Risk Assessment for Radiosurgery

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Objectives

1. Learn how to characterize radiosurgery process for risk assessment
2. Be able to identify potential failure modes for radiosurgery procedures and learn risk mitigation techniques
3. Be able to customize FMEA examples and templates for use in radiosurgery clinic
**FMEA**

- FMEA is a systematic method of identifying and preventing product and process problems before they occur.
- FMEA is focused on preventing problems, enhancing safety, and increasing customer (patient) satisfaction.
- Emphasis on Failure Prevention.

**Risk assessment tools**

- Process Tree (Mapping)
- Failure Modes and Effects Analysis (FMEA)
- Fault Tree Analysis (FTA)
- Establishment of a risk-based QM program
Risk assessment for Radiosurgery

- Very high dose delivered in single fraction
- No do-overs for radiosurgery
- Comprehensive & intensive safety layers required
- A wide variety of techniques for radiosurgery
- Consequence of failure mode could be very serious

Surface Image Guided Radiosurgery

- Motivation
  - Process/Device changes
- Technologies
  - Eclipse, ARIA, TrueBeam, VisionRT
- Number of workflow steps
  - 91 (16 were specific to surface image guidance)
- FMEA Team: 4 Phys, Dosi, 2 RTTs

### Failure Modes and Effects Analysis

<table>
<thead>
<tr>
<th>Step</th>
<th>Potential Failure Modes</th>
<th>Potential Cause of Failure</th>
<th>Potential Effects of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>84. Monitor SIG deltas to ensure patient movement is within tolerance</td>
<td>Not performed</td>
<td>Inattention</td>
<td>Geometric miss</td>
</tr>
<tr>
<td></td>
<td>SIG system fails to detect patient movement</td>
<td>SIG system failure</td>
<td>Geometric miss</td>
</tr>
<tr>
<td></td>
<td>SIG system indicates movement, yet patient did not move</td>
<td>SIG system failure</td>
<td>Make unnecessary shifts</td>
</tr>
<tr>
<td></td>
<td>Not all metrics were being monitored</td>
<td>Inattention</td>
<td>Geometric miss</td>
</tr>
</tbody>
</table>

### Processes with the highest RPN (overall)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Step</th>
<th>Potential Failure Modes</th>
<th>Potential Cause of Failure</th>
<th>Potential Effects of Failure</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>31. Contour critical structures</td>
<td>Inaccurate contours</td>
<td>Poor image quality. Poor registration. Insufficient training.</td>
<td>Excessive dose to critical structure</td>
<td>6</td>
<td>8</td>
<td>6</td>
<td>288</td>
</tr>
<tr>
<td>1</td>
<td>79. Apply CBCT couch shifts</td>
<td>Inaccurate registration</td>
<td>Poor image quality. Inattention.</td>
<td>Geometric miss</td>
<td>6</td>
<td>8</td>
<td>6</td>
<td>288</td>
</tr>
<tr>
<td>2</td>
<td>29. Previous tx CT registered to planning CT</td>
<td>Inaccurate registration</td>
<td>Failed to save registration. Registration error</td>
<td>Retreat previous target.</td>
<td>5</td>
<td>8</td>
<td>7</td>
<td>280</td>
</tr>
<tr>
<td>4</td>
<td>39. Review OAR statistics</td>
<td>Critical structure doses not checked</td>
<td>Inattention</td>
<td>Excessive dose to critical structure</td>
<td>5</td>
<td>8</td>
<td>6</td>
<td>240</td>
</tr>
<tr>
<td>4</td>
<td>29. Previous tx CT registered to planning CT</td>
<td>Not done</td>
<td>Inattention</td>
<td>Retreat previous target.</td>
<td>5</td>
<td>8</td>
<td>6</td>
<td>240</td>
</tr>
</tbody>
</table>
Processes with the highest RPN (SIG)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Step Description</th>
<th>Failure Modes</th>
<th>Cause of Failure</th>
<th>Effects of Failure</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Monitor SIG deltas to ensure patient movement is within tolerance</td>
<td>SIG system fails to detect patient movement</td>
<td>SIG failure</td>
<td>Geometric miss</td>
<td>3</td>
<td>8</td>
<td>8</td>
<td>192</td>
</tr>
<tr>
<td>26</td>
<td>Monitor SIG deltas to ensure patient movement is within tolerance</td>
<td>Not done</td>
<td>Inattention</td>
<td>Geometric miss</td>
<td>4</td>
<td>8</td>
<td>4</td>
<td>128</td>
</tr>
<tr>
<td>26</td>
<td>Ensure surface imaging system passed QA</td>
<td>Not checked</td>
<td>Inattention</td>
<td>System may be out of tolerance</td>
<td>6</td>
<td>4</td>
<td>4</td>
<td>96</td>
</tr>
<tr>
<td>26</td>
<td>Monitor SIG deltas to ensure patient movement is within tolerance</td>
<td>Not all metrics were monitored</td>
<td>Mental lapse</td>
<td>Pt position may be out of tolerance</td>
<td>4</td>
<td>6</td>
<td>4</td>
<td>96</td>
</tr>
<tr>
<td>30</td>
<td>Monitor SIG deltas to ensure patient movement is within tolerance</td>
<td>SIG system indicates movement, yet patient did not move</td>
<td>SIG system ISO drift</td>
<td>Prolong treatment to investigate movement</td>
<td>10</td>
<td>3</td>
<td>3</td>
<td>90</td>
</tr>
</tbody>
</table>

Fault Tree Analysis

- SIG system failure
- SIG camera malfunction
- Camera occlusion
- Inaccurate calibration
- QA not performed recently
- SIG system out of tolerance
Corrective Actions

- Corrective actions are meant to:
  - Decrease lack of detectability
  - Decrease occurrence
  - Decrease severity

Root factor: System not properly calibrated
CA: Update procedure to include QA of SIG system on tx day

Root factor: QA not performed recently
CA: Create a daily checklist to ensure daily QA passed

Root factor: SIG system not monitoring surface
CA: Require active monitoring of SIG system by a covering physicist.

