Safety Risk Management in RT: A Software Manufacturer Perspective

Jim Schewe, Ph.D.
Philips Radiation Oncology Systems
AAPM Spring Clinical Meeting
March 16, 2014

PHILIPS

Learning Objectives

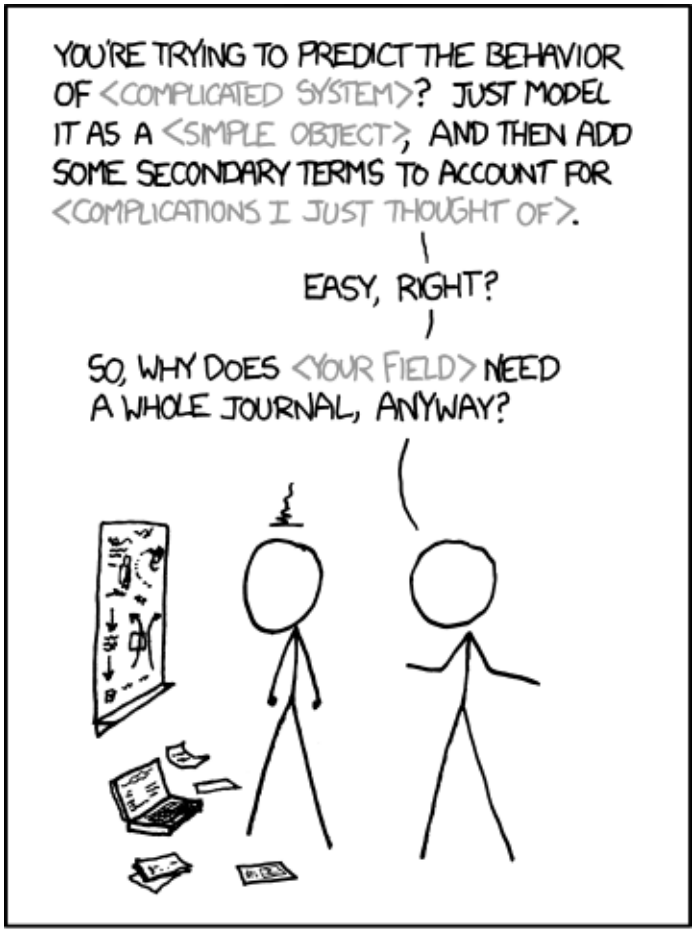
For the session

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

I'm a^ clinical 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:

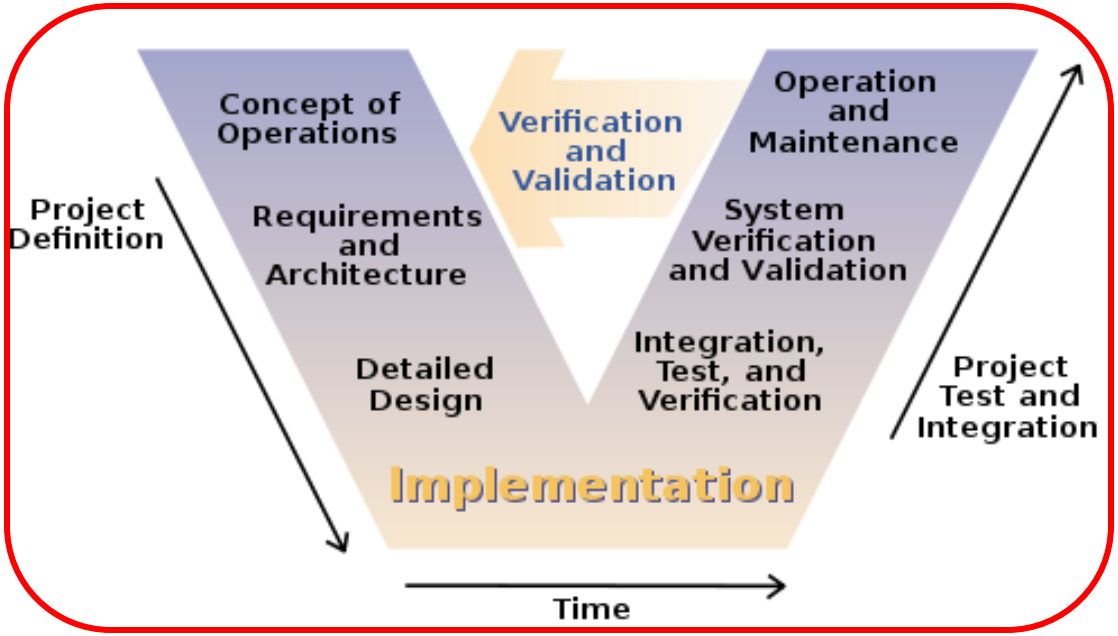
… central to any medical device. It drives:
- Requirements
- Design
- Testing
- Documentation

… 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”



Complexity vs. Time

- Requirements
- Design
- Implementation
- Testing

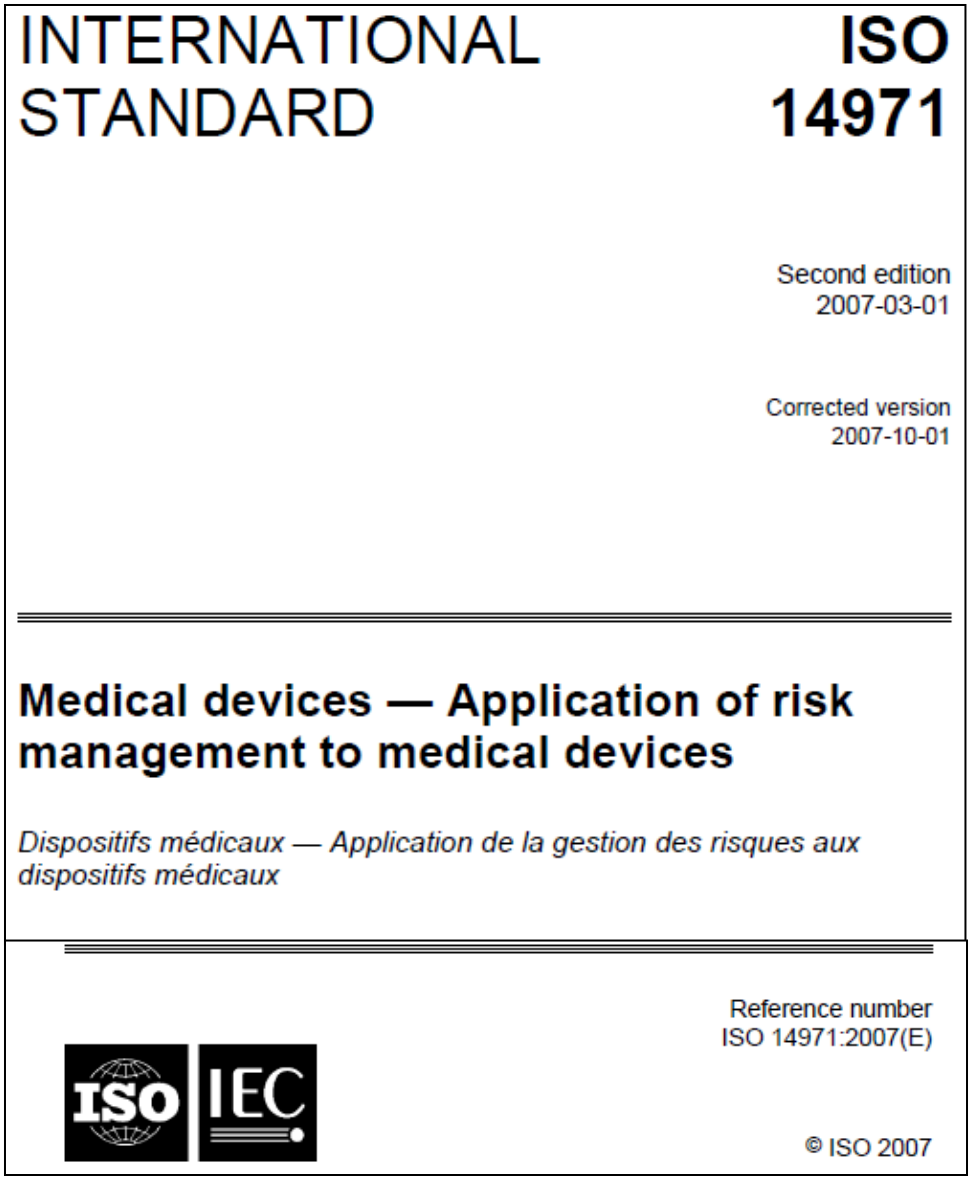
Safety Risk Management

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



INTERNATIONAL STANDARD

ISO 14971

Second edition
2007-03-01

Corrected version
2007-10-01

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

15 Pages

"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

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:

