XAVIER HEALTH

ISO 13485:20XX and Risk Management

Bill Brodbeck, Ph.D.
STERIS Corporation

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Familiar Terms

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

Harm - physical injury or damage to the health of people, or damage to property or the environment

Hazard - potential source of harm

Hazardous Situation - circumstance in which people, property, or the environment are exposed to one or more hazard(s)

Familiar Terms

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

What You Should Have

Policies – Risk Management Policy

Procedures – Standard Operating Procedure

Practices – Work Instruction, Records, Documents, Forms

What You Should Have

Analyzing

- Identify characteristics related to the safety of the medical device
- Identify hazards
- Estimate the risks for each hazardous situation

Evaluating

- Combining the probability and severity to determine if risk reduction is required.

What You Should Have

Controlling

- Inherent safety by design, protective measures
- May not use information for safety to control risks

Monitoring

- Continuously check for information to identify new risks or potential changes in estimations for already identified risks
- Analyze, Evaluate and Control newly identified risks

What To Expect

Incorporation of risk management into post-market activities

Design Changes

"The review of design and development changes shall include evaluation of the effect of the changes on:
a) constituent parts and product in process or already delivered,
b) outputs of risk management, and
c) product realization processes."

Design Changes

Design Change Process

Propose Change

- Determine the significance of the change to:
  - product function
  - performance
  - safety
  - applicable regulatory requirements for the intended use

Design Changes

Design Change Process

Evaluate the Change

- Prior to implementation, ensure that the change is appropriately
  - reviewed
  - verified
  - validated, as appropriate
  - approved

Design Changes

Risk Management and Design Changes

- Does the change introduce any new risks?
- Does the probability of occurrence of the risk change?
  - Evaluate potential effects of the design change on probability of occurrence
- Does the severity of the risk change?
  - Evaluate potential effects of the design change on severity

Design Changes

Risk Management and Design Changes

- Does the estimated risk change?
  - Evaluate whether a change in probability and/or severity change the overall risk estimation
- Is risk control through previous verification and validation valid?
  - Review prior verification/validation to ensure that they appropriately control the risk following the design change
- Is the overall risk still acceptable?
  - Determine if changes in previously identified failure modes or introduction of new failure modes affect the overall risk acceptability of the device.

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Design Changes

Risk Management and Design Changes

- Is the particular failure mode risk benefit analysis still valid?
  - Determine if changes in previously identified failure modes or introduction of new failure modes affect the fact that the benefits outweigh the risks for each failure mode.
- Is the overall risk benefit analysis still acceptable?
  - Determine if changes in previously identified failure modes or introduction of new failure modes affect the fact that the overall benefits of the device outweigh the risks.
- Are these considerations and justifications **documented**?

What To Expect

Incorporation of risk management into post-market activities

Monitoring and Measurement

"The information gathered in the feedback process shall serve as input into risk management for monitoring and maintaining the product requirements as well as potential input into the product realization processes."

Post Market Surveillance

What Information?

Quality Data as presented during Management Review

or

Emergency Review based on Quality Data

Post Market Surveillance

What Information?

- Quality Data should include trending of:
  - Complaints
  - MDRs
  - CAPAs
  - NCRs
  - Etc.

Post Market Surveillance

What about input into Risk Management?

- Quality data provides “real” numbers (probability) and outcomes (severity)
- Refer back to original risk analysis
  - Update probability
  - Update Severity
  - Update risk

Post Market Surveillance

What about input into Risk Management?

- Address whether
  - verification and validation still provide appropriate risk control
  - the overall device risk is still acceptable
  - the failure mode risk benefit assessment is still valid
  - the overall risk benefit assessment is still valid

Post Market Surveillance

What about output from Risk Management?

- Document Appropriately!!!
- Drive additional actions
  - Design Change
  - Corrective/ Preventive Actions
  - Corrections and Removals

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Need to continually assess the device throughout the total product life cycle and update risk management appropriately to make appropriate risk based decisions

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Thank You!

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