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

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

ISO 14971
Published March 1, 2007
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
Manufacturer Shall Establish a Risk Management Process

Risk Analysis
Risk Evaluation
Risk Control

Production and post production information – Monitoring
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.*
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
Once a policy is 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

11th Conference of the Global Harmonization Task Force
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 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