Risk Management Activities Within A Quality System

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Risk Management Activities

Source: Rev.1 engineering

Learning Objectives

- Define key risk management terms
- Explain the reasons for conducting risk management activities
- Identify when to use risk management activities within a quality system
- List techniques for conducting risk management activities

Key Risk Management Terms

Key Terms

- **Benefit:** positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health
- ***Harm:*** injury or damage to people, or damage to property or the environment
- ***Hazard:*** potential source of harm
- ***Hazardous situation:*** circumstances in which people, property or the environment is/are exposed to one or more hazards

ANSI/AAMI/ISO 14971:2019

Key Terms

- ***Risk***: the combination of probability of occurrence of harm and the severity of that harm.
- **Risk Analysis:** systematic use of available information to identify hazards and to estimate the risk
- ***Risk management:*** the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk

ANSI/AAMI/ISO 14971:2019

Reasons for Conducting Risk Management Activities

Why Conduct Risk Management Activities?

Why conduct risk management activities?

Risk analysis is a regulatory requirement

To identify device design problems prior to distribution

FDA regulatory submissions require risk analysis information

To ensure safety of the device

Why conduct risk management activities?

To reduce the possibility of failure of the device

To identify hazards with use of the device

To evaluate the risk with use of the device and decide whether to use the device or not

It is the right thing to do

Knowledge Check

What is the combination of the probability of occurrence of harm and the severity of that harm?

a. Risk management

b. Benefit

c. Risk

d. Harm

When To Use Risk Management Activities Within A Quality System

When to Use Risk Management Activities

- When conducting risk analysis, where appropriate, as required
- When making risk based decisions including:
  - Identifying design outputs that are essential for the proper functioning of the device
  - Defining the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants

21 Code of Federal Regulations, Part 820 (21 CFR 820)

When to Use Risk Management Activities

- When making risk based decisions including:
  - Describing necessary process controls
  - Documenting major equipment used for validated processes, where appropriate
  - Determining necessary approvals for in-process acceptance activities

21 CFR 820

When to Use Risk Management Activities

- When making risk based decisions including:
  - Determining the need for an investigation of nonconforming product
  - Conducting internal audits

21 CFR 820

Knowledge Check

You should conduct risk management activities for all of the following reasons EXCEPT:

