Concept of Risk Management in Medical Equipment
Application of ISO 14971 in IEC 6060-1 3rd Edition

By Pierre de RUVO
Executive Secretary IECEE
Medical electrical equipment- Part 1: General Requirements for Safety and Essential Performance

“Specifies general requirements and serves as the basis for particular standards and collateral standards which are extending the scope of the general standard”
Risk management is the process of assessing risks and taking steps to either eliminate or to reduce them (as far as is reasonably practicable) by introducing control measures.

Health and safety legislation states that risk ‘expresses the likelihood that harm from a particular hazard is realised’, and that a hazard is ‘something with the potential to cause harm.’
IEC 60601-1 Edition 3: 2005
Risk Management: Causes of Hazard

Clinical hazard classes
(Human physiology affected)

Device level hazard classes
Contact
Substances
Energy
Information
Bio-Matter
Environmental Conditions
Patient/User/Service

Patient
Environment
Device
User
Service

Indirect Patient Device interface via Environment

Direct Patient Device interface

Figure 4-1. Hazard/cause continuum.
Thus, there have been several theories and attempts to quantify risks. Numerous different risk formulae exist, but perhaps the most widely accepted formula for risk quantification is:

Rate of occurrence multiplied by the impact of the event equals risk
## Levels of Risks

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Severity</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Catastrophic</td>
<td>Critical</td>
<td>Marginal</td>
<td>Negligible</td>
<td></td>
</tr>
<tr>
<td>A—frequent</td>
<td>I-A</td>
<td>II-A</td>
<td>III-A</td>
<td>IV-A</td>
<td></td>
</tr>
<tr>
<td>B—probable</td>
<td>I-B</td>
<td>II-B</td>
<td>III-B</td>
<td>IV-B</td>
<td></td>
</tr>
<tr>
<td>C—occasional</td>
<td>I-C</td>
<td>II-C</td>
<td>III-C</td>
<td>IV-C</td>
<td></td>
</tr>
<tr>
<td>D—remote</td>
<td>I-D</td>
<td>II-D</td>
<td>III-D</td>
<td>IV-D</td>
<td></td>
</tr>
<tr>
<td>E—improbable</td>
<td>I-E</td>
<td>II-E</td>
<td>III-E</td>
<td>IV-E</td>
<td></td>
</tr>
<tr>
<td>F—incredible</td>
<td>I-F</td>
<td>II-F</td>
<td>III-F</td>
<td>IV-F</td>
<td></td>
</tr>
</tbody>
</table>

**Legend**
- Intolerable risk
- Undesirable risk
- Tolerable risk
- Negligible risk
Device inputs can directly affect the patient.

Device outputs and consequences can feed back and influence device inputs.

* Environmental impact and patient responses are not strictly speaking, device outputs. They are consequences of the interaction between the device, environment, and patient.
IEC 60601-1 Edition 3: 2005
Risk Management: Methods

1. identify, characterize, and assess threats

2. assess the vulnerability of critical assets to specific threats

3. determine the risk (i.e. the expected consequences of specific types of attacks on specific assets)

4. identify ways to reduce those risks

5. prioritize risk reduction measures based on a strategy
Risk Management: Principles

- be tailored
- take into account human factors
- be transparent and inclusive
- be dynamic, iterative and responsive to change
- be capable of continual improvement and enhancement

...... Continue next slide
Risk Management: Principles

- create value
- be an integral part of organizational processes
- be part of decision making
- explicitly address uncertainty
- be systematic and structured
- be based on the best available information
ISO/IEC 14971 is expected to obviate the need for IEC 60601-1-4, so understanding the requirements in this standard is important.
Risk Management: Potential risk treatments

• Avoidance (eliminate, withdraw from or not become involved)
• Reduction (optimise - mitigate)
• Sharing (transfer - outsource or insure)
• Retention (accept and budget)
The manufacturer of electromedical equipment and systems must have a formal Risk Management System in place in order to comply with the third edition of IEC 60601-1.
4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

A RISK MANAGEMENT PROCESS shall be carried out, applying ISO 14971.

