AAPM TASK GROUP 100 IN OUR CLINICS: APPLYING RISK ANALYSIS TECHNIQUES TO ROUTINE QA

KOREN SMITH

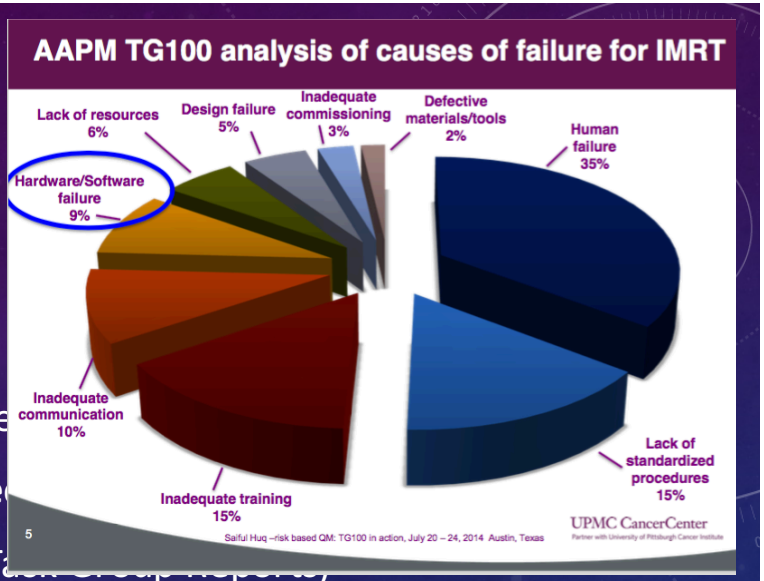
MARY BIRD PERKINS CANCER CENTER, BATON ROUGE, LA

MARCH 6 2016

OUTLINE

- Introduction to TG100/FMEA
- Applications of FMEA Risk Analysis to Routine QA
  - FMEA of External Beam Process in a Community Hospital Setting
  - Risk Analysis of Linear Accelerator QA
    - AAPM TG265/MPPG 8.a.
    - FMEA of TG142 – Jennifer O'Daniel's Work at Duke University
- Summary of Considerations for Applications of FMEA for Routine QA

INTRODUCTION TO TG100/FMEA



- TG100 is a new approach to quality assurance/quality manageme
- Quality management should include both a **Reactive and Prospe**
- **Reactive** → Example: Prescriptive Quality Assurance Protocols (Ta
  - Task Group Reports are often published years after technologies have been implemented in the clinic
  - We devote a substantial amount of time to traditional physics QA based on these protocols. Errors often occur through miscommunication and/or misunderstanding of the use of devices
- TG100/FMEA is **Prospective** in nature
  - Relies on predictions of experienced experts of events that could occur

To Be Published: "The Report of Task Group 100 of the AAPM: Application of Risk Analysis Methods To Radiation Therapy Quality Management" Huq et al.

INTRODUCTION TO TG100/FMEA

- TG100 Risk Analysis Methodology
  - Process Map – Illustration of different steps of a process that demonstrates the flow and interrelationship of these steps from start to end
  - FMEA
    - Identification of potential failure modes (and causes for those failure modes) for each process step
    - Determination of the impact of each failure mode on the outcome of the process
      - Score Occurrence, Severity, and Detectability to determine RPN = O*S*D
    - Assume that there was no QA/QC step in place
  - Fault Tree – developed from the FMEA to visually display failures and their causes and to prompt work on determining QA steps to detect failures. A group may choose to focus on failure modes with high RPN or Severity Scores.

To Be Published: "The Report of Task Group 100 of the AAPM: Application of Risk Analysis Methods To Radiation Therapy Quality Management" Huq et al.

INTRODUCTION TO TG100/FMEA

- Limitations of TG100 risk based analysis
  - Lack of measured data on occurrence and detection probabilities
  - Forced to rely on expert consensus for scoring

To Be Published: "The Report of Task Group 100 of the AAPM: Application of Risk Analysis Methods To Radiation Therapy Quality Management" Huq et al.

OUTLINE

- Introduction to TG100/FMEA
- **Applications of FMEA Risk Analysis to Routine QA**
  - **FMEA of External Beam Process in a Community Hospital Setting**
  - Risk Analysis of Linear Accelerator QA
    - FMEA of TG142 – AAPM TG265/MPPG 8.a.
    - FMEA of TG142 – Jennifer O'Daniel's Work at Duke University
- Summary of Considerations for Practical Applications of FMEA for Routine QA

FMEA OF EXTERNAL BEAM PROCESS

A streamlined failure mode and effects analysis

Eric C. Ford,[a] Koren Smith, Stephanie Terezakis, Victoria Croog, Smitha Gollamudi, Irene Gage, Jordie Keck, Theodore DeWeese, and Greg Sibley
Department of Radiation Oncology and Molecular Radiation Sciences, Johns Hopkins University, Baltimore, MD 21287

- FMEA exercise conducted over a one-month period
- Sibley Memorial Hospital in DC treats approximately 60 patients per day
- Followed a structured plan
- Identified a "Facilitator" and Core Group of individuals to guide the process

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

FMEA OF EXTERNAL BEAM PROCESS

- Structured Plan
  - Prior to 1st Meeting, educational materials were distributed describing the basic aspects of FMEA. The scope of the FMEA exercise was determined. Determined how each meeting would be structured and what, if any, work could be done as "take home assignments".
  - 1st Meeting – Generate process map. Review three example failure modes
  - 2nd Meeting – List failure modes using the process map as a guide of the patient experience
  - 3rd Meeting – Score all failure modes for risk priority number. Rank failure modes
  - 4th Meeting – Identify safety improvement interventions for top-ranked failures modes

TABLE I. Structured process for streamlined FMEA. A clear goal was identified for each session, each of which was typically a 1-h meeting.

Session	Goal	Staff present	Take-home tasks
Pre	Determine scope of FMEA. Identify core leadership group, and facilitator(s). Distribute premeeting educational materials.	N/A	N/A
1	Generate process map. Review three example failure modes.	Core group	Write down known failure modes.
2	List failure modes. No scoring.	All	Collect further failure modes.
3	Score all failure modes for risk priority number. Rank failure modes.	Core group	Distribute list of ranked failure modes.
4	Identify safety improvement interventions for top-ranked failure modes.	All	N/A

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2(

FMEA OF EXTERNAL BEAM PROCESS

- 1st Meeting (Core Group) – Process Map
- Used a list of typical workflow steps as a guide. Started with sticky notes of different colors for each major step.

