Risk Management

Fundamental elements of risk management
Overview of ISO 14971

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San Diego PSES Chapter
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Learning Objectives

- Identify the source of Risk Management requirements
- Identify the six main elements of the Risk Management Process
- Identify how the six main elements of the Risk Management process relate to a Quality System,
- Identify the Executive Management responsibilities of the Risk Management process, and
- Recognize and use specific risk management terms.
Risk – Combination of the probability of occurrence of harm and the severity of that harm

\[(\text{Severity of Harm}) \times (\text{Probability of Harm Occurrence}) = (\text{Risk})\]
Terminology

- **Hazard** - A potential source of harm.
- **Hazardous Situation** - Circumstance in which people, property, or the environment are exposed to one or more hazard(s).
- **Harm** - Physical injury or damage to the health of people, or damage to property or the environment.

Severity – Measure of the possible consequences of a hazard.
Hazard or Harm?

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Razor Blade</td>
<td></td>
</tr>
<tr>
<td>Broken Arm</td>
<td></td>
</tr>
<tr>
<td>Bruise</td>
<td></td>
</tr>
<tr>
<td>Exposed Live Wire</td>
<td></td>
</tr>
</tbody>
</table>

Probability of Harm Occurrence - The Probability of Harm, \( P(\text{Harm}) \) is the combination of a hazardous situation occurring coupled with that situation causing harm.

(P1) Probability of Hazardous Situation Occurring

(P2) Probability of Hazardous situation leading to harm

Risk = Combination of the probability of occurrence of harm and the severity of that harm.

Safety = Freedom from unacceptable risk.

Risk Management = Systematic application of management policies, procedures, and practices, to the tasks of analyzing, evaluating, monitoring, and controlling risk.

Top Management = person or group of people who direct(s) and control(s) a manufacturer at the highest levels.
Top Management Responsibilities

- Define the policy for determining acceptable risk
  - relevant international standards,
  - national or regional regulations.

- Provision of adequate resources

- Ensure assignment of trained personnel for…
  - management
  - performance of work
  - assessment activities

- Review results of risk management activities at defined intervals to ensure continuing suitability and effectiveness of the risk management process.
- Document in risk management file.
A process that continues and evolves throughout the product lifecycle
Fill In the Blanks…

Hazard

Hazardous Situation

Exposure ($P_1$)

Harm

$P_2$

Severity of the Harm

Probability of Harm Occurrence

RISK
Risk Analysis Procedure

- Minimum information needed:
  - Description and identification of the medical device
  - Identification of the person(s) doing RA
  - Identification of organization(s) doing RA
  - Date(s) of RA
  - Method used

- May use RA done on similar device
  - Systematically document similarities / differences
  - Design, usage, changes, mfg.
  - Demonstration of similarity based on evaluation

- Document in RMF
Intended Use / Purpose

• Describe the intended use / intended purpose
• Describe any reasonably foreseeable misuse

• **Usage Parameters**
  - Who, What, Where, Why, When
  - Environment of use
  - Cognitive & physical demands
  - Activity and task workload

• Clinical and Patient Demographics

• Document in RMF

• (…in 510(k), product proposal, Risk Management Plan…)**
Hazards / Harms

• Compile a list of known or foreseeable hazards
  – Normal conditions
  – Fault conditions
  – Previous hazards
  – Sequences of events (leading to hazardous situations)
• Mechanisms to keep list current
• Document in RMF
<table>
<thead>
<tr>
<th>Hazard</th>
<th>Foreseeable sequence of events</th>
<th>Hazardous situation</th>
<th>Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic energy (Line voltage)</td>
<td>(1) Electrode cable unintentionally plugged into power line receptacle</td>
<td>Line voltage appears on electrodes</td>
<td>Serious burns</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Heart fibrillation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Death</td>
</tr>
<tr>
<td>Chemical (Volatile solvent)</td>
<td>(1) Incomplete cleaning of volatile solvent used in manufacturing</td>
<td>Development of gas bubbles in the blood stream during dialysis</td>
<td>Gas embolisms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Brain damage</td>
</tr>
<tr>
<td></td>
<td>(2) Solvent residue converts to gas at body temperature</td>
<td></td>
<td>Death</td>
</tr>
<tr>
<td>Biological (Microbial contamination)</td>
<td>(1) Inadequate instructions provided for decontaminating re-used anaesthesia tubing</td>
<td>Bacteria released into airway of patient during anaesthesia</td>
<td>Bacterial infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>(2) Contaminated tubing used during anaesthesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electromagnetic energy (ESD)</td>
<td>(1) Electrostatically charged patient touches infusion pump</td>
<td>Failure to deliver insulin unknown to patient with elevated blood glucose level</td>
<td>Minor organ damage</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Decreased consciousness</td>
</tr>
<tr>
<td></td>
<td>(2) ESD causes pump and pump alarms to fail</td>
<td></td>
<td>Coma, death</td>
</tr>
<tr>
<td></td>
<td>(3) Insulin not delivered to patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Function (No output)</td>
<td>(1) Implantable defibrillator battery reaches the end of its useful life</td>
<td>Device cannot deliver defibrillation shock when an arrhythmia occurs</td>
<td>Death</td>
</tr>
<tr>
<td></td>
<td>(2) Inappropriately long interval between clinical follow-up visits</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Table E.1 — Examples of hazards

