ISO 14971: Overview of the standard

Risk Management Through Product Life Cycle: An Educational Forum

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Medical devices - Application of risk management to medical devices
- 14 pages in body
- 63 pages in 10 Annexes

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Annexes
- Rationale
- Overview
- Identifying device characteristics that have risk
- Risk concepts
- Examples of hazards
- Risk management plan
- Techniques
- In vitro
- Biological hazards
- Residual risk

Observations on 14971
- It is “voluntary”
- It is cited and recognized by FDA
  A search within FDA for ISO 14971 produces 564 items!
- It’s useful application requires knowledge and diligence
Observations on 14971

- The reasons to undertake risk management (guided by 14971) are that:
  - Reducing risk is a good thing
  - Compliance is also a good thing
- Don’t let the compliance imperative overwhelm the risk control imperative

Direct citations of 14971 in submitted documents

- From an MDR: ...risk analysis (performed according to ISO 14971 2000...)
- From a 510(k) Summary: ...risk analysis preformed identified...by ISO 14971 and QSR and internal procedures for risk analysis.
General principles

- Risk is commonly described as having two principle components:
  - Severity
    - if the harm occurs
  - Probability
    - of the harm occurring

A few definitions

- Harm is the adverse event
- Hazard is the potential cause of the harm
  Note: You can detect a hazard before it causes harm, but detecting harm means the harm already occurred
- Safety is the absence of unacceptable risks
  But unacceptable to whom?
General principles

- Risk management is something that you have to \textit{actively do}
- It is not simply a byproduct of general good intentions and good engineering

General principles

- Risk can often not be reduced to zero...\textit{but this is not an excuse for all hazards and harms}
- There may be “residual risks” \textit{after appropriate} risk evaluation and control
- Residual risks must undergo acceptance and communication activities
The process - part 1

Risk Analysis → Risk Evaluation → Risk Control

Risk Assessment

Cycle!
The process - part 2

- Risk Analysis
- Risk Evaluation
- Risk Control
- Acceptability?

Cycle!

The process - part 3

- Risk Analysis
- Risk Evaluation
- Risk Control
- Acceptability?
- Report
- Post Production

Cycle!

Risk Management
A note on post production

- Manufacturing deviations
- Complaints and complaint handling
- CAPA
- Recalls

General requirements in 14971 (Section 3)

- A formal (documented) process and plan in place
- Management commitment
  - Resources
  - Personnel
- Qualified personnel
- Documented results
### Risk analysis (Section 4)

- Intended use and misuse
- Risk related characteristics
- Hazard identification
  - known and foreseeable
- Risk estimation
  - systematic
  - based on available and general information

### Risk evaluation (Section 5)

- Manufacturer determined criteria for Risk acceptability decision making

- There is not a predetermined, all purpose acceptable level of risk
  - no equation
  - no regulation
Risk control (Section 6) - Engineering

- Elimination by (re)design
- Protective measures to protect against the risk - both physical and alarms
- Information (IFUs, training)

*Preferably in this order!*

You shouldn’t try to fix a dangerous design with a warning (if you could have reasonably designed it out)!

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Risk control (Section 6) - Management

- Residual risk evaluation *after controls are applied*
- Another round of acceptance decision making including
  - Risk/benefit analysis (Section 6.5)
    > an effort to make otherwise unacceptable risks acceptable - *which is potentially confusing*
- If accepted --- disclosure decision making
Overall risk (Section 7) - Management

- After all individual risk control activity has been done... then decision making applied to complete design

  Note: assessing the collective risk that results from the individual risks is a challenging and imprecise procedure

Report (Section 8)

- Review pre product release
  - Appropriately implemented
  - Overall residual risk is acceptable
  - Post production processes are in place

- Documented
Post production (Section 9)

- Collect and review
- Attention to previously unrecognized risks
- Attention to severity or rate of occurrence above originally estimated
- Include feedback into risk management process itself

Annexes

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Annex C - Questions - examples

- Intended and means of use (& user)
- Materials and components
- Sterile, or user sterilization
- Measurements and data interpretation
- Use in conjunction with...
  - interfacing
- Unwanted outputs (e.g. Noise, heat, EMI)
- Susceptible to environment, forces, etc.

Annex C - Questions (cont)

- Software (& menus)
- Reuse, intended and single use
- Installation & use training
- New manufacturing processes
- Transmittal of user information
- User interface issues - human factors
  - distractions
  - alarms
  - predictable misuse
Note

- Lists of questions, lists of hazards, check lists, pull down menus, etc are not a substitute for thoughtful analysis by a knowledgeable person.