20%	1. During requirements writing
20%	2. During product development
20%	3. During beta testing
20%	4. During a complaint investigation
20%	5. During the whole product life-cycle

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)

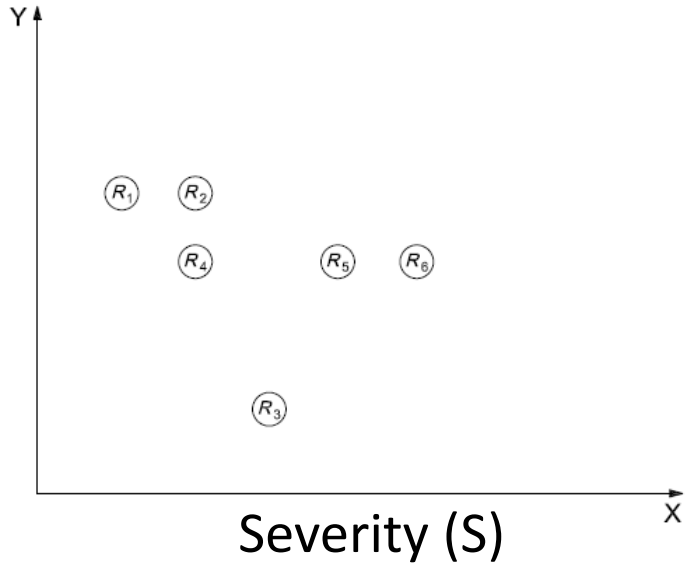
Risk: combination of the probability of occurrence of harm and the severity of that harm

- 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



Key
X increasing severity of harm
Y increasing probability of occurrence of harm

Figure D.1 — Example of a risk chart

P = 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 x S (in general)

Risk is the combination of:

20%	1. Harm & its potential source
20%	2. Damage to health & property
20%	3. Probability of harm & its severity
20%	4. Probability of harm & its detectability
20%	5. A hazardous situation & its cause

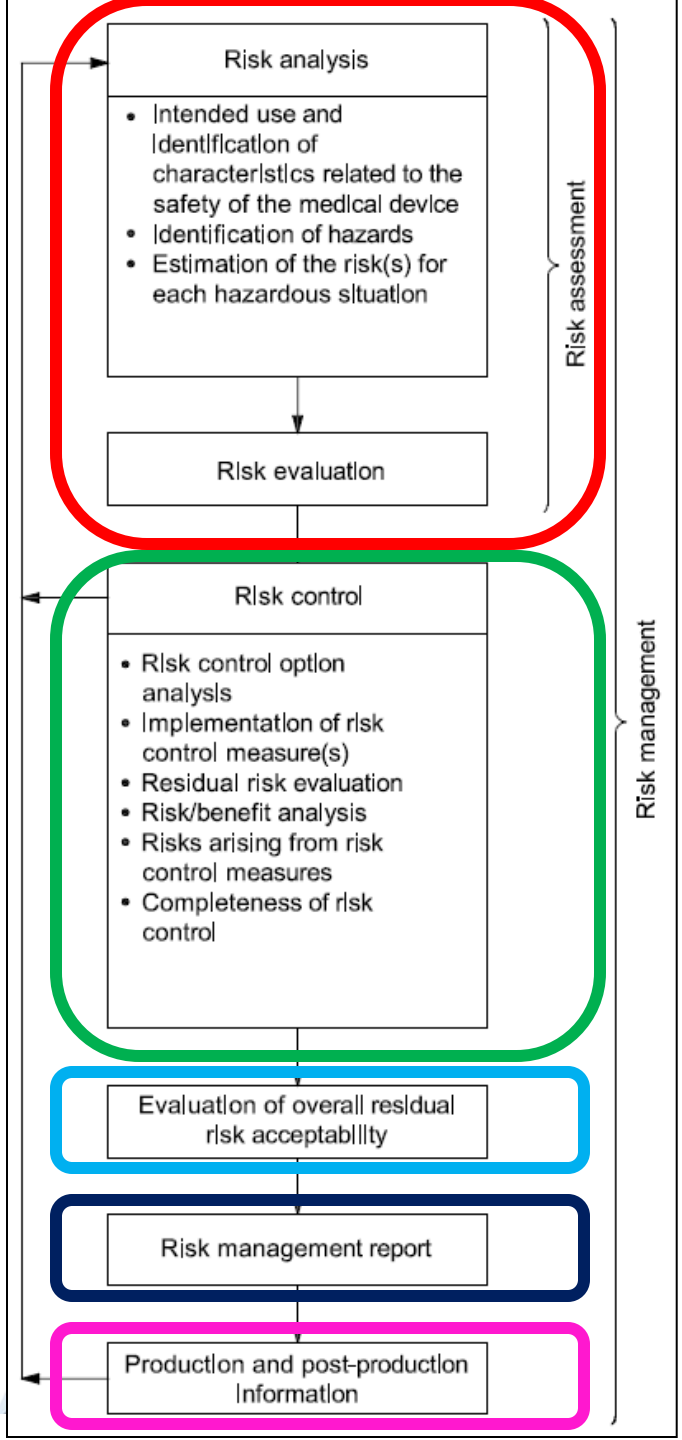
Risk is the combination of:

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

[ISO/IEC Guide 51:1999, definition 3.2]