<table>
<thead>
<tr>
<th>Examples of energy hazards</th>
<th>Examples of biological and chemical hazards</th>
<th>Examples of operational hazards</th>
<th>Examples of information hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic energy</td>
<td>Biological</td>
<td>Function</td>
<td>Labelling</td>
</tr>
<tr>
<td>Line voltage</td>
<td></td>
<td>Incorrect or inappropriate output or functionality</td>
<td>Incomplete instructions for use</td>
</tr>
<tr>
<td>Leakage current</td>
<td>Biological</td>
<td>Incorrect measurement</td>
<td>Inadequate description of performance characteristics</td>
</tr>
<tr>
<td>— enclosure leakage current</td>
<td></td>
<td>Energetic data transfer</td>
<td>Inadequate specification of intended use</td>
</tr>
<tr>
<td>— earth leakage current</td>
<td>Biological</td>
<td>Loss or deterioration of function</td>
<td>Inadequate disclosure of limitations</td>
</tr>
<tr>
<td>— patient leakage current</td>
<td></td>
<td>Use error</td>
<td>Operating instructions</td>
</tr>
<tr>
<td>Electric fields</td>
<td>Biological</td>
<td>Attentional failure</td>
<td>Inadequate specification of accessories to be used with the medical device</td>
</tr>
<tr>
<td>Magnetic fields</td>
<td></td>
<td>Memory failure</td>
<td>Inadequate specification of pre-use checks</td>
</tr>
<tr>
<td>Radiation energy</td>
<td>Biological</td>
<td>Rule-based failure</td>
<td>Over-complicated operating instructions</td>
</tr>
<tr>
<td>Ionizing radiation</td>
<td></td>
<td>Knowledge-based failure</td>
<td>Warnings</td>
</tr>
<tr>
<td>Non-ionizing radiation</td>
<td>Biological</td>
<td>Routine violation</td>
<td>Of side effects</td>
</tr>
<tr>
<td>Thermal energy</td>
<td></td>
<td></td>
<td>Of hazards likely with re-use of single-use medical devices</td>
</tr>
<tr>
<td>High temperature</td>
<td>Biological</td>
<td></td>
<td>Specification of service and maintenance</td>
</tr>
<tr>
<td>Low temperature</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical energy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gravity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>— falling</td>
<td>Biological</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— suspended masses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibration</td>
<td>Stored energy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moving energy</td>
<td>Moving parts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Torsion, shear and tensile force</td>
<td>Torsion, shear and tensile force</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moving and positioning of patient</td>
<td>Moving and positioning of patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acoustic energy</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>— ultrasonic energy</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>— infrasound energy</td>
<td></td>
<td></td>
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<tr>
<td>High pressure fluid injection</td>
<td>High pressure fluid injection</td>
<td></td>
<td></td>
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<tr>
<td>— sound</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bio-compatibility</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Toxicity of chemical constituents, e.g.:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>— allergenicity/irritancy</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>— pyrogenicity</td>
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</tbody>
</table>
Risk Estimation

• Separate Risk Factors
• Evaluate Factors Separately
• Combine to Determine Risk
  ▪ Individual Risks
  ▪ Overall Product Risk
• Primary Factors
• Secondary Factors
Risk Estimation

Risk = (Probability of Harm) x (Severity)

Primary Factors
- Severity of Harm
- Probability of Harm
Risk Estimation

• **Secondary Factors**
  – Hazards in normal / abnormal use
  – Initiating event(s) / circumstance(s)
  – Sequence of events
  – Probability of hazardous situation occurring
    ▪ \( P_1 = P(\text{Occ.}) \)
  – Probability of hazardous situation leading to harm
    ▪ \( P_2 = P(\text{Haz-Sit}) \)
Risk Estimation

- Estimate risks for each identified hazard & overall product
  - Normal condition
  - Fault condition
  - Quantitative or qualitative
- Provide basis for estimates – data, history, etc.
  - System for determining probability (primary / secondary)
  - System for determining severity
- List possible consequences of all hazards that the occurrence probability cannot be estimated
- Document in RMF.
Risk Estimation Information

