Risk analysis to inform physics plan review recommendations

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Disclosures and Acknowledgements

- Member of TG275
- **Volunteers**: Review FMs (RTTs, CMDs, MDs), Scoring FMs
- Some Material and Slides Provided by Other TG275 Members
  - Eric Ford
  - Stephanie Parker
  - Anne Greener
  - Luis Fong de los Santos
  - Perry Johnson
  - Debbie Schofield

Workflow for TG275 Risk Assessment Study

1. Develop Online FMEA Tool on AAPM Website
2. Create Process Map
3. Create Database of Failure Modes
4. Enter Failure Modes and Causes into Online Tool
5. Score FM's using Abbreviated Scale
6. Analyze Results of 3 Point Scale FMEA

Workflow for TG275 Risk Assessment Study

7. Remove Low Scoring FM's & Combine Causes
8. Score FM's using Standard 10 Point Scale
9. Analyze Results of 10 Point Scale FMEA
10. Correlate FM's with Survey Results
11. Develop Recommendations

Create Database of Failure Modes

- Experience of TG-275 Members
  - Individual Lists Generated by Each TG Member
  - Excel Workbook with Worksheet for Each Process Step
- SAFRON
  - 51 Event Identified
    - Potential to be detected on physics review
    - List compared to Current Lists
  - 38 FM/Cause Combinations Added to Database

IAEA | SAFRON

https://rpop.iaea.org/RPOP/RPoP/Modules/login/safron-register.htm

Create Database of Failure Modes

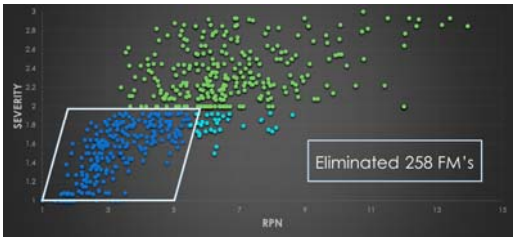
- Validation of Database Against RO-ILS
  - 113 events related to Physics Checks identified by E. Ford
  - List compared to database generated by Task Group
    - Excellent agreement
    - 97 of 113 events already included in database
    - 10 of the events resulted in new causes
    - 6 events resulted in new failure modes
      - 4 of 6 of minor importance and excluded

RO-ILS | RADIATION ONCOLOGY® INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

https://www.astro.org/RO-ILS.aspx

Generate the final list of FMs

- Started with 594 Failure Mode/ Cause Combinations
- Eliminated 258 that Fell Below the Threshold
- 336 Remaining - Still too many
- Combined Causes for Many FM's
- Final Result for 10 Point Scale Scoring
  - 118 FM/Cause Combinations



- Review the final list of FMs
- 14 volunteers from various institutions
  - 8 Radiation therapists
  - 3 Physicians
  - 3 dosimetrists

Score FMs using Standard 10 Point Scale

- Scoring Open June 27- July 11, 2016
- 1 to 1.5 Hours to Complete Scoring
- ~1.3 FM/min

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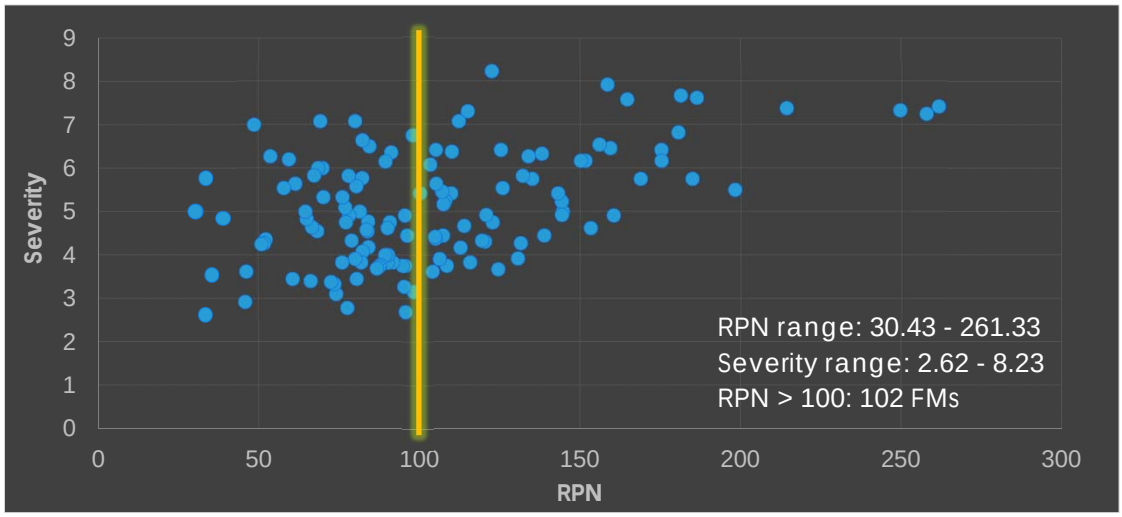
Main
TG275 Committee Tree
AAPM Home