Risk Management Process

The Big Picture

Risk Assessment

Risk Control

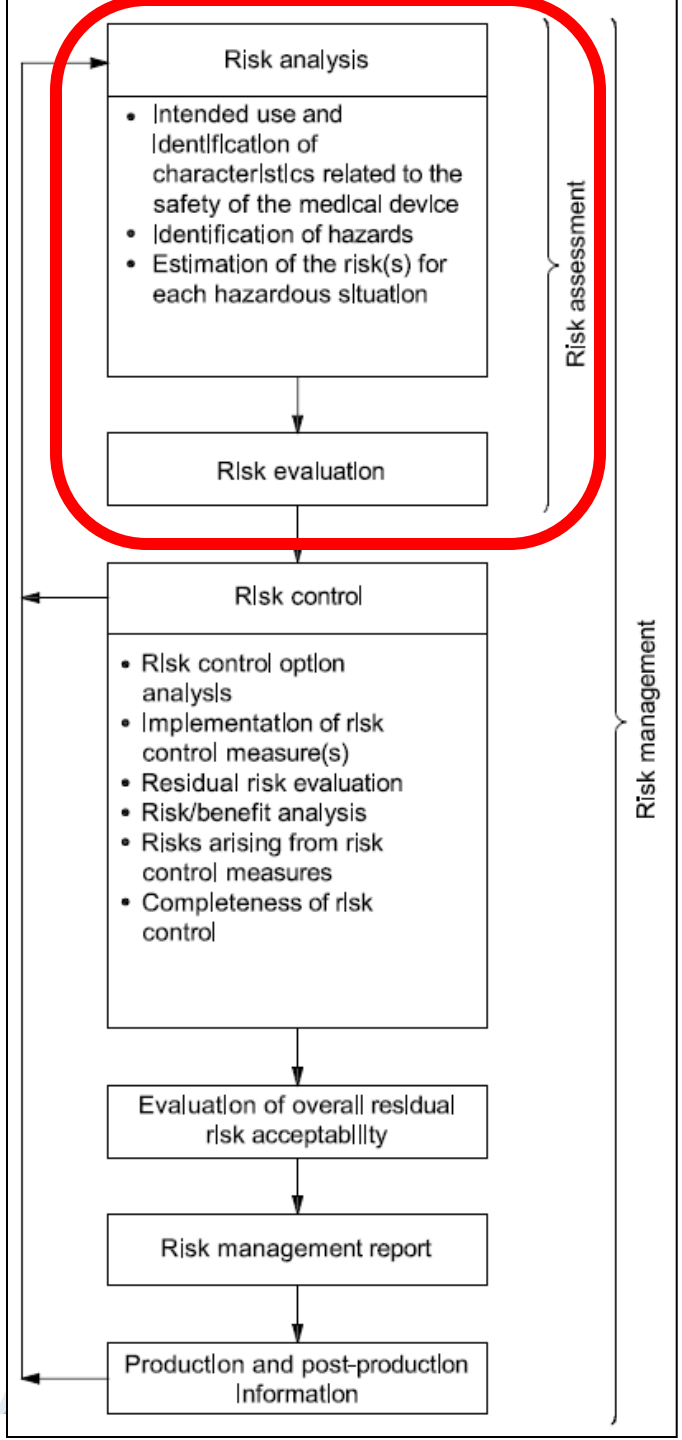
Overall Risk Evaluation

Risk Management Report

Production & post-production

Schewe: Safety Risk Management

PHILIPS



Risk Assessment

Analysis & Evaluation

Risk Analysis:

- Document intended use and "reasonably foreseeable misuse."
- Identify Hazards
- Estimate Risks

Risk Evaluation

- Is the (individual) risk Acceptable?

Schewe: Safety Risk Management

PHILIPS

Estimating Risk

Example **Qualitative** S and P Levels

Table D.1 — Examples of qualitative severity level

Common terms	Possible description
Significant	Death or loss of function or structure
Moderate	Reversible or minor injury
Negligible	Will not cause injury or will injure slightly

Table D.2 — Simplified examples of qualitative probability levels

Common terms	Possible description
High	Likely to happen, often, frequent
Medium	Can happen, but not frequently
Low	Unlikely to happen, rare, remote

Estimating Risk

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

Table D.3 — Example of five qualitative severity levels

Common terms	Possible description
Catastrophic	Results in patient death
Critical	Results in permanent impairment or life-threatening injury
Serious	Results in injury or impairment requiring professional medical intervention
Minor	Results in temporary injury or impairment not requiring professional medical intervention
Negligible	Inconvenience or temporary discomfort

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

Common terms	Examples of probability range
Frequent	$\geqslant 10^{-3}$
Probable	$< 10^{-3}$ and $\geqslant 10^{-4}$
Occasional	$< 10^{-4}$ and $\geqslant 10^{-5}$
Remote	$< 10^{-5}$ and $\geqslant 10^{-6}$
Improbable	$< 10^{-6}$

Probability

Questions to ask

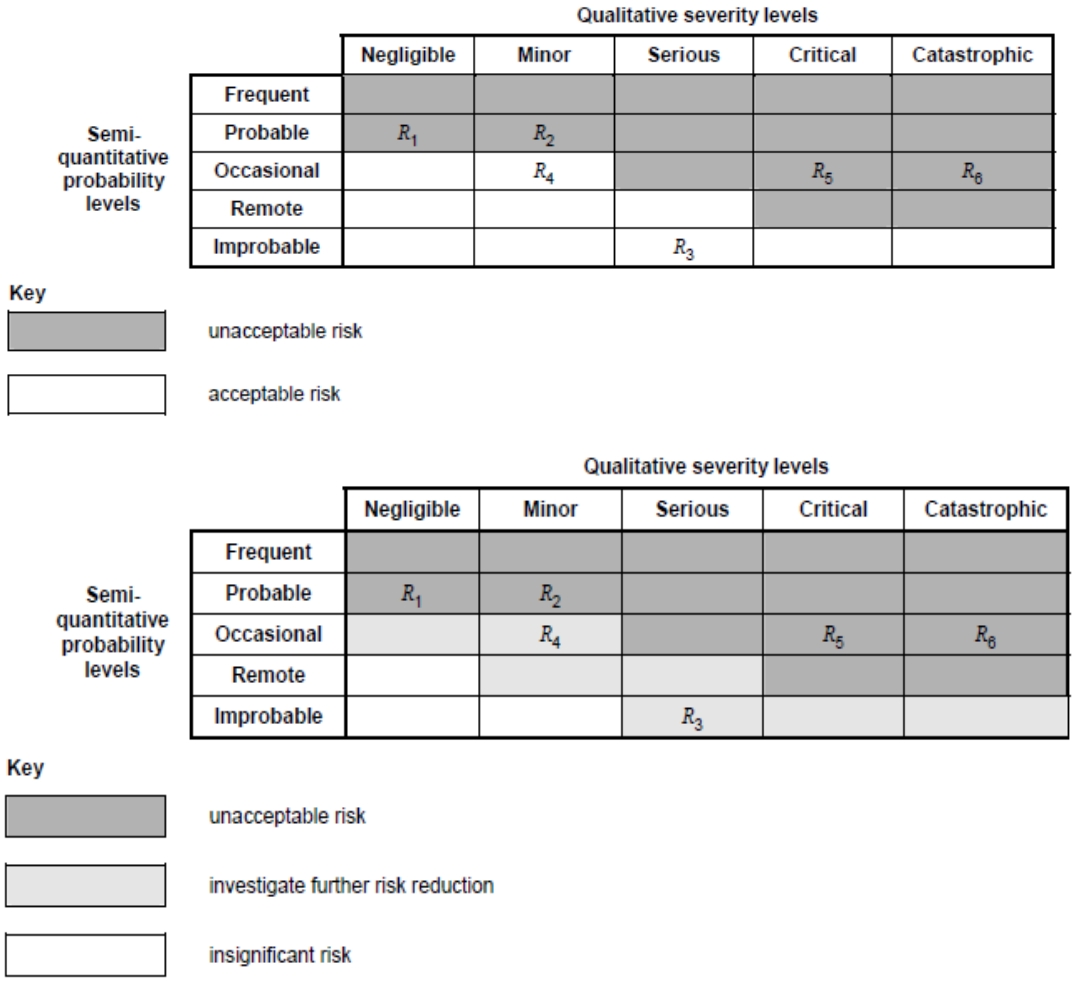
General:

- 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

General Device Warnings

Do not load non-system software onto the computer used by this system without the direct authorization of Philips Medical Systems. Feature performance and safety may be compromised.

To assure proper treatment, it is critical that a qualified medical person review and verify all system treatment plan parameters using an independent verification method prior to treating patients using the plan.

We recommend that you review TG40, TG53, and other pertinent radiation therapy treatment standards and incorporate those methods into your clinical practice to ensure that your use of the system results in the most accurate treatment plans. TG40, TG53, and other reports are availab Physicists in Medicine (AAPM) website.

