# FMEA Analysis of TG-142

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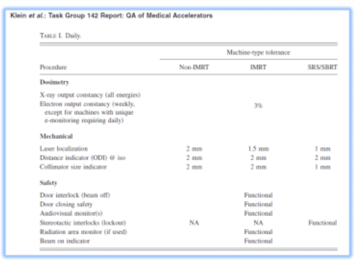
## Acknowledgments

- Thanks to Saiful Huq for an illuminating conversation about the application of TG-100
- Thanks to all of the physicists and therapists at Duke University, who have spent many hours collecting the QA data used in this analysis

## AAPM: Task Group-142

- Multitude of linear accelerator quality assurance tasks
- Prescribed acceptance limits and testing frequency
- Debate about effectiveness and efficiency



Klein *et al.*: Task Group 142 Report: QA of Medical Accelerators

Table I. Daily.

| Procedure | Machine-type tolerance: Non-IMRT | IMRT | SRS/SBRT |
|---|---|---|---|
| **Dosimetry** | | | |
| X-ray output constancy (all energies) | | | |
| Electron output constancy (weekly, except for machines with unique e-monitoring requiring daily) | | 3% | |
| **Mechanical** | | | |
| Laser localization | 2 mm | 1.5 mm | 1 mm |
| Distance indicator (ODI) @ iso | 2 mm | 2 mm | 2 mm |
| Collimator size indicator | 2 mm | 2 mm | 1 mm |
| **Safety** | | | |
| Door interlock (beam off) | | Functional | |
| Door closing safety | | Functional | |
| Audiovisual monitor(s) | | Functional | |
| Stereotactic interlocks (lockout) | NA | NA | Functional |
| Radiation area monitor (if used) | | Functional | |
| Beam on indicator | | Functional | |

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## Institution-specific TG-142?

- "Institutional deviations from some of these recommendations are expected based upon the institution's policy and procedures…"
- To change the frequency of a particular test:
  - Review an appreciable history of results
  - Consider the potential impact of failure
  - Perform an FMEA analysis

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## Method for Evaluating QA Needs in Radiation Therapy

*Chair: M. Saiful Huq – TG-100 (Start: 8/1/2003, End: no date on file)*

**Charge:** Specific charges of this task group are defined below. The final report may include additional material deemed necessary during the preparation of the final report.

1. Review and critique the existing guidance from the AAPM in documents such as TG-40, 56, 59, 43 old and new, 60, 64, and guidance from ACR and ACMP reports on QA in Radiation Oncology, ESTRO report on QA in radiotherapy, IEC publications on functional performance of radiotherapy equipment, and finally ISO guidelines on quality management and quality assurance. The objective will be to determine the specific areas that have been omitted and need better coverage and also develop a suitable general quality assurance program.

2. Identify a structured systematic QA program approach that balances patient safety and quality versus resources commonly available and strike a good balance between prescriptiveness and flexibility.

3. After the identification of the hazard analysis for broad c

## Failure-Mode & Effects Analysis

- Create a process map
- Identify weak points
- Score each weak point
  - Occurrence = frequency of failure
  - Severity = effect of failure
  - Detectability = probability of ***not*** detecting the failure
- Rank and prioritize by score
  - RPN = Risk Priority Number = O*S*D
- Develop mitigation strategies

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S Huq et al, IJROBP 71, 2008
E Ford et al, IJROBP 74, 2009

## TG-100 FMEA Analysis of IMRT

- Human error (44%)
  - Human failure
  - Inadequate training
  - Lack of communication
- Inadequate procedures/resources (31%)
- Hardware/software failures (13%)
- Design or commissioning failure (8%)
- Others (4%)

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S Huq, New paradigms for quality management in radiation therapy. Presentation at 2011 AAPM summer school. AAPM Virtual Library.

## Top Ten Failure Modes of External Beam Radiotherapy

| 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 |
| Tomotherapy blocks turned off. Directional blocking for critical structure. | Oversight by physicist in planning. | Tx planning | 5 | 3 | 10 | 150 |
| RTT unaware of Rx or fractionation change, e.g., change when boost starts. | Communication lapse between teams. | On-Tx Mgmt | 3 | 8 | 5 | 120 |
| Unclear setup instructions from simulation, e.g., two scans performed. (Supine vs prone) for planning evaluation. | Communication lapse between teams as to final directives for setup. | Tx planning | 4 | 5 | 6 | 120 |
| Prior treatment records not available. | Chart archived offsite or patient arrives without records. | Pt assessment | 10 | 2 | 5 | 100 |
| Wrong couch kicks or table angles entered in R&V system. | Oversight of planner. Confusion due to different labeling conventions on different machines. | Tx planning | 10 | 9 | 1 | 90 |
| Treatment planner unclear if physician contouring is complete. | Communication lapse between teams. | Tx planning | 10 | 3 | 3 | 90 |

