate processes needed for the quality management system (4.1.2) • controls shall be proportionate to the risk involved and ability of external party to meet requirements (4.1.5) - controls over outsourced processes • specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software (4.1.6)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 6.2	**Human Resources** • methodology used to check effectiveness (*of actions taken*) is proportionate to the risk associated with the work for which the training or other action is being provided (NOTE, *for guidance and understanding*)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 7.1	**Planning of product realization** • document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 7.3	**Design and development** • inputs shall include: - applicable output(s) of risk management [7.3.3(c)] - other requirements essential for design and development of the product and processes [7.33(e)] • design and development outputs shall: - specify the characteristics of the product that are essential for its safe and proper use (7.3.4)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 7.3	**Control of design and development changes** • review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes (7.3.9)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 7.4	**Purchasing** • The criteria for the evaluation and selection of suppliers shall be: - proportionate to the risk associated with the medical device (7.4.1) • Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements (7.4.1)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 7.4	**Purchasing** • The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product (7.4.3)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 7.5	**Production and service provision** • Specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications (7.5.6)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 7.6	**Control of monitoring and measuring equipment** • specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 8.2	**Monitoring and measurement** • information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes (8.2.1)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 8.3	**Control of nonconforming product** • When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity (8.3.3)

QMSR Requirements: Risk Management, Risk-Based Approach, and Risked-Based Decisions

- ISO 13485:2016 Incorporated by Reference

ISO 13485 Clause	
Clause 8.5	**Improvement** • Corrective actions shall be proportionate to the effects of the nonconformities encountered. (8.5.2) • Preventive actions shall be proportionate to the effects of the potential problems. (8.5.3)

Examples: Risk Documentation

Examples: Risk Documentation

- Examples of useful standard and documents:
  - AAMI/ANSI/ISO 14971:2019 Medical devices-Application of risk management to medical devices (ISO 14971)
    - ➢ Systematic approach to conducting risk management activities
  - AAMI/ISO TIR24971:2020-Medical devices- guidance on the application of ISO 14971
    - ➢ Provides guidance on the application of ISO 14971

Examples: Risk Documentation

Method	Purpose	When to Use
Risk Management Plan	Outlines risk management scope, responsibilities, and criteria	At the start of product development
Risk Analysis Report	Identifies hazards, hazardous situations, and estimated risks in normal and fault conditions	During design & development
Risk Evaluation Summary	Justifies acceptability of individual and overall risk	Post-analysis, before mitigation
Risk Traceability Matrix	Demonstrates that risks are addressed and mitigated throughout the product lifecycle	After completing the previous documents to ensure risks are mitigated, where appropriate; Continue to update throughout the device lifecycle
Risk Management File (RMF)	Centralized record of all risk-related documentation	Maintained throughout device lifecycle

Examples: Risk Documentation

Method	Purpose	When to Use
Design Review Meeting Minutes	Captures discussions and rationale for risk-based decisions	During formal design reviews
Change Control Records	Evaluates risk of proposed changes and documents decisions	When modifying design, process, or labeling
Improvement Documentation	Links corrective actions to risk evaluations	Post-market issues or nonconformities
Production/Process FMEA (pFMEA)	Assesses manufacturing process risks	During design and development transfer, process development, and validation of processes
Benefit-Risk Analysis Report	Justifies why benefits outweigh residual risks	When residual risks remain after controls

Resources

Slide Number	Cited Resource	URL
6	Medical Devices; Quality System Regulation Amendments Final Rule	www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments
5,6	ISO 13485 and ISO 9000 standards (read/view only)	ibr.ansi.org/standards/iso1.aspx
5,6	ISO 13485 and ISO 9000 standards (for purchase)	ibr.ansi.org/
23	ANSI/AAMI/ISO 14971:2019 Medical devices – Applications of risk management to medical devices	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=40369 (for purchase from standards organization)
23	ANSI/AAMI/ISO TIR 24971:2020 Medical devices- Guidance on the application of ISO 14971	www.iso.org/standard/74437.html (for purchase from standards organization)

Summary

- Risk Management is integral to safe and effective devices and an effective quality management system.
- QMSR incorporates risk management principles, and risk-based approaches throughout the total life of the device and incorporates risk-based decision making within the quality management system by incorporating by reference ISO 13485:2016.

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

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 (9 am – 12:30 pm; 1 – 4:30 pm ET)

Call To Action

- Review the QMSR requirements for risk management, risk-based approach, and risk-based decisions.
- Document risk management activities thoroughly and revisit frequently.
- Use risk management as a framework for sound decision making within the QMS to provide assurance that devices will be safe and effective.


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