- **Comprehensive QA for radiation oncology: Report of AAPM Radia *Medical Physics* 21(4), 1994.**
- **American Association of Physicists in Medicine Radiation Therapy assurance for clinical radiotherapy treatment planning. *Medical Phy***

The following clinical practices are recommended to verify the accura

- **An independent calculation of the monitor units for each beam of brachytherapy plan.**
- **Acquisition and review of portal images or review of multi-leaf colli the treatment system.**
- **A chart check prior to the plan being delivered or during the first**
- **Independent review of the treatment plan prior to the delivery.**
- **Cross-functional review of the plan in a weekly chart round.**
- **Manual verification of record and verify settings after transfer to th**
- **Verification of the SSD and field shape during patient setup.**

These reviews should be performed for a new plan or when a change

Use of Pinnacle^3 in Radiation Therapy

Risks and Benefits

A White Paper

Approved By	Name	Signature and Date
Clinical Reviewer, Certified Medical Dosimetrist	Lisa Beckett, RT(R)(T), CMD	Lisa Beckett
Clinical Reviewer, Certified Medical Physicist	Jim Schewe, Ph.D., DABMP	Jim Schewe
Author, Certified Medical Physicist	Mark Pepelea, Ph.D., DABR	Mark Pepelea
Manager, Systems Engineering	Don Wellnitz	Don Wellnitz
Quality and Regulatory	Jill Kaeder	Jill Kaeder
Director, Development Engineering	Terry Ward	R. Terry Ward
Senior Manager, Radiation Health & Product Safety	Dominic Siewko	Dominic Siewko

…

"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:

20%	1. The ISO 14971 standard
20%	2. The IAEA 1540 Report
20%	3. The manufacturer
20%	4. The AAPM TG-100 report
20%	5. The FDA

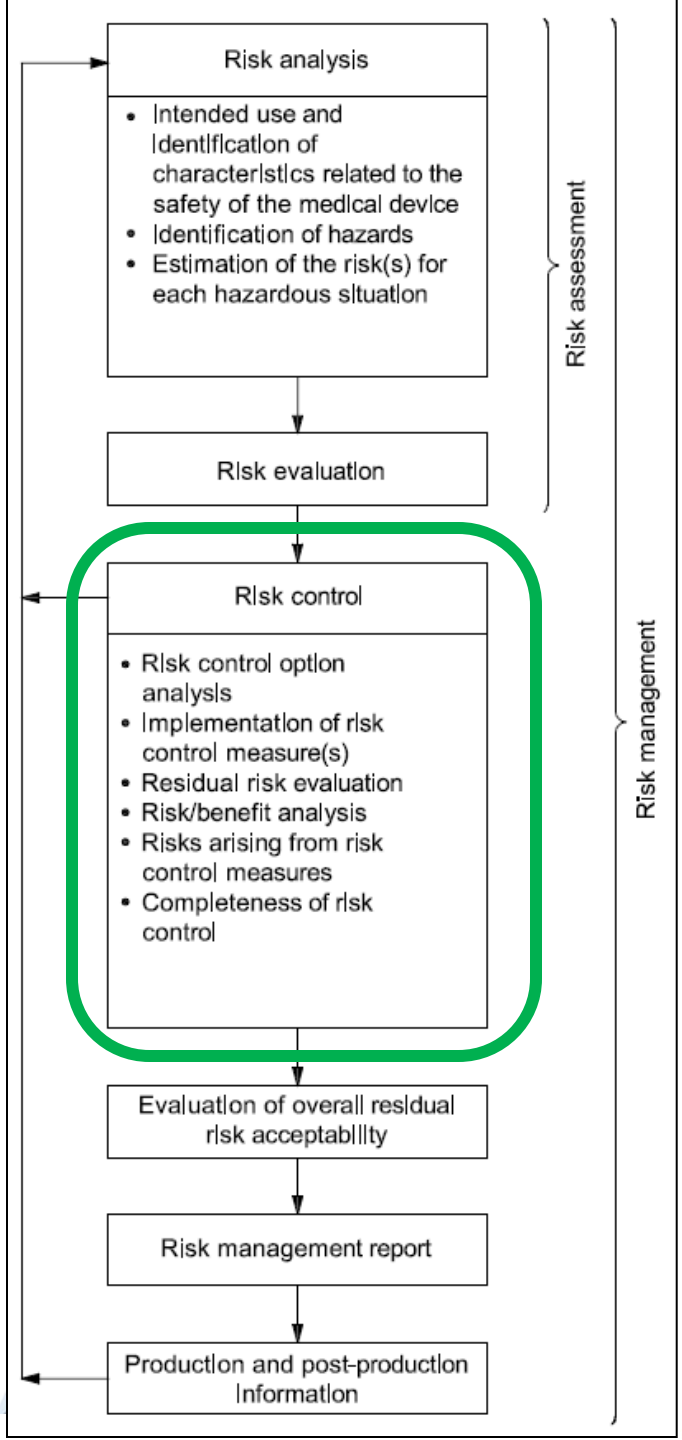
Acceptable risk levels are set by:

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)

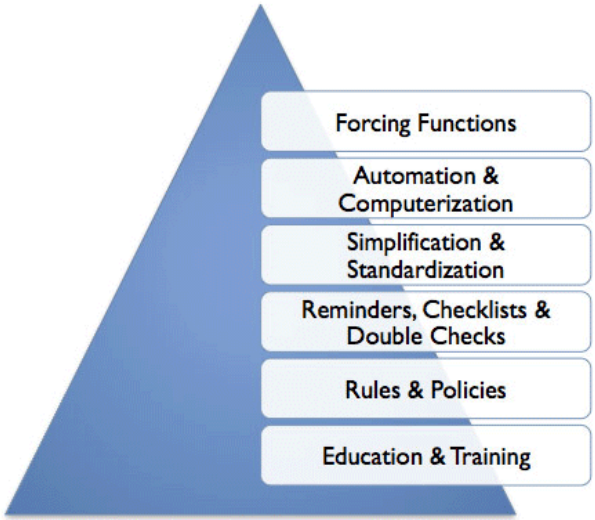


Risk Control

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/

PHILIPS

Which is the best risk control to prevent use of an unapproved plan?

20%	1. Extra training
20%	2. Preventing data export
20%	3. A warning message in the GUI
20%	4. An explanation in the user manual
20%	5. Displaying “Unapproved” in a big font

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;