Ford et al, Med. Phys. 41, (2014)

## Top Ten Failure Modes of External Beam Radiotherapy

- Human error = 4
- Communication lapse = 3
- Policy not followed = 2
- Outside our realm of influence = 1
- Hardware/software errors = 0

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Ford et al, Med. Phys. 41, (2014)

## Extending FMEA Analysis to TG-142

- The previous FMEA analysis did not touch materials related to treatment machine failures
- TG-142 is a comprehensive QA protocol for testing the performance of medical linear accelerators
- The purpose of this presentation is to extend the conventional FMEA analysis to treatment machine related as TG-142 described

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## How to Determine the Relative Importance of TG-142 Tests?

- Determine detectability
- Determine failure rate → occurrence
- Determine severity if that failure should occur
- Need to account for the frequency of each test
  - % of time the failure was present over a course of treatment
  - Number of patients affected by the error →Introducing patient-load-weighted RPN

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## Ranking: Detectability

| Rank | Estimated Probability of the Failure Going Undetected (%) |
|---|---|
| | TG-100 and This Study |
| 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 |

**Assumptions:**

- TG-142 → only way to detect error
- All tests → 100% accurate
- All tests → same detectability

## Additional Assumptions

- Routine preventative maintenance tasks are performed on schedule
  - e.g. Image quality is adjusted regularly (CBCT recalibrated annually, kV & MV dark/flood fields redone on a regular basis)
- When accidents/repairs/service occur, appropriate QA tasks are done afterwards
- Errors will be caught before the tolerance limit is passed → modelled at the tolerance limit

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## Data: Occurrence

- 3 Linacs (Varian 21EX) x 3 years = 9 years
  - Daily, weekly, monthly & annual QAs
  - Post-TG-142 implementation
- 2,348 treatment days analyzed
- Minimum detectable occurrence rate
  - 1/2348 = 0.04%

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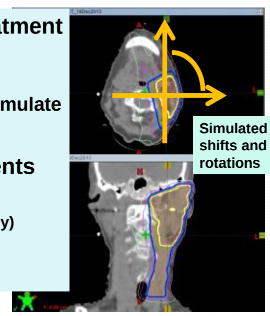
## Ranking: Occurrence

| Rank | Frequency of Failure (%) | |
|---|---|---|
| | TG-100 | 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 (117/2348) |
| 10 | > 5 | > 5 |

## Data: Severity

- Model error in treatment planning system (Eclipse v11)
  - Dose change for simulate shift and rotations
- 10 H&N IMRT patients
  - Prescription
    - Primary PTV (40-50Gy)
    - Boost PTV (50-70Gy)
  - Spinal cord dose

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## Ranking: Severity

| Rank | TG-100 (Qualitative) | This Study (Quantitative) | |
|---|---|---|---|
| | | Change in %-Volume of PTV at Rx Dose | Change in Maximum Dose to Cord (cGy) |
| 1 | No effect | ≤ 1% | ≤ 45 (1%) |
| 2 | Inconvenience | ≤ 2% | ≤ 90 (2%) |
| 3 | | ≤ 3% | ≤ 135 (3%) |
| 4 | Minor dosimetric error | ≤ 4% | ≤ 180 (4%) |
| 5 | Limited toxicity or tumor underdose | ≤ 5% | ≤ 225 (5%) |
| 6 | | ≤ 10% | ≤ 450 (10%) |
| 7 | Potentially serious toxicity or tumor underdose | ≤ 15% | ≤ 675 (15%) |
| 8 | | ≤ 20% | ≤ 900 (20%) |
| 9 | Potentially very serious toxicity or tumor underdose | > 20% | > 900 (20%) |
| 10 | Catastrophic | Severe Event | Severe Event |

## Sample TG-142 FMEA Analysis

- In the following presentation, we will present two samples of using FMEA analysis for TG-142
  - Daily QA
  - Monthly QA

## Analysis 1: Daily QA (Non-SRS)

- Output (3%)
- Laser localization (1.5mm)
- ODI @ iso (2mm)
- Jaws vs. light field (2mm)
- MV/kV/CBCT*: position/reposition (2mm)
- MV/kV/CBCT: imaging vs. treat. isocenter (2mm)
- Linac safety: door interlock, door operation, A/V, radiation area monitor, beam on indicator
- Imaging safety: collision interlocks