Consensus recommendations for incident learning database structures in radiation oncology

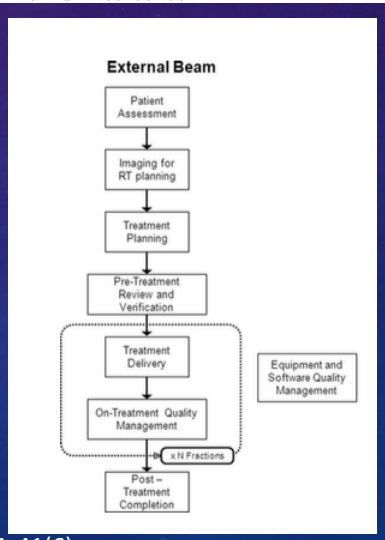
E. C. Ford[a)]
Department of Radiation Oncology, University of Washington Medical Center, Box 356043, 1959 Northeast Pacific Street, Seattle, Washington 98195

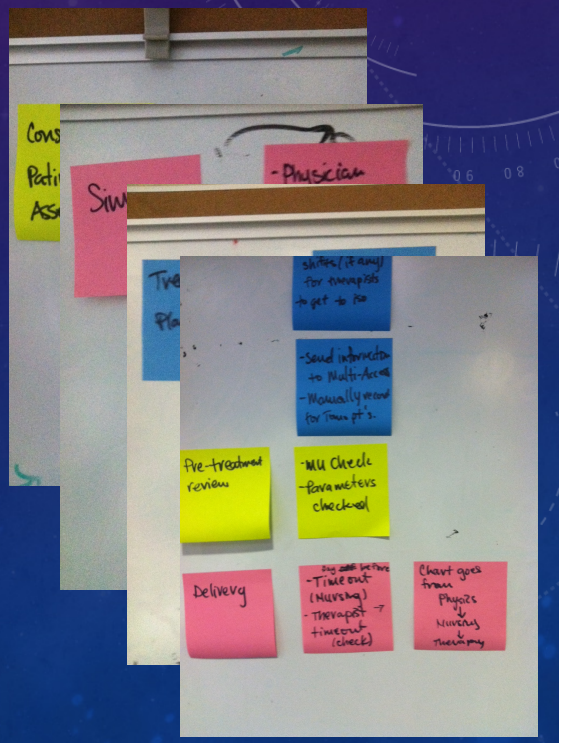
L. Fong de Los Santos
Department of Radiation Oncology, Mayo Clinic, Rochester, Minnesota 55905

T. Pawlicki
Department of Radiation Medicine and Applied Sciences, University of California, San Diego, La Jolla, California 92093

S. Sutlief
VA Puget Sound Health Care System, 1660 South Columbian Way, Seattle, Washington, 98108

P. Dunscombe
Department of Oncology, University of Calgary, Calgary, Alberta T2N 1N4, Canada



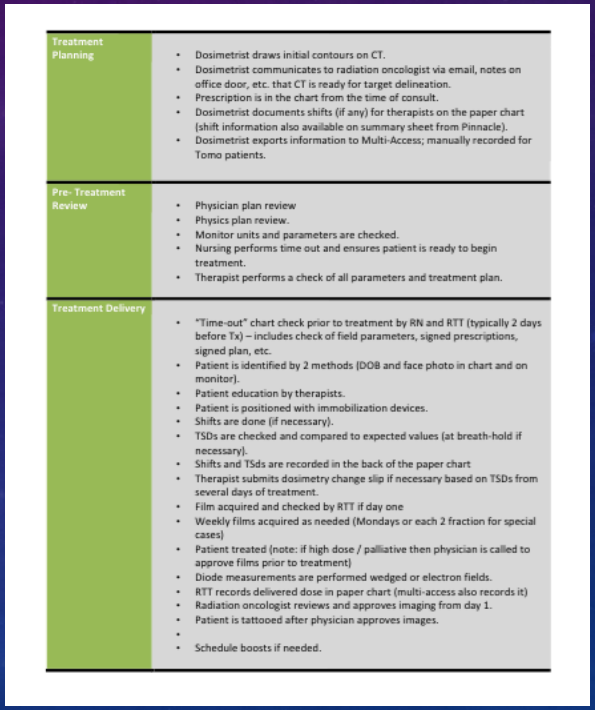


2016 Spring Clinical Meeting - Salt Lake City, Utah

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

FMEA OF EXTERNAL BEAM PROCESS

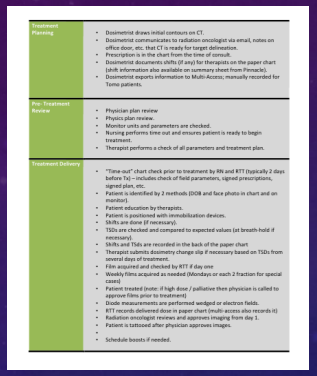
- 1st Meeting (Core Group) – Process Map
- Facilitator later translated sticky notes into a formal process map. Kept the illustration of the process map simple in order to save time.



Treatment Planning	• Dosimetrist draws initial contours on CT. • Dosimetrist communicates to radiation oncologist via email, notes on office door, etc. that CT is ready for target delineation. • Prescription is in the chart from the time of consult. • Dosimetrist documents shifts (if any) for therapists on the paper chart (shift information also available on summary sheet from Pinnacle). • Dosimetrist exports information to Multi-Access; manually recorded for Tomo patients.
Pre- Treatment Review	• Physician plan review • Physics plan review. • Monitor units and parameters are checked. • Nursing performs time out and ensures patient is ready to begin treatment. • Therapist performs a check of all parameters and treatment plan.
Treatment Delivery	• "Time-out" chart check prior to treatment by RN and RTT (typically 2 days before Tx) – includes check of field parameters, signed prescriptions, signed plan, etc. • Patient is identified by 2 methods (DOB and face photo in chart and on monitor). • Patient education by therapists. • Patient is positioned with immobilization devices. • Shifts are done (if necessary). • TSDs are checked and compared to expected values (at breath-hold if necessary). • Shifts and TSds are recorded in the back of the paper chart • Therapist submits dosimetry change slip if necessary based on TSDs from several days of treatment. • Film acquired and checked by RTT if day one • Weekly films acquired as needed (Mondays or each 2 fraction for special cases) • Patient treated (note: if high dose / palliative then physician is called to approve films prior to treatment) • Diode measurements are performed wedged or electron fields. • RTT records delivered dose in paper chart (multi-access also records it) • Radiation oncologist reviews and approves imaging from day 1. • Patient is tattooed after physician approves images. • • Schedule boosts if needed.