a. It is a regulatory requirement

b. To determine if you should register the device

c. To reduce the possibility of device failure

d. To control the risk with use of the device

Techniques for Conducting Risk Management Activities

Risk Management Process

AAMI/ANSI/ISO 14971:2019

Medical devices- Application of risk management to medical devices

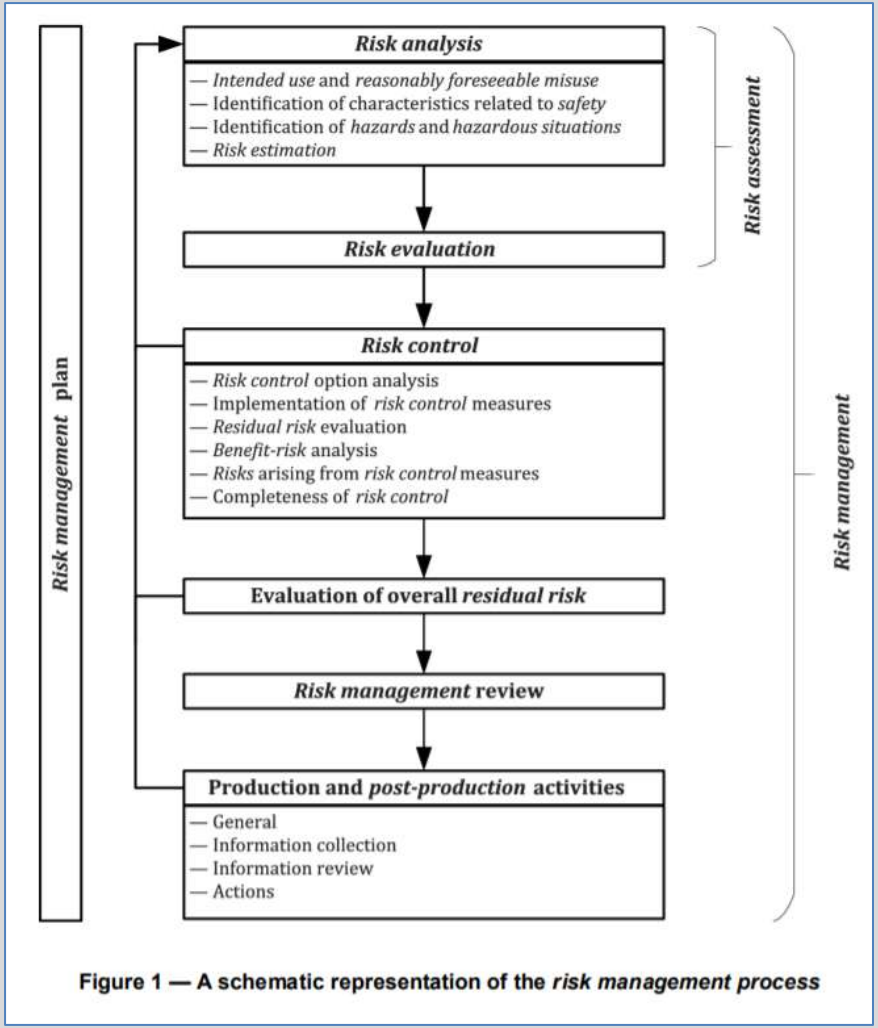

Figure 1 — A schematic representation of the *risk management process*

Risk Management Process

- AAMI/ANSI/ISO 14971:2019 Medical devices-Application of risk management to medical devices (ISO 14971)
  - Used to conduct risk analysis activities as required by regulation
  - 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

Risk Management Techniques

- Preliminary Hazard Analysis (PHA)
- Fault Tree Analysis
- Failure Mode and Effects Analysis (FMEA)
- Benefit-Risk Analysis

Risk Management Techniques

Preliminary Hazard Analysis

- Used in risk analysis as a means of identifying hazards and hazardous situations
  - Few device design details known
  - Conducted early in device development
  - Useful in prioritizing hazards

Risk Management Techniques

Preliminary Hazard Analysis

- List possible hazards
  - Brainstorm for possible hazards
  - Use previously published literature
  - Use information in international standards

Risk Management Techniques

Questions to identify characteristics

#	Question	Factors/Characteristics to consider
1.	Does the medical device have a restricted shelf life?	Can the device deteriorate over time; impact of storage conditions; communication of expiry date (labeling, indicators); use after expiry date; the disposal of expired device

Risk Management Techniques

Severity of Harm Descriptions

Identifier	Term	Description
S-5	Critical	Results in death
S-4	Serious	Results in permanent impairment
S-3	Major	Results in injury
S-2	Minor	Results in temporary injury
S-1	Negligible	Results in temporary discomfort

Risk Management Techniques

Probability of Harm Descriptions

Identifier	Term	Description
P-3	Frequent	Likely to occur daily
P-2	Occasional	Likely to occur monthly
P-1	Remote	Unlikely to occur but possible

Risk Management Techniques

Preliminary Hazard Analysis

#	Hazard	Hazardous situation	Harm	Severity	Probability	Risk control
	Pt. gets incorrect test result	Dr. believes the result is accurate and administers insulin	Hypoglycemia; Pt. suffered a seizure	S-4	P-3	Redesign test; build in internal control; change chemical

Other Risk Management Techniques

- Risk Acceptability Chart
  - For evaluating risk (initial and residual risk)
- Risk Control Option Analysis
  - For controlling risk
- Risk Management Report
  - To capture relevant review of production and post production risk information

Knowledge Check

Which technique below can be used to evaluate hazards?

a. Risk Management Report

b. Fault Tree Analysis

c. Process Flow Diagram

Summary

- Risk management activities are required throughout the product life cycle
- PHA, FTA, and FMEA are different types of risk management techniques
- Manufacturers can use more than one risk management technique in their risk management process

Resources

Slide Number	Cited Resource	URL
5, 6, 8, 18	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)
14, 15, 16	21 CFR 820 Quality System Regulation	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820
19	ANSI/ISO TIR24971:2020 Medical devices- Guidance on the application of ISO 14971	https://www.iso.org/standard/74437.html (for purchase from standards organization)
20	Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-regarding-benefit-risk-medical-device-product-availability-compliance-and
20	4 CDRH Benefit-Risk Guidance documents:	https://www.fda.gov/regulatory-information/search-fda-guidance-documents

Questions


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