TG-142 recommendation

## Occurrence: Daily QA (Non-SRS)

| Daily QA Test | Number of Adjustments | Occurrence (% of total days of operation) |
|---|---|---|
| Output | 86 | 3.7% (=86/2348) |
| Laser | 19 | 0.8% |
| ODI | 2 | 0.09% |
| Jaws vs. Light Field (LF) | 0 | < 0.05% |
| Imaging Pos/Repos | 0 | < 0.05% |
| Imaging vs. Tx Iso | 0 | < 0.05% |
| Imaging Safety | 0 | < 0.05% |
| Linac Safety | 0 | < 0.05% |

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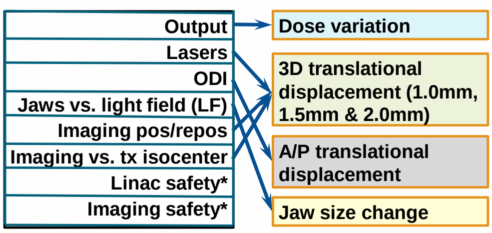
## Severity: Associated Errors

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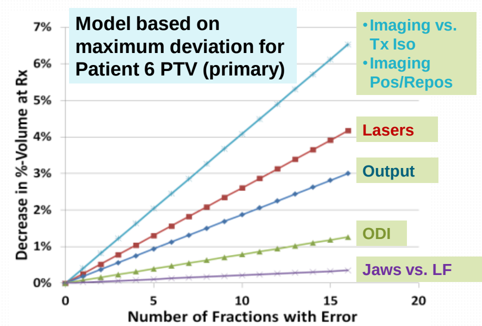
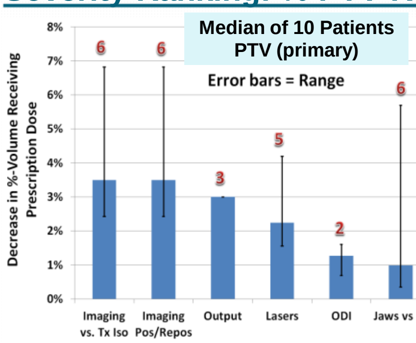
## Severity: %-PTV Reduction @Rx




## Severity Ranking: %-PTV Reduction




| R | % PTV Rx dose change | Change in max cord dose (cGy) |
|---|---|---|
| 1 | ≤ 1% | ≤ 45 (1%) |
| 2 | ≤ 2% | ≤ 90 (2%) |
| 3 | ≤ 3% | ≤ 135 (3%) |
| 4 | ≤ 4% | ≤ 180 (4%) |
| 5 | ≤ 5% | ≤ 225 (5%) |
| 6 | ≤ 10% | ≤ 450 (10%) |
| 7 | ≤ 15% | ≤ 675 (15%) |
| 8 | ≤ 20% | ≤ 900 (20%) |
| 9 | > 20% | > 900 (20%) |
| 10 | Severe Event | Severe Event |

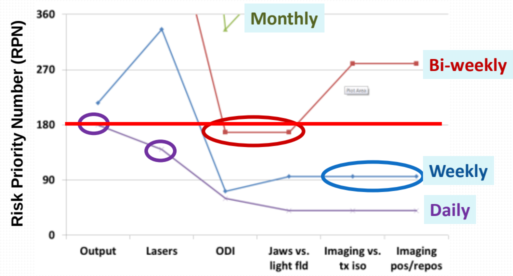
## Daily QA: Weighted RPN

| QA Frequency → | Daily | Weekly | Bi-weekly | Monthly | Bi-monthly |
|---|---|---|---|---|---|
| Errors present (days) | 1 | 5 | 10 | 22 | 44 |
| Output | 180 | 216 | 504 | 1008 | 1476 |
| Lasers | 140 | 336 | 588 | 1307 | 1913 |
| ODI | 60 | 72 | 168 | 336 | 492 |
| Imaging vs. Tx Iso | 40 | 96 | 280 | 448 | 656 |
| Imaging Pos/Repos | 40 | 96 | 280 | 448 | 656 |
| Jaws vs. LF | 40 | 96 | 168 | 448 | 656 |

Patient-Load-Weighted RPN: Occurrence * Severity (QA frequency) * Number of Patients Affected (QA frequency)

Examples: Daily-RPN = 9 * 1 * 20 = 180
Weekly-RPN = 9 * 1 * 24 = 216 (added 4 new patients)

## Daily QA: Weighted RPN

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## Summary: New Frequencies for TG142 Daily QA (Non-SRS)

| Daily: | Weekly: | Bi-Weekly: |
|---|---|---|
| > Output | > Imaging vs. Tx Iso | > ODI |
| > Lasers | > Imaging Pos/Repos | > Jaws vs. LF |

Note: All tests performed by therapist

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## Analysis 2: Monthly QA (Non-SRS)

