Risk Management & Human Factors Engineering

Prof. Steven S. Saliterman
Department of Biomedical Engineering, University of Minnesota
http://saliterman.umn.edu/

Topics

- ISO 14971
- Risk Management as Part of Design Control
- Human Factors and Usability Engineering
  - Definitions
  - How People Interact with Technology
  - Inherent Safety by Design
  - Protective Measures
  - Information for Safety
  - Report for Pre-Market Submission
- IEC 60601-1 – Medical Electrical Equipment
  - General requirements for basic safety and essential performance.

ISO 14971

- Risk Management – "The systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk."*
  - **ISO 14971:2007** Medical Devices – "Application of Risk Management to Medical Devices."
  - **ISO/TR 24971 in ISO TC210 (2013)** – Expert guidance on application of the standard.
  - **EN ISO 14971:2012** applies only to manufacturers with devices intended for the European market.

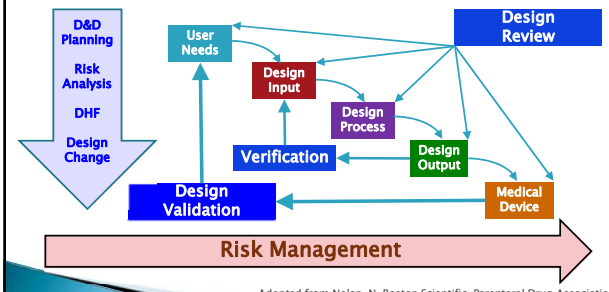
*ISO 14971:2007 "Medical Devices"

Four Stages of Risk Management...

ISO 14971:2007

Adopted from Nolan, N. Boston Scientific, Parenteral Drug Association, *Quality Risk Management – The Medical Device Experience*, 2011.

Risk Management as Part of Design Controls...



Adopted from Nolan, N. Boston Scientific, Parenteral Drug Association, *Quality Risk Management – The Medical Device Experience*, 2011.

Intent of Risk Management...

- Requires *procedures and practices* for analyzing, evaluating, controlling, and monitoring product risks.
- Management tool: Includes management's role in making product risk-based decisions and reviewing system effectiveness.
  - Connections to Design, Complaint, CAPA and QS Management reviews.

Nolan, N. Boston Scientific, Parenteral Drug Association, *Quality Risk Management – The Medical Device Experience*, 2011.

Overview of Risk Management…

- Risk Management Plan
- Risk Management File
- Risk Analysis
- Evaluation of Risk Acceptability (Risk/Benefit)
- Risk Management Report
- Production and Post Production Information

Nolan, N. Boston Scientific, Parenteral Drug Association, *Quality Risk Management – The Medical Device Experience*, 2011.

Risk Management Plan…

- Scope of risk management activities, including the intended use of the device and product lifecycle
- Assignment of responsibilities and authorities
- Review requirements for risk management
- Risk acceptability criteria
- Risk Verification
- Production activity data collection and review
- Post Production activity data collection and review.
- Risk = Severity x Probability

Nolan, N. Boston Scientific, Parenteral Drug Association, *Quality Risk Management – The Medical Device Experience*, 2011.

Human Factors & User Interface

- Abnormal use (unintended use – no recourse).
- Critical task (harm if task not or incorrectly performed).
- Formative evaluation (assessing user interface & interactions throughout device development).
- Hazard (potential source of harm).
- Hazardous situation (hazard plus sequence of events).

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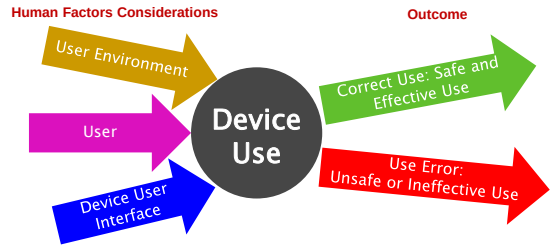
- Task (what the user does).
- Use error (user action or inaction different than the manufacturer expected that could or did cause harm).
- Use safety (no use-related risk).
- User (person using the device).
- User interface (all user device interactions).

How People Interact with Technology…



Adopted from *Applying Human Factors and Usability Engineering to Medical Devices* . U.S. Department of Health and Human Services Food and Drug Administration. February 3, 2016.

Hazards…

- Physical hazards (sharp corners or edges).
- Mechanical hazards (kinetic or potential energy from a moving object).
- Thermal hazards (high-temperature components).
- Electrical hazards (electrical current, EMI).

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- Chemical hazards (toxic chemicals).
- Radiation hazards (ionizing and non-ionizing).
- Biological hazards (allergens, bio-incompatible agents and infectious agents).

