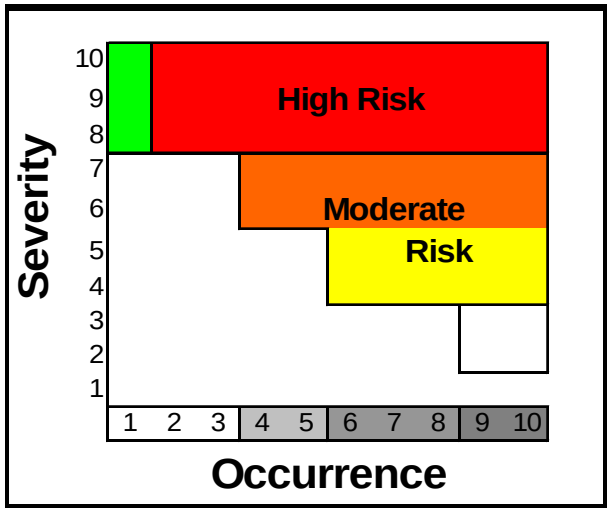
Severity Attribute

Outcome Possibilities	Severity
A. Terminal injury or death Terminal injury with warning system	10 9 8
B. Major injury	7
C. Minor injury	6
D. Major system problem May affect the patient	5 4
E. Moderate system problem May affect the patient	3 2
F. Slight annoyance May affect the system	1

Occurrence Ranking

Likelihood of Occurrence	Probability	Occurrence Ranking
A. Very High Documented, almost certain error	1 in 20 1 in 10	10 9
B. High Documented and frequent	1 in 100 1 in 50	8 7 6
C. Moderate Documented, but infrequent	1 in 200	5 4
D. Low Possible, but no known data	1 in 5000	3 2
E. Remote No known occurrence	1 in 10,000	1



Detection Ranking

Likelihood of Occurrence	Probability	Occurrence Ranking
A. Very High System will always detect error	9 out of 10	1
B. High Error likely to be detected before product reaches patient	7 out of 10	2 3
C. Moderate Moderate likelihood of detection before product reaches patient	5 out of 10 4 out of 10	4 5 6
D. Low Low likelihood that error will be detected before product/service reaches patient	2 out of 10 1 out of 10	7 8
E. Remote Detection not possible at any point within system	0 out of 10	9 10

Quality Associates International
(248) 280 – 2800
AUS 011 61 (03) 9770 – 2842
www.quality-one.com

The FMEA Process: Key Questions to Be Asked and Answered at Each Step

Step 1. Select a high-risk process and assemble a team
- What processes occurring within our organization are high-risk ones that are likely to impact the safety of individuals served by the organization.
- What sources can we use to identify such high-risk processes?
- What process is our "first pick" for FMEA and why?
- Who should be on the FMEA team? What role should each individual play?
- What training is needed to educate all team members about FMEA, additional performance improvement tools and techniques, and the process under study?
- What is the scope of the FMEA?

Step 2. Diagram the process
- What are the steps in the process? If an existing process, how does it currently occur and how should it occur? If a new process, how should it occur?
- How are the steps interrelated? (For example, are they sequential or do they occur simultaneously?)
- How is the process related to other health care processes?
- What tools should we use to diagram the process?

Step 3. Brainstorm potential failure modes and determine their effects
- Which steps in the process or linkages between steps could fail?
- What can go wrong with each step? (Examine each element of the process, including people, materials, equipment, methods, and environment)
- What could happen if the failure mode occurred? What might the effects be?
- What other processes or steps might be affected?

Step 4. Prioritize failure modes
- What is the likelihood that this failure would occur?
- What is the likelihood that the effects of the failure mode will reach an individual receiving care or services?
- If this failure mode occurred, how severe would the effects be?
- If this failure mode occurred, how likely is it that it would not be detected?
- What system or tool should we use to prioritize and document prioritization of failure modes?

Step 5. Identify root cause of failure modes
- What might cause each failure mode? (What are the possible proximate causes and possible root causes?)
- Might the possible root cause(s) be due to human resources issues, information management issues, environmental management issues, or leadership and communication issues, among others?
- How do we know whether we have identified all possible root causes?
- Would the potential failure mode occur if each possible cause were not present?
- Will correction or elimination of the possible root cause prevent the potential failure mode's reoccurrence?

Step 6. Redesign the process
- How can we change the process to prevent this failure mode from occurring?
- What design/redesign strategies and tools should we use? How do we evaluate their likely success?
- Who should be involved in the design/redesign process?

Step 7. Analyze and test the new process
- How will we measure if the change is successful in preventing future failure? What will be measured, by whom, and with what frequency?
- What strategy should we use to test the new process?

Step 8. Implement and monitor the redesigned process
- How will the new process be implemented?
- How will the new process be monitored? What monitoring tools will we use?
- How is the new revised process working?
- What modifications need to be made and why?