### Output

**Dosimetry**

X-ray output constancy
Electron output constancy
Backup monitor chamber constan

### Mechanicals

**Mechanical**

Light/radiation field coincidence[b]
Light/radiation field coincidence[b] (asymmetric)
Distance check device for lasers compared with front pointer
Gantry/collimator angle indicators (@ cardinal angles) (digital only)
Accessory trays (i.e., port film graticle tray)
Jaw position indicators (symmetric)[c]
Jaw position indicators (asymmetric)[d]
Cross-hair centering (walkout)
Treatment couch position indicators[e]
Wedge placement accuracy
Compensator placement accuracy[f]
Latching of wedges, blocking tray[g]
Localizing lasers

### Imaging

**Planar MV imaging (EPID)**

Imaging and treatment coordinate coincidence (four cardinal angles)
Scaling[b]
Spatial resolution
Contrast
Uniformity and noise

**Planar kV imaging[d]**

Imaging and treatment coordinate coincidence (four cardinal angles)
Scaling
Spatial resolution
Contrast
Uniformity and noise

**Cone-beam CT (kV and MV)**

Geometric distortion
Spatial resolution
Contrast
HU constancy
Uniformity and noise

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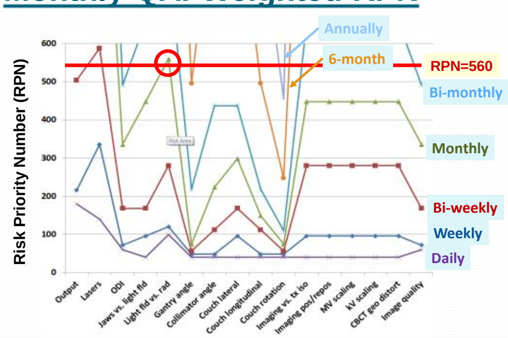
## Monthly QA: Weighted RPN

| | Daily | Weekly | Bi-weekly | Monthly | Bi-monthly |
|---|---|---|---|---|---|
| Error Present (Days) | 1 | 5 | 10 | 22 | 44 |
| Lasers | 140 | 336 | 588 | 1307 | 1913 |
| Output | 180 | 216 | 504 | 1008 | 1476 |
| Light Field vs. Rad | 100 | 120 | 280 | 560 | 820 |
| >Imaging vs. Tx Iso, >Imaging Pos/Repos, >Scaling | 40 | 96 | 280 | 448 | 656 |
| Jaws vs. LF | 40 | 96 | 168 | 448 | 656 |
| Image Quality, ODI | 60 | 72 | 168 | 336 | 492 |
| Couch Lateral | 40 | 96 | 168 | 299 | 437 |

Patient-Load-Weighted RPN: Occurrence * Severity (QA frequency) * Number of Patients Affected (QA frequency)

To keep RPN number ≤ 560 (largest seen on monthly QA), then…..

## Monthly QA: Weighted RPN




## Summary: New Frequencies for TG142 Monthly QA (Non-SRS)

| Monthly: | Bi-Monthly: | Semi-annual: | Annual: |
|---|---|---|---|
| > Output<br>> Lasers<br>> Jaws vs. LF<br>> LF vs. Rad<br>> Imaging vs. tx iso<br>> Image scaling<br>> Imaging pos/repos | > Collimator<br>> Couch Lat<br>> ODI<br>> Image quality | > Gantry<br>> Couch lng | > Couch angle |

Note: All tests performed by physicist

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## Comparison to Medical Physics Practice Guideline (MPPG) for IGRT

| | Recommended Frequency | | |
|---|---|---|---|
| Test | TG-142 | This Study | MPPG |
| Imaging vs. Tx iso | Daily | Weekly | Weekly |
| Position/Reposition | Daily | Weekly | Weekly |
| Image scaling / Geometric distortion | Monthly | Monthly | Semi-annually |
| 2D image quality | Monthly | Bi-monthly | Annually |
| 3D image quality | Monthly | Bi-monthly | Annually |

Note: image quality includes contrast, spatial resolution, and uniformity

*Reference: J Fontenot, et al. AAPM Medical Physics Practice Guidelines 2.a: Commissioning and quality assurance of X-ray based image-guided radiotherapy systems. JACMP 15(1), 2014.*

## Efficient and Effective Linac QA

- "…the QA program should be flexible enough to take into account quality, costs, equipment condition, available test equipment, and institutional needs."

  – TG-142

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## Efficient and Effective Linac QA

- Depend upon equipment & patient population
- Focus on tests with high severity and/or high occurrence ranks
- Varian 21EX Linacs & H&N IMRT patients:
  - Focus on lasers and output
  - Daily QA: consider reducing imaging QA to weekly frequency, certain mechanicals to bi-weekly frequency
  - Monthly QA: consider reducing frequency of image quality QA & certain mechanical QA tests

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*Thanks for your attention!*

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