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

FMEA OF EXTERNAL BEAM PROCESS



- 2nd Meeting (All clinical staff) – Failure Modes
- Brainstormed about potential failure modes.
- Used the process map as a guide to get people thinking about potential failure modes at each step. 52 failure modes for 62 steps in the process were identified.
- Take home assignment – each clinical staff member come up with other potential failure modes. This was helpful as not all staff members feel comfortable speaking up in a group setting. 52 failure modes were collected: 22 at meeting and 30 from take home assignment.

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

FMEA OF EXTERNAL BEAM PROCESS

- 3rd Meeting (Core Group) – Scoring Failure Modes
- Facilitator created an Microsoft Access database to list each identified:
  - → Failure Mode
  - → Cause
  - → Step in Process Map where failure occurs
- This database was used as a presentation to the core group. It also included drop down lists to define O, S, D.

TABLE II. Scoring scales for occurrence, detectability, and severity used in this exercise.

Score	Severity	Occurrence		Detectability
0	No harm			
1	Temporary side effects—intervention not indicated	1 in 20 years	1/10 000	0.01%
2	Temporary side effects—intervention indicated	1 in 10 years	2/10 000	0.2%
3	Temporary side effects—major treatment or hospitalization	1 in 4 years	5/10 000	0.5%
4	Temporary side effects—major treatment or hospitalization	1 in 2 years	1/1.000	1%
5	Permanent minor disability or grade 1/2 permanent toxicity	1 per year	<0.2%	2%
6	Permanent minor disability or grade 1/2 permanent toxicity	3 per year	<0.5%	5%
7	Permanent minor disability or grade 3/4 permanent toxicity	5 per year	<1%	10%
8	Life threatening—intervention essential	10 per year	<2%	15%
9	Life threatening—intervention essential	1 per 2 weeks	<5%	20%
10	Premature death	>1 per 2 weeks	>5%	>20%

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

FMEA OF EXTERNAL BEAM PROCESS

- 3rd Meeting (Core Group) – Scoring Failure Modes
- Failure modes were scored in a group setting. 43 of 52 failure modes were scored. The remaining 9 were left unscored as their RPN score would have clearly been low.
- Once the scoring was complete, the failure modes were ranked by RPN score and this list was distributed to the group.

TABLE II. Scoring scales for occurrence, detectability, and severity used in this exercise.

Score	Severity	Occurrence		Detectability
0	No harm			
1	Temporary side effects—intervention not indicated	1 in 20 years	1/10 000	0.01%
2	Temporary side effects—intervention indicated	1 in 10 years	2/10 000	0.2%
3	Temporary side effects—major treatment or hospitalization	1 in 4 years	5/10 000	0.5%
4	Temporary side effects—major treatment or hospitalization	1 in 2 years	1/1.000	1%
5	Permanent minor disability or grade 1/2 permanent toxicity	1 per year	<0.2%	2%
6	Permanent minor disability or grade 1/2 permanent toxicity	3 per year	<0.5%	5%
7	Permanent minor disability or grade 3/4 permanent toxicity	5 per year	<1%	10%
8	Life threatening—intervention essential	10 per year	<2%	15%
9	Life threatening—intervention essential	1 per 2 weeks	<5%	20%
10	Premature death	>1 per 2 weeks	>5%	>20%

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

FMEA OF EXTERNAL BEAM PROCESS

TABLE III. Top ten ranked failure modes with associated scores for FMEA severity, *S*, occurrence, *O*, detectability, *D*, and Risk Priority Number, *RPN*, calculated according to the formula $RPN = S \times O \times D$.

Failure mode	Cause	Process step	S	O	D	RPN
Delay in film check.	Films not assigned to physician in queue.	Tx delivery	8	10	5	400
No pacemaker protocol/consent for patient with a pacemaker.	Simulation staff did not check H&P or query patient.	Simulation	10	5	5	250
Critical structure not contoured in treatment planning system.	Oversight of physician.	Tx planning	10	4	6	240
Pregnant patient simulated without the team's knowledge of the pregnancy.	Patient does not know she is pregnant and/or was not asked. Unclear policy.	Simulation	10	2	10	200

- 4th Meeting (All Clinical Staff)
- Failure Modes with an RPN score of 150 or greater were discussed and considered for safety improvement interventions.
- Safety interventions were considered for 4 highest-ranked failure modes. Two of these were collected as a group and two from take assignment.
- Discussion focused on redesign of processes to prevent errors over human inspection to detect them.

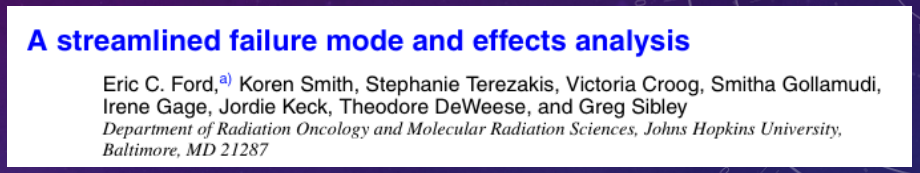
Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

FMEA OF EXTERNAL BEAM PROCESS

- Total Time Spent on FMEA
  - Total Staff Time: 55 hours
    - Core Group (7 people): 5.3 hours per person
    - Clinical Staff (12 remaining people): 1.5 hours per person
  - Total Facilitator Time: 75 hours (preparation for meetings, collection/review of data, distribution of materials)

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

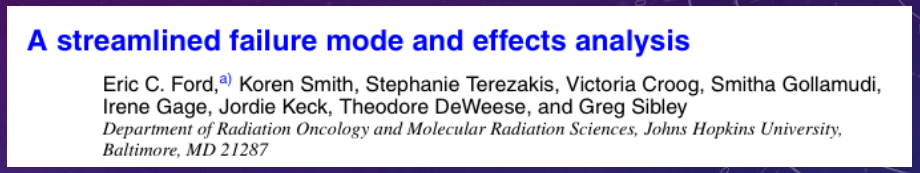
FMEA OF EXTERNAL BEAM PROCESS



- Factors for Success
  - Support by local and health system leadership. In particular, the Department Chair was part of the Core Group and his participation was critical to build engagement and enthusiasm with the staff.
  - Well defined, structured plan that was articulated to all participants throughout the exercise. Staff members had clear expectations for their role in meetings and for take home assignments.
  - Role of the Facilitator was crucial for communication/education about the FMEA process and for setting expectations. A significant effort was required for the facilitator.
  - Unexpected yet successful strategy: take-home assignments. Not all staff are comfortable in a group setting. This highlights the importance of creating a pathway for various staff to contribute in a meaningful way.

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

FMEA OF EXTERNAL BEAM PROCESS



- Lessons Learned
  - The power of an FMEA exercise lies in identifying as many failure modes as possible to highlight the most serious failures.
  - FMEA is "prospective" in nature, yet the process of identifying failure modes is "retrospective" in nature in that it relies on clinical experience. It is often difficult to recall or imagine all the ways in which a process can fail.
  - We identified 52 failure modes for 62 process steps (less than 1 failure mode per process step) which is likely low.
  - Care should be taken to identify as many failure modes as possible.
    - Conduct streamlined FMEA exercises regularly, thereby gradually adding to the list of failure modes.
    - Use incident learning systems to complement FMEA.

Ford EC et al. A streamlined failure mode and effects analysis. Med Phys. 2014; 41(6)

OUTLINE

- Introduction to TG100/FMEA
- Applications of FMEA Risk Analysis to Routine QA
  - FMEA of External Beam Process in a Community Hospital Setting
  - **Risk Analysis of Linear Accelerator QA**
    - **FMEA of TG142 – AAPM TG265/MPPG 8.a.**
    - FMEA of TG142 – Jennifer O'Daniel's Work at Duke University
- Summary of Considerations for Practical Applications of FMEA for Routine QA

FMEA OF TG142 – TG265/MPPG 8.A.

- TG265/Medical Physics Practice Guideline (MPPG) 8.a. – Performance Tests for Linear Accelerators
- Goal of MPPG 8.a.:
  - Review current QA recommendations for traditional (C-arm) linear accelerators and determine practical guidelines for performance tests that will enable the greatest detection of errors.
  - Sought to prioritize tests by their implication on quality and safety.
- FMEA methodology used to conduct a risk analysis of performance tests from current protocols (primarily from TG142).

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Risk Analysis of Performance Tests
  - Process Map = the daily, monthly and annual QA process on a linear accelerator
  - Failure Modes = clinical parameters that affect patient dose, setup or safety
  - Causes = failure, malfunction or incorrect calibration of clinical parameter

  - Each test (clinical parameter being tested) is considered a potential failure mode.
  - Each test is scored for Occurrence (O), Severity (S) and lack of Detectability (D)

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Risk Analysis of Performance Tests – FMEA Scoring Table
- Adopted TG100 Scoring Table. Changed definitions for the scope of our work.

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

TG100 Scoring Table

Table II. Descriptions of the O, S, and D values used in the TG-100 FMEA

Rank	Occurrence (O)		Severity(S)		Detectability (D)
	Qualitative	Frequency in %	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01	No effect		0.01
2		0.02	Inconvenience	Inconvenience	0.2
3	Relatively	0.05			0.5
4	few failures	0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume	2.0
6	Occasional failures	<0.5			5.0
7		<1	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2			15
9		<5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume	20
10	Failures inevitable	>5	Catastrophic		>20

MPPG 8.a. Scoring Table

Table for FMEA Scoring of Linear Accelerator Performance Tests

Instructions

(1) Assume clinical parameter in question is NOT being tested by the particular test you are scoring.
(Example: Consider the failure of the output if it were NOT tested daily.)

(2) Score each test independently. Assume you are eliminating one test at a time and all other tests are as currently recommended.
(Example: Output is NOT tested daily but is still checked monthly.)

	What if the test is NOT performed and the clinical parameter fails? What is the effect on the patient?		What is the likehood that the clinical parameter will fail?		How detectable is a failure? Are there other tests or machine interlocks that monitor this parameter?	
Score	**Severity (S)**		**Occurrence (O)**		**Detectability (D)**	
	Qualitative - Relative Harm to Patient	**Outcome of Failure**	**Qualitative Description**	**Frequency in %**	**Qualitative Description**	**Estimated Probability of Failure Going Undetected in %**
1	No Effect	Unlikely Dosimetric or Positional Error	Failure Unlikely	0.01	Always Detectable via Another Method	0.01
2	Minimal - No Side Effects	Minimal Dosimetric or Positional Error		0.02	Easily Detectable via Another Method	0.2
3			Relatively Few Failures	0.05		0.5
4	Minor Harm - No Side Effects	Minor Dosimetric or Positional error		0.1	Moderately Detectable via Another Method	1
5	Minor Harm - Minor Side Effects			<0.2		2
6			Occasional Failures	<0.5		5
7	Major Harm - Serious Side Effects	Major Dosimetric or Positional Error		<1	Difficult to Detect via Another Method	10
8			Repeated Failures	<2		15
9	Major Harm - Life Threatening	Severe Dosimetric or Positional Error		<5	Very Difficult to Detect via Another Method	20
10	Death	Catastrophic Dosimetric or Positional Error	Failure Inevitable	>5	Never Detectable via Another Method	>20

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Risk Analysis of Performance Test – Example of Scoring
- Test being scored: Daily Test of ODI
- Failure Mode = SSD setup of the patient is incorrect. Cause = ODI is out of tolerance.
- How do we score this failure?
- Occurrence (O)
  - Considerations
    - Committee members used their experience to determined how often the ODI is known to fail.
  - How likely is it that the ODI will fail?

	What is the likehood that the clinical parameter will fail?	
Score	**Occurrence (O)**	
	Qualitative Description	**Frequency in %**
1	Failure Unlikely	0.01
2		0.02
3	Relatively Few Failures	0.05
4		0.1
5		<0.2
6	Occasional Failures	<0.5
7		<1
8	Repeated Failures	<2
9		<5
10	Failure Inevitable	>5

2016 Spring Clinical Meeting - Salt Lake City, Utah
To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Risk Analysis of Performance Test – Example of Scoring
- Test being scored: Daily Test of ODI
- Failure Mode = SSD setup of the patient is incorrect. Cause = ODI is out of tolerance.
- How do we score this failure?
- Severity (S)
  - Considerations
    - The daily ODI test is NOT being performed
    - How much is the ODI out of tolerance when it does fail?
  - What is the severity of harm to the patient if the patient were treated with an out-of-tolerance ODI?

	What if the test is NOT performed and the clinical parameter fails? What is the effect on the patient?	
Score	**Severity (S)**	
	Qualitative - Relative Harm to Patient	**Outcome of Failure**
1	No Effect	Unlikely Dosimetric or Positional Error
2	Minimal - No Side Effects	Minimal Dosimetric or Positional Error
3		
4	Minor Harm - No Side Effects	Minor Dosimetric or Positional error
5	Minor Harm - Minor Side Effects	
6		
7	Major Harm - Serious Side Effects	Major Dosimetric or Positional Error
8		
9	Major Harm - Life Threatening	Severe Dosimetric or Positional Error
10	Death	Catastrophic Dosimetric or Positional Error

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Risk Analysis of Performance Test – Example of Scoring
- Test being scored: Daily Test of ODI
- Failure Mode = SSD setup of the patient is incorrect. Cause = ODI is out of tolerance.
- How do we score this failure?
- Lack of Detectability (D)
  - Considerations
    - The daily ODI test is NOT being performed
    - Committee members used experience to decide is the ODI failure could be detected via another pathway
  - How detectable is an ODI failure?

	How detectable is a failure? Are there other tests or machine interlocks that monitor this parameter?	
Score	**Detectability (D)**	
	Qualitative Description	**Estimated Probability of Failure Going Undetected in %**
1	Always Detectable via Another Method	0.01
2	Easily Detectable via Another Method	0.2
3		0.5
4	Moderately Detectable via Another Method	1
5		2
6		5
7	Difficult to Detect via Another Method	10
8		15
9	Very Difficult to Detect via Another Method	20
10	Never Detectable via Another Method	>20

2016 Spring Clinical Meeting - Salt Lake City, Utah
To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Risk Analysis of Performance Tests – Scoring Participants
  - Initially, **7** committee members submitted scores for each test considered. We determined the average score for O, S and D and used this to determine an average RPN score.
  - Power in the numbers: We decided to engage our colleagues in the same exercise to validate our own scoring and to have more power in the resulting scores.
  - We each asked 5 colleagues for their input.
  - Scoring participants must have substantial experience in doing QA on linacs. Experience in FMEA was a bonus but not necessary.

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Risk Analysis of Performance Tests – Scoring Participants
  - Scoring participants represent practicing medical physics from all over the country.
  - Variety of experience and background. We asked participants to record some demographic information.
    - Years of experience: Range from 5-37 years
    - Type of institution: Academic, community hospital, government, consulting group
    - Vendor of Linear Accelerator: Varian, Elekta, Siemens.

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

Section	Performance Test	Frequency	Tolerance		Severity	Occurrence	Detectability
			IMRT	SBRT			
Dosimetry	X-Ray and Electron Output Constancy	Daily	3%				
Mechanical	Laser localization	Daily	1.5 mm	1 mm			
	ODI	Daily	2mm				
	Collimator Size Indicator	Daily	2mm	1 mm			
Safety	Door Interlock	Daily	Functional				
	Door Closing Safety	Daily	Functional				
	Audio / Visual monitors	Daily	Functional				
	Stereotactic interlocks (lockout)	Daily	NA	Functional			
	Radiation Area Monitor (if used)	Daily	Functional				
	Beam On Indicator	Daily	Functional				
Wedge	Morning Check Out Run for One Angle	Daily	Functional				
MLC	MLC Qualitative Test (Picket Fence)	Weekly	Visual Inspection				
Dosimetry	X-Ray, Electron, and Backup Chamber Output Constancy	Monthly	2%				
	Typical IMRT Dose Rate Output Constancy	Monthly	2% @ IMRT DR	2% @ Stereo DR			
	Photon and Electron Beam Profile Constancy	Monthly	1%				
	Electron Beam Energy Constancy	Monthly	2% /2mm				
Mechanical	Light / Radiation Field Coincidence	Monthly	2 mm or 1% on a side				
	Light / Radiation Field Coincidence (Asymmetric)	Monthly	1 mm or 1% on a side				
	Laser / ODI Check with Front Pointer	Monthly	1 mm				
	Gantry /Collimator Angle Indicators	Monthly	1 deg				
	Accessory Trays (i.e., Graticle or Dot Tray)	Monthly	2 mm				
	Digital Graticle	Monthly					
	Jaw Position Indicators (Symmetric)	Monthly	2 mm				
	Jaw Position Indicators (Asymmetric)	Monthly					
	Cross-hair Centering	Monthly	1 mm				
	Treatment Couch Position Indicators	Monthly	2mm / 1 deg	2mm / 0.5 deg			
	Wedge Placement Accuracy/Compensator Placement	Monthly	2 mm				
	Latching of Wedges, Block trays	Monthly	Functional				
	Localizing Lasers	Monthly	+/-1mm	< +/-1mm			
Safety	Laser Guard-Interlock Test	Monthly	Functional				
Wedge	Wedge Factor for All Energies	Monthly	Dyn/Uni [2% for 45˚ or 60˚], Vir [5% from unity or 2%]				
MLC	Backup Diaphragm Settings (Elekta only)	Monthly	2 mm				
	Travel speed (IMRT)	Monthly	Loss of 0.5 cm/s				
	Leaf Position Accuracy (IMRT)/Setting vs Radiation (Non-IMRT)	Monthly	1 mm/2mm				
Dosimetry	X-Ray/Electron Flatness Change from Baseline	Annual	1% from baseline				
	X-Ray/Electron Symmetry Change from Baseline	Annual	± 1% from baseline				
	SRS Arc Mode	Annual	NA	MU/Arc [1MU/1˚ or 2%]			
	X-Ray and Electron Output Calibration (TG-51)	Annual	+/-1%				
	Field Size Dependent Output Factors (2 or More FS)	Annual	2% for FS < 4x4, 1% ≥ 4x4				
	Electron Applicator Output Factors (One Applicator/Energy)	Annual	2% from baseline				
	X-Ray Beam Quality (PDD10 or TMR 20/10)	Annual	+/- 1% from baseline				

- Risk Analysis of Performance Tests – Scoring Participants
  - Scoring participants were contacted personally by committee members.
  - Each participant was given a blank scoring sheet which indicated the list of tests to score.
  - Each participant was given the FMEA scoring table which included an example of how to score the test and what considerations (assumptions) needed to be made.

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

Section	Performance Test	Frequency	Tolerance		Severity	Occurrence	Detectability
			IMRT	SBRT			
Dosimetry	X-Ray and Electron Output Constancy	Daily	3%				
Mechanical	Laser localization	Daily	1.5 mm	1 mm			
	ODI	Daily	2mm				
	Collimator Size Indicator	Daily	2mm	1 mm			
Safety	Door Interlock	Daily	Functional				
	Door Closing Safety	Daily	Functional				
	Audio / Visual monitors	Daily	Functional				
	Stereotactic interlocks (lockout)	Daily	NA	Functional			
	Radiation Area Monitor (if used)	Daily	Functional				
	Beam On Indicator	Daily	Functional				
Wedge	Morning Check Out Run for One Angle	Daily	Functional				
MLC	MLC Qualitative Test (Picket Fence)	Weekly	Visual Inspection				
Dosimetry	X-Ray, Electron, and Backup Chamber Output Constancy	Monthly	2%				
	Typical IMRT Dose Rate Output Constancy	Monthly	2% @ IMRT DR	2% @ Stereo DR			
	Photon and Electron Beam Profile Constancy	Monthly	1%				
	Electron Beam Energy Constancy	Monthly	2% /2mm				
Mechanical	Light / Radiation Field Coincidence	Monthly	2 mm or 1% on a side				
	Light / Radiation Field Coincidence (Asymmetric)	Monthly	1 mm or 1% on a side				
	Laser / ODI Check with Front Pointer	Monthly	1 mm				
	Gantry /Collimator Angle Indicators	Monthly	1 deg				
	Accessory Trays (i.e., Graticle or Dot Tray)	Monthly	2 mm				
	Digital Graticle	Monthly					
	Jaw Position Indicators (Symmetric)	Monthly	2 mm				
	Jaw Position Indicators (Asymmetric)	Monthly					
	Cross-hair Centering	Monthly	1 mm				
	Treatment Couch Position Indicators	Monthly	2mm / 1 deg	2mm / 0.5 deg			
	Wedge Placement Accuracy/Compensator Placement	Monthly	2 mm				
	Latching of Wedges, Block trays	Monthly	Functional				
	Localizing Lasers	Monthly	+/-1mm	< +/-1mm			
Safety	Laser Guard-Interlock Test	Monthly	Functional				
Wedge	Wedge Factor for All Energies	Monthly	Dyn/Uni [2% for 45˚ or 60˚], Vir [5% from unity or 2%]				
MLC	Backup Diaphragm Settings (Elekta only)	Monthly	2 mm				
	Travel speed (IMRT)	Monthly	Loss of 0.5 cm/s				
	Leaf Position Accuracy (IMRT)/Setting vs Radiation (Non-IMRT)	Monthly	1 mm/2mm				
Dosimetry	X-Ray/Electron Flatness Change from Baseline	Annual	1% from baseline				
	X-Ray/Electron Symmetry Change from Baseline	Annual	± 1% from baseline				
	SRS Arc Mode	Annual	NA	MU/Arc [1MU/1˚ or 2%]			
	X-Ray and Electron Output Calibration (TG-51)	Annual	+/-1%				
	Field Size Dependent Output Factors (2 or More FS)	Annual	2% for FS < 4x4, 1% ≥ 4x4				
	Electron Applicator Output Factors (One Applicator/Energy)	Annual	2% from baseline				
	X-Ray Beam Quality (PDD10 or TMR 20/10)	Annual	+/- 1% from baseline				

- Risk Analysis of Performance Tests – Scoring Participants
  - We attempted to have everyone on the same page as far as "how to score" each test.
  - 7 different people explaining the project to 35 different people. Handouts were as detailed as possible to have consistent communication to scoring participants.
  - Results: We received 18 responses – 25 Total Scoring Participants Including Committee
    - For 3 individuals, we had to re-explain the scoring process after realizing that the scoring was done incorrectly. Scores were resubmitted from those individuals.

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

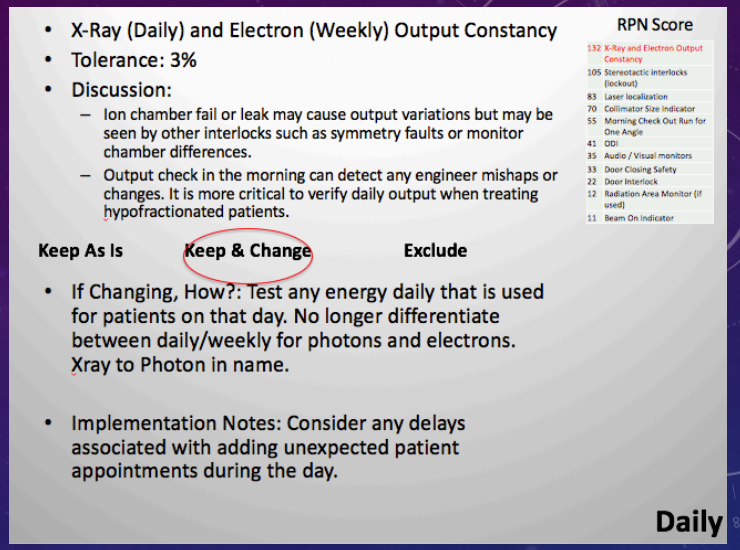
- Risk Analysis of Performance Tests – Scoring of Daily Tests

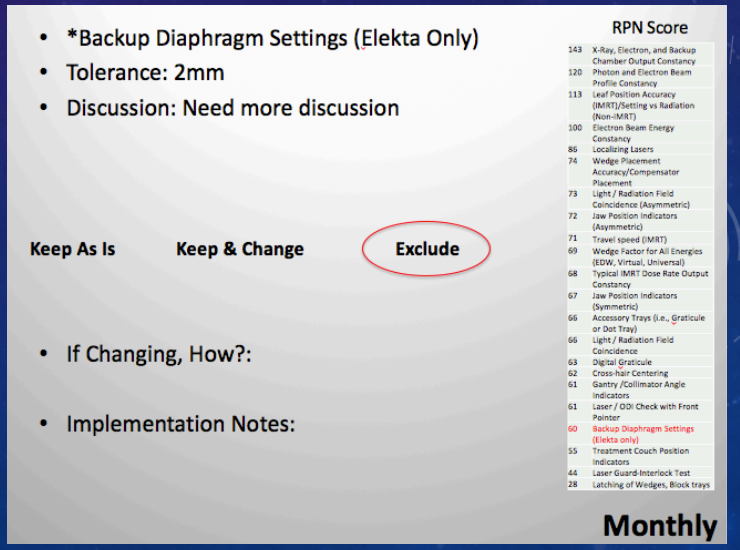
Rank Order		Rank Order	
RPN Score - Committee Only		**RPN Score - All Scoring Participants**	
82	Wedge Check Out Run	132	X-Ray and Electron Output Constancy
76	X-ray and Electron Output constancy	105	Stereotactic Interlocks (Lockout)
75	Collimator Size Indicator	83	Laser Localization
43	Stereo Interlocks (Lockout)	70	Collimator Size Indicator
40	Laser Localization	55	Wedge Check Out Run
39	Door Closing Safety	41	ODI
29	ODI	35	Audio/Visual Monitors
21	Audio/Visual Monitors	33	Door Closing Safety
8	Door Interlock	22	Door Interlock
7	Beam On Indicator	12	Radiation Area Monitor
6	Radiation Area Monitor	11	Beam On Indicator

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Risk Analysis of Performance Tests
- Our committee had a face-to-face meeting to finalize performance tests that would be included in the guideline. We reviewed our previous discussions on each test and used scoring information from all the scoring participants to determine whether to Keep or Exclude the test.





2016 Spring Clinical Meeting - Salt Lake City, Utah
To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Conclusion - Risk Analysis of Performance Tests
- One perceived deficiency of previous reports on quality assurance tests is that the tests are treated as equally important without any regard to reduction of quality in the radiation delivery based on linear accelerator performance.
- This committee sought to prioritize tests by their implication on quality and safety.
- Performance tests for linear accelerators that are set forth in the guideline are derived from a combination of results from the risk analysis of currently recommended tests and the consensus of the committee.

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Factors for Success
- "Facilitator", Chair of Committee, prepared written materials to distribute to scoring participants to have consistent language and communication about the scoring process.
- Committee members carefully chose scoring participants. Expertise on the subject of risk analysis is key. FMEA tools can be taught but in order to contribute meaningfully to FMEA process, participants must have in depth knowledge of the subject matter being analyzed and scored.

To Be Published: "MPPG 8.a. Performance Tests for Linear Accelerators" Smith et al. 2016

FMEA OF TG142 – TG265/MPPG 8.A.

- Lessons Learned
- FMEA in this setting required some flexibility in the process.
  - The traditional definitions of “process map”, “failure mode” needed to be adapted for the task.
  - The scoring table needed to be adapted so as to make sense in the environment of this FMEA.
- Consistent communication is key. Committee members agreed to certain language and explanations before approaching colleagues to participate.

To Be Published: “MPPG 8.a. Performance Tests for Linear Accelerators” Smith et al. 2016

FMEA FOR ROUTINE QA TWO DIFFERENT SETTINGS

- Small Community Hospital Setting
- Controlled group of participants for key steps (core group to do scoring)
- Experienced Facilitator
- Department Chair committed to the FMEA task who motivated staff and drove the process along

- AAPM Practice Guideline Committee
- National participation – Scoring conducted in uncontrolled environment
- Inexperienced Facilitator
- Motivated Committee Chair to use FMEA risk analysis tools in an unconventional setting

OUTLINE

- Introduction to TG100/FMEA
- Applications of FMEA Risk Analysis to Routine QA
  - FMEA of External Beam Process in a Community Hospital Setting
  - **Risk Analysis of Linear Accelerator QA**
    - FMEA of TG142 – AAPM TG265/MPPG 8.a.
    - **FMEA of TG142 – Jennifer O'Daniel's Work at Duke University**
- Summary of Considerations for Practical Applications of FMEA for Routine QA

FMEA OF TG142 – O'DANIEL AT DUKE UNIVERSITY

- FMEA of TG142 – Quantitative Risk Analysis
- Determine Occurrence with actual failure rates
- Determine Severity by simulating failure rates in the planning system
- Account for frequency of test performance
  - Determine the percent of time the failure was present over the course of treatment
  - Determine the number of patients affected by the error

2015 AAPM Spring Clinical Meeting Presentation: "FMEA Analysis of TG-142" Jennifer O'Daniel, Duke University Medical Center

FMEA OF TG142 – O'DANIEL AT DUKE UNIVERSITY

Occurrence

- FMEA of TG142 – Quantitative Risk Analysis
- Determine Occurrence with actual failure rates
- Occurrence: 3 Varian 21EX linear accelerators x 3 years = 9 years of data
  - Daily, weekly, monthly and annual QA
  - Post TG142 implementation
- 2348 treatment days analyzed

FMEA OF TG142 – O'DANIEL AT DUKE UNIVERSITY

Occurrence

- FMEA of TG142 – Quantitative Analysis
- Determine Occurrence with actual failure rates

Ranking: Occurrence

Rank	Occurrence: Frequency of Failure (%)	
	TG100	This study
1	<= 0.01%	<= 0.01%
2	<= 0.02%	> 0.043% (0/2348)
3	<= 0.05%	<= 0.043% (1/2348)
4	<= 0.1%	<= 0.1%
5	<= 0.2%	<= 0.2%
6	<= 0.5%	<= 0.5%
7	<= 1%	<= 1%
8	<= 2%	<= 2%
9	<= 5%	<= 5%
10	> 5%	> 5%

2015 AAPM Spring Clinical Meeting Presentation: "FMEA Analysis of TG-142" Jennifer O'Daniel, Duke University Medical Center

FMEA OF TG142 – O'DANIEL AT DUKE UNIVERSITY

Occurrence

- FMEA of TG142 – Quantitative Analysis
- Determine Occurrence with actual failure rates

Occurrence: Daily QA

Daily QA Test	Number of Adjustments	Occurrence (% of total days of operation)
Output	86	3.7%
Laser	19	0.8%
CBCT Pos/Repos	10*	0.5%
ODI	2	0.09%
Jaws vs. Light Field	0	< 0.05%
kV/MV Pos/Repos	0	< 0.05%
Imaging vs. Tx Iso	0	< 0.05%
Imaging Safety	0	< 0.05%
Linac Safety	0	< 0.05%

