

Basics of Risk Management for Quality Systems

**FDA Small Business
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Learning Objectives

- Understand risk, risk analysis and risk management and be aware of changes to risk and when to make updates
- Know the Quality System regulatory requirements for risk and the relationship to risk management
- Learn about the ISO 14971 standard and identify risk analysis tools and resources

Definition of Risk

- **No formal FDA definition of the term “risk.”**
- **Starting Point:**
 - The risk of the medical device to patients, end users and environment, which includes the risk of the device if it were to fail, i.e., not operate as intended.
- **From ISO 14971:2007 2.16:**
 - Combination of the probability of occurrence of harm and the severity of that harm.

```
graph TD; A[HAZARD – Potential Source of Harm] --> B[HAZARDOUS SITUATION]; B --> C[\"HARM – Physical injury or damage to the health of people or damage to property or the environment\"]; C --> D[\"SEVERITY of Harm\"]; C --> E[\"PROBABILITY of Harm\"]; D --> F[RISK]; E --> F;
```

The flowchart illustrates the sequence of events leading to risk. It begins with a box labeled **HAZARD** – Potential Source of Harm. An arrow points down to a box labeled **HAZARDOUS SITUATION**. Another arrow points down to a box labeled **HARM** – Physical injury or damage to the health of people or damage to property or the environment. From the **HARM** box, two arrows point down to two separate boxes: **SEVERITY of Harm** and **PROBABILITY of Harm**. These two boxes are enclosed in a dashed-line rectangle. An arrow points from the right side of this dashed rectangle to a final box labeled **RISK**. A vertical label on the left side of the diagram, oriented vertically, reads **SEQUENCE OF EVENTS**.

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Regulatory Requirements

What you are required to comply with:

- Federal Food, Drug and Cosmetic Act
- Safe Medical Device Amendments of 1990
- Title 21 Code of Federal Regulations
- 21 CFR Part 820 – Quality System Regulation

Quiz

D2S4-1

View Votes
Edit
End Poll

D2S4-1: What section of the Quality System Regulation requires Risk Analysis?

<input type="radio"/> 21 CFR 820.70 - Production and Process Controls		0%	(0)
<input type="radio"/> 21 CFR 820.30 - Design Controls		0%	(0)
<input type="radio"/> 21 CFR 820.100 - Corrective and Preventive Action		0%	(0)
<input type="radio"/> 21 CFR 820.50 - Purchasing		0%	(0)
<input checked="" type="radio"/> No Vote			

☐ Broadcast Results

Risk Analysis in the Quality System Regulation

21 CFR 820.30 (g) Design Validation:

“Design validation shall include software validation and risk analysis, where appropriate”

What is Risk Analysis?

Intent of Risk Analysis per Preamble Comment #83:

- Identify possible hazards, including user error
- Calculate risk, under normal and fault conditions
- Determine risk acceptability
- Reduce unacceptable risks to acceptable levels
- Ensure changes made do not introduce new hazards

Risk-Based Decisions in the QS Regulation Preamble

CFR Section	Name	Comment #
820.1	Scope	4, 13
820.30	Design Controls	81, 83
820.50	Purchasing Controls	115
820.65	Traceability	121
820.70	Production/Process Control	31
820.90	Non-Conforming Product	161
820.100	CAPA	159
820.200	Servicing	200

Scope – Risk-Based Decisions

“...gives the [manufacturer the flexibility](#) to determine the controls that are necessary commensurate with risk. The [burden is on the manufacturer](#), however, to describe the types and degree of controls and how those controls were decided upon.”

Preamble Comment #4

Scope – Risk-Based Decisions (cont.)

“The [extent of the documentation](#) necessary to meet the regulation requirements may vary with the... [risk](#) associated with the failure of the device, among other factors.”

