Systematic Risk Analysis Based Approach to Quality Management – Process Failure Mode and Effects Analysis

Frank Rath
University of Wisconsin
and
The Center for the Assessment of Radiological Sciences
Learning Objectives

• Basics of Process FMEA
• Steps to performing a Process FMEA
• Understanding Process FMEA outcomes and corrective actions
Process FMEA Forms

• Standard/most used Process FMEA form
### Potential Process FMEA

**Process Description**

<table>
<thead>
<tr>
<th>Review Process Step Name &amp; Seq #</th>
<th>Review Process Function</th>
<th>Potential Failure Modes</th>
<th>Potential Causes of Failures</th>
<th>Potential Effects of Failures</th>
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FMEA Dates  | Original Analysis  | Latest Revision  | Approved By  |
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Resulting: O | S | D | RPN

Approved By: ____________________________
Standard Process FMEA Forms

• Software is available
• Most use spread sheets
Completing a P FMEA

1. List each process step from the process map in the first column of the P-FMEA form
2. For each process step – identify each intended function or outcome – be as specific as possible using targeted process outcome metrics if available
High Level Flow Chart - Physician Completing Rounds

1. Enter Patient's Room
2. Review Chart
3. Question Patient
4. Examination Required
   - Yes
     - Examine Patient
   - No
     - Wash Hands to Sanitize
       - Yes
         - Find Sanitizer
         - Dispense Sanitizer into Palm of Hand
       - No
         - Spread Sanitizer to Cover Surface of Hands, Etc.
5. Leave Room
For the Process Step – “Wash hands to sanitize”

• What are the intended process functions or outcomes?
Completing a P FMEA

3. For each process step – identify all potential failures – always best to define failure modes as “not” meeting process requirements or intended outcomes

– What are the potential failure modes associated with the process step “Wash hands to sanitize”? 
Completing a P FMEA

4. For each potential Failure Mode – identify all of the causes that could produce that failure.
   - Focus on process related causes of failure modes
     - lack of or poor:
       - training,
       - standard procedures,
       - communication
       - poor operator/device or software interface
       - work place stress
     - lack of time to complete tasks
Completing a P FMEA

• What are the process related causes for the failure mode – “hands not washed and sanitized”?
Completing a P FMEA

• What are the process related causes for the failure mode – “hands not washed and sanitized”?  
  – Forgot or decided not to  
  – Could not find or locate dispenser  
  – Dispenser empty  
  – Etc.
5. For each potential failure – identify the effects of that failure mode

- Priority of effects (safety, function, convenience)
- If an effect could occur you should consider that it will
- Always consider the worst case
Completing a P FMEA

• What are the effects or what could happen if the Failure Mode – “Hands not washed and sanitized” occurs?
Completing an P FMEA

6. Current controls – judge the capabilities of the current process controls to:
   • Prevent the cause of a failure from occurring
     – Documented work procedures or instructions, standard work, formal training programs, visual work instructions, skill set certification program, resource modeling and planning, formal process development programs, process capability studies, Statistical Process Controls, etc.
Completing an P FMEA

• Detect a failure when it occurs
  – Inspection
  – Radiation dose/location monitoring technology (21st Century Oncology)
  – Error, incident or accident detection/reporting
Completing an P FMEA

• Moderate the severity of a failure when it occurs
  – Almost impossible for radiation therapy
Completing an FMEA

- Most effective and lowest cost controls are those that prevent causes of failure modes
Completing a P FMEA

• What are some process controls (preventive, detection or severity moderating) that a clinic or hospital might have in place to insure that “wash hands to sanitize” always occurs?
Completing a P FMEA

• Judging the effectiveness of current process controls
• Occurrence, Detection and Severity rankings
Occurrence of the cause of failure mode  
Detection of failure mode  
Severity of the effect when a failure mode occurs

<table>
<thead>
<tr>
<th>Rank</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Probability that the cause will occur and lead to the failure mode</td>
<td>Probability that the failure mode will be detected before resulting in the end effect</td>
<td>Seriousness of the end effect when it occurs</td>
</tr>
<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>
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<tr>
<td>3</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4</td>
<td>Moderate probability</td>
<td>Moderate likelihood</td>
<td>Moderate effect</td>
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<td>6</td>
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<tr>
<td>7</td>
<td>High probability</td>
<td>Low likelihood</td>
<td>Serious effect</td>
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<tr>
<td>8</td>
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<tr>
<td>9</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>
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</table>

