Assessing Risk in Radiotherapy

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Disclosures

- No current conflicts
- Member, TG-100
- Member, Radiation Oncology Health Advisory Council (ROHAC) for the Radiation Oncology Incident Learning System (RO-ILS) supported by ASTRO/AAPM/ClarityPSO
- Past research and/or travel funding: Varian, Elekta, Siemens, Sun Nuclear

Objectives

- Description of risk assessment methodologies used in healthcare and industry
- Discussion of radiation oncology-specific risk assessment strategies and issues
- Evaluation of risk in the context of medical imaging and image quality

Assessing Risk in Radiotherapy

- Introduction, Risk-based QM and TG-100
- Assessing Risk in Radiotherapy
- Issues for Risk Assessment and Evaluation
- Conclusions

Process-Oriented Risk-Aware Quality Methods

- Risk-aware quality methods have long been used in engineering, nuclear power plant safety, + air travel
- Goal is to improve quality and safety, while (hopefully) making our quality management efforts more efficient and effective
- This approach integrates evaluation of procedural problems with technical + device-related problems

→ TG-100

Process-Oriented Risk-Aware Quality Methods

After only 13 years . . .

Medical Physics
The International Journal of Medical Physics Research and Practice

The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

M. Saiful Huq[1,a)], Benedick A. Fraass[2], Peter B. Dunscombe[3], John P. Gibbons Jr.[4], Geoffrey S. Ibbott[5], Arno J. Mundt[6], Sasa Mutic[7], Jabinder R. Palta[8], Frank Rath[9], Bruce R. Thomadsen[10], Jeffrey F. Williamson[11] and Ellen D. Yorke[12]

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Med. Phys. 43, 4209 (2016); http://dx.doi.org/10.1118/1.4947547

Process-Oriented Risk-Aware Quality Methods

TG-100

1. Map the process to be studied
2. Analyze how the process can fail, what the effect of each failure will be, and the risk associated w/ those failures: [FMEA: Failure modes + effects analysis]
3. Once all the failure modes and effects are identified, map how the faults propagate: [FTA: Fault tree analysis]
4. Find efficient ways to minimize propagation of errors through the process: [QM, QA, QC]

Huq et al, TG-100, Med Phys 43: 4209 (2016)

There are lots of possible failure modes.

How do we decide what to work on first ?

Let's use Risk!

Assessing Risk in Radiotherapy

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Assessing Risk in Radiotherapy

- Introduction, Risk-based QM and TG-100
- ►Assessing Risk in Radiotherapy
  - Scoring risk: Risk Probability Number
  - What can we learn from publications?
  - Incident Learning System Data
    - RO-ILS
    - Local Incident Learning Systems
  - Experience

Typical Hospital Error Scoring System

Rank	Qualitative Description	Harm
1	Capacity for Error	No
2	Did not reach patient	No
3	Reached patient	No
4	Monitor patient	No
5	Intervention required	Temporary
6	Extended stay	Temporary
7	Permanent harm	Permanent
8	Intervention to sustain life	Harm
9	Death	Death

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Assessing Risk in Radiotherapy

- In the context of developing our QM analysis (as in TG-100), risk will be used to prioritize issues to mitigate.
- Severity of an error is clearly important
- However, risk is more than severity, it includes the likelihood that a given error will occur
- The errors which actually cause harm are those which do not get discovered before the harm is done, so our ability to identify errors is also important

Assessing Risk in Radiotherapy

Scoring risk: Risk Probability Number

RPN # = O x S x D:

- O: Frequency with which the fault occurs
- S: Severity
- D: Likelihood failure will NOT be detected

RPN = O x S x D: (O) Occurrence

Rank	Qualitative	Frequency (%)
1		0.01
2	Failure unlikely	0.02
3		0.05
4	Relatively few failures	0.1
5		< 0.2
6	Occasional failures	< 0.5
7		< 1
8	Repeated failures	< 2
9		< 5
10	Failures inevitable	> 5

Huq et al, TG-100, Med Phys 43: 4209 (2016)

RPN = O x S x D: Severity (S)