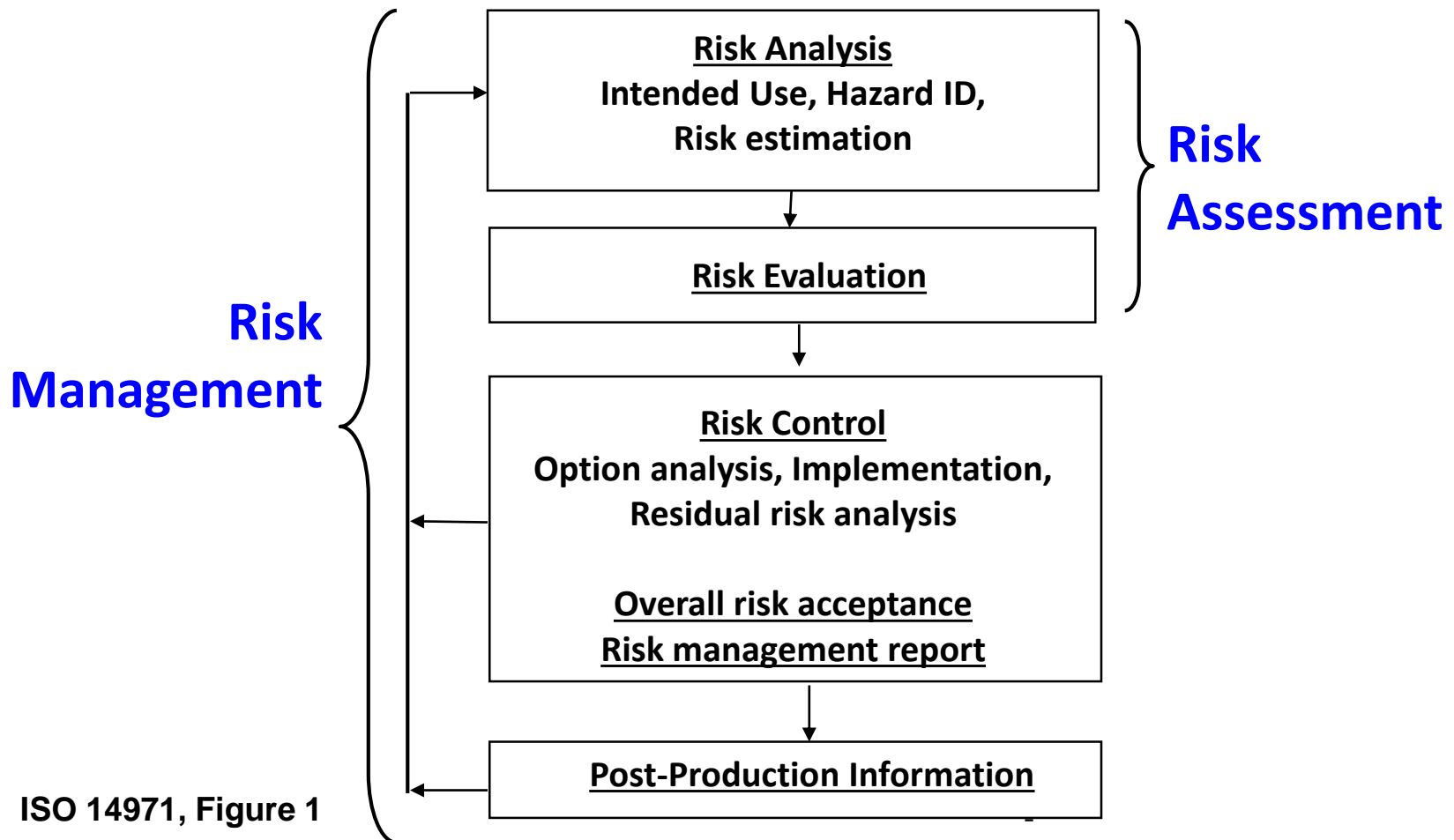
Preamble Comment #13

Who makes these Risk-Based decisions?

Management has final responsibility in making these risk based decisions. They:

- Provide the resources
- Establish the policy and objectives for and commitment to quality
- Determine the organization
- Decide on their Quality System

Risk Management and Risk Assessment



ISO 14971, Figure 1

What is Risk Management?

