Quality Risk Management -
The Medical Device Experience

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Agenda

Intent of Risk Management (RM) and Associated Regulations

Overview of RM Elements and Terminology

Discussion on Watch-Outs & Best Practices throughout

Challenges Implementing RM in the Medical Device Industry
ISO 14971:2007 Medical Devices – “Application of Risk Management to Medical Devices”

**Note 1:** ISO 14971:2007 = EN ISO 14971:2009

**Note 2:** Conformity to EN ISO 14971:2007 expired on March 21, 2010
ISO 13485:2003 - Medical Devices Quality Management Systems Requirements for Regulatory Purposes

• Clause 7.1 requires, “…risk management throughout product realization.”
  – In addition, “Records arising from risk management shall be maintained”.
  – The standard cross references ISO 14971 for guidance related to risk management.

• Clause 7.3.2 states that design and development inputs include risk management outputs
FDA’s Quality System Regulation
Requirements for Risk Analysis

Risk Assessment is required as part of design validation (820.30 (g))

Note: Design Validation is defined as “establishing by objective evidence that device specifications conform with user needs and intended use(s)."
Risk Management Integrated as part of Design Controls

D&D Planning
Risk Analysis
DHF
Design Change

Design Input
Design Verification
Design Output
Design Validation
Design Review
Design Output (Final Product)
Design Transfer

Risk Management
What is Risk Management?

**Definition of Risk Management**

“The systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk.”

**The four stages** of the Risk Management Process:

- Management Leadership and Involvement
- Risk Management Process and control
- Product and Process Monitoring
- Risk Management System Support

...each represent multiple clauses within the ISO 14971 standard that we must abide by throughout a product’s lifecycle.

** Courtesy of ISO 14971:2007 “Medical Devices - Application of risk management to medical devices”, Terms and Definitions, 2.22
What is the intent of Risk Management?

Decision making process relating to safety of a medical device throughout the design, development and product lifecycle

- Differentiates most critical product features related to safety/harm
- Quantifies and determines acceptability of risk
- Provides focus and priority for product development and lifecycle activities (such as V&V, CAPA, etc.)
What is the intent of Risk Management?

- Requires procedures and practices for analyzing, evaluating, controlling, and monitoring product risks
- Management tool: Includes management’s role in making product risk-based decisions and reviewing system effectiveness
  - Connections to Design, Complaint, CAPA and QS Management reviews
<table>
<thead>
<tr>
<th>ISO 14971: 2007 Definition</th>
<th>Aligns with ICH Q9 Definition?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk</strong> – Combination of the probability of occurrence of harm and the severity of that harm</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Hazard</strong> – the potential source of harm</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Hazardous Situation</strong> – circumstance in which people, property, or the environment are exposed to one or more hazard(s)</td>
<td>Different Terminology Used</td>
</tr>
<tr>
<td><strong>Harm</strong> - physical injury or damage to the health of people, or damage to property or the environment</td>
<td>Variance in Definition</td>
</tr>
<tr>
<td><strong>Severity</strong> – measure of the possible consequences of a hazard</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Residual Risk</strong> – risk remaining after risk control measures have been taken</td>
<td>✓</td>
</tr>
</tbody>
</table>
## Terminology Examples:

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Hazardous Situation</th>
<th>Harms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tip- Sharp</td>
<td>Tip perforates vessel wall</td>
<td>Vessel trauma-major</td>
</tr>
<tr>
<td>Inflated Balloon</td>
<td>Blocked blood flow</td>
<td>Angina</td>
</tr>
<tr>
<td>SDS Catheter not sterile</td>
<td>Infectious agents from catheter released into body</td>
<td>Infection, systemic</td>
</tr>
</tbody>
</table>
Risk Management Process Flowchart

Risk Management planning

Risk analysis

Risk evaluation

Risk control

Evaluation of overall residual risk

Risk management reporting

Production/post-production information collection
Risk Management Plan

- Scope
- Responsibilities and Authorities
- Acceptance Criteria
- Known Risks
- Review Activities
- Verification Activities
- Information Collection Methods

RMP
The implementation of EN ISO 14971:2009 is not completely traceable. Some items are not found, e.g. but not limited to:

Risk Management Plan: Assignment of responsibilities and authorities not found.

The functional areas of those personnel who participated in the formulation of the FMEAs and Risk Management Report are not provided so it could not be verified that representatives from all relevant functional areas were included.
Risk Management Plan

Risk Management activities need an overall plan:

• Scope of risk management activities, including the intended use of the device and product lifecycle
• Assignment of responsibilities and authorities
• Review requirements for risk management
• Risk acceptability criteria
• Risk Verification
• Production activity data collection and review
• Post Production activity data collection and review
The Risk Management File shall provide traceability for each identified hazard to:

• the risk analysis
• the risk evaluation
• the implementation and verification of the risk control measures
• the assessment of the acceptability of any residual risk(s)
Risk Analysis

Systematic use of available information to identify hazards and to estimate the risk

Risk Assessment

Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
Risk Analysis

- Document both the intended use and foreseeable misuse of the device
- Identify known and foreseeable hazards associated with the device
- Estimate the risk for each hazardous situation

Hazard + Sequence of events = Hazardous Situation
Severity × Probability = Risk
Risk Evaluation

• The Risk Management Plan defines the risk evaluation criteria for each hazardous situation
• Evaluate each Hazardous situation, individually, against the criteria in the Risk Management Plan

If risk reduction is required, follow clauses 6.2 to 6.6

If risk reduction is not required, go to clause 6.7

Example
• A Risk Management Plan defines five risk levels, 1 to 5, and shows how to calculate them using severity and probability.
• Any risk of level 4 or 5 must be reduced to level 1, 2, or 3.
Risk Control

Hazardous Situation Identified

Risk Estimated

Risk reduction required?

Yes

Option Analysis (6.2)

Implementation (6.3)

Residual Risk (6.4)

Risk Benefit (6.5)

New Risks (6.6)

No

Completeness Check (6.7)

Overall Risk (7)
Evaluation of overall residual risk acceptability

- The Risk Management Plan defines risk evaluation criteria for overall risk
- After the risk control measures are implemented and validated, review the overall risk
- If the overall risk is unacceptable, determine if the medical benefits outweigh the overall residual risk
Please provide the expertise of the personnel involved in the risk analysis.

The FMEA does not include the hazards associated with reuse and re-sterilization.

The warnings and contra-indications in the DFU do not match the FMEA.

Activities regarding risk control are not traceable. The result of verification activities is not traceable.
Risk Management Report

- Deviations
- Medical Benefits
- RBE Summary
- Risks of Concern
- Conclusions
- RMF
The re-evaluation of the acceptability of the overall residual risk is not found in the report.
Prior to release of the device, you need to review the risk management process:

The review ensures:
• The Risk Management Plan is implemented
• Overall residual risk is acceptable
• Measures are in place to obtain production and post-production information

The reviews results become the Risk Management Report, and is included in the risk management file
Production and Post Production Information

Collect information about your device in the production phase.

• Review acceptance data
• Look closely at validated processes and their controls

In the post production phase review:

• Installation and servicing reports
• Customer Complaints
• New or revised standards
• Public information, including similar medical devices
Challenges

• Integrating Risk Management as part of the Quality System

• Overall maintenance of Risk Management information throughout the product lifecycle

• Risk Assessment Tools