Rank	Qualitative	Categorization
1	No effect	
2	Inconvenience	Inconvenience
3		
4	Minor dosimetric error	Subopt. plan or Tx
5	Limited toxicity or tumor underdose	Wrong dose, dose distrib, location, or volume
6		
7	Potentially serious toxicity or tumor underdose	
8		
9	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distrib, location, or volume
10	Catastrophic	

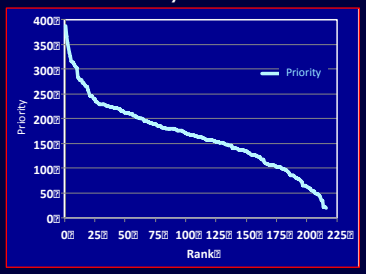
Huq et al, TG-100, Med Phys 43: 4209 (2016)

RPN = O x S x D:
Detectability (D)
(Estimated probability of error going undetected)

Rank	Prob. Undetected (%)
1	0.01
2	0.2
3	0.5
4	1.0
5	2.0
6	5.0
7	10
8	15
9	20
10	>20

Huq et al, TG-100, Med Phys 43: 4209 (2016)

TG-100 IMRT Analysis
RPN Priority Score vs Rank



TG-100, IMRT analysis

Assessing Risk in Radiotherapy

What can we learn from publications?

What do we know about treatment delivery errors?

Radiotherapy Errors

(detected with independent Record/Verify System)

Error Rate	Author
3 % / Session	Kartha, 1977
1% / Field	Podmaniczky 1985
0.18% / Field	Macklis, 1998 *

* Some errors caused by R/V

The modern computer-controlled Tx delivery process has changed things

- **Had opportunity to compare errors between manual and computer-controlled Tx (UM CCRS)**
- **All ExtBeam Txs 7/96 thru 9/97 were studied (>34k fractions)**
- **Tx delivery errors from QA logs, retrospective e-chart analysis, logged by therapists**

B Fraass et al: The Impact Of Tx Complexity + Computer-Control Delivery Technology On Tx Delivery Errors. IJROBP 42: 651-659, 1998

Overall Error Analysis

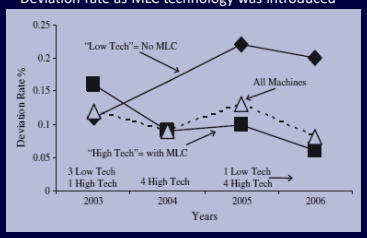
	Manual Tx		CCRS	
Errors	M1	M2	M3	M4
Machine (%/seg)	>0.12	>0.22	0.03	0.003
Setup/Script (%/session)	>0.05	>0.17	<0.28	<0.18

While computer control has removed many of the old random delivery errors, the new process is still susceptible to systematic errors which make it thru the planning/delivery process

B Fraass et al: The Impact Of Tx Complexity + Computer-Control Delivery Technology On Tx Delivery Errors. IJROBP 42: 651-659, 1998

Process and Expectations are Important

Deviation rate as MLC technology was introduced



LB Marks et al: The impact of advanced technologies on Tx deviations in radiation treatment delivery. IJROBP 69: 1579-1586, 2007

Technology, by itself, is not the problem

Type of Error	Rel. Risk (95% CL)
MLC	1.9 (1.3 - 2.9)
External Blk	4.4 (3.1 - 6.3)

- External Block required direct daily actions by RTT, while MLC was set by control system

G Huang, et al: Error in the delivery of radiation therapy: results of a QA review: IJROBP 61: 1590-1595, 2005

Technology, by itself, is not the problem

Type of Error	Rel. Risk (95% CL)
MLC	1.9 (1.3 - 2.9)
External Blk	4.4 (3.1 - 6.3)
External Wdg	1.3 (0.8 – 1.9)
Internal Wdg	2.6 (1.4- 4.5)

- External Block required direct daily actions by RTT, while MLC was set by control system
- External Wdg had direct visual check by RTT, while programmed internal Wdg did not.

