

# Complying with the FMEA Requirements of the New Patient Safety Standards

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1

## Requirements of LD.5.2

- Conduct a Failure Mode and Effects Analysis (FMEA)
  - Assess the intended and actual implementation of the process to identify the steps in the process where there is, or may be, undesirable variation (i.e., what engineers call potential "failure modes")

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2

## Step 1

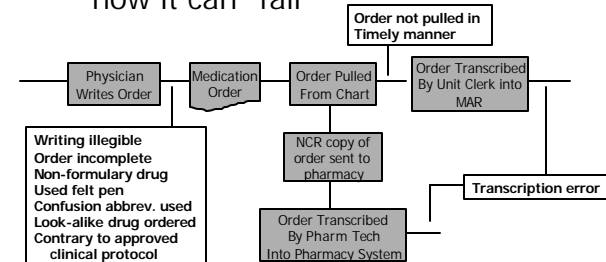
- Construct a Detailed Flow Chart of the Process
  - Multi-disciplinary participation of all those involved in the process
  - Allocate plenty of time for this step
  - Be as detailed and complete as possible
  - Learn the flow chart process and symbols
    - Flow charting software can help

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## Step 2

- Determine each step that can "fail" and how it can "fail"



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## Requirements of LD.5.2

- For each identified "failure mode" identify the possible effects on patients (what engineers call the "effect"), and how serious the possible effect on the patient could be (what engineers call the "criticality" of the effect)

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## Step 3

- Determine the "effect" of each possible "failure"

Illegible handwriting	Wrong drug, dose, freq, route
Incomplete order	Wrong dose, freq, route
Non-formulary drug	More expensive therapy
Used felt pen	Cannot be read on NCR copy
Confusing abbreviation used	Wrong dose
Look alike drug name used	Wrong drug
Doesn't followed approved clinical protocol	Wrong drug, dose, freq, route

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## Step 4

- Determining how serious the possible effect(s) can have on the patient – criticality
- For each effect:
  - Estimate likelihood of failure (occurrence scale rank)
  - Estimate severity of failure (severity scale rank)
  - Estimate probability that failure is detected (detection scale rank)
  - Then compute criticality index
    - is product of above three or  $CI = OSR \times SSR \times DSR$

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## Occurrence Scale

<u>Likelihood</u>	<u>Probability</u>
■ Remote (1) <ul style="list-style-type: none"> <li>■ No known occurrence</li> </ul>	1 in 10,000
■ Low (2, 3, 4) <ul style="list-style-type: none"> <li>■ Possible, but no known data</li> </ul>	1 in 5,000
■ Moderate (5, 6) <ul style="list-style-type: none"> <li>■ Documented but infrequent</li> </ul>	1 in 200
■ High (7, 8) <ul style="list-style-type: none"> <li>■ Documented and frequent</li> </ul>	1 in 100
■ Very High (9, 10) <ul style="list-style-type: none"> <li>■ Documented, Almost certain</li> </ul>	1 in 20

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## Severity Scale

### Outcome possibilities

- Slight annoyance (1)
  - May affect the system
- Moderate System Problem (2, 3)
  - May affect the patient
- Major System Problem (4, 5)
  - May affect the patient
- Minor Injury (6)
- Major Injury (7)
- Terminal Injury or Death (8, 9)

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9

## Detection Scale

### Likelihood

- Very High (1)
  - Error always detected
- High (2, 3)
  - Error likely to be detected
- Moderate (4, 5, 6)
  - Moderate likelihood of detection
- Low (7, 8)
  - Low likelihood of detection
- Remote (9)
  - Detection not possible at any point

### Probability

9 out of 10  
7 out of 10  
5 out of 10  
2 out of 10  
0 out of 10

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## Step 4 (cont)

- Rank prioritize the failure modes based on their criticality index.

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11