Failure Modes and Effects Analysis (FMEA)

A tool to balance cost and schedule while maintaining facilities readiness.

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In the October issue of *Controlled Environments,* Richard Bilodeau, "Ask the Facilities Guy" wrote about establishing an "Equipment Reliability" program. While clearly an important issue, it is one that often facilities departments have a hard time getting their arms around—as Richard points out. One tool that we have found quite useful in supporting high facility on-stream time and process yield factors, as well as sustainability, is the equipment or hardware FMEA (Failure Modes and Effect Analysis). The FMEA exercise will provide the facilities team with a prioritized "risk burn-down" plan for ensuring readiness and can serve as a convenient basis for capital and operating expense budget creation and execution.

We have recently performed FMEA exercises for aerospace assembly, integration, and test facilities, aseptic filling laminar flow units and accompanying HVAC systems, thermal vacuum test chambers, powder metallurgy processing lines, precision cleaning equipment, and continuous web processing machinery. In many cases not only were predictive and preventive maintenance issues uncovered and addressed with corrective action plans developed as a consensus among customers, users, service providers, and subject matter experts, but in a few cases, serious life safety and product safety issues were brought to light and effectively dealt with before a catastrophe—likely one without warning—could occur.

An FMEA identifies the severity, occurrence, and detection of failure effects and then establishes priority-ranked corrective action plans. A cross-functional team including the customer or process owner, subject matter experts, facilities and maintenance specialists, quality assurance, and design engineering participate in a brain-storming exercise that identifies each potential failure and ranks the possible effects of each failure and develops a resulting RPN or "Risk Priority Number." The RPN is the arithmetic product of the severity multiplied by the (probability of) occurrence multiplied by the (ability of) detection.

The objectives of the FMEA are to:

- Ensure that potential failure modes and their effects are identified and ranked as to severity, occurrence, and detection.
- Provide assessment as to risk ranking based on RPN (Risk Priority Number) and generate action register to burn down risk—thereby reducing life cycle costs, improving reliability and durability of systems.
- Prioritize the engineering efforts and resources based on the assessment of potential failure impacts to the product and eliminate or minimize the impact of potential failures to the product.
- Provide information for development of an efficient and effective preventive maintenance plan.
- Establish closer links between production, quality, facilities engineering, and maintenance.

Examples of suggested scales for severity, detection, and occurrence might be:

Severity (Effect)	Rank	Criteria
None	1	Process parameter variability within specification limits. Adjustment to process controls can be done during normal maintenance.
Minor	2	Downtime of up to 30 minutes but not out of specification environment.
Low	3	Downtime of greater than 30 minutes and less than 4 hours and/or out of specification environment.
High	4	Downtime of greater than 4 hours and/or out of specification environment.
Hazardous/ Very High	5	High Severity ranking—affects personnel and safety and/or causes non-compliance with government regulations with or without warning.

Occurrence	Rank	Criteria: Possible Number of Failures within Hours of Operation
Failure occurs every 5 years	1	1 in 25,000
Failure occurs every year or more	1	1 in 5,000
Failure occurs every 3 months	2	1 in 1,000
Failure occurs every week	3	1 in 80
Failure occurs every shift	4	1 in 8

Detection	Rank	Criteria
Certain	1	Controls certain to detect a potential cause and subsequent failure. Controls will prevent an imminent failure and isolate the cause.
High	2	High chance that controls will detect a potential cause and subsequent failure. Controls will prevent an imminent failure and isolate the cause.
Medium Likelihood	3	Medium chance that controls will detect a potential cause and subsequent failure. Controls will provide an indication of imminent failure and may, or may not, prevent failure.
Low Likelihood	4	Controls do not prevent failure from occurring. Controls will isolate the cause and failure mode after the failure has occurred.
Remote Likelihood	5	Very remote chance that controls will detect a potential cause and subsequent failure mode, or there are no controls.

Typically the deliverables of the FMEA include a Pareto Chart illustrating the number of failure items and risk effects that were identified and subsequently ranked by RPN during the brainstorming and analysis sections of the exercise, and then either a projected or an achieved burndown of the RPNs after development and execution of the Corrective Action Plan.

FMEAs are an easy to apply tool and provide a structure for a cohesive, well thought out approach to prioritizing and resolving facilities and equipment issues. The hardest part of any FMEA exercise is that when a team of true "problem solvers" is first brought together, the greatest temptation is to jump right to the action register without first taking the time to really understand the contributors to the risk and the risk ranking. A good facilitator makes all the difference in our experience.

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