Failure Mode and Effects Analysis (FMEA, FMECA)

Presented by
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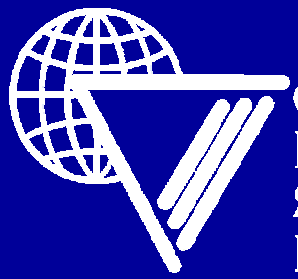
Dade Behring
28 April, 2006



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- No good deed goes unpunished.
- Every action, no matter how well intentioned, has unintended consequences that may have a negative effect,
  - Some of them will be serious and some minor
  - The goal is to use our collective knowledge to reduce the number of negative occurrences.

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Agenda

- What is an FMEA
  - What are the components of an FMEA
- How is an FMEA conducted
  - What and who are needed
  - Identifying significant risks
  - Development of mitigating actions
- Discussion of specific elements of an FMEA
- Follow up activities
  - Post action risk
- Advantages
- Disadvantages and pitfalls

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What is an FMEA - Definitions

- **Failure mode effects analysis (FMEA):** A procedure in which each potential failure mode in every subitem of an item is analyzed to determine its effect on other subitems and on the required function of the item.
- **Failure mode effects and criticality analysis (FMECA):** A procedure that is performed after a failure mode effects analysis to classify each potential failure effect according to its severity and probability of occurrence.

ASQ Quality Glossary
http://www.asq.org/glossary/f.html

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For Our Purposes

- The two can be done concurrently. Therefore:

FMEA = FME(C)A

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What is an FMEA

- Step by step approach to identifying all possible failures in a process or service
  - "Failure modes" – The ways (modes) in which something might fail. Failures are errors or defects, especially ones that affect the customer
  - "Effects analysis" A study of the consequences of those failures
  - Also documents current knowledge and actions about risks and failures for continuous improvement

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What is an FMEA (cont.)

- It is a bottom up approach to examining a process
- It is “proactive” in that it is usually conducted before the process is implemented
  - Therefore it is preventive in nature
- It is a detailed analysis of possible failures of the process and results in actions to minimize unacceptable risks
- For an FMEA to be effective, it relies on the knowledge and candor of the participants in the FMEA

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When Are FMEAs Done?

- When a new process or service is to be implemented
- When a process is revised
- When there are a enough reported negative incidents for a given process to suggest that the process needs to be reviewed

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Conducting an FMEA - Overview

- Select a process or service
- Define the process and the scope of the FMEA
- Obtain a process map (flow chart) and any appropriate procedures
- Obtain any written procedures that describe the process
- Recruit the FMEA “team”

- continued

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Conducting an FMEA - Overview (continued)

- Identify the “process experts”
  - A Facilitator for the FMEA
  - Personnel who conduct the tasks and know the process well
  - Process owner (if different than above)
  - People with knowledge of
    - Customer needs
    - Quality requirements
    - Others that may be interested in the process

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Conducting an FMEA - Overview

- Schedule the FMEA
  - The amount of time depends on the complexity of the process
- Send the preparation materials (flow chart, procedures, etc.) to the team ahead of time
- Conduct the FMEA
  - Train the team
  - Follow the “form”

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The FMEA Form (first half)

			FMEA Number			**Prepared by**				
			Process/Machine Name			**Product/Service Application**				
			Design Responsibility			**Review Date**				
Line #	Process Function or Step	Potential Failure Mode	Potential Effect(s) of Failure	Severity (S)	Potential Cause of Failure	Occurrence (O)	Current Controls	Detection (D)	Risk Priority # (S*O*D)	
1									0	
2									0	
3									0	
4									0	
5									0	
6									0	
7									0	
8									0	
9									0	
10									0	
11									0	
12									0	

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The FMEA Form (second half)

		Page	**of**				
		FMEA Date					
		Core Team					
Risk Priority # (S*O*D)	Recommended Actions	Responsibility & Target Completion Date	Actions Taken	Severity (S)	Occurrence (O)	Detection (D)	RPN (SOD)
0							0
0							0
0							0
0							0
0							0
0							0
0							0
0							0
0							0
0							0
0							0
0							0

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Guides for Entries

Column Header	What to Enter	Example
Process Step	What is being done	Filling out test requisition
Potential Failure Mode	Incorrect Name entered	Wrong patient drawn
Severity (pull down tabs)	Use Chart on Severity Tab	Numerical entry
Potential Cause	Enter Cause	Human error
Occurrence (pull down tabs)	Use occurrence codes	Numerical entry

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Guides for Entries – cont.

Column Header	What to Enter	Example
Enter Current Controls	What is done to control the potential error	Electronic form is proofread before entering
Enter Likelihood of Detection (pull down tabs)	Use detection codes	Numerical Entry
Risk Priority	**Calculated (severity X Occurrence X Detect ability**	Value between 1 and 1000
Recommended Actions	Risk mitigating actions	Develop entry checks for nonsense data

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Guides for Entries – cont.

Column Header	What to Enter	Example
Responsibility and Target Completion	Who will do it and when	R. Miller May 30, 2006
Actions Taken	List actions taken	Developed double entry system
New entries for Severity, Occurrence, and Detection	Based on Mitigation	Same as before
Is the new risk acceptable	Yes/No	If no, what else can be done?

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Severity Codes

Rating	Classification	Example
10	Dangerously high	Injury or death
9	Extremely high	Regulatory non-compliance
8	Very high	Ineffective service or treatment
7	High	High Customer Dissatisfaction
6	Moderate	Potential ineffectiveness
5	Low	Customer Complaint
4	Very Low	Lowered effectiveness
3	Minor	A nuisance to the customer
2	Very minor	Not apparent; minor effect
1	None	Not apparent; no effect

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Frequency Of Occurrence Codes

Rating	Classification	Example
10	Very High	Inevitable failure
8	High	Repeated failures
6	Moderate	Occasional failures
3	Low	Few Failures
1	Remote	Failure unlikely

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Likelihood of Detection Codes

10	**Absolute uncertainty**
9	**Very remote**
8	**Remote**
7	**Very low**
6	**Low**
5	**Moderate**
4	**Moderately High**
3	**High**
2	**Very High**
1	**Almost Certain**

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Risk Priorities

- Calculated as:

  Severity X Occurrence X Detection = Priority
- Priorities will be between 1 and 1000
- Some users define priorities in their procedure:
  - < 201 acceptable
  - 201 – 500 undesirable
  - > 500 unacceptable
- Not recommended until there is a sufficient experience in completing FMEAs and definitions have been uniformly applied.

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Complete the Report

- Report issues and suggestions to mitigate to senior management.
  - Those risks that have not been reduced to an acceptable level
    - Suggestions for further actions
    - Considerations made but not implemented and why
  - The entire team should be named in the report
    - And sign the FMEA

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FMEA Advantages

- Structured, detailed approach
  - Patient focused
  - Internal customer focused
  - Bottom up
    - Requires that all known or suspected potential failures to be considered
- Relies on the collective expertise of all areas affected by the process
- Stimulates open communication of potential failures and their outcomes
- Results in actions to reduce failures
- Includes a follow up system and re-evaluation of potential failures

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FMEA Disadvantages

- The required detail makes the process time consuming.
  - Some complex processes can take hours or days to complete the FMEA
- Assumes the causes of problems are all single event in nature (combinations of events are captured as a single initiating event)
- Requires open communication and cooperation of the participants to be effective
  - The personnel involved need to be candid about issues in their own area
- The process relies on recruiting the right participants
- Without the follow up sessions, the process will not be effective.
- Examination of human error is limited and sometimes overlooked.

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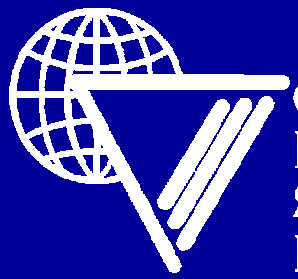
Questions?



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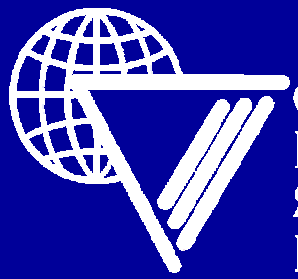
FMEA Exercise 1: Patient Identification, Specimen Collection and Labeling

(Flow charts provided by S. Weber)



