Failure Modes and Effects Analysis (FMEA) Guide

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August 7, 2022

Introduction

Product development and operations managers can run a failure modes and effects analysis (FMEA) to analyze potential failure risks within systems, classifying them according to severity and likelihood, based on a repository of integrated information relating to similar products or processes. The object of FMEA, according to Stamatis (2019), is to help design innovation policy through diagnostic analysis with monetary terms or in terms of control designs leading corrective action, required resources, and budgetary allowance. While the costs do not always lend themselves to economic flows between different industries with environmental burden caused by these industries and allow calculating total upstream ecological impacts associated with the production of one monetary unit output in a specific industrial sector (Suh and Huppes, 2005; Kitzes, 2013; Kjaer et al., 2015), the planning, engineering, and value analysis are primarily determined by strengths, weaknesses, opportunities, and threats (SWOT) variables, correlations between possible corrective actions, and the internal and external factors of both the environment and the institution as they impact the institute's vision, and RPNs of service failures (Sutrisno et al., 2016). According to (CIOFU, 2018), FMEA defines the term failure mode to identify defects or errors, potential or actual, in a product development process exemplified by emphasizing those affecting in terms of what the customer or end-user may perceive or experience. The study of consequences of identified failures is called effects analysis (Stamatis, 2019).

While predicting every failure mode is impossible (Bonfiglio et al., 2015), it yields a univariate approximation at a higher-order reliability analysis when the covariates are assumed to be fully correlated (Rahman & Wei, 2006). Therefore, the prediction method using the combination of failure modes can be applied to verify the system reliability with more specific predictions of the failure modes.

Definitions and Use of FMEAs

Conventionally, reliability has been accomplished through widespread testing and applying methods such as probabilistic reliability modeling. The challenge is to devise quality and reliability early in the expansion phase. Failure Modes and Effects Analysis (FMEA) as a tactic, according to Hayat & Winkler (2022), is a flexible application executed at various steps in the product life cycle that can be applied to recognize probable failure modes, conclude their effect on the production process, and categorize actions to diminish the failures. There are many several types of FMEA, and each is used to address particular design conditions, including the following (Mago, 2020):

- Design FMEA (DFMEA): Used to recognize, identify, and evaluate stereotyped components that represent behaviors in a model
- Process FMEA (PFMEA): Used to recognize, identify, and evaluate operational processes in the industry, manufacturing, and assembly
- Functional FMEA (FFMEA): Used to identify, document, and prioritize how input to output could fail
- System FMEA (SFMEA): Focuses on actions derived from the macro analysis; wherein one component can result in complete failure of the entire system
- Software (FMEA): Used to analyze requirements, design, and code implementation for embedded control systems

Benefits of FMEA

FMEA is a system-level catalyst for constructing approaches to solving classification, prediction, recognition patterns, and knowledge extraction. Where inputs and outputs applications focus on changeable qualities, which make the prognostic task more challenging and complex (Montgomery, 2020), FMEA contributes to unity with the context within the development, item qualification, acceptance, and evaluation, among others. These benefits include:

1. Contribution to improved methods for products and processes (Kreiner et al., 2016):
    a) Reliability in evaluation instruments
    b) Create sustainability value
    c) Conceptualization of Safe-by-Design
2. Improved quality control measures (Knapcikove et al., 2022)
    a) Increases user satisