

Electronic Intracavitary Brachytherapy Quality Management Based on Risk Analysis: The Report of AAPM TG 182

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Disclosure

I am the President of the Center for the Assessment of Radiological Sciences, a 501c3 non-profit Patient Safety Organization listed with the Agency for Healthcare Research and Quality. The Center is dedicated to improving patient safety in radiotherapy and radiology.



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Charges for TG 182

1. Review the manufacturers'-suggested quality-assurance (QA) procedures.
2. Develop a rational, risk-based set of quality management (QM) procedures...
3. Suggest designs for needed tools that do not yet exist. There did not seem to be a lack.
4. Suggest quality improvement procedures. These were to apply risk-based quality management.

The list of members of the task group is shown in the next presentation.



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Learning Objectives for this Session

1. To understand the basics of electronic brachytherapy,
2. To understand the approach TG 182 took to model the development of QM for these units,
3. To learn what the report of TG 182 presents, and what it does not.



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NOTA BENE

1. To understand how to do the design of QM from risk analysis, please read the report from TG 100 and attend a training.
2. TG 182 only considered electronic brachytherapy units that could perform intracavitary brachytherapy.
(Orthovoltage units were not addressed)



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Presentations for this Session

1. The first presenter (Bruce Thomadsen) will provide the overview of the work TG 182 presents in the context of the use of risk analysis in developing a quality management (QM) program.
2. The second presenter (Mark Rivard) will discuss the Xofig electronic brachytherapy system and its risk-analysis-derived QM.
3. The third presenter (Susha Pillai) will discuss the INTRABEAM system and its risk-analysis-derived QM.



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As Noted by TG 100

- How things can go wrong (potential failure modes) depends in interconnected ways on the procedure, the equipment, the personnel and the environment.
- Thus, quality and safety procedures can only be designed for a particular setting via risk analysis.
- **No prescriptive list can apply to all practices or provide comprehensive safety.**
- TG 182 presents a sample of how to perform the design.



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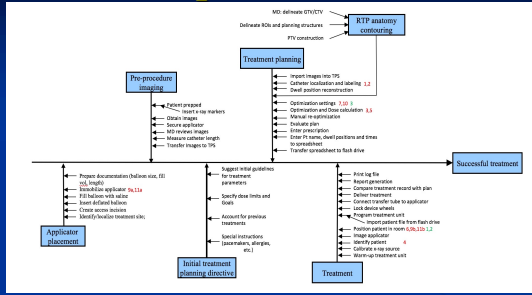
Risk-Analysis-Based QM Development

1. Assemble a team of all the player groups
2. Understand the process – Process Map
3. Assess the hazards - FMEA
4. Establish the failure propagation - Fault Tree
5. Address the hazards
6. Test and evaluate



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Process Map for APBI with Xovert



Often just having all groups agree on the process eliminates issues and friction in a department.

Failure Modes and Effects Analysis - FMEA

Helps develop a list of potential failure modes and give some idea about relative risk

Process Step	Potential Failure Mode	Potential Cause(s) of Failure	Severity (S)	Occurrence (O)	Detectability (D)	Risk Priority Number (SxOxD)
Look up setup parameters: SSD, FS, depth, energy, etc.						

FMEA: The Whole Thing

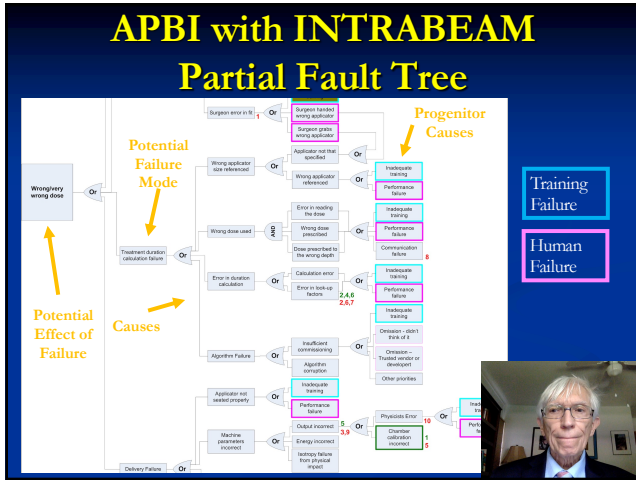
Major steps all in one color (helps keep track of the steps if you sort)