G Huang, et al: Error in the delivery of radiation therapy: results of a QA review: IJROBP 61: 1590-1595, 2005

Errors Detected by Systematic In Vivo Dosimetry

7519 patients, in vivo dosimetry (5 years)

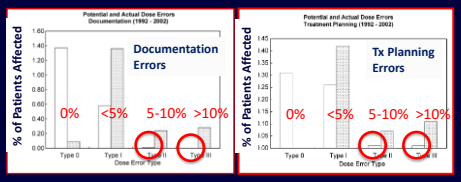
Tx Preparation		Tx Execution	
3	Prescription	7	Tx Setup
3	Planning	19	Delivery
46	Calculation	1	Technical Failure

78 / 79: involved human error

A Noel et al: Detection of errors in individual patients in radiotherapy by systematic in vivo dosimetry. Radioth + Oncol 34:144-151, 1995

How Big are the Errors ?

13,385 patients, 10 years



Actual Dose Error

Potential Dose Error

TK Yeung et al: Quality assurance in radiotherapy: evaluation of errors and incidents recorded over a 10 year period. Radioth + Oncol 74: 283-291, 2005

A big challenge:
The rate of dosimetrically-significant errors (>10%) is << 0.1 %

>>> We are looking for such errors in 1-2 patients per year in a normal clinic

Planning Errors Detected by Independent Check

6272 plans (5 years)

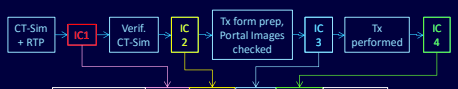
Errors found in independent check	
217 (3.5%)	Any error
70 (1.1%)	Error >5% of daily dose
37 (0.6%)	Error >10 % daily dose

3/650 patients (0.45%):
In vivo detected error after the check: two >10%

R Calandrino et al: Detection of systematic errors in external radiotherapy before treatment delivery. Radiotherapy + Oncology 45:271-274, 1997

How well do independent checks work?

(622 patients)



Dose Error	IC1	IC2	IC3	IC4	Total
< 1%	0	1	1	1	5
1-5%	12	1	1	0	14
5-10%	4	2	1	0	7
>10%	15	2	4	0	21

AG Morganti,et al: Complexity index (COMIX) and not type of treatment predicts undetected errors in radiotherapy planning and delivery. Radioth + Oncol 74: 283-291, 2005

Assessing Risk in Radiotherapy

Radiation Oncology Incident Learning System (RO-ILS)

- Sponsored by ASTRO and AAPM
- Managed by Clarity PSO
- Go-live: June 2014
- Participating: 104 institutions with 212 facilities
- Events reported to date: 1941
- Methods and Data analyzed by Radiation Oncology Health Advisory Board (RO-HAC)

Patient Safety Organizations (PSOs)

Made possible by Patient Safety + Quality Improvement Act (2005)

PSOs created to address needs identified in 1999 Institute of Medicine Report "To Err is Human":

- Share the goal of improving the quality and safety of health care delivery
- Collect and analyze data to identify and reduce the risks and hazards associated with patient care.
- Create a secure, non-punitive environment through confidentiality and privilege protections.

RO-ILS Quarterly Reports

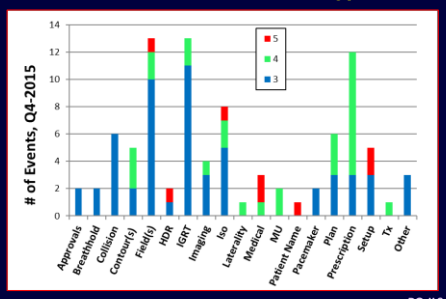
- **Aggregate summary of types of events, techniques, severity**
- **RO-HAC scores events with 5 point scale (5 is most important/severe/worrying)**
- **RO-HAC develops detailed descriptions and commentary for interesting or representative event reports**
- **Additional analysis of specific issues**

RO-HAC Scoring of Events

Severity Index	Severity Description	Criteria
1	No potential or real harm	Event does not pose downstream risk in workfl w. Event is not related to patient safety or quality of treatment.
2	Mild potential or real harm	Event may enhance the risk of other downstream errors. Event may cause emotional distress or inconvenience to patient with no clinical impact.
3	Moderate potential or real harm	Event enhances the risk of other critical downstream errors. Temporary pain or discomfort for patient. Deviations from best practices, but with no obvious clinical impact.
4	Severe potential or real harm	Limited barriers to prevention of problem. Event with potential clinical impact that is non-critical.
5	Critical potential or real harm	Extremely limited barriers to prevention of problem. Event with potentially critical clinical impact.