- The more unique/different your device is, the less likely it is that pre-prepared lists will be comprehensive.

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Annex D - Risk concepts

- Probability and severity scales
  Qualitative - 3 and 5 level scales are shown

Severity

<table>
<thead>
<tr>
<th>Severity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>Death</td>
</tr>
<tr>
<td>Critical</td>
<td>Permanent impairment or life threatening</td>
</tr>
<tr>
<td>Serious</td>
<td>Medical intervention</td>
</tr>
<tr>
<td>Minor</td>
<td>No medical intervention</td>
</tr>
<tr>
<td>Negligible</td>
<td>Inconvenience or temporary</td>
</tr>
</tbody>
</table>

Probability - with verbal or numerical descriptors

<table>
<thead>
<tr>
<th>Probability</th>
<th>14971</th>
<th>other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>$&gt;10^{-3}$</td>
<td>highly likely</td>
</tr>
<tr>
<td>Probable</td>
<td>$&lt;10^{-3}$ and $\geq 10^{-4}$</td>
<td>will occur</td>
</tr>
<tr>
<td>Occasional</td>
<td>$&lt;10^{-4}$ and $\geq 10^{-5}$</td>
<td>may occur</td>
</tr>
<tr>
<td>Remote</td>
<td>$&lt;10^{-5}$ and $\geq 10^{-6}$</td>
<td>possible but unlikely</td>
</tr>
<tr>
<td>Improbable</td>
<td>$&lt;10^{-6}$</td>
<td>very unlikely</td>
</tr>
</tbody>
</table>
Annex D - Risk concepts

- **Scale issues**
  - How many levels?
    - 3? 5? 10?
  - Levels are often ill defined
    - especially probability
  - Often imprecise, yet precision is pretended
  - Tendency to be optimistic (if not cheat)

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Annex D - Risk concepts

- **Matrix**

```
    Severity
     0   1   2   3   4   5

    Probability
    0   1   2   3   4   5
```

Probability

Severity
Annex D - Risk concepts

Matrix

<table>
<thead>
<tr>
<th>Severity</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good (more or less)</td>
<td></td>
</tr>
<tr>
<td>Bad (more or less)</td>
<td></td>
</tr>
</tbody>
</table>

Good (more or less)
Annex D - Risk concepts

Matrix

<table>
<thead>
<tr>
<th>Severity</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bad (more or less)</td>
<td>Good (more or less)</td>
</tr>
<tr>
<td>Challenging!</td>
<td>And the rest?</td>
</tr>
</tbody>
</table>

And the rest?
Annex D - Risk concepts

- There is no zone that is automatically acceptable or unacceptable
- The manufacturer must have their own decision and sign off process

Analysis of Risk: Are Current Methods Theoretically Sound?

Applying risk assessment may not give manufacturers the answers they think they are getting

Nataly F. Youssef and William A. Hyman

http://www.mddionline.com/article/analysis-risk-are-current-methods-theoretically-sound
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Annex G- Risk management techniques

- Preliminary hazard analysis (PHA)
  
  early review of potential risks and their possible causation

  early guidance on what will need to be controlled
Annex G- Risk management techniques

- Fault tree analysis (FTA)
  - define a bad event
  - identify what can lead to that event
  - identify what can lead to the things that lead to the event
  - etc

FTA

Bad event #1
- Cause #1
  - Cause (a) of cause #1
  - Cause (b) of cause #1
- Cause #2
- Cause #3

Annex G- Risk management techniques

- Failure Modes and Effects Analysis (FMEA)
  - identify a failure mode of component, device, or user
  - identify the effects of that failure mode
  - perform risk assessment to determine if the effect requires action

- Hazard and Operability Study (HAZOP)
  - similar to FMEA
  - emphasis on use of system

- Hazard Analysis and Critical Control Points
  - similar to or uses many of the same methods
  - emphasis on processes (e.g. manufacturing)
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Annex J- Residual risk

Communication

- Audience
- Method
- Effectiveness
SUMMARY

- Risk management is a good thing... even if there wasn’t an FDA
- 14971 is a well recognized guide to risk management methodology
- But... it is not a cook book, or a check list, or an alternative to conscientious effort
- The objective is to use it thoughtfully as opposed to going through the motions to meet regulatory requirements

Questions?