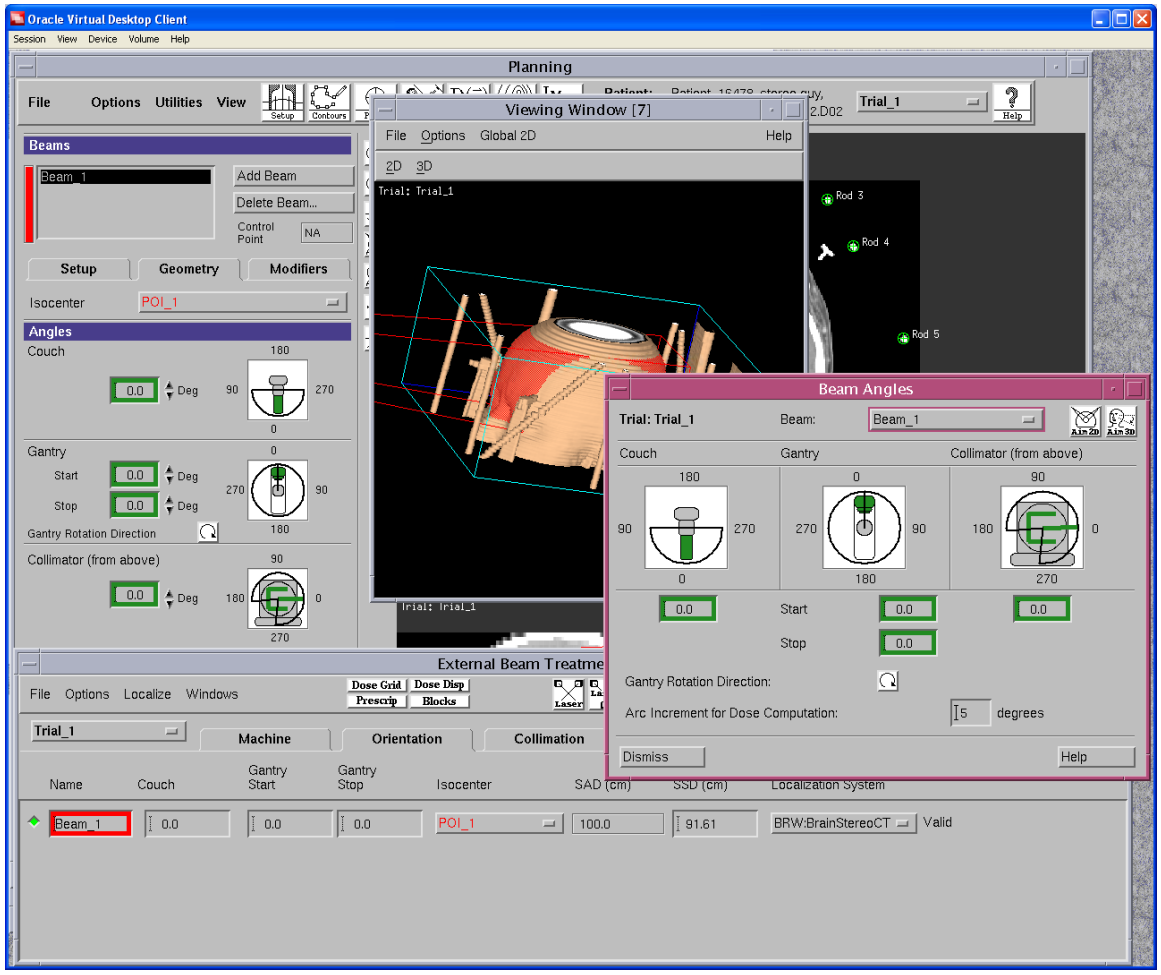
b) protective measures in the medical device itself or in the manufacturing process;

~~c) information for safety."~~

Section 6.2, Risk control option analysis

Example: State Management

Keeping things in sync

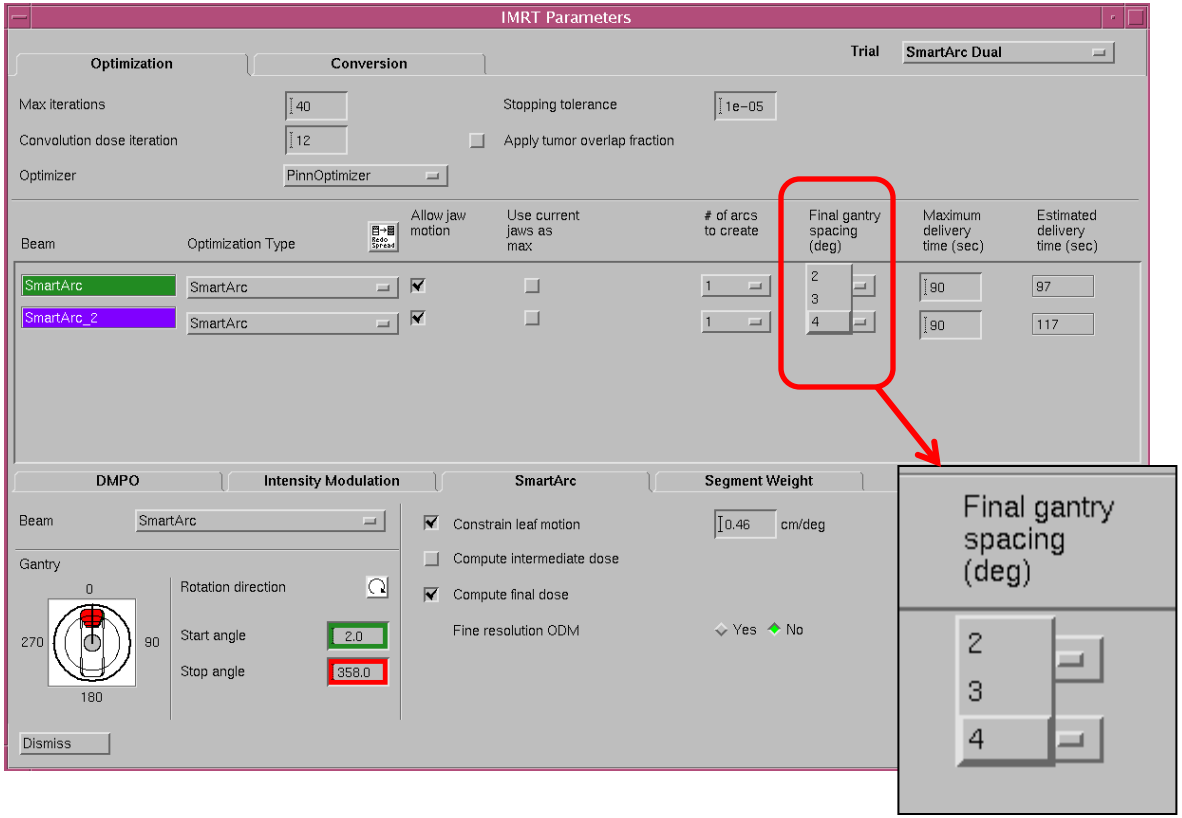


"The system must invalidate dose if the user changes the couch, gantry, or collimator angles after dose has been computed."

