

General

- RPN = S x O x D. Criticality = S x O. These are indicators of risk only. Avoid comparisons by not applying thresholds.
- Bring quality and field performance data, if available, to better reflect Occurrence.
- Do not worry about high numbers during the FMEA development; this is a normal part of the process in order to obtain accurate results.
- After corrective action has been **identified** estimate and record new Sev, Occ, & Det.
- When identifying processes for risk assessment, consider incident reports, loss experience/claims data, worker's compensation reports, and anything that even intuitively, warrants analysis. Consider, also, those accidents that have high severity or occur with great frequency.
- Catastrophic events are sentinel events and any of the Sentinel Event Alerts issued by the JCAHO may yield opportunities for possible analysis.
- Although JCAHO at least one proactive risk assessment be performed each year, your organization may benefit from conducting as many as possible.

Process Function / Requirements

- Integrated into the FMEA to insure all process steps are analyzed for risk.
- Performance requirements describe what the process needs to do to satisfy a customer, size, location, presence, etc.
- It can help in identifying all patients and effects.
- Describe in verb / noun format.
- Assign a unique operation number for each step in the process including sub-processes.
- Use common terms wherever possible

Potential Failure Mode

- Remember "Potential". The Failure Mode may not have occurred in the past. But, can it happen?
- Be specific.
- Do not consider Failure Modes from incoming, suppliers, or design.
- Most processes will have multiple Failure Modes.
- Ignore the Process Controls.
- Do not rush. Allow ample discussion time to ensure the team identifies all possible potential Failure Modes.

Potential Effect of Failure (Severity)

- Ask yourself, What is the effect if there are no Process Controls?
- **Consider** all patient effects, including the End User. Do not ask how far it will get, or where we will catch it? Ask what is the effect?
- Be specific. Avoid patient dissatisfied, etc.
- What can go wrong and who will sense it?
- Individually rank each effect of failure.
- Choose the highest ranked Effect for Severity.
- Consider a catastrophic event to be nearly the same as a sentinel event.
- Rank all like Effects with the same Severity

Potential Cause (Occurrence)

- Cause must be correctable and controllable.
- Avoid ambiguous phrases – "Nursing Error" or "Equipment Malfunction"
- Consider multiple causes.
- Assume equipment is manufactured to print.
- Occurrence is defined as how often the cause leads to the Failure Mode.

Current Process Controls (Detection)

- 2 types; prevent the Cause / Failure Mode; detect the cause, / Failure Mode before causing patient harm.
- What detects or prevents a failure?
- Individually rank each Detection type Process Control.
- Prevention type Controls should reflect in the occurrence ranking.
- Choose the lowest ranked Control-that is the best "gate" to rely on to Detect the problem.