Do not try to read

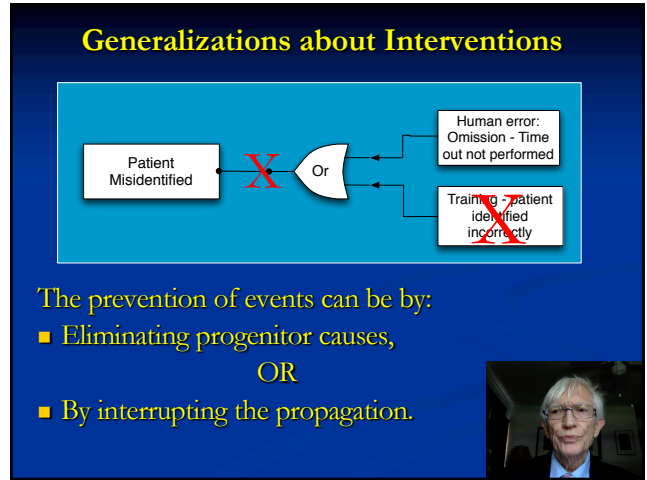
FMEA Close-up

No.	Step	Function	Subsystem/process	Potential Failure Mode	Potential Failure Mode-Details
18	Treatment planning	Find a set of treatment parameters that satisfy the patient's needs	2. Import images into TPS	3. Localization images deleted	assuming such an error possible in system
19	Treatment planning	Find a set of treatment parameters that satisfy the patient's needs	4. Catheter entry	1. Catheter entered backwards end-to-tip	possible inadequate balloon to skin distance
20	Treatment planning	Find a set of treatment parameters that satisfy the patient's needs	4. Catheter entry	2. 1st dwell position misidentified	possible inadequate balloon to skin distance
21	Treatment planning	Find a set of treatment parameters that satisfy the patient's needs	5. Optimization and dose calculation	1. Optimization points placed incorrectly	defectably depends on process
22	Treatment planning	Find a set of treatment parameters that satisfy the patient's needs	5. Optimization and dose calculation	1. Optimization points placed incorrectly	defectably depends on process

No.	Potential causes	Potential Effects of failure	Avg O	Avg S	Avg D	Avg RPN
18	Dosimetrist or physicist error	Delay	2.0	1.7	1.3	4.7
19	Dosimetrist or physicist error	Wrong dose distribution, wrong treatment site	3.5	5.3	6.0	113.5
20	Dosimetrist or physicist error	Wrong dose distribution, wrong treatment site				
21	1. Dosimetrist or physicist error	Wrong dose distribution				
22	2. Miscommunication	Wrong dose distribution (not as intended)				



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Prerequisites for a Safe Program

Then consider the *key core components* identified by AAPM TG 100:

- Adequate staff, physical and IT resources
- Maintenance of hardware and software resources
- Clear lines of communication among staff
- Standardized procedures
- Adequate training of staff

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Possible Interventions 1: Redesign

- The best way to avoid potential errors at some step is to redesign the procedure to eliminate the progenitor cause, so that error is not possible (i.e., what leads to it no longer exists).

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Possible Interventions 1: Redesign

- The best way to avoid potential errors at some step is to redesign the procedure so that error is not possible.
- Re-evaluate after a redesign because new possible errors may have been produced.



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Possible Interventions 2

1. First correct any environmental problems.
 2. Fix technical problems.
- Usually is a relatively inexpensive but effective.
 - Administrators understand these problems and are likely to pay to fix them.



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After Checking Key Core Components and considering Redesign...

For the remaining propagation pathways, consider:

- Commissioning (not just equipment but procedures),
- Quality management, which includes
 - QA as checks on outputs.
 - QC on inputs, and



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After Checking Key Core Components and considering Redesign...

All fault tree branches eventually need to be covered somewhere in the propagation before the far left box!



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Summary 2

- TG 100 recommended a methodology for designing QM based on risk analysis, and this methodology was used by TG 182, which included four steps:
 - Process mapping,
 - Failure Modes and Effects Analysis (FMEA),
 - Fault-tree analysis,
 - Designing QM based on the guidance provided in the TG-100 report.



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Summary 3

- Task Group 182 provides two examples explaining how to design QM, one for each of the two electronic brachytherapy units common in the United States, and an additional example showing how to modify QM for a new process.



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