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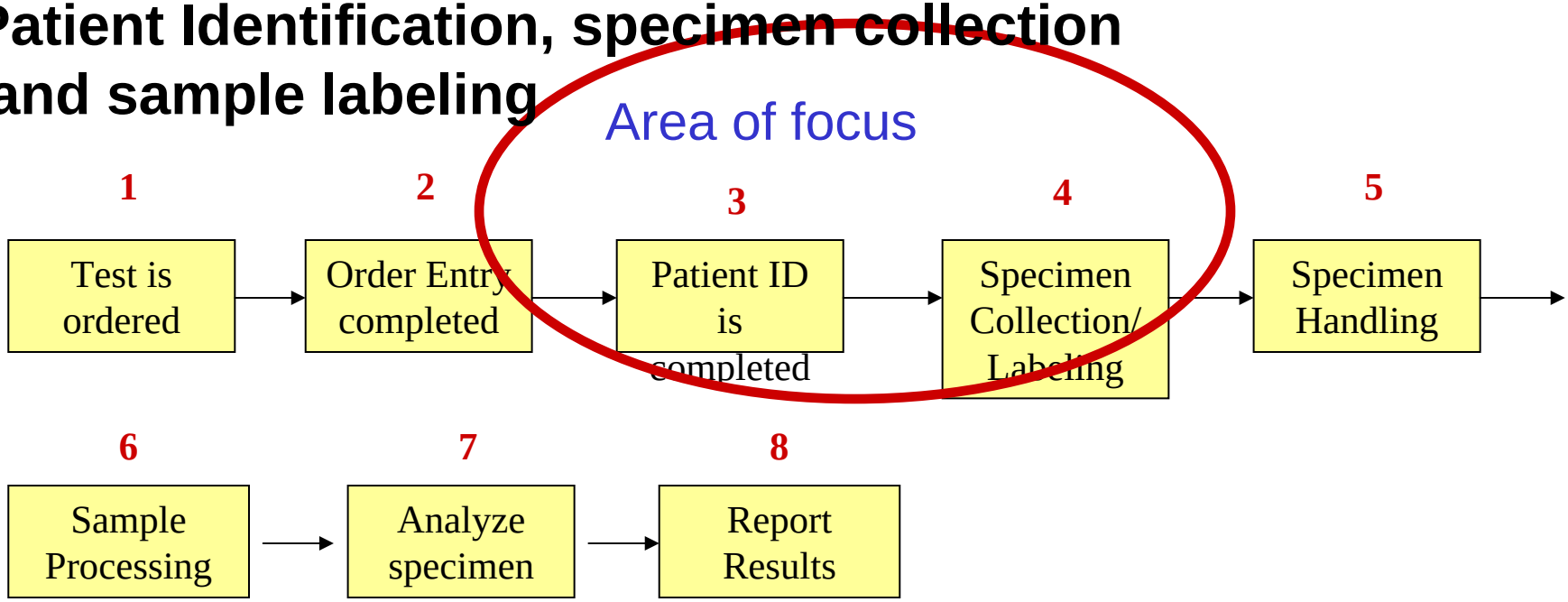
Step 1 Define the Process

Patient Identification, specimen collection and sample labeling



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Identify the Team

- FMEA Facilitator R. Miller
- Content experts
  - **Clinics**
  - **Nursing (Med Surg, ED, OR)**
  - **Emergency Department**
  - **Residency Program**
  - **Laboratory**
  - **Cancer Center**
  - **Surgery**
  - **Organizational Improvement**
  - **Pharmacy**

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Identifying the Sub-processes

Patient Identification

Sub-processes:

A. Outpatient: Ask patient to state his/her full name and date of birth

B. Compare information patient provides to Order / Requisition

C. Inpatient / Patient with ID band: Ask patient to state his/her full name and compare demographic information on ID band to the order, MAR, worksheet or printed patient labels.

D. Correct any discrepancies

E. If patient cannot provided information, parent or relative provides information and confirmed identity

Specimen Collection

Sub-processes:

A. Following patient identification step, wash hands

B. Position patient

C. Prepare equipment

D. Prepare patient site and apply PPE

E. Collect specimen using appropriate specimen requirements per protocol (correct specimen containers and adequate amounts)

F. Take care of patient site (apply pressure, etc)

G. Remove PPE and wash hands

Specimen Labeling

Sub-processes:

A. Labels specimens with the following information:

- Patient's full name
- Medical record number
- Date and time of collection
- Specimen collector's initials

B. Preprinted labels may be applied to specimens.

C. Labeling completed at the point of collection by the person collecting the specimens

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FMEA Exercise 2: Reduce the monitoring of external Q.C. from daily to once / week

EQC Option #2

- The analyte is PSA
- The manufacturer of the XYZ immunoassay instrument has Internal procedural controls to monitor reaction temperature, reagent and sample delivery volumes and mechanisms to assure the acceptability of reaction rates on each sample. This monitoring includes “flags” to alert the user if any of these parameters are outside of acceptable limits.
- This manufacturer has informed the laboratory that if these internal controls are monitored, the external quality control frequency can be reduced to once a week after the system has been qualified in your laboratory according the EQC option 2.

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EQC Option 2 – Continued:

- Consistent to EQC Option 2, requirements, three controls were run daily for 30 consecutive days. During the 30 day period, there were no internal flags on any of the samples run and the controls met all acceptance criteria.
- At this point, all regulatory requirements have been met to revise the external q.c. evaluation frequency to once a week.
- Prior to doing this, we wish to evaluate the additional risks that may take place as a result of this process change.

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Review Process Maps

- See the maps in the handout

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Recruit the Team

- Facilitator –

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