TG 275 FMEA TOOL

ID	Project	Committee		
8	DNU	TG275	Scores	Failure Mode
12	GYN Intracavitary HDR EOT Check	TG275	Scores	Failure Mode
11	GYN Intracavitary HDR Initial Plan Check	TG275	Scores	Failure Mode
9	TG275: Proton FMEA	TG275	Scores	Failure Mode
6	TG275: EBRT FMEA -10 Point Scale	TG275	Scores	Failure Mode
4	TG275: EBRT FMEA 3 Point Scale	TG275	Scores	Failure Mode
7	Weekly and EOT Check FMEA	TG275	Scores	Failure Mode

Analyze Results of 10 Point Scale FMEA



Hi-RPN FMs of EBRT

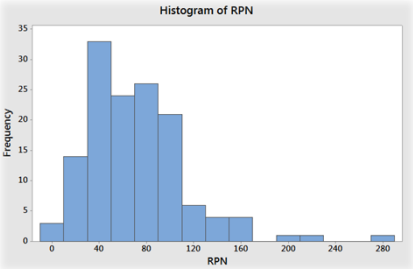
Rank000	Process Step	Failure Mode	Cause	RPN
1	Tx Plan	"Wrong" or inaccurate MD contours	Workflow/Communication Issue, e.g., Attending MD does not review resident contours, MD does not clearly identify dose levels, Incorrect CT dataset, Fusion incorrect or with wrong image set, Target motion not considered, Wrong set of contours imported	261.3
2	Pt Assmnt	Miscommunication about prior dose, pacemaker, pregnancy	Information not communicated or available information incorrect	214.1
3	Tx Plan	Improper margins for PTV	Structural issues, e.g. policies and procedures inadequate or non-existent, margins not provided	198.0
4	Tx Plan	Unintentional re-irradiation of a previously treated area	Technical Issue: Inadequate medical records in hospital data base, Re-creation of prior plan incorrect, Missing previous RT dose structure, No records available (foreign country, distant past, lost)	181.2
5	Pt Assmnt	Incorrect or missing pathology	pathology report incorrect or not read by MD	180.3

External Tx. Weekly & End of Treatment

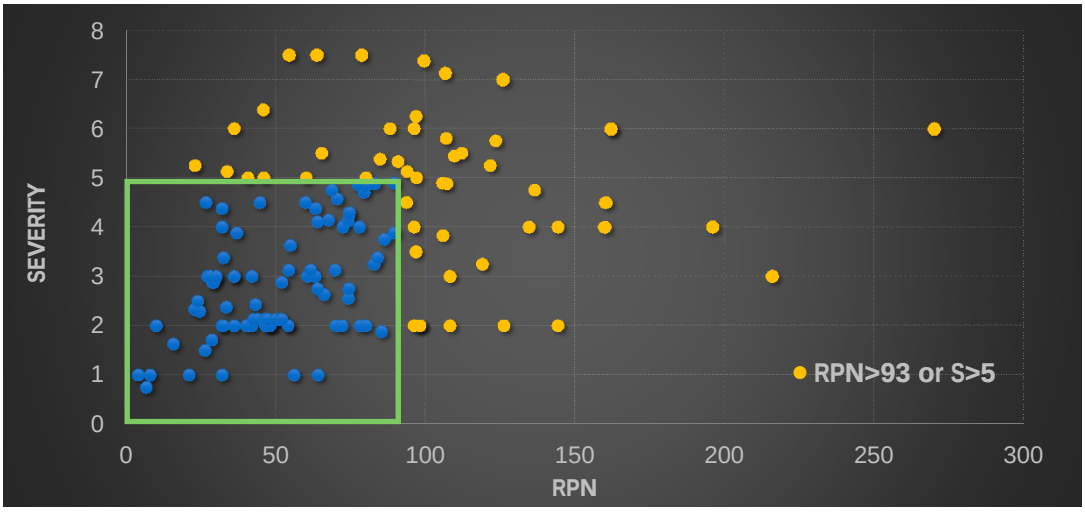
- Total 138 FMs are generated and scored.

Pre-tx. review & verification | Treatment Delivery | On-tx. Quality management | Post-tx. completion

- 4 categories of FMs for weekly chart review
  - FMs during the pre-Tx review and verification.
  - FMs to obtain or record the requested information.
  - FMs for changes in prescription.
  - FMs for Tx delivery.