Revised RPNs

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Corrective Actions

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<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>84.</td>
<td>SIG system fails to SIG failure detect patient movement</td>
<td>SIG failure</td>
<td>Geometric miss</td>
<td>2</td>
<td>8</td>
<td>5</td>
<td>80</td>
</tr>
</tbody>
</table>
Example 1. Conventional Linac SRS

- Motivation
  - Risk assessment for newly developed SRS program/process
- Technologies:
  - Brainlab conical collimators and iPlan, 21iX linac, ARIA, Brainlab noninvasive frame
- FMEA Team: 2 Phys, 2 MDs, 2 Dosi, 3 RTTs, 2 Administrators


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Presumed high-risk items

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient orientation incorrect on MRI</td>
<td>213</td>
</tr>
<tr>
<td>KV/CBCT isocenter out of tolerance</td>
<td>61</td>
</tr>
<tr>
<td>Incorrect jaw size used for treatment</td>
<td>56</td>
</tr>
<tr>
<td>Incorrect cone size used for treatment</td>
<td>44</td>
</tr>
<tr>
<td>Plan not completed on time</td>
<td>27</td>
</tr>
</tbody>
</table>

Highest ranking FMs

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient moves during treatment</td>
<td>228</td>
</tr>
<tr>
<td>Patient orientation incorrect on MRI</td>
<td>213</td>
</tr>
<tr>
<td>Incorrect volumes in contours or variability</td>
<td>207</td>
</tr>
<tr>
<td>Mask does not immobilize sufficiently</td>
<td>192</td>
</tr>
<tr>
<td>Contours accidentally changed during review</td>
<td>161</td>
</tr>
</tbody>
</table>
Example 2. Conventional Linac SRS

- **Motivation**
  - Risk assessment for current (since 2008) intracranial SRS
- **Technologies**
  - Clinac 600, circular cones with Xknife head frame
  - FMEA Team = 3 Phys, 8 MDs, 4 RTTs, RN, 2 MD residents


<table>
<thead>
<tr>
<th>FM</th>
<th>RPN</th>
<th>Corrective measure</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choice wrong collimator</td>
<td>180</td>
<td>Second check by a physician, a physicist, and a radiation therapist.</td>
<td>36</td>
</tr>
<tr>
<td>Wrong coordinates on LTLF device</td>
<td>135</td>
<td>Exportation isocenter data to the localization independent system: Vision RT</td>
<td>27</td>
</tr>
<tr>
<td>Wrong volume (GTV, OARs)</td>
<td>70</td>
<td>Contours review</td>
<td>14</td>
</tr>
<tr>
<td>Exchange of clinical documentation and/or images</td>
<td>63</td>
<td>Cross-checks physician-nurse</td>
<td>21</td>
</tr>
</tbody>
</table>

Example 2. Conventional Linac SRS

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Other risk assessment techniques

**FMEA**

1. **START** Identify failure mode
2. Determine the effects of each failure
3. Determine the cause of each failure
4. Evaluate severity ranking (S)
5. Evaluate occurrence ranking (O)
6. Evaluate detectability ranking (D)
7. Calculate risk priority number (RPN)
8. Correction action required?
   - YES → STOP
   - NO → Recommended corrective action

**HFMEA**

1. **START** Identify failure mode
2. Does this risk involve a sufficient likelihood of severity and frequency to warrant that it be controlled? (Is the risk score high?)
   - YES
     - YES → STOP
     - NO → Proceed to re-HFMEA step 5
   - NO
     - Does an effective control measure exist for the identified risk? (Controlability)
       - YES → STOP
       - NO → Proceed to re-HFMEA step 5
     - Is the risk so obvious and readily apparent that a control measure is not warranted? (Detectability)
       - YES → STOP
       - NO → Proceed to re-HFMEA step 5

**Occurrence**

- **Frequent**
  - Very High
  - High
  - Moderate
  - Low
- **Occasional**
  - Very High
  - High
  - Low
  - Very Low
- **Uncommon**
  - High
  - Low
  - Very Low
- **Remote**
  - Low
  - Very Low

**Severity**

- **Catastrophic**
  - Very High
  - High
  - Moderate
  - Low
- **Major**
  - Very High
  - High
  - Moderate
  - Low
- **Moderate**
  - Very High
  - High
  - Moderate
  - Low
- **Minor**
  - Very Low
  - Low
  - Very Low
  - Very Low

**Hazard Scoring Matrix**

<table>
<thead>
<tr>
<th>Occurrence</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
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**Decision Tree**

- **START** Identify failure mode
- Does this risk involve a sufficient likelihood of severity and frequency to warrant that it be controlled? (Is the risk score high?)
  - YES → STOP
  - NO
    - Does an effective control measure exist for the identified risk? (Controlability)
      - YES → STOP
      - NO
        - Is the risk so obvious and readily apparent that a control measure is not warranted? (Detectability)
          - YES → STOP
          - NO → Proceed to re-HFMEA step 5