ISO 14971, 2007 Risk Management for all Medical Devices The New Global Era

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ISO/IEC Joint Working Group on Application of risk management to medical devices

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ISO 14971: Medical Devices — Risk Management — Application of Risk Management to Medical Devices

ISO 14971

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ISO 14971: Medical Devices — Risk Management — Application of Risk Management to Medical Devices

- World-wide standard
- Management standard
- Risk management process
- Established risk management concepts
- Life cycle standard
- Adopted in regulations
- Integrated within standards

Risk Management of Medical Devices

Ensuring Safety and Efficacy through ISO 14971

ISO 14971 2007

What does it say?

Ensuring Safety and Efficacy through ISO 14971

- ISO 14971 2000
  - World standard for medical devices
  - Management standard
  - 11 pages requirements
  - 21 pages Annexes
- ISO 14971 2007
  - World standard for medical devices
  - Management standard
  - 14 pages requirements
  - 69 pages Annexes

Risk Management Process

ISO/IEC 14971

Manufacturer Shall Establish a Risk Management Process

Risk Analysis

Risk Evaluation

Risk Control

Production and post production information – Monitoring

14971:General Requirements
Clause 3

- Must have that particular defined and documented RM Process that addresses risk analysis, evaluation and control, collection of production and post-production data to validate or change previous risk determinations.

Management Responsibilities

The manufacturer shall:

- **ensure the provision of adequate resources**
- **ensure the assignment of qualified personnel for management, performance of work and assessment activities**
- **define and document his policy for determining criteria for risk acceptability, taking into account relevant International Standards, and national or regional regulations**
- **review the suitability of risk management activities at defined intervals to ensure continuing effectiveness of the risk management process and document actions taken**

Compliance is checked by inspection of the risk management file..

Policy on Establishing Risk Acceptability

- Management needs to develop a risk acceptability policy to determine criteria for risk acceptability & guide product development (clause 3.2 Management Responsibility)
  - Application of International standards
  - National or regional regulations
  - Available information on device(s)
  - State of the art
  - That risk will be brought down to the best technological level available

Risk Management Plan

ISO/IEC 14971

- Scope of the plan
  - Applicable life cycle phases
- Responsibilities
- Requirements for review
- Criteria for acceptability
- Verification plan
- Collection of post production information
- Record

Criteria for Risk Acceptability

- Once a policy is a defined, proceed with defining the acceptability criteria level using information from:
  - National and regional regulations;
  - the company's history with similar device or platform;
  - information gathered about competitors;
  - current industry level;
  - stakeholder concerns;
  - alternative therapies.

Risk Management File Records

ISO/IEC 14971

- Risk Management Plan
- Identification of Hazards
- Estimation of Risks
- Risk Evaluation
- Measures for Control
- Evaluation of Effectiveness
- Risk Management Report
- Verification
- Residual Risks

Differences 2000-2007

- Definitions
  - IVD Devices; life cycle; post-production; risk estimation; top management; use error
- Risk Management Report
- Production and Post-Production Information
- Annexes

Clause 8;Risk Management Report

- Review of Risk Management process
  - Risk Management Plan appropriately implemented

(traceability for each hazard not required)

  - Overall residual risk acceptable
  - Post production information system in place
  - Part of Risk Management File

Clause 9: Post Production Information

- Systematic Procedure
- Production and Post production
- Mechanisms for generating information
- Identification new hazards
- New Hazards
- Changes acceptability
- Feedback loop
- Record in Risk Management File

Annexes

- Annex A –Rationale *(Annex H Amd1)*
- Annex B – Flow diagram *(Figure 2)*
- Annex C –Characteristics *(Annex C)*
- Annex D –Risk Concepts *(Annex E)*
- Annex E –Examples Hazards *(Annex D)*
- Annex F – Risk Management Plan
- Annex G – Techniques *(Annex F)*
- Annex H –IVD Devices *(Annex B)*
- Annex I –Biological Hazards *(Annex C)*
- Annex J –Residual Risk