RO-ILS 2015 Q4 Report

Characterization of Event Types



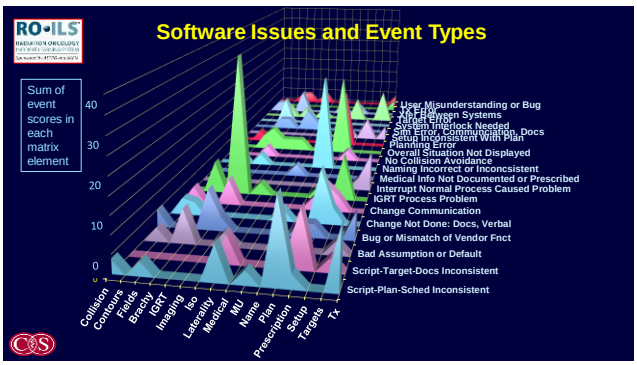
RO-ILS 2015 Q4 Report

Software-Related Issues

To evaluate what kinds of software issues were potentially involved in the various events in the RO-ILS database:

- Studied 167 events with highest scores (4, 5)
- For each event, assign category, then guesstimate one or two software issues which appear to be involved
- Result is a matrix of categories vs issues, with # of events and their score

Software Issues and Event Types

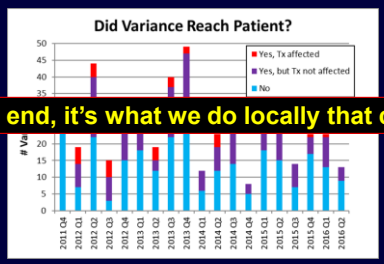


There is much more useful information about the weaknesses in our processes and our software systems, as long as

- We get detailed reports about what actually went on for each event, and
- We are clever enough to aggregate the specific problems into reasonably well-defined areas that need attention within the software designs and implementations.

Assessing Risk in Radiotherapy

Incident Learning System Data: Local Systems



In the end, it's what we do locally that counts

Setup+Prescription Errors (%/session)

	Manual Tx		CCRS	
Setup + Script Errors	M1	M2	M3	M4
Patient setup	.03	.07	.21	.12
Patient/Plan choice	0	0	.04	.03
Prescription/Chart	.01	.10	.04	.03
Total/session (%)	.05	.17	.28	.18

1 specific process problem: 90% of these errors

Fraass IJROBP 42 (1998)

Setup+Prescription Errors (%/session)

	Manual Tx		CCRS	
Setup + Script Errors	M1	M2	M3	M4
Patient setup	.03	.07	.02	.01
Patient/Plan choice	0	0	.04	.03
Prescription/Chart	.01	.10	.04	.03
Total/session (%)	.05	.17	.10	.07

1 specific process problem: 90% of these errors

Fixing this one process problem changes these results significantly

Fraass IJROBP 42 (1998)

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Issues for Risk Assessment and Evaluation

Analyzing risk:
some results from the TG-100 Example FMEA of IMRT

Rank	RPN #	FMEA #	Sub-Process	Step
#1	388	31	4. Other Pre-Tx Imaging for CTV Localization	6. Image interpretation
	FM: Incorrect interpretation of tumor or normal tissue.			

Rank	RPN #	FMEA #	Sub-process	Step
#216	18	10	3. CT-sim	Image set saved or sent to Tx Planning
	FM: Simulation data accidentally deleted			

How Should We Prioritize Issues to Fix?

TG-100: Priorities for Mitigation

There are many valid ways to prioritize problems:

1. RPN (Risk Priority #) = O x S x D
2. Severity
3. Other

- TG-100 used RPN and then added in high severity issues (even if their RPN's were low).
- One of the most difficult prioritization issues: those FMs which are catastrophic but highly unlikely (high S, low O and D)

How Should We Prioritize Issues to Fix?

Catastrophic Errors and 'Risk'

What do we do with catastrophic or "Never" events?

For true "never" events: Is it enough to just rank this "risk" very high, even though the occurrence or frequency is expected to be extremely small?

Or should we:

- Do rigorous hazard analysis
- Change the process to avoid potential triggers
- Develop/implement rigid QC process immediately before potential triggers

Let's discuss a few high priority example failure modes, and understand what led those problems to be scored as "high risk"

Rank	TG-100
#1	FM: Pre-Tx imaging: Incorrect interpretation of tumor or normal tissue.

