Safety Risk Management in RT: A Software Manufacturer Perspective

Jim Schewe, Ph.D.
Philips Radiation Oncology Systems
AAPM Spring Clinical Meeting
March 16, 2014
Learning Objectives
For the session

1. Understand the structure and mission of the Radiation Oncology Safety Stakeholders’ Initiative (ROSSI).
2. Learn about how the clinical community and vendors are collaborating to help improve the usability, quality, and safety of medical devices and clinical practice.
3. **Understand the basics of Safety Risk Management, its relationship to the product lifecycle, and the similarities and differences in how it applies to products and clinical practice.**
4. Understand the basics of Usability and its relationship to the safety of medical devices, including problems and recommended improvements with the content and frequency of software error messages.
Outline

• Background
• Risk Management Process
  – The Standard: ISO 14971
  – Practical Examples
• Discussion
  – Industry vs. the Clinic: Similarities and Differences
  – General Comments
Conflicts of Interest

I work for Philips

I’m not a:
• Regulatory Affairs Expert
• Software Engineer
• Usability/Human Factors Engineer

clinical
I’m a\(^\wedge\) physicist

http://xkcd.com/793/
So...

What would you say you *do* here?

**Day Job: Design Engineering**
- Requirements
- Risk Management
- Testing
- Documentation
- Defect Review
- Change Management

“**Other Duties As Assigned**”
- Third-Tier Support
- Complaint Investigations
- Regulatory Support
- Sales & Marketing Support
- ROSSI & MITA & etc.
- ...
Background: Context

Safety Risk Management is:

... central to any medical device. It drives:
  – Requirements
  – Design
  – Testing
  – Documentation

... related to ROSSI concerns:
  – Quality Assurance
  – Training
  – Usability
  – Error Messages
  – Risk Management (pending approval)

... potentially a driver of RT clinical practice
  – Any device you use is a part of that practice
Background: Process Stuff

Product Development Process: “Waterfall”

- Requirements
- Design
- Implementation
- Testing

Complexity vs. Time

Safety Risk Management

Complaints, Bugs, etc.

Feedback into the system

http://en.wikipedia.org/wiki/V-Model
Outline

• Background
• Risk Management Process
  – The Standard: ISO 14971
  – Practical Examples
• Discussion
  – Industry vs. the Clinic: Similarities and Differences
  – General Comments
Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

Reference number
ISO 14971:2007(E)

© ISO 2007
Contents

The Devil is in the Details

Formal Content:
1. Scope
2. Terms & Definitions
3. General Requirements
4. Risk Analysis
5. Risk Evaluation
6. Risk Control
7. Evaluating Overall Acceptability
8. Risk Management Report
9. Production & Post-Production

“Informative” Annexes
A. Rationale for requirements
B. Process overview
C. Questions to ask about the device
D. Risk concepts and medical devices
E. Hazards, foreseeable sequences of events, & hazardous situations
F. Risk Management Plan
G. Info on RM techniques
H. Guidance for in vivo devices
I. Guidance for bio hazards
J. Info about residual risk

15 Pages

65 Pages
Scope
Section 1

“This International Standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device.

This International Standard does not apply to clinical decision making.

This International Standard does not specify acceptable risk levels.

This International Standard does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.”
The duration of the Risk Management process is:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>1. During requirements writing</td>
</tr>
<tr>
<td>20%</td>
<td>2. During product development</td>
</tr>
<tr>
<td>20%</td>
<td>3. During beta testing</td>
</tr>
<tr>
<td>20%</td>
<td>4. During a complaint investigation</td>
</tr>
<tr>
<td>20%</td>
<td>5. During the whole product life-cycle</td>
</tr>
</tbody>
</table>
The duration of the Risk Management process is:

5: During the whole product life-cycle

“The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device.”

(Section 1: Intro)
Terminology
Section 2: A subset

**Harm**: physical injury or damage to the health of people, or damage to property or the environment

**Hazard**: potential source of harm

**Hazardous Situation**: circumstance in which people, property, or the environment are exposed to one or more hazard(s)

**Risk**: combination of the probability of occurrence of harm and the severity of that harm
- Residual Risk
- Risk Analysis
- Risk Assessment
- Risk Control
- Risk Estimation
- Risk Management

**Safety**: freedom from unacceptable risk
Hazardous Situations, Risk, and Harm

Not the same thing

\[ P = \text{Probability of harm} \]
- Not of a fault (defect)
- Not of a mistake
- Not of a hazardous situation

⇒ Chain of events is important

No separate detectability score

Risk ≠ P × S (in general)
Risk is the combination of:

<table>
<thead>
<tr>
<th>20%</th>
<th>1. Harm &amp; its potential source</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>2. Damage to health &amp; property</td>
</tr>
<tr>
<td>20%</td>
<td>3. Probability of harm &amp; its severity</td>
</tr>
<tr>
<td>20%</td>
<td>4. Probability of harm &amp; its detectability</td>
</tr>
<tr>
<td>20%</td>
<td>5. A hazardous situation &amp; its cause</td>
</tr>
</tbody>
</table>
Risk is the combination of:

3: Probability of harm & its severity

ISO 14971:2007(E)

2.16 risk
combination of the probability of occurrence of harm and the severity of that harm

Risk Management Process

The Big Picture

Risk Assessment

Risk Control

Overall Risk Evaluation

Risk Management Report

Production & post-production

Risk analysis

- Intended use and identification of characteristics related to the safety of the medical device
- Identification of hazards
- Estimation of the risk(s) for each hazardous situation

Risk evaluation

Risk control

- Risk control option analysis
- Implementation of risk control measure(s)
- Residual risk evaluation
- Risk/benefit analysis
- Risks arising from risk control measures
- Completeness of risk control

Evaluation of overall residual risk acceptability

Risk management report

Production and post-production Information
Risk Assessment
Analysis & Evaluation

Risk Analysis:
- Document intended use and “reasonably foreseeable misuse.”
- Identify Hazards
- Estimate Risks

Risk Evaluation
- Is the (individual) risk Acceptable?
Estimating Risk
Example **Qualitative** S and P Levels

<table>
<thead>
<tr>
<th>Common terms</th>
<th>Possible description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant</td>
<td>Death or loss of function or structure</td>
</tr>
<tr>
<td>Moderate</td>
<td>Reversible or minor injury</td>
</tr>
<tr>
<td>Negligible</td>
<td>Will not cause injury or will injure slightly</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Common terms</th>
<th>Possible description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Likely to happen, often, frequent</td>
</tr>
<tr>
<td>Medium</td>
<td>Can happen, but not frequently</td>
</tr>
<tr>
<td>Low</td>
<td>Unlikely to happen, rare, remote</td>
</tr>
</tbody>
</table>
Estimating Risk

Example **Semi-Quantitative** S and P Levels

Table D.3 — Example of five qualitative severity levels

<table>
<thead>
<tr>
<th>Common terms</th>
<th>Possible description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>Results in patient death</td>
</tr>
<tr>
<td>Critical</td>
<td>Results in permanent impairment or life-threatening injury</td>
</tr>
<tr>
<td>Serious</td>
<td>Results in injury or impairment requiring professional medical intervention</td>
</tr>
<tr>
<td>Minor</td>
<td>Results in temporary injury or impairment not requiring professional medical intervention</td>
</tr>
<tr>
<td>Negligible</td>
<td>Inconvenience or temporary discomfort</td>
</tr>
</tbody>
</table>

Table D.4 — Example of semi-quantitative probability levels

<table>
<thead>
<tr>
<th>Common terms</th>
<th>Examples of probability range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>$\geq 10^{-3}$</td>
</tr>
<tr>
<td>Probable</td>
<td>$&lt; 10^{-3}$ and $\geq 10^{-4}$</td>
</tr>
<tr>
<td>Occasional</td>
<td>$&lt; 10^{-4}$ and $\geq 10^{-5}$</td>
</tr>
<tr>
<td>Remote</td>
<td>$&lt; 10^{-5}$ and $\geq 10^{-6}$</td>
</tr>
<tr>
<td>Improbable</td>
<td>$&lt; 10^{-6}$</td>
</tr>
</tbody>
</table>
Probability
Questions to ask

General:
• Does the hazardous situation occur in the absence of a failure?
• Does the hazardous situation occur in a fault condition?
• Does the hazardous situation occur only in a multiple-fault condition?
• How likely is it that a hazardous situation will lead to harm?

Context:
• How often is the device used?
• What is its lifetime?
• Who makes up the user and patient populations?
• What is the number of users/patients?
• How long and under what circumstances is the user/patient exposed?
Risk Evaluation and Acceptability

A given risk can be:
- Unacceptable
- Acceptable
  - “Insignificant”
  - “Further investigation”

“This International Standard does not specify acceptable risk levels.”
Acceptable Risk
Context is Important

“because this International Standard does not define acceptable risk levels, **top management** is required to establish a policy on how acceptable risks will be determined;”

...
Acceptable risk levels are set by:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>1. The ISO 14971 standard</td>
</tr>
<tr>
<td>20%</td>
<td>2. The IAEA 1540 Report</td>
</tr>
<tr>
<td>20%</td>
<td>3. The manufacturer</td>
</tr>
<tr>
<td>20%</td>
<td>4. The AAPM TG-100 report</td>
</tr>
<tr>
<td>20%</td>
<td>5. The FDA</td>
</tr>
</tbody>
</table>
Acceptable risk levels are set by:

3: The manufacturer

... “because this International Standard does not define acceptable risk levels, top management is required to establish a policy on how acceptable risks will be determined;” (Section A.2.3.2)

... “Top management shall define and document the policy for determining criteria for risk acceptability; this policy shall ensure that criteria are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns;” (Section 3.2)
Risk Control

Mitigation

“The manufacturer shall use one or more of the following risk control options in the priority order listed:

a) inherent safety by design;
b) protective measures in the medical device itself or in the manufacturing process;
c) information for safety.”

“Hierarchy of Effectiveness”

http://www.cassiemcdaniel.com/blog/hierarchy-of-effectiveness-process/
Which is the best risk control to prevent use of an unapproved plan?

<table>
<thead>
<tr>
<th>Option</th>
<th>Percentage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Extra training</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>2. Preventing data export</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>3. A warning message in the GUI</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>4. An explanation in the user manual</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>5. Displaying “Unapproved” in a big font</td>
<td>20%</td>
<td></td>
</tr>
</tbody>
</table>
Which is the best risk control to prevent use of an unapproved plan?

2: Preventing data export

“The manufacturer shall use one or more of the following risk control options in the priority order listed:

a) inherent safety by design;

b) protective measures in the medical device itself or in the manufacturing process;

c) information for safety.”

Section 6.2, Risk control option analysis
Example: State Management
Keeping things in sync

“The system must invalidate dose if the user changes the couch, gantry, or collimator angles after dose has been computed.”

- Severity / Probability
- inherent safety by design;
- protective measures in the medical device itself or in the manufacturing process;
- information for safety.
Example: Limit Checking
How bad can it be?

“The system shall allow the user to specify the final control point spacing of 2, 3, or 4 degrees.”

- **Severity / Probability**
- inherent safety by design;
- protective measures in the medical device itself or in the manufacturing process;
- information for safety.
Example: Combining Controls

“The software shall print "NOT FOR CLINICAL USE" watermark across the printed reports and color prints, for any trials that are not for clinical use, in addition to printing "NOT FOR CLINICAL USE" in the plan authorization line. “

Also tilde on MU
Also export restrictions

• Severity / Probability
• inherent safety by design;
• protective measures in the medical device itself or in the manufacturing process;
• information for safety.
Wrapping it Up
Overall Acceptability and Report

“Overall Residual Risk Acceptability”
• Marginal issues can add up

RM Report: Formal Summary
• Can be a meta-document
Production & Post-Production Feedback

You learn from:
• Testing
• Defects
• Complaints
• Etc.

Risk Management File is a “living document”
Example: Post-Production Feedback

Default Isocenter for Setup Beams

“There shall be no default isocenter assigned to the setup beams.”

“There shall be no default machine assigned to the setup beams.”

- Severity / Probability
- inherent safety by design;
- protective measures in the medical device itself or in the manufacturing process;
- information for safety.
Other Standards and Human Factors Issues
Automation, Defaults, and Forcing Functions
Outline

• Background
• Risk Management Process
  – The Standard: ISO 14971
  – Practical Examples
• Discussion
  – Industry vs. the Clinic: Similarities and Differences
  – General Comments
Rules and Regulators
Different Rules and Enforcement

Industry
– Standards: ISO, IAEA, IEC...
– Enforcement: FDA

Clinic
– Standards: AAPM, ASTRO, ACR...
– Enforcement: State, NRC

Mechanical process details may vary
– Scoring, Testing, Traceability, Documentation...
Scope
Both Bigger and Smaller
“Device” vs. “Process”

**Industry**: General solutions for your specific clinic
- Different types of centers
  - Big/Academic vs. Small/Community
  - Different practices and equipment
- Interoperability with other systems (and vendors)
  - Imaging
  - Treatment Planning Systems
  - Linear Accelerators
  - Brachytherapy
  - Treatment Management Systems

**Clinic**: Any product is a *subset* of your system
- May have multiple centers & techniques
- Your workflow is unique
Stakeholders

Both Worlds are Interdisciplinary

⇒ Safety has to be too

Industry:
• Clinicians, Engineers, Marketing, Regulatory, Support, Management

Clinic:
• Physics, Dosimetry, MDs, Therapists, IT, Management

Both:
• Somebody has to own it
• Everybody has to buy into it
• Communication is a big deal
• Cultural issues are important
  – Fear of blame
  – Deferral to “experts”
  – Lack of empowerment to speak up
Change Is Impactful
Even change for the better

Any change can alter “understood” risks
New technology → new risks
• May also change old ones

Communication is key

Change is Impactful (2)

“There are probably children out there holding down spacebar to stay warm in the winter! YOUR UPDATE MURDERS CHILDREN.”

https://xkcd.com/1172/
There are Always Trade-Offs

How Much Redundancy In Risk Controls?

Some is good! ➔ Robustness
But: A few good mitigations is better than a lot of bad ones
• More is only better if they are independent
• Implementing & testing takes time: spend it wisely
• Fatigue can be a problem

There are Always Trade-Offs

Competing Priorities

- Regulatory Compliance
- Legal Issues
- Business
- Workflow & Efficiency
  - Speed vs. Accuracy
  - Efficiency vs. explicit user action
    - Automation
    - Defaults
Final Comments

Practical Stuff

The process is (almost) as important as the end product
- Get started
- Talk to each other

Don’t let the perfect be the enemy of the good
- Keep it as simple as you can
- Big Picture vs. Details

Feedback is important
- This is a life-cycle process: you are never “done”
- Learn from your mistakes… and other people’s too
Thank You