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

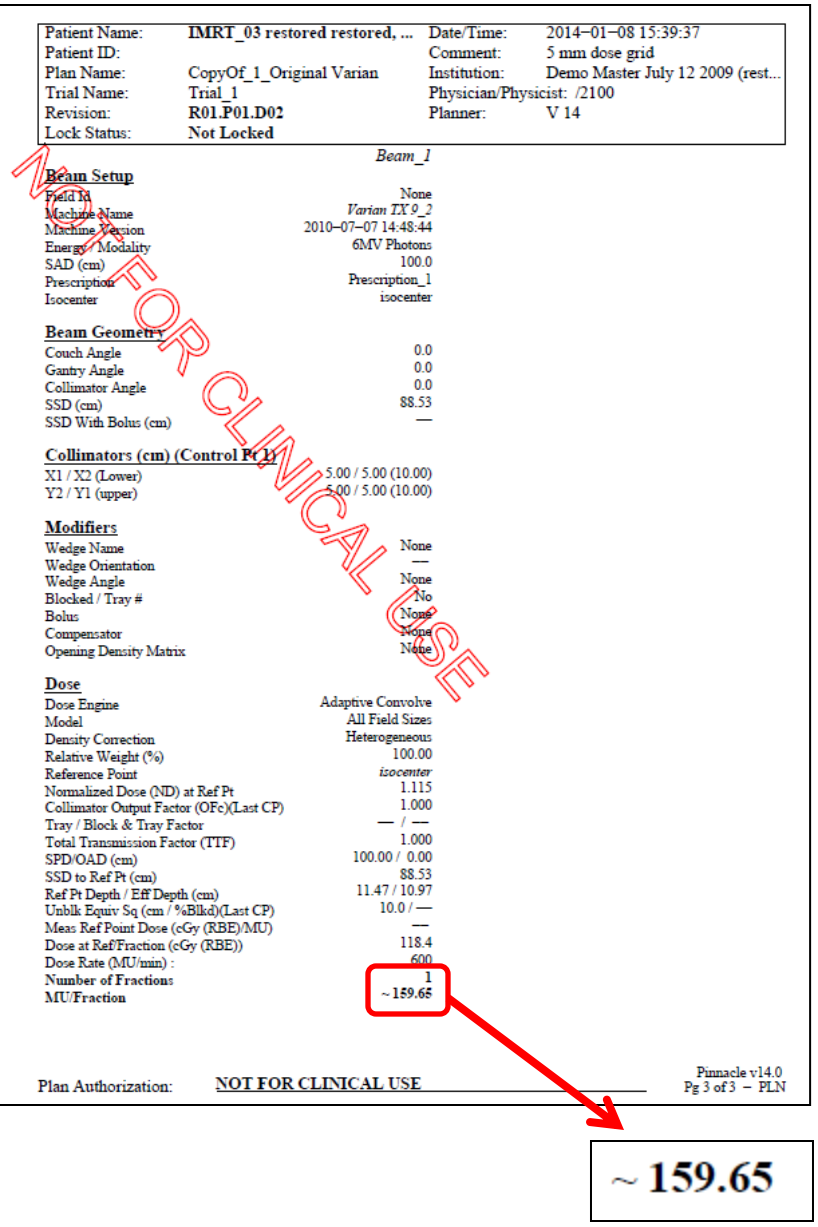
Example: Limit Checking

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.



Patient Name:	IMRT_03 restored restored, ...	Date/Time:	2014-01-08 15:39:37
Patient ID:		Comment:	5 mm dose grid
Plan Name:	CopyOf_1_Original Varian	Institution:	Demo Master July 12 2009 (rest...
Trial Name:	Trial_1	Physician/Physicist:	/2100
Revision:	R01.P01.D02	Planner:	V 14
Lock Status:	Not Locked		

Beam_1

Beam Setup

Field Id	None
Machine Name	*Varian TX 9_2*
Machine Version	2010-07-07 14:48:44
Energy / Modality	6MV Photons
SAD (cm)	100.0
Prescription	Prescription_1
Isocenter	isocenter

Beam Geometry

Couch Angle	0.0
Gantry Angle	0.0
Collimator Angle	0.0
SSD (cm)	88.53
SSD With Bolus (cm)	—

Collimators (cm) (Control Pt 1)

X1 / X2 (Lower)	5.00 / 5.00 (10.00)
Y2 / Y1 (upper)	5.00 / 5.00 (10.00)

Modifiers

Wedge Name	None
Wedge Orientation	—
Wedge Angle	None
Blocked / Tray #	No
Bolus	None
Compensator	None
Opening Density Matrix	None

Dose

Dose Engine	Adaptive Convolve
Model	All Field Sizes
Density Correction	Heterogeneous
Relative Weight (%)	100.00
Reference Point	*isocenter*
Normalized Dose (ND) at Ref Pt	1.115
Collimator Output Factor (OFc)(Last CP)	1.000
Tray / Block & Tray Factor	— / —
Total Transmission Factor (TTF)	1.000
SPD/OAD (cm)	100.00 / 0.00
SSD to Ref Pt (cm)	88.53
Ref Pt Depth / Eff Depth (cm)	11.47 / 10.97
Unblk Equiv Sq (cm / %Blkd)(Last CP)	10.0 / —
Meas Ref Point Dose (cGy (RBE)/MU)	—
Dose at Ref/Fraction (cGy (RBE))	118.4
Dose Rate (MU/min) :	600
Number of Fractions	1
MU/Fraction	~159.65

Plan Authorization: NOT FOR CLINICAL USE

Pinnacle v14.0
Pg 3 of 3 – PLN

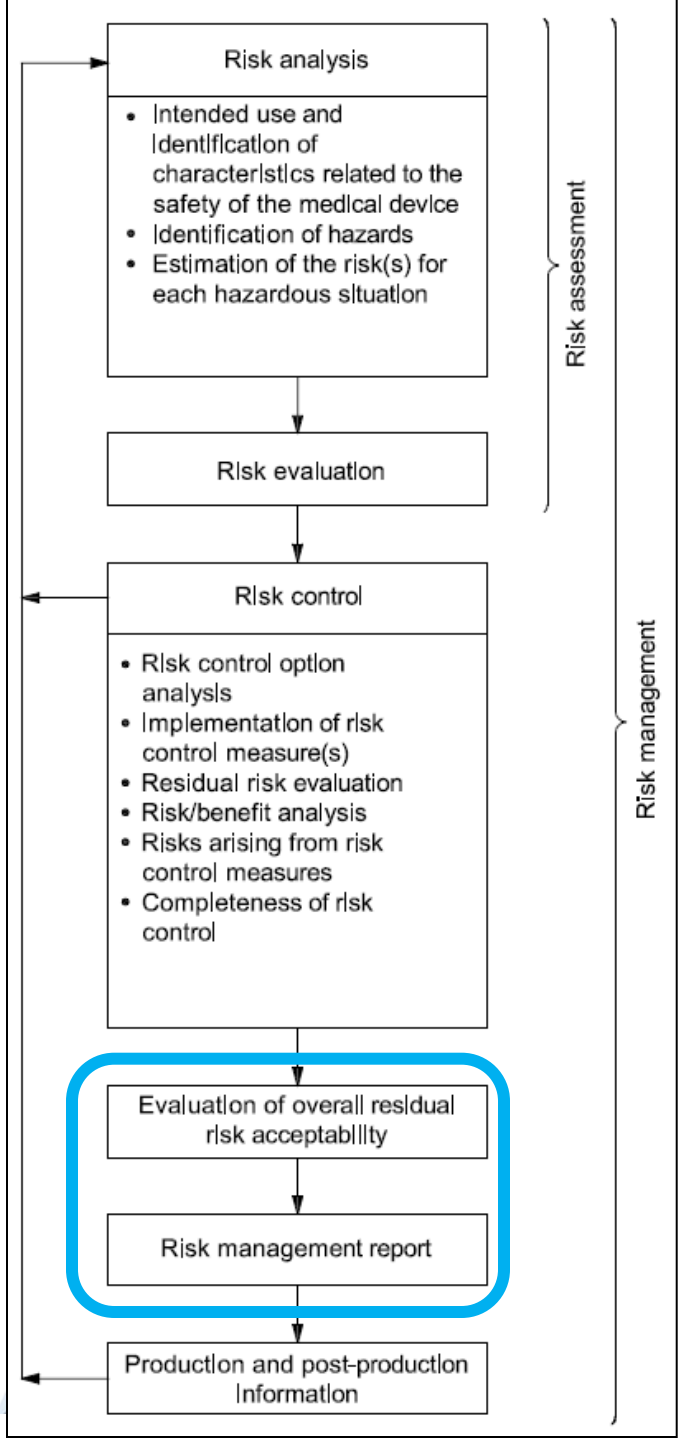
~ 159.65

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"

