INCOSE 2006
Ensuring Safety and Efficacy for Medical Devices through ISO 14971

16th International Symposium
Orlando Florida,
July 9-13, 2006
Risk Management of Medical Devices: Implementation

The New Global Era:
ISO 14971:2000 Medical Devices
Application of Risk Management to Medical Devices

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Risk Management of Medical Devices

Ensuring Safety and Efficacy through ISO 14971

♦ Regulations
♦ Standards
Risk Management of Medical Devices

Ensuring Safety and Efficacy through ISO 14971

♦ Regulations
♦ …intended to ensure that finished devices will be safe and effective….
♦ ..manufacturer shall ensure that medical device meets the safety and efficacy requirements
Standards

“This standard applies to the safety of Medical Electrical Equipment . . .”

“The purpose of this standard is a) to ensure the safe performance and construction of pressure regulators, gauges, and flow metering devices, and b) to minimize hazards . . .”

“. . .includes requirements for the performance and safety of oxygen analyzers”

IEC60601-2-13 “Medical Electrical equipment - Particular requirements for the safety of anaesthetic workstations”
ISO 14971: Medical Devices — Risk Management — Application of Risk Management to Medical Devices

ISO 14971
Published December 15, 2000
Ensuring Safety and Efficacy for Medical devices
Safety and Efficacy: Issues

- Increased complexity
- Increased integration
- Technological innovation
- Internationalization
- Wide variety devices – IVD to Linacs
- Time delay for standards
- Time delay for regulations
Safety and Efficacy: Development

- Technical Product Standards
- Implicit recognition of risk management principles
- IEC 60601-4 Programmable Systems
- Explicit recognition of risk management principles
Medical Devices
Medical devices
Risk Management

- Risk Assessment
- Safety
- Risk Estimation
- Hazard
- Hazard Identification
- Risk Control
- Hazard Estimation

- Risk
- Harm
- Risk Analysis
- Risk Evaluation
- Hazard Analysis
Risk Management
Early History

♦ Galileo; 1623
♦ Blaise Pascal; 1654
♦ Pierre de Fermat; 1654
♦ John Graunt; 1662
♦ Edmund Halley; 1693
♦ Edward Lloyd; 1696
♦ Daniel Bernoulli; 1738
Definitions

♦ Hazard
♦ Risk
Hazard

♦ A source of potential harm
Harm

- Loss or damage to something we value.
Hazard

- Natural
- Technological
- Use
- Social
- Lifestyle
Risk

♦ A measure of the incidence, likelihood, and severity that a hazard will result in harm
Risk Management

Risk Management

Risk Assessment
- Risk Analysis
  - Hazard Identification
  - Risk Estimation
- Risk Evaluation
- Risk Acceptance
- Option Analysis

Risk Control
- Decision making
- Monitoring
ISO 14971: Medical Devices — Risk Management — Application of Risk Management to Medical Devices

♦ Covers all medical devices
♦ Life cycle of device
♦ Covers safety and efficacy
♦ QUANTUM LEAP!
What is the Difference between ISO 14971 and other Standards?

- Scope of ISO 14971 is all Medical Devices
- Horizontal Standard
- Process and System Standard
- Complete lifecycle including design, manufacture, installation, servicing
- Not a Performance or Type Standard
Risk Management
General Requirements
ISO/IEC 14971

♦ **Scope** (Clause 1)

♦ **Risk Management Process** (Clause 3.2)

♦ **Management Responsibility** (Clause 3.3)
  ♦ *Risk Acceptability*
  ♦ *Assign Personnel*
  ♦ *Resources*
  ♦ *Management Review*

♦ **Qualifications Personnel** (Clause 3.4)

♦ **Risk Management Plan** (Clause 3.5)

♦ **Risk Management File - Records** (Clause 3.6)
Management Responsibilities

The manufacturer shall:

♦ define his policy for determining acceptable risk, taking into account relevant International Standards, and national or regional regulations

♦ ensure the provision of adequate resources

♦ ensure the assignment of trained personnel for management, performance of work and assessment activities

♦ review the results of risk management activities at defined intervals to ensure continuing suitability and the effectiveness of the risk management process

♦ Compliance is checked by inspection of the risk management file.
Requirements Risk Management Process
ISO/IEC 14971

- Risk analysis (clause 4)*
- Risk evaluation (clause 5)
- Risk control (clause 6)
- Risk acceptance (clause 7)
- Risk report (clause 8)
- Post Production Information (clause 9)
Risk analysis

• Intended purpose identification
• Hazard identification

Risk estimation

• Risk acceptability decisions

Risk control

• Option analysis
• Implementation
• Residual risk evaluation
• Overall risk acceptance

Post-production

• Post-production information
  • Review of post-production experience

Risk Assessment
Risk Management

ISO 14971
(simplified process)
Risk analysis

- Intended purpose identification
- Hazard identification
- Risk estimation
- Risk evaluation
- Risk acceptability decisions
- Risk control
  - Option analysis
  - Implementation
  - Residual risk evaluation
  - Overall risk acceptance

Post-production information
  - Post-production experience
  - Review of post-production experience

Risk Assessment
Risk Management

Functional Analysis
Fault Tree Analysis
HACCP
FMEA
The pieces of the puzzle … … are there!

An integrated Risk Management Process (for all phases of the MD life-cycle)

Risk Graph

Post-Production Monitoring

Implementation of Risk Control measures

Residual Risk

Verification of Effectiveness

Risk Hazard Cause

Training of personnel

Culture on Risk Communication

RM Policy
But the pieces need a … structure

An integrated Risk Management Process
(for all phases of the MD life-cycle)

Culture on Risk Communication

Risk Graph

Residual Risk

Implementation of Risk Control measures

Verification of Effectiveness

Risk Hazard Cause

Post-Production Monitoring

Training of personnel
And the structure needs … connection!
ISO 14971

Criteria for Risk Acceptability

An integrated Risk Management Process
(for all phases of the MD life-cycle)

Implementation of Risk Control measures

Training of personnel

Residual Risk

Verification of Effectiveness

Post-Production Monitoring

Risk Graph

Risk Hazard Cause

Culture on Risk Communication
What Do We Need to Know?

ISO/IEC 14971

- World-wide standard
- Management standard
- Risk management process
- Established risk management concepts
Medical Devices
Assurance of Safety and Effectiveness

Risk Management

Quality Management

Performance Standards
The Risk Management Standard ISO 14971 provides a structure and framework which other Standards are using to define safety characteristics for product or family specific:

- hazards
- risks (both acceptable and unacceptable)
- risk mitigation methods
- residual risks
- product verification and validation requirements
- documentation requirements
Managing *risks* effectively through ISO 14971
Ensures the Safety and Effectiveness of Medical Devices

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