AAPM TG-100: A new paradigm for quality management in radiation therapy

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Disclosures

• I have nothing to disclose
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TG100 analysis of causes of failure for IMRT

- Human failure: 35%
- Lack of standardized procedures: 15%
- Inadequate training: 15%
- Inadequate communication: 10%
- Hardware/Software failure: 9%
- Lack of resources: 6%
- Design failure: 5%
- Inadequate commissioning: 3%
- Defective materials/tools: 2%
Recent reports

As technology and processes change

➢ **Retrospective** approaches to QM are not sufficient
➢ All-inclusive QC checks may not be feasible
➢ Develop proactive approaches to failure modes
➢ Evaluate risks from each failure mode
➢ Develop risk based approaches to QM
Safety approach in industry

• Hazard identification and control approach is the basis for safety planning procedures for manufacturing

• The design phase of the ISO safety strategy includes
  - identifications of hazards
  - assessment of the associated risk
  - removal of the hazards as much as practicable
Quality management in industry

- Systematic application of specific tools that improve process controls producing more consistent and closer to optimal outcomes and reduce the risk of mistakes, errors or hazardous outcomes
Process controls

• Process controls for grilling a steak
  – Experience/training – how much charcoal to pile in the middle of the grill, etc.
  – Measurement tools – watch (steak goes on the grill 20 minutes after igniting the coals)
  – Because there are some variables that are difficult to control – meat thermometer (135 deg. F)
Healthcare environment

• Can the concept of risk identification and process control be applied to healthcare to improve the quality of care for patients?
• Yes, of course. Healthcare situations readily lend themselves to a similar risk identification and control approach.
What is risk?

- Risk: frequently defined as the answers to three questions
  - What can go wrong?
  - How likely is it to go wrong?
  - What are the consequences if it goes wrong?
Risk assessment

- Risk assessment is the process of analyzing the hazards involved in a process
- Many risk assessment and analysis tools/techniques exist in industry
- These tools can be easily adapted to RT to enhance safety and quality of treatment process
- TG100 used some of these tools to develop new guidelines for RT QM
Risk assessment tools

- Process tree (mapping)
- Failure mode and effects analysis (FMEA)
- Fault tree analysis (FTA)
- Establishment of a risk based QM program
What is a process tree?

- Visual representation of the various steps in a process
- Demonstrates the flow of steps from process start to end
- Delineate and then understand the steps in the process
Simple example of a process map

1. Patient enters linac vault
2. Setup patient to CT marks
3. Shift
4. Treat
5. TP shift instruction

Courtesy: Darek Brown
Complicated example: TG100 IMRT process tree

Start of tx

- Patient database information entered
- CT simulation

Immobilization and positioning

Other pre-treatment imaging

- Transfer images and other DICOM data
- RTP anatomy contouring

Initial treatment planning directive

Treatment planning

Plan preparation

Plan approval

Initial tx (Day 1)

End of tx

Subsequent tx (Day N)
FMEA

• A risk assessment tool used to identify weaknesses or deficiencies (inadequate controls) in processes that could lead to mistakes, errors, and potential hazardous outcomes
Strategy for improving patient safety: FMEA & FTA

• Begins with a complete and thorough understanding of the process – flow charts, process maps
• Perform a Process FMEA (P-FMEA) to identify weaknesses or inadequate controls in the process
• Develop process controls that either reduce the risk or improve the process
• Use FTA to identify root causes of potential process failures and develop recommendations to improve quality control of the process
Completing an process FMEA

- **Create a team**
  - Ideally cross functional representing every function involved in the process
  - Oncologists, medical physicists, dosimetrists, therapists, IT personnel, administrators
  - Effort should be led by a facilitator trained in or familiar with the tools used in the analysis
  - Consider providing training
Completing an process FMEA

• Select a process – key step
  - Scale is important
  - Opportunity – Quality issues, past problems, not happy with the level of success, …
  - Realistic opportunity to make improvements
  - Complexity or size
Process FMEA – for each step in a process

Failure Modes

- Detect
- Cause

Effects

FM: Inability of a process step to produce the desired optimal outcome
Completing an FMEA

For a given process:

<table>
<thead>
<tr>
<th>Step</th>
<th>Potential failure modes</th>
<th>Potential causes of failure</th>
<th>Potential effects of failure</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>RPN</th>
<th>Comment</th>
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</tbody>
</table>

$$\text{RPN} = \text{O} \times \text{S} \times \text{D} \quad [ 1 \leq \text{RPN} \leq 1000 ]$$
Completing an FMEA