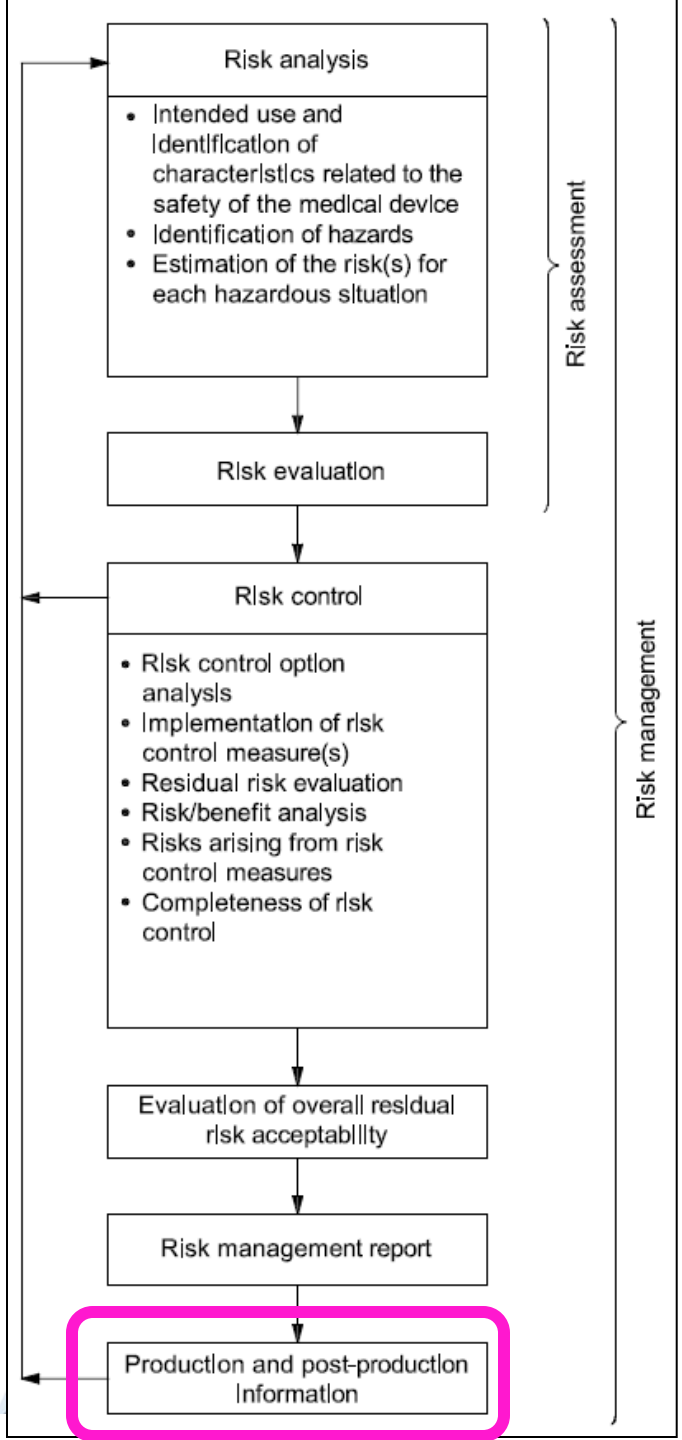
- Marginal issues can add up

RM Report: Formal Summary

- Can be a meta-document

Schewe: Safety Risk Management

PHILIPS



Production & Post-Production

Feedback

You learn from:

- Testing
- Defects
- Complaints
- Etc.

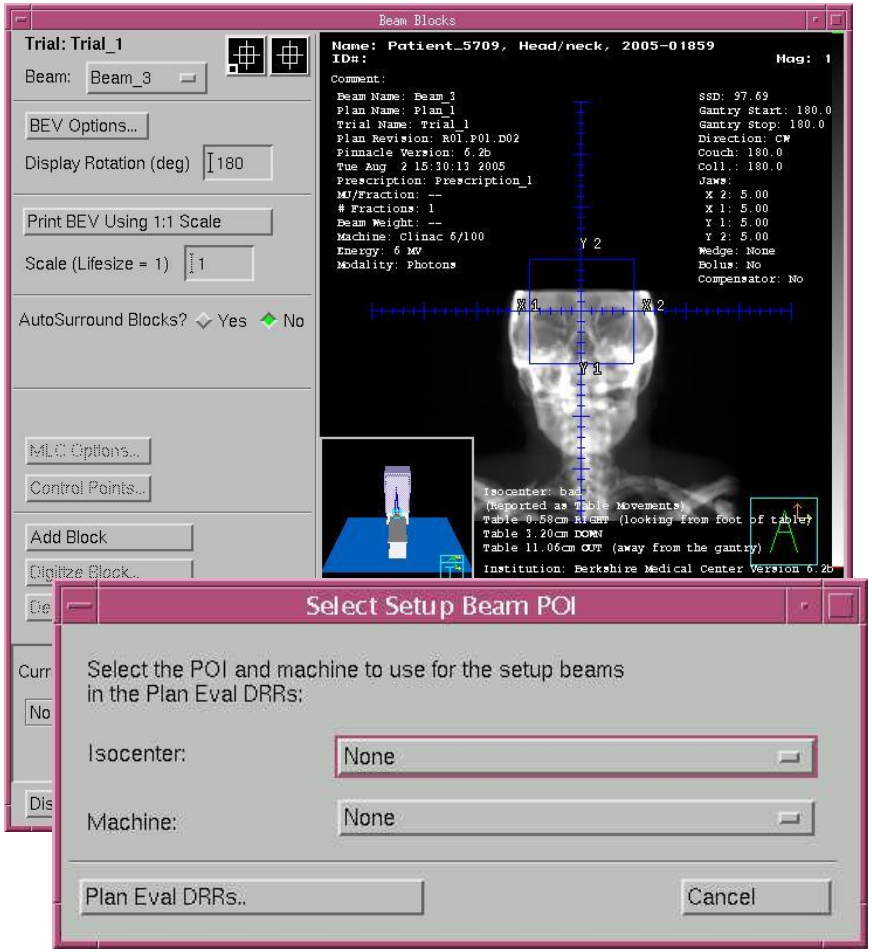
Risk Management File is a “living document”

Schewe: Safety Risk Management

PHILIPS

Example: Post-Production Feedback

Default Isocenter for Setup Beams



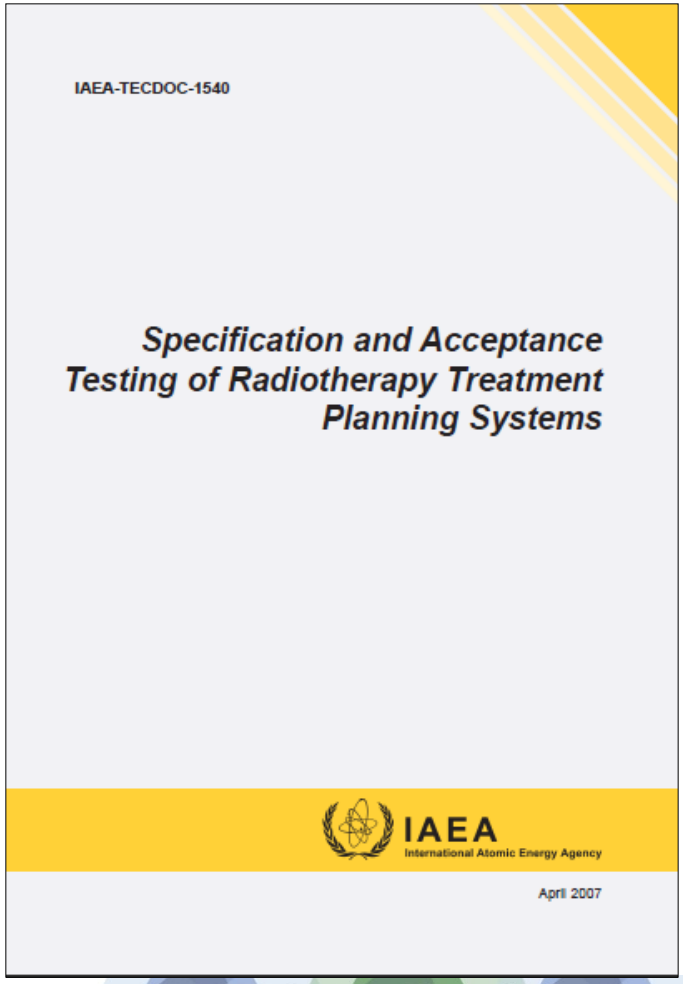
"There shall be no default isocenter assigned to the setup beams."