External Tx. Weekly & End of Treatment



Hi-RPN FMs of weekly review & EOT

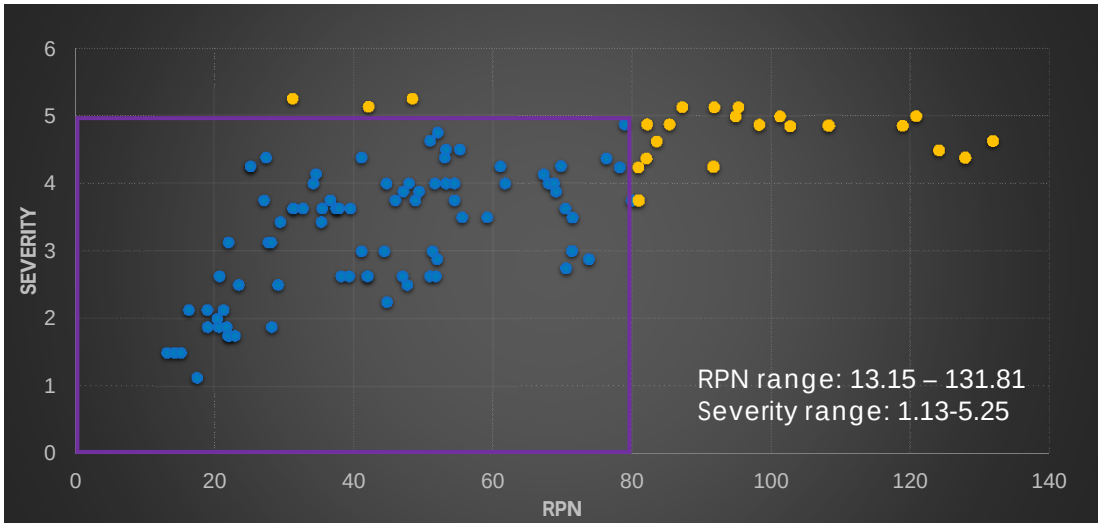
Rank	Failure Mode	Process Step	Cause	RPN	
1	Incorrect dose administered	Treatment Delivery	Incorrect orientation of electron cutout	270.00	Not Catchable
2	Incorrect dose administered	Treatment Delivery	Patient not able to physically maintain position for treatment	216.00	
3	Fraction not delivered as intended	Treatment Delivery	Inattention by physician during image review	196.00	Not Catchable
4	Incorrect dose administered	Treatment Delivery	Incorrect manual shift used	162.00	Not Catchable
5	Collision of delivery system with patient	Treatment Delivery	Treatment fields not checked pre-treatment	162.00	Not Catchable

GYN HDR Plan Check - FMEA

- Scope: GYN Intracavity HDR Initial Plan Check
- Process Steps

- Total 109 Failure Modes scored
  - Applicator Placement: 34 FMs
  - Imaging: 23 FMs
  - Planning: 52 FMs
- Recommendations will be developed based on FMEA results after cross-comparison with a collection of checklists.

GYN HDR Initial Plan Check - FMEA



Hi-RPN HDR FMs

Rank	Failure Mode	Process Step	Cause	RPN
1	Wrong MD contours	Planning	Physical environment - interruptions, MD rushed, etc.	131.81
2	Catheters digitized incorrectly (e.g. wrong offset, digitizing something other than the catheter)	Planning	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc.	120.82
3	Incorrect treatment length planned	Planning	Communication - MD intention not relayed properly to planner	118.95
4	Wrong distal reference length entered into TPS	Planning	Planner not familiar with procedure or confused - poor training, vague policies, incomplete documentation, etc.	98.26
5	Incorrect measurement and/or documentation of channel lengths or number	Imaging	Slip or lapse caused by inattention, distraction, etc. - staff misread measurement	95.29

Proton Plan Check - FMEA

- Total 71 proton specific FMs scoring: cross-comparison on-going

Rank	Failure Mode	Step	Cause	RPN
1	Tumor growth while waiting for treatment start	Treatment Planning	Waiting for insurance clearance	150.48
2	Strong, unrepairable metal artifacts	Simulation	patient has extensive or high density metal causing severe CT scan artifacts	148.72
3	Over-dosing normal structures	Treatment Planning	Prior radiation was not considered carefully	133.7
4	Inaccurate proton range calculation	Treatment Planning	Failure to consider organ motion or setup uncertainties in the beam path	117.92
5	Adaptive plan was not created	On-Treatment Quality Management	Failed to review or detect any significant/meaningful changes in patient's anatomy in the beam path due to inadequate staff training or no well-established guideline etc.	111.62

Summary

- Risk assessment has been completed.
  - EBRT physics plan review
  - Weekly chart review/ETO
  - GYN HDR
  - Proton Therapy
- Cross - check with the survey result in progress.
- Develop recommendations in progress based on FMEA & survey results.