



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

Alfred M Dolan

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



11th Conference of the Global Harmonization Task Force





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

ISO 14971

Published March 1, 2007



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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





4971: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 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