- Is the current approach
- Is both systematic and comprehensive
- Begins with product design and follows it through the Total Product Life Cycle (TPLC)
- From a practical standpoint, you would integrate risk management into your Quality System.

Risk Management Standard

International Standard Organization 14971

Title: Medical devices – Application of risk management to medical device

ISO/ANSI/AAMI 14971:2007(R)2010

FDA-Recognized Consensus Standard

ISO 14971: Overview

- **Main Content Body**
 - Normative text with nine sections
- **Ten Annexes**
 - Informative with ten annexes

ISO 14971: Main Body Content

- 1) Scope
- 2) Terms and Definitions
- 3) General Requirements
- 4) Risk Analysis
- 5) Risk Evaluation
- 6) Risk Control
- 7) Evaluation of Overall Residual Risk Acceptability
- 8) Risk management report
- 9) Production and post-production information

ISO 14971: Scope

The international standard specifies a process for medical device manufactures to:

- Identify hazards
- Estimate and Evaluate Risk
- Control the Risk
- Monitor the Effectiveness of the Controls
- Evaluate the Residual Risk Acceptability

and are applicable to all stages of Total Product Life Cycle (TPLC)

ISO 14971: General Requirements

- Risk management process, as noted in scope
- Management responsibilities
- Qualification of personnel
- Risk management plan
- Risk management file

ISO 14971: Annexes

Annex	Title
A	Rationale for requirements
B	Overview of the risk management process for medical devices
C	Questions that can be used to identify medical device characteristics that could impact safety
D	Risk concepts applied to medical devices

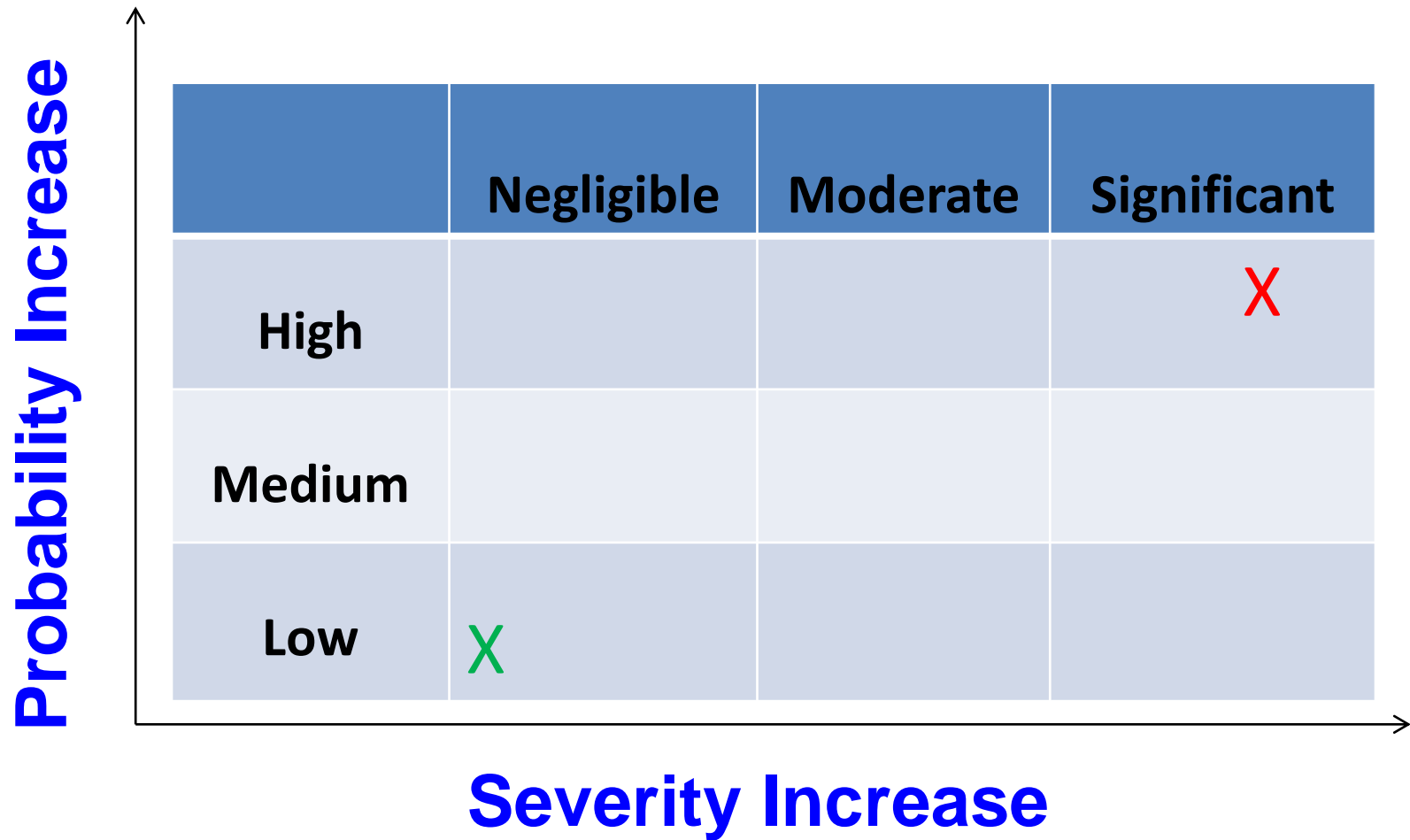
ISO 14971: Annexes (cont.)

Annex	Title
E	Examples of hazards, foreseeable sequences of events and hazardous conditions
F	Risk management plan
G	Information on risk management techniques

ISO 14971: Annexes (cont.)

Annex	Title
H	Guidance on risk management for <i>in vitro</i> diagnostic medical devices
I	Risk Analysis for Biological Hazards
J	Information for safety and about residual risk

Risk Concepts

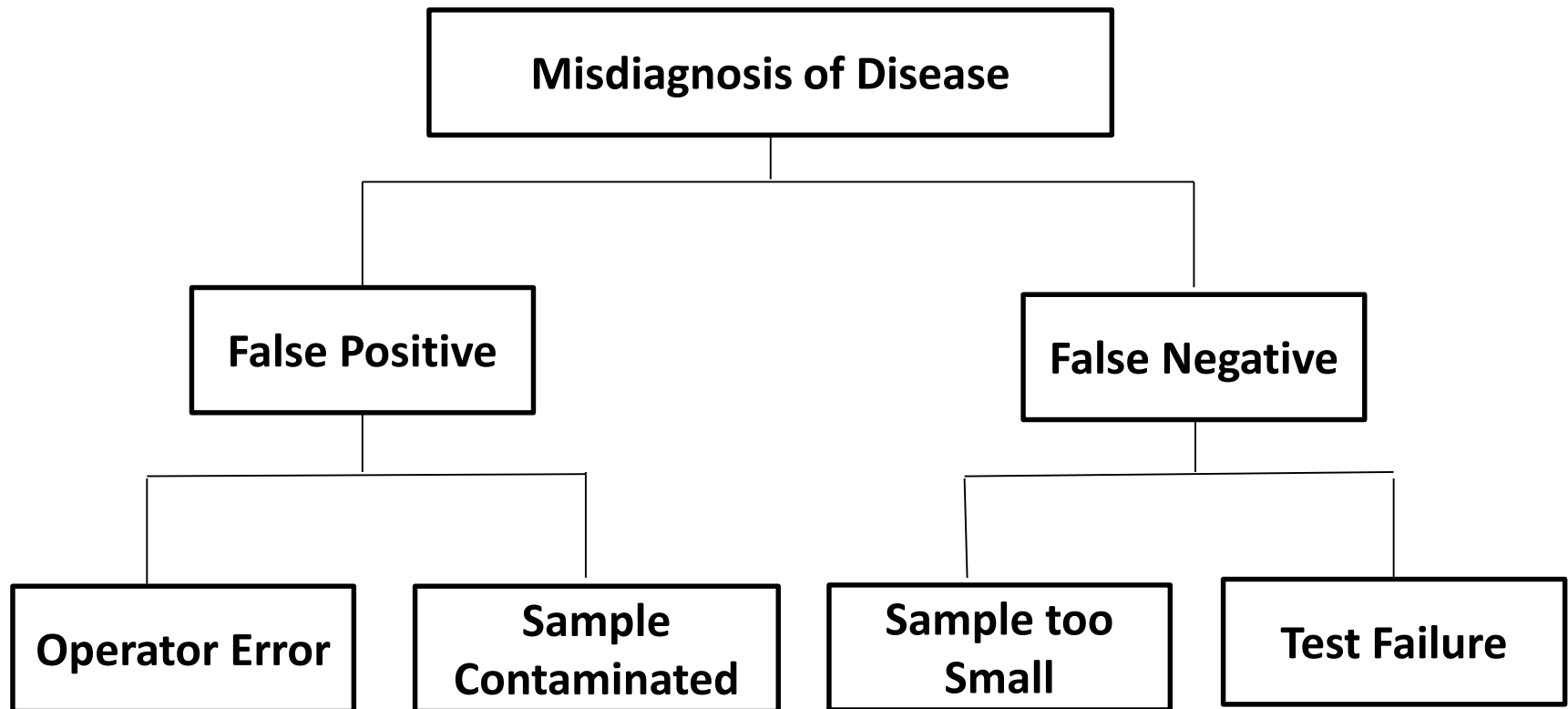


Risk Analysis Tools

- Preliminary hazard analysis (PHA)
- Fault Tree Analysis (FTA)
- Failure Mode Event Analysis (FMEA)
- Hazard and Operability Study (HAZOP)
- Hazard Analysis and Critical Control Point (HACCP)

Example of Risk Analysis Tool

Fault Tree Analysis (FTA): IVD



Example of Risk Analysis Tool

Failure Mode Event Analysis (FMEA)

Requirement	Potential Failure Mode	Potential Effects	Severity (S) (1-5)	Occurrence (O) (1-5)	Detection (D) (1-5)	RPN
Implant Strength	Break	Failure Replace	5	1	2	10
Implant Sterility	Contami-nation	Infection	4	2	4	32
Sterile Package	Broken Seal	Infection	4	3	2	24
Implant Label (IFU)	Misread	Improper Placing	3	2	3	18

Risk Mitigations

Mitigation is a broad term for my purpose here, meaning the elimination, reduction or control of the risk by:

- Design and redesign
- Protections and Alarms
- Labeling
- Training

Risk Benefit Determination

Used to justify remaining residual risk once all reasonable measures to reduce risk have been applied.

- Decision applies to the device as a whole
- Can be used to justify abandoning design
- Considers anticipated clinical benefits
- Final determination must be approved and communicated

Post-Production Information

- Purchasing information
- Manufacturing and process deviations
- Non-conforming product
- Complaints and Medical Device Reporting
- Recalls
- Corrective and Preventive Action

Additional Resources on Risk

- Implementation of risk management principles and activities within a Quality Management System - GHTF - 2005

<http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n15r8-risk-management-principles-qms-050520.pdf>

- Guidance for Industry and Food and Drug Administration Staff - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm267829.htm>

Questions

Please complete the session survey:

surveymonkey.com/r/DEV-D2S4

Your Call to Action

- Medical Devices pose a risk both to their end users and patients. Understand what is meant by risk.
- Manufacturers are obligated to understand the risk their devices pose, understand your devices risk.
- Know your regulatory requirements for risk analysis and for making risk based decisions and meet or exceed them.

Your Call to Action (cont.)

- Learn about the ISO 14971 standard, a useful tool for understanding and establishing risk management.
- The utilization of risk management will help you understand your devices risk and assist in device design, manufacturing and decision-making.