Rank	TG-100
#2	FM: GTV/CTV: Large segmentation errors: wrong organ, wrong site, wrong expansions

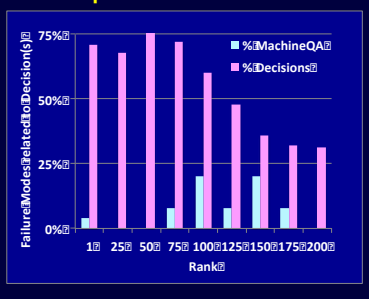
Rank	TG-100
#4	FM: Tx Planning Directive: Wrong or missed summary of previous radiation treatment

Rank	TG-100
#5	FM: GTV/CTV: Excessive delineation errors in target contouring

The common threads for many of these (and other) high priority failure modes are:

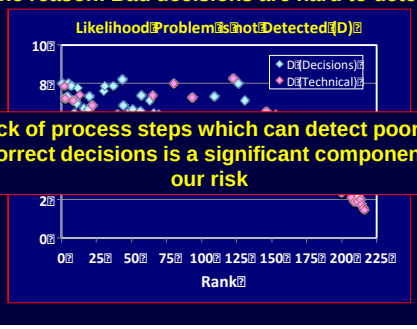
- Problems that lead to systematic error in Tx for the whole treatment course
- Many of the issues are geometric, not dosimetric
- Decisions that are qualitative and/or dependent on complex clinical judgment (i.e., not technical)
- Failure early in the planning process is unlikely to be detected by anyone later
- Technical QA checks are unlikely to identify many of these problems

Qualitative issues are a majority of the top 100 failure modes!



TG-100
IMRT analysis

One reason: Bad decisions are hard to detect



Lack of process steps which can detect poor or incorrect decisions is a significant component of our risk

Issues for Risk Assessment and Evaluation

Balancing Risks

- Our risk environment is different from typical industrial applications of FMEA: they have normal people as their "target".
- In the RadOnc environment, we must balance risks – the risk of problems during treatment compared to the clear risk of major problems if treatment does not happen. This is a very different tradeoff situation.
- It is important to proceed with care as we implement risk-based QM so we accommodate the (different) risk environment that we operate in.

Issues for Risk Assessment and Evaluation

Risks We Can Affect

Rank	RPN	Step#	Process	Step
#2	366	58	7. RTP Anatomy	Delineate GTV/CTV (MD) and other structures
	FM: > 3σ contouring error, wrong organ, site, or expansions			

- This FM is very large target contouring errors (>3x the expected inter-operator delineation error)
- However, definition (as opposed to delineation) is one of the weakest links in our whole process, something that needs to be addressed with new science. We cannot truly resolve this fundamental problem until we know the right answer !

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Conclusions

- TG-100 introduces medical physics to a risk-based paradigm for design of QM programs
- Here, we discuss "risk" as a metric used to prioritize issues to mitigate
- Risk is a combination of many factors, including (at least) severity, frequency, and our ability to detect a given error when it occurs
- Risk is not absolute: risk associated with treatment for cancer has to be traded off against the (usually very bad) outcome when there is no treatment.

Tx Delivery Error Analysis

Machine Errors (%/Segment)
(34K Tx sessions, 114K segments)

Machine Errors	Manual Tx M1	Manual Tx M2	CCRS M3	CCRS M4
Machine Setup	.03	.13	.02	.003
Accessories	.09	.09	.02	.003
Total/Segment (%)	.12	.22	.03	.006

Expect that these errors are under-reported, probably are 1-2 %

Fraass IJROBP 42 (1998)

Setup+Prescription Errors (%/session)

Almost no way to find errors except weekly portal images.