FMEA ranking scales for Occurrence, Detection and Severity.
 Completing a P FMEA

7. Assessing risk – calculate the Risk Priority Number (RPN) for each process step function/failure mode/cause combination
   • RPN = Occurrence ranking X Severity ranking X Detection ranking
### Process FMEA

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<tr>
<td>X</td>
<td>Y</td>
<td>Z</td>
<td>A D</td>
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<td>9 8 6 432</td>
<td></td>
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<td>Gregory 96</td>
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<td>6 6 9 324</td>
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<td>Laura 48</td>
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**Review Process Step Function**

**Potential Failure Modes**

**Potential Causes of Failures**

**Potential Effects of Failures**

**Current Controls**

**Existing Conditions**

**Recommended Actions**

**Resulting**

<table>
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<th>Occ</th>
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• Risk Priority Number (RPN) –
  – Range of RPNs (1 -1000)
  – Typical scenario –RPNs over 400!
  – Highest RPNs must be addressed first
  – Then work down to lower risk process steps
• 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?
Completing a P FMEA

8. Developing corrective actions

– Should reduce the likelihood that the cause of a Failure Mode will occur

– Increase the likelihood that a Failure Mode will be detected before resulting in a negative effect

– The severity of the effects resulting from a Failure Mode are moderated (difficult in RT)
Completing a P FMEA

9. Estimate the Occurrence, Detection and Severity ranking (and resulting RPN) based on the impact the recommended actions will have
Completing a P FMEA

• Process maps and P FMEA are ongoing efforts to drive continuous improvement and/or assess the impact that technology changes will have on a specific process.
Next – Perform a Fault Tree Analysis to Identify Root Causes of High Probability Failures Identified in FMEA

- Fault tree analysis (FTA) is a top-down approach to failure analysis, starting with a potential undesirable event (accident) called a TOP event, and then determining all the ways it can happen.
- TG100 “poured” the Process FMEA into a Fault Tree to get a visual representation of the most frequent root causes of failure modes.
  - Most common root causes were lack of formal procedures or work instructions, lack of communication and lack of time/stress.
Case Study

- Radiotherapy & Oncology
  - Journal of the European Society for Therapeutic Radiology and Oncology and affiliated to the Canadian Association of Radiation Oncology
  - Applying failure mode effects and criticality analysis in radiotherapy: Lessons learned and perspectives of enhancement; *Radiotherapy and Oncology, Marta Scorsetti, Chiara Signori, Paola Lattuada, Gaetano Urso, Mario Bignardi, Pierina Navarria, Simona Castiglioni, Pietro Mancosu, Paolo Trucco*
From the Discussion Section of this Article

Our study attempted to enhance patient safety performance in a radiation oncology department by introducing clinical risk management principles and techniques, achieving the following goals:

1) to set up an efficient and systematic procedure to assess the risk of the entire RT process;
2) to disseminate patient safety and risk management culture among all the professionals involved (physicians, physicists, technicians and clerks).

It is likely that the study contributed to an observed reduction in the number of errors reported, mainly by means of the improvement of technical procedures, quality checks and communication flows. This reduction was particularly evident as regards errors in patient identification, that had been evaluated as the FM with the highest CI by the experts.

As an example we report the fact that, after the present study, the adverse events registered by the hospital incident reporting system, showed an important decrease in the RT unit, in terms of severity of the event.

In fact, while the criticalities or near misses reported and corrected together with the risk management team increased, thanks to the strict involvement and awareness of the RT operators, the adverse events and near misses that could be classified as dangerous for the patient were set at zero. For example, errors in patient identification during the treatment, happened a pair of times in the months before the present study, were never pointed out in the following year.

This was probably due to the implementation of new procedures introduced as corrective actions derived from the FMECA analysis.

Besides this, the FMECA study was very well accepted by the operators and further increased their commitment to patient safety, mainly thanks to an improved understanding of clinical risk; they became very proactive during FMECA sessions and after that they showed a continuous effort in promoting patient safety. Thus our experience further supports one of the major reported benefits of prospective analysis in clinical risk management, that is the promotion of organisational learning and the enforcement of safety culture among healthcare professionals [15].
Exercise

• Begin a P FMEA on the process you mapped.
  – Listing at least two process steps,
  – List several functions for each step listed,
  – List several causes for one of the functions listed.
  – List all of the current process controls that your team collectively has in place to prevent the causes from occurring, detecting Failure Mode and moderating the severity of the Failure Mode when it does occur
  – Calculate the Occurrence, Detection and Severity rankings and the RPN
  – Identify corrective actions for the highest RPNs
  – Enter new occurrence, detection and severity rankings based on the expected impact the corrective actions will have and the resulting RPN
Questions?