- Published standards
- Scientific technical data,
- Field data from similar medical devices already in use including published reported incidents,
- Usability tests employing typical users,
- Clinical evidence,
- Results of appropriate investigations,
- Expert opinion,
- External quality assessment schemes.
Risk Evaluation

• “Top Management” Decision
  • acceptability levels
  • Evaluate risks of each hazard
    ▪ No risk reduction necessary,
    ▪ As Low As Reasonably Practicable (ALARP),
    ▪ Mandatory reduction necessary

• May elect to address even if minimal risk.
• Document decisions in RMF.
Risk Evaluation

Severity (of Harm)

Probability (of Harm)
Risk Evaluation

Severity (of Harm)

Probability (of Harm)
Risk Evaluation

Severity (of Harm)

Probability (of Harm)
Risk Evaluation

Probability (of Harm)

Severity (of Harm)
Risk Evaluation

Severity (of Harm)

Probability (of Harm)
• Risk Controls MUST be documented

• Risk Controls put in place are documented as described in your risk management plan
Risk Reduction Options

• Risk reduction occurs three ways:
  ▪ Reduce severity of harm
  ▪ reduce probability of occurrence of harm
  ▪ reduce both.

• Reduction Methods
  ▪ Design, inherent safety
  ▪ Protective, in device or mfg.
  ▪ Safety Information
Risk Reduction Priorities

• Design Measures
  – Elimination of hazard
  – Reduce harm probability / severity
  – Redundant systems or components

• Protective Measures
  – Automatic cut-offs, safety valves
  – Visual and audible alarms

• Information for safety
  – Labeling on product
  – Warnings and/or instructions in manuals
  – Communications to user
  – Operator training
  – Specific maintenance actions or intervals
Residual Risk

- Residual risks may remain after risk control measures
- Evaluate residual risks (if any)
- Use previously established criteria
- If unacceptable, further mitigation necessary
Risk Estimation

- **Primary Factors**
  - Severity of Harm
  - Probability of Harm

- **Secondary Factors**
  - Initiating event(s) / circumstance(s)
  - Hazards in normal / abnormal use
  - Sequence of events that could lead to hazardous situation
  - Likelihood of hazardous situation occurring
  - Likelihood of hazardous situation leading to harm
Residual Risk Estimation

- Hazard
- Hazardous Situation
- Harm
- Severity of the Harm
- Probability of Harm Occurrence
- RISK

- Exposure ($P_1$)
- Probability of Harm Occurrence ($P_2$)
- $P_1 \times P_2$

- Severity (of Harm)
- Probability (of Harm)
• ALARP – As Low As Reasonably Practicable – Risk has been reduced to the “lowest level practicable”. It is not technically possible, or economically feasible, to reduce the risk further.

• Risk Benefit Analysis – Argument as to why the Medical Benefit outweighs the Risk presented by the feature, function, or product. (Required in order to accept an Unacceptable risk)
Risk Benefit Analysis (RBA)

- Applies to individual and overall risks.
- Residual risks may be unacceptable and further controls impossible
- Comparison between medical benefits and residual risks
  - Based on medical data and literature reviews,
  - Intended use / purpose.
- If acceptable, fully document and proceed.
- If unacceptable, terminate project
- Requires sign off by top management
Overall Residual Risk Evaluation

- Use criteria specified in risk management plan
- Examine for systemic and random failures
- May be difficult and time consuming

- Unacceptable risks require further risk / benefit evaluation

- Document evaluations in RMF.
Quiz: Definitions

________ is freedom from unacceptable risk.

A) Insurance  
B) Risk Index 1  
C) Safety  
D) Happiness
Risk Management Report

- Documents all results of the process.
- Provides traceability for each hazard to the...
  - Risk analysis, evaluation
  - Implementation of control measures,
  - Verification of the risk control measures,
  - Residual risk acceptability.
  - Statement of completeness
  - Signed and approved by Top Management

- Include in RMF.
- (Documented in Risk Management Report)
Production & Post-Market Assessment

- Field Monitoring System / Complaint Handling
- Collect / Review / Evaluate
  - Detailed information
  - Symptoms and effects
  - FM’s, hazards, hazardous situation, harm
- Observations Dictate Multiple Actions
  - Regulatory – MDR, Recalls,
  - CAPA / Investigations,
  - Risk (re) estimation and (re) assessment,
  - Previously unrecognized hazards / harms,
  - Unacceptable change in estimated risks,
  - Continued trending.

- Document in RMF.
Best Practice –
Insure evaluation is the same as pre-market evaluation, same criteria for acceptability etc.
Question & Answers

Thank You!