1. For each process step – identify all potential failure modes – always best to define failure modes as “not” meeting process requirements

2. For each potential failure mode – identify all of the causes that could produce that failure
   a. Focus on process related causes of failure modes
Completing an FMEA

3. For each potential failure mode – identify the effects of that failure mode
Completing an FMEA

4. Current controls – judge the current capabilities of the process controls to:
   a. Prevent the cause of a failure from occurring
   b. Detect a failure when it occurs
   c. Moderate the severity of a failure when it occurs
Completing an FMEA

• Most effective and lowest cost controls are those that prevent causes of failure modes
FMEA ranking scales for Occurrence, Detection, Severity*

Occurrence of the cause of failure mode: O  
Detection of failure mode: D  
Severity of the effect when failure mode occurs: S

<table>
<thead>
<tr>
<th>Rank</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Severity</th>
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<tbody>
<tr>
<td>1</td>
<td>Remote probability</td>
<td>Always</td>
<td>No effect</td>
</tr>
<tr>
<td>2</td>
<td>Low probability</td>
<td>High likelihood</td>
<td>Minor effect</td>
</tr>
<tr>
<td>3</td>
<td>Moderate probability</td>
<td>Moderate likelihood</td>
<td>Moderate effect</td>
</tr>
<tr>
<td>4</td>
<td>Moderate probability</td>
<td>Moderate likelihood</td>
<td>Moderate effect</td>
</tr>
<tr>
<td>5</td>
<td>High probability</td>
<td>Low likelihood</td>
<td>Serious effect</td>
</tr>
<tr>
<td>6</td>
<td>High probability</td>
<td>Low likelihood</td>
<td>Serious effect</td>
</tr>
<tr>
<td>7</td>
<td>High probability</td>
<td>Low likelihood</td>
<td>Serious effect</td>
</tr>
<tr>
<td>8</td>
<td>Very high probability</td>
<td>Very low likelihood</td>
<td>Injury</td>
</tr>
<tr>
<td>10</td>
<td>100% probable</td>
<td>Never</td>
<td>Death</td>
</tr>
</tbody>
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FMEA ranking scales for Occurrence, Detection, and Severity.  

*Not used by TG100
Completing an FMEA

- Risk Priority Number (RPN)
  - Occurrence ranking X Severity ranking X Detection ranking
  - Range of RPNs (1 - 1000)
  - RPN of 125 or higher is problematic either in terms of safety or process capability
  - Typical scenario – RPNs over 400!
  - Highest RPNs must be addressed first
  - Then work down to lower risk process steps
Completing an FMEA

• Risk Priority Number (RPN)
  – Beware of patterns potentially hidden by low overall RPNs
    ➢ Occurrence = 10, Severity =10, Detection=1 - RPN of 100 but …..
    …..
    ➢ Occurrence=1, Severity=10, Detection=10 – RPN of 100 but ….  
    ➢ Severity of 10 – even if Occurrence and Detection are both a 1  
      can you or do you want to risk it?
Top/Down FMEA approach

- Start with the major “branches” of the selected process
- Perform a PFMEA to identify which “branches” are the weakest (most likely to produce sub-optimal results or errors/mistakes)
- Drill down deeper into those “branches” – more detailed process map and PFMEA
Fault Tree

Evaluates propagation of failures

Visual representation of propagation of failures

Begins on the left with a failure mode

Works backwards in time

(to the right to identify causes of failure)
Fault Tree

Evaluates propagation of failures

Visual representation of propagation of failures

Begins on the left with a failure mode

Works backwards in time (to the right to identify causes of failure)

Error in
calculated value
for patient

Error in
data

Error in
data input

Error in
calculation algorithm

Error in
prescription
Fault Tree

- Error in calculated value for patient
- Error in calculation
- Error in QA
- Error in data
- Error in QC
- Error in data input
- Error in QC
- Error in calculation algorithm
- Error in QC
- Error in prescription
- Error in QC
Summary

• Current QA guidance documents are based on prescriptive approaches evaluating technical performances of radiotherapy equipment

• There has been a growing recognition that quality and safety impairment arises from weakness in radiotherapy processes

• Hence the change in approach in QM in TG100
Our job is not to prevent errors, but to keep the errors from injuring the patients.

Lucian Leape

It is useful to report all accidents before consequences appear.

It is impossible to make anything foolproof because fools are so ingenious.

Arthur Bloch, Murphy’s law