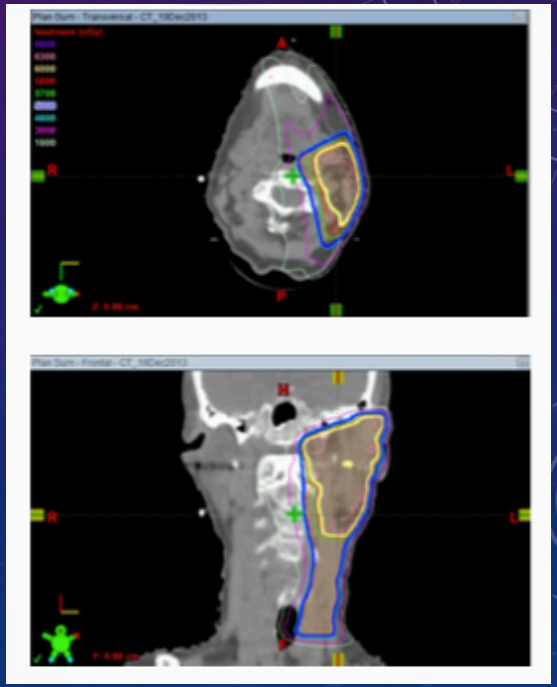
DukeMedicine

2015 AAPM Spring Clinical Meeting Presentation: "FMEA Analysis of TG-142" Jennifer O'Daniel, Duke University Medical Center

FMEA OF TG142 – O'DANIEL AT DUKE UNIVERSITY

Severity

- FMEA of TG142 – Quantitative Risk Analysis
- Determine severity by simulating failures in the planning system
- Severity: model error in treatment planning system (Eclipse)
  - 10 head-and-neck IMRT patients
  - Primary PTV (40-50Gy) and boost PTV (50-70Gy)
  - Spinal cord



2015 AAPM Spring Clinical Meeting Presentation: "FMEA Analysis of TG-142" Jennifer O'Daniel, Duke University Medical Center

FMEA OF TG142 – O'DANIEL AT DUKE UNIVERSITY

Severity

- FMEA of TG142 – Quantitative Risk Analysis
- Determine severity by simulating failures in the planning syste
- Severity: model error in treatment planning system (Eclipse)
  - 10 head-and-neck IMRT patients
  - Primary PTV (40-50Gy) and boost PTV (50-70Gy)
  - Spinal cord

Ranking: Severity

Rank	TG100	This study	
		Change in %-Volume of PTV at Rx Dose	Change in Maximum Dose to Cord
1	No effect	<= 1%	<= 45cGy (1%)
2	Inconvenience	<= 2%	<= 90cGy (2%)
3		<= 3%	<= 135cGy (3%)
4	Minor dosimetric error	<= 4%	<= 180cGy (4%)
5	Limited toxicity or tumor underdose	<= 5%	<= 225cGy (5%)
6		<= 10%	<= 450cGy (10%)
7	Potentially serious toxicity or tumor underdose	<= 15%	<= 675cGy (15%)
8		<= 20%	<= 900cGy (20%)
9	Potentially very serious toxicity or tumor underdose	> 20%	> 900cGy (20%)
10	Catastrophic	Medical Event	Medical Event

TG265/MPPG 8.A vs O'DANIEL RPN SCORES

Commonly Scored Daily Tests

Local RPN[1]	Performance Test Ranking[1] MPPG 8.a.	Local RPN[2]	Performance Test Ranking[2] O'Daniel
132	Output Constancy	180	Output Constancy
83	Laser localization	140	Laser Localization
70	Collimator size indicator	60	Distance indicator (ODI) @iso
41	Distance indicator (ODI) @iso	40	Collimator size indicator

Commonly Scored Monthly Tests

Local RPN[1]	Performance Test Ranking[1] MPPG 8.a.	Local RPN[2]	Performance Test Ranking[2] O'Daniel
143	Output Constancy	180	Output Constancy
86	Laser Localization	140	Laser Localization
73, 66	Light/radiation field coincidence (asym, sym)	100	Light/radiation field coincidence
72, 67	Jaw position indicators (asym, sym)	60	Distance check device
61	Distance check device	40	Jaw position indicators
55	Treatment couch position indicators	40	Treatment couch position indicators

FMEA OF TG142 – O'DANIEL AT DUKE UNIVERSITY

- FMEA of TG142 – Quantitative Risk Analysis
- Important work as it attempts to provide measured data for Occurrence and Severity probabilities. Compared to other industries, radiation oncology has little data on probabilities that go into FMEA scoring of failure modes.

2015 AAPM Spring Clinical Meeting Presentation: "FMEA Analysis of TG-142" Jennifer O'Daniel, Duke University Medical Center

FMEA FOR ROUTINE QA SUMMARY OF LESSONS LEARNED

- FMEA Can be Used for Any Clinical Process
  - The scope of an FMEA risk analysis can be any clinical process. From a short clinical procedure to process for an entire treatment modality.
  - Define the scope and develop a well structured plan to achieve the your goal.

FMEA FOR ROUTINE QA SUMMARY OF LESSONS LEARNED

- Engage Participants with Expertise in the Process Being Evaluated
  - FMEA tools can be taught. Experts in the process being evaluated will be better able to identify weak points or failure modes in the process.
  - Engage participants with knowledge on different aspects of the process.
  - Ensure that participants are able to contribute in a meaningful way.

FMEA FOR ROUTINE QA
SUMMARY OF LESSONS LEARNED

- Role of a Facilitator is Crucial
  - This has been noted in surveys of FMEA participants. One goal in the coming years is to build expertise in the radiation oncology community to the point where there is a critical body of experts who can facilitate FMEA exercises.
  - Institutions may also be able to employ the help of risk management experts at the hospital level.

FMEA FOR ROUTINE QA
SUMMARY OF LESSONS LEARNED

- Big Picture!
  - Easy to get bogged down in different phases of the FMEA exercise (Process Map, Scoring)

- Overall Goal of FMEA: Identify and Create Quality Improvement Steps for High-Ranking Failure Modes
  - Quality Control Measures to mitigate risks

THANK YOU

- Eric Ford
- MPPG 8.a. Committee Members:
  - Peter Balter
  - John Duhon
  - Gerald White
  - Robin Miller
  - Dave Vassy
  - Christopher Serago
- Jennifer O'Daniel