Inherent Safety by Design –examples…

- Use specific connectors that cannot be connected to the wrong component.
- Remove features that can be mistakenly selected or eliminate an interaction when it could lead to use error.
- Improve the detectability or readability of controls, labels, and displays.
- Automate device functions that are prone to use error when users perform the task manually.

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Protective Measures – examples…

- Incorporate safety mechanisms such as physical safety guards, shielded elements, or software or hardware interlocks.
- Include warning screens to advise the user of essential conditions that should exist prior to proceeding with device use, such as specific data entry.
- Use alerts for hazardous conditions, such as a "low battery" alert when an unexpected loss of the device's operation could cause harm or death.
- Use device technologies that require less maintenance or are "maintenance free."

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Information for Safety – examples…

- Provide written information, such as warning or caution statements in the user manual that highlight and clearly discuss the use-related hazard.
- Train users to avoid the use error.

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Outline of an HFE/UE Report

1) Conclusion.
2) Descriptions of intended device users, uses, use environments, and training.
3) Description of device user interface.
4) Summary of known use problems.
5) Analysis of hazards and risks associated with use of the device.
6) Summary of preliminary analyses and evaluations.
7) Description and categorization of critical tasks.
8) Details of human factors validation testing.

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The IEC 60601-1

- Standard for electro-medical equipment safety.
- International Electrotechnical Commission (IEC) 3rd Edition.

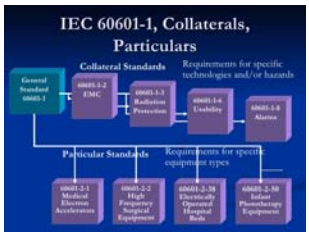

Image courtesy of MassMEDIC

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- Part 1: General requirements for basic safety and essential performance.
- Part 2: Electromagnetic compatibly.
- Part 3: Radiation protection in diagnostic X-ray equipment.
- Part 6: Usability
- Part 8: Tests and guidance for alarm systems.

- A standard covering electrical equipment used in medical practice.
- Covers *essential performance* & *basic safety* – both fundamental in addressing *hazards*.
- Addresses *accuracy of power or therapeutic substance delivery* and *display of physiological data* that will effect patient management.
- Includes:
  - Classification
  - Requirements
  - Test specifications
  - Risk management.

Consider an Infusion Pump…

- If you were the manufacturer of this medical device, what *basic safety and essential performance concerns* would you have?

Image courtesy of Smiths Medical

60601-2-24 Infusion Pumps & Controllers

- Regulating flow of fluids into a patient under pressure generated by a pump.
  - Type 1 – Continuous only.
  - Type 2 – Non-continuous only.
  - Type 3 – Discrete delivery of a bolus.
  - Type 4 – Profile pump.

201.4 General requirements…

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS and SYRING OR CONTAINER PUMPS	201.12.1.102
Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 1	201.12.1.103
Accuracy tests for INFUSION PUMP FOR AMBULATORY USE type 2	201.12.1.104
Accuracy tests for INFUSION PUMP type 3	201.12.1.105
Accuracy tests for INFUSION PUMP type 4	201.12.1.106
Accuracy tests for INFUSION PUMP type 5	201.12.1.107
Protection against UNINTENDED BOLUS volumes and occlusion	201.12.4.4.104
ALARM SIGNALS of HIGH PRIORITY according to Table 208.101 NOTE For ALARM CONDITIONS resulting from ME EQUIPMENT failure no EMC and environmental testing is necessary.	208.6.1.2.101

Other Requirements…

- 201.5 General requirements for testing of ME EQUIPMENT.
- 201.6 Classification of ME EQUIPMENT and ME SYSTEMS.
- 201.7 ME EQUIPMENT identification, marking and documents.
- 201.8 Protection against electrical HAZARDS from ME EQUIPMENT.
- 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.
- 201.10 Protection against unwanted and excessive radiation HAZARDS.
- 201.11 Protection against excessive temperatures and other HAZARDS.
- 201.12 Accuracy of controls and instruments and protection against hazardous outputs

Electromagnetic Compatibility (EMC)

- Emissions testing measures Electromagnetic (EM) interference radiated or conducted out of the device. Emissions from the device can cause malfunctions in nearby equipment.

Image courtesy of Com-Power

Image courtesy of Metaldetectors

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- Susceptibility testing measures the device's immunity to external EM interference conducted or radiated into the device. An example of external interference is Electrostatic Discharge (ESD).

Image courtesy of Teseq

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Summary

- ISO 14971 and a Risk Management Plan.
- Application of HFE/UE initially reduces the need for design modifications and costly updates after market introduction and offers competitive advantages.
- A HFE/UE report included in a premarket submission should provide information pertaining to device use safety and effectiveness in summary form.
- IEC 6061-1 Medical Electrical Equipment basic safety and essential performance.

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