

# Quality Tools

# Failure Mode and Effects Analysis

## Description

This template is for use by Product Resources to record the Process Failure Mode and Effects Analysis (DFMEA) for medical and other devices. FMEA is also referred to as Failure Modes, Effects, and Criticality Analysis (FMECA).

# Process FMEA

## Instructions

- Please see the guidance in 90-2000-7.1 regarding FMEA process before beginning an FMEA
  - Initiate action to reduce the RPN
  - Re-evaluate the RPN value after completion of the recommended actions



Assumptions for this PFMEA:

Misc. Assumptions: (itemize and describe below)

1. All provisions of Product Resources' ISO 9001 QMS apply and are implemented.
- 2.
- 3.
- 4.
- 5.

Severity (Sev): (alter if needed to be appropriate for this PFMEA)	Sev
the lowest severity	1
	2
	3
	4
moderate severity	5
	6
	7
high severity / trigger level for mitigation action required	8
	9
the highest severity	10

Occurrence (Occur): (alter if needed to be appropriate for this PFMEA)	Occur
the lowest likelihood of occurrence	1
	2
	3
	4
moderately likely to occur	5
	6
	7
	8
	9
the highest likelihood of occurrence	10

Detection (Detec): (alter if needed to be appropriate for this PFMEA)	Det
the highest ability to detect	1
	2
	3
	4
moderate ability to detect	5
	6

the lowest ability to detect

7  
8  
9  
10

Examples:

User is unlikely to notice and/or a cosmetic item  
Customer is inconvenienced and/or annoyed

Potential to cause operator anxiety or uncertainty  
Not performed the intended test, may require some later action

Bodily harm caused to operator  
Test will be performed with a potentially inaccurate/incorrect result  
Severe bodily harm caused to operator

nearly 0% / very improbable  
1 in 100 chance  
1 in 10 chance

1 in 3 chance

1 in 2 chance

nearly 100% / very probable

nearly 100% / very probable

1 in 2 chance

1 in 3 chance

1 in 10 chance

1 in 100 chance

nearly 0% / very improbable