Risk Management

Covering Standards, Regulations, Guidance, and Techniques

Objectives

- Understand ISO 14971 & other RM standards, regulations, and guidances
- Understanding how to identify, estimate, and review control options for risks
- Review examples of risk management for other Quality System processes
- Understand external risk management expectations

Agenda

- Overview of the ISO 14971 standard
- Which to use: 2007 or 2012 or neither?
- ISO 14971 in design and development process
- Applying risk management to aspects of the Quality System

Agenda, con'd

- IEC 80002-1
- FDA Guidances
- EU Guidances
- PHA for a new app
- S/W Development & RM for a new app
- RM for app changes
- PPRM for existing apps

ISO 14971 – the present

Issued as EN ISO 14971:2012 in JUL 2012 same as 2009 with clarification in 3 Z Annexes

Clarifications: ALARP vs ALAP vs. economy, No Reduction of Risk by Labeling, treatment of negligible risks, risk/benefit analysis always required – more on this later

3nd Edition: EN ISO 14971:2012 became effective for CE marking on 30 AUG 2012

Scope of ISO 14971

A procedure by which a manufacturer can:

- identify the hazards associated with medical devices and their accessories, including *in vitro* diagnostic medical devices,
- estimate and evaluate the risks,
- control these risks, and
- monitor the effectiveness of the control

applicable to all stages of the life cycle of a medical device.

Does not:

- apply to clinical judgments relating to medical device use
- specify acceptable risk levels
- require that a formal quality system.

  However, risk management can be an integral part of a quality system

ISO 14971 Structure/Organisation

- Scope
- Terms and Definitions
- General Requirements
- Detailed Requirements
- Annexes

Risk Management Process

Establish and maintain a process for:

- Risk Analysis
- Risk Evaluation
- Risk Control
- Monitoring effectiveness of control in post production information

Process shall be documented (in the RMF)

Compliance verified by inspection of the RMF

Risk Management Plan

The scope of the planned RM activities, identifying and describing the medical device and the life cycle phases for which the plan is applicable;

- Verification activities;
- Allocation of responsibilities;
- Requirements for review of risk management activities; and
- Criteria for risk acceptability based on mfr's policy and criteria for accepting risks when probability of harm not estimate-able

The risk management plan shall be part of the RMF.

If the plan changes during the medical device life cycle, a record of the changes maintained in the RMF.

Compliance is checked by inspection of the RMF

Risk Management File

- Results of all risk management activities shall be recorded and maintained in the RMF.
- *The records and other documents that make up the RMF can form part of other documents and files required, for example, by a manufacturer's quality management system.*
- *The RMF need not physically contain all the documents relating to this International Standard. However, it should contain at least references or pointers to all required documentation. The manufacturer should be able to assemble the information referenced in the RMF in a timely fashion.*

ISO 14971 Detailed Requirements

- Risk Analysis (clause 4)
- Risk Evaluation (clause 5)
- Risk Control (clause 6)
- Overall residual risk evaluation (clause 7)
- Risk Management Report (clause 8)
- Post production information (clause 9)

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