In addition, there are no less than 118 additional references to Risk Management as a crucial factor in complying with individual requirements.
The third edition still contains objective tests and pass/fail criteria.

Manufacturer must follow such requirements.

There are however more than 100 decision points where risk management process requirements must be assessed.
Sub clause 4.2 states that…..

“The requirements of this clause and all requirements of this standard referring to inspection of the RISK MANAGEMENT FILE are considered to be satisfied if the MANUFACTURER has:

- Established a RISK MANAGEMENT PROCESS;
- Established acceptable levels of RISK; and
- Demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK(S)”
- Establish consensus to determine compliance with clauses of IEC 60601-1 Ed. 3.

- Develop Guideline for implementation of ISO 14971 to meet requirements of IEC 60601-1 Ed. 3.

- Develop an addendum to the Test Report Form IEC 60601-1 to cover the requirements of ISO 14971.

- Set up trainings workshops on implementation of Risk Management

- Serve as Advisory Group on common understanding of ISO 14971 related to IEC 60601-1.
IECEE Task Force Risk Management

- **Guidelines - how to apply ISO 14971 in IEC 60601**
  - General
  - Implementation
  - Workflow
  - ISO 14971 Mapping Guide

- **Technical Report File IEC 60601 clauses**
  - Specific requirements IEC 60601
  - Compliance Risk Management Results Tables

- **Training workshops**
Conclusion

- All parties must adjust to a more comprehensive view of assuring device safety

- IEC 60601-1 requires the application of risk management of ISO 14971

- Where devices comply with specific IEC 60601-1 requirements the risk addressed by those requirements should be considered acceptable

- Certification Bodies will need to become expert in review of the ISO 14971 risk management process
IEC 60601 has numerous specific risk management requirements which call up particular clauses of ISO 14971. The CBTL’s determination of compliance to the 60601 requirements is to confirm in the manufacturer’s documentation, that these particular ISO 14971 clauses have been addressed. That will be recorded in the risk management results table tied to the specific 60601 requirement.
For example, IEC 60601 requires that a manufacturer have a policy for determining criteria for risk acceptability and record it in the risk management file. That policy must address national & regional regulations, relevant international standards and current values of society. The evaluation made by the CBTL of the risk management file is to confirm that the manufacturer’s policy has addressed those regulations and relevant international standards.
Similarly, the manufacturer also has to develop criteria for risk acceptability and the criteria must be determined based on the policy. The CBTL evaluates the risk management file to confirm that the criteria for risk acceptability has been determined based on the manufactures policy.
One of the important tasks of Testing Laboratories is to evaluate the objective evidence (in the RM File) that the Risk Management as required (in IEC 60601-1), performed and recorded by the Manufacturer.
<table>
<thead>
<tr>
<th>Testing Laboratory Question</th>
<th>IECEE COMMON UNDERSTANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>We face the problem to spend a considerable amount of time to seek the information we need in the Risk Management File. How can we improve the efficiency in finding the right information for evaluation within a reasonable amount of time?</td>
<td>The Manufacturer shall provide, together with its Risk Management File, a cross reference to make it possible for the Testing Laboratory, to easily identify where the information is.</td>
</tr>
</tbody>
</table>
Risk Management for MED IEC 60601-1(ed.3)

Manufacturer

- Complete Technical File including Risk Management File

CBTL

- Safety testing
- Review of Risk Management File
- IECCE CB Test Report

ISSUING NCB A

- Issuing
- IECCE CB Test Certificate

RECOGNIZING NCB B

- Test Certificate
Documentation to be established by the Manufacturer

- Technical documents
- Risk Management File
- Clinical Review
- QMS

Complete Technical File
Documentation Required by the Issuing NCB/CBTL

Cross reference between requirement in IEC 60601-1 and RM

Any other Technical Information as need be
MANUFACTURER

IECEE CB Test Report

IECEE CB Test Certificate

Complete Technical File including Risk Management File

Contacts

- **IECEE Website:**  [www.iecee.org](http://www.iecee.org)

- **IECEE Executive Secretary:**
  Mr Pierre de RUVO
  
  **E-mail:** pro@iec.ch
  
  **Direct Line:** +41 22 919 02 07