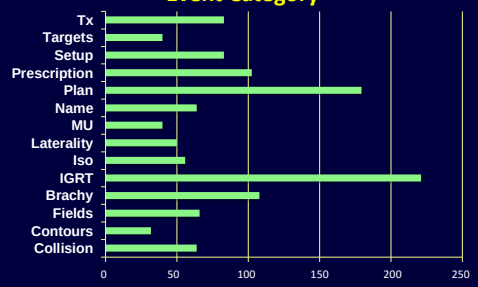
Setup + Script Errors	Manual Tx M1	Manual Tx M2	CCRS M3	CCRS M4
Patient setup	.03	.07	.21	.12
Patient/Plan choice	0	0	.04	.03
Prescription/Chart	.01	.10	.04	.03
Total/session (%)	.05	.17	.28	.18

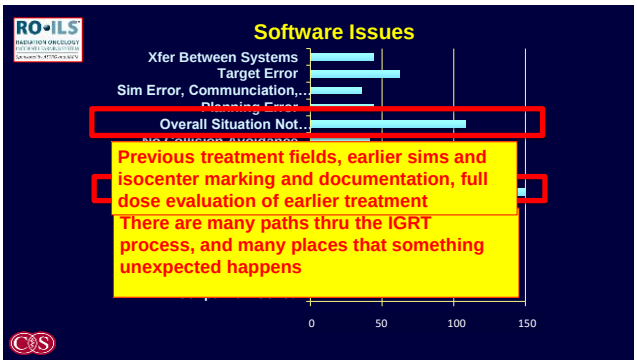
No way to identify these manual errors

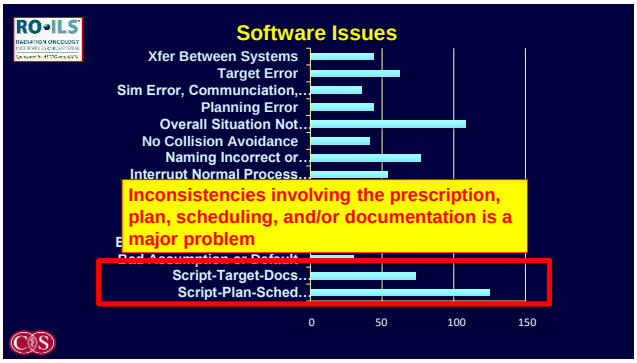
- Includes any table coord issue (1 mm)
- 1 specific process problem: 90% of these errors

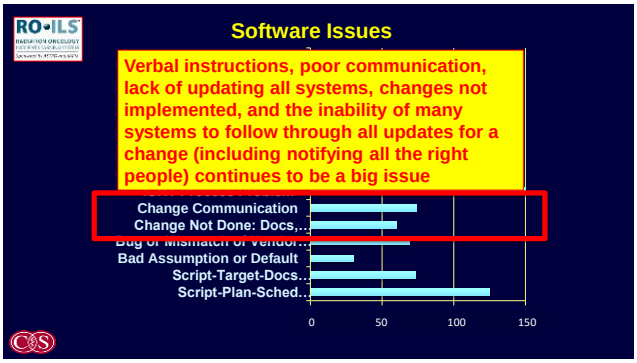
Fraass IJROBP 42 (1998)

Event Category




Software Issues
Xfer Between Systems
Target Error
Sim Error, Communciation,..
Overall Situation Not..
0
50
100
150
Previous treatment fields, earlier sims and isocenter marking and documentation, full dose evaluation of earlier treatment
There are many paths thru the IGRT process, and many places that something unexpected happens


Software Issues
Xfer Between Systems
Target Error
Sim Error, Communciation,..
Planning Error
Overall Situation Not..
No Collision Avoidance
Naming Incorrect or..
Interrupt Normal Process..
Script-Target-Docs..
Script-Plan-Sched..
0
50
100
150
Inconsistencies involving the prescription, plan, scheduling, and/or documentation is a major problem


Software Issues
Change Communication
Change Not Done: Docs,..
Bad Assumption or Default
Script-Target-Docs..
Script-Plan-Sched..
0
50
100
150
Verbal instructions, poor communication, lack of updating all systems, changes not implemented, and the inability of many systems to follow through all updates for a change (including notifying all the right people) continues to be a big issue

TG -100 Section 9:

Using Risk Analysis to Design Radiation Therapy QM Programs: IMRT as a Case Study

- Detailed description of 216 failure modes (FMs), their potential causes and effects, and examples
- Ranking of FMs
- Example parts of a QM program derived (in part) from the analysis
- Discussion and analysis of the RPN estimations performed by the task group
- Discussion of trade-offs involved in the different methods of prioritization of mitigation efforts
- Broad analysis of many issues highlighted by the example FMEA, FTA, + QM program development