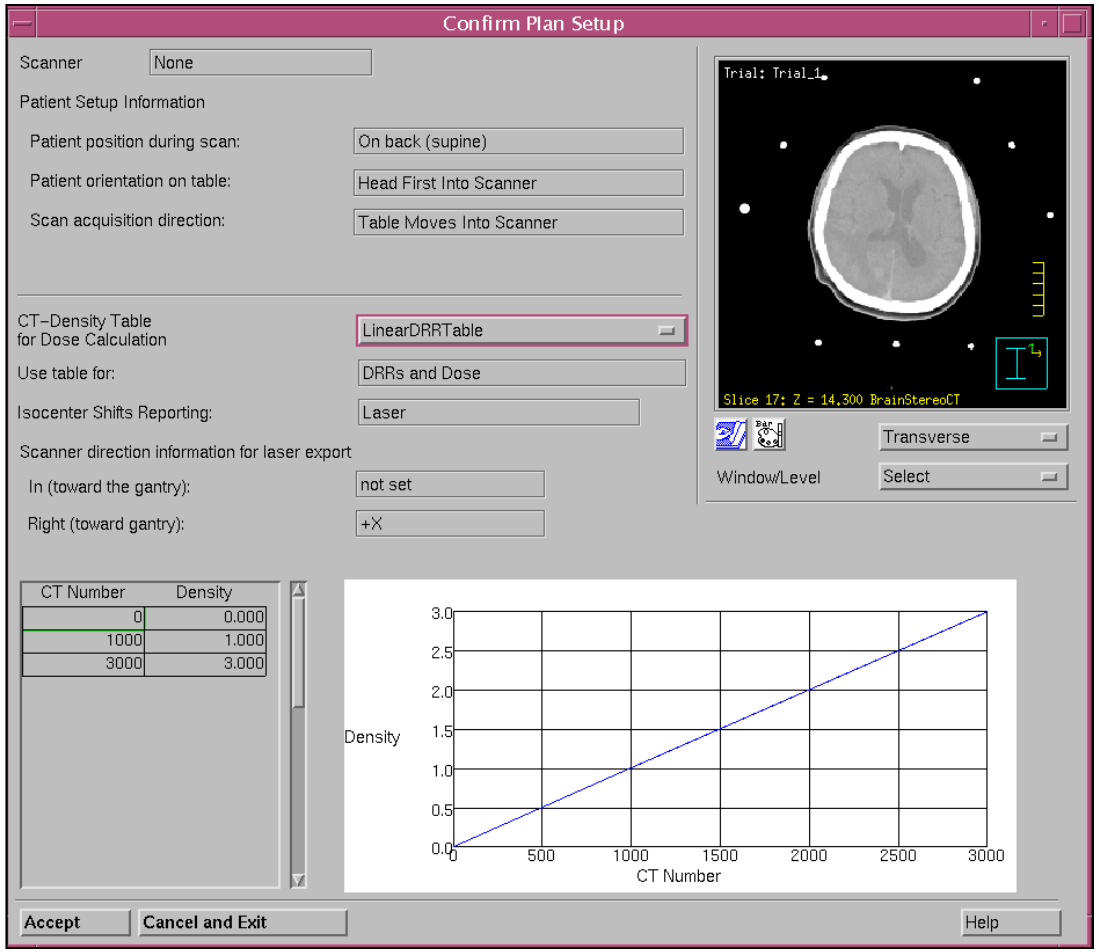
"There shall be no default machine assigned to the setup beams."

- 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

Special Article

The challenge of maximizing safety in radiation oncology

Lawrence B. Marks MD[a,*], Marianne Jackson MD, MPH[a], Liyi Xie MD[a,b], Sha X. Chang PhD[a], Katharin Deschesne Burkhardt MS, DABR[a], Lukasz Mazur PhD[c], Ellen L. Jones MD, PhD[a], Patricia Saponaro MS[a], Dana LaChapelle RTT[a], Dee C. Baynes RN, BSN[a], Robert D. Adams EdD, CMD[a]

[a]*Department of Radiation Oncology, University of North Carolina, Chapel Hill, North Carolina*
[b]*Department of Radiation Oncology, Fudan University Shanghai Cancer Center and Department of Oncology, Shanghai Medical College, Fudan University, Shanghai, China*
[c]*Industrial Extension Service, North Carolina State University, Raleigh, North Carolina*

Practical Radiation Oncology (2011) 1, 2–14

Change Is Impactful

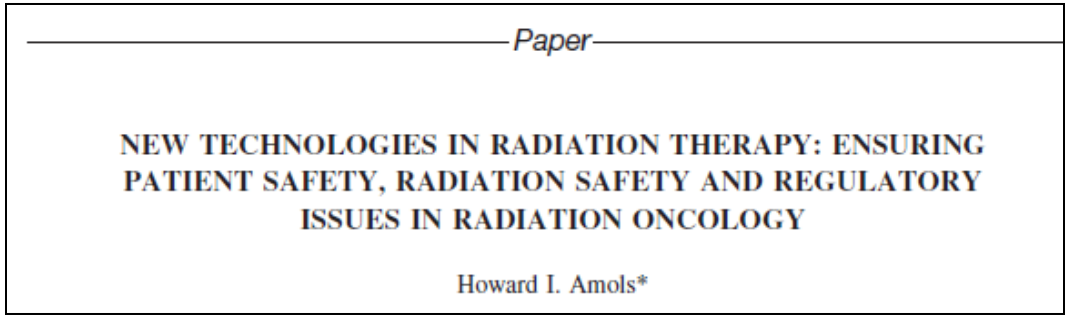
Even change for the better

Any change can alter "understood" risks

New technology→new risks

- May also change old ones

Communication is key



Paper

NEW TECHNOLOGIES IN RADIATION THERAPY: ENSURING PATIENT SAFETY, RADIATION SAFETY AND REGULATORY ISSUES IN RADIATION ONCOLOGY

Howard I. Amols*

Health Phys. 2008;95:658-665.

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/

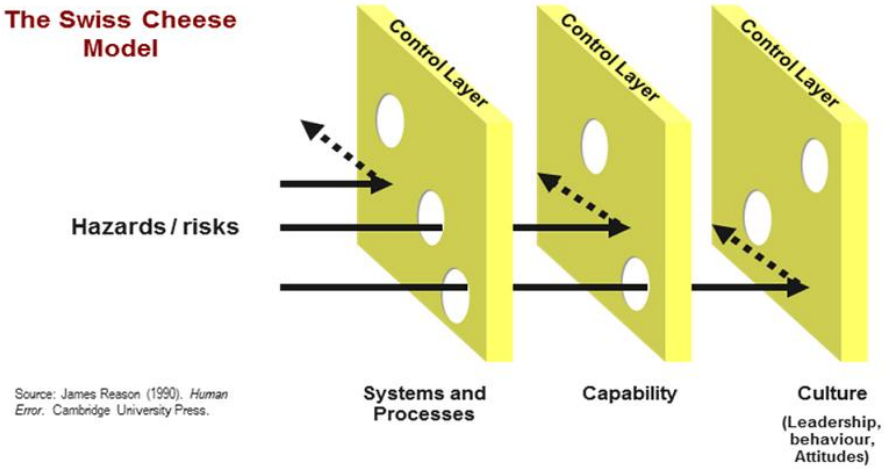
There are Always Trade-Offs

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



http://www.riskmanagementmagazine.com.au/opinion/risk-culture-all-talk-and-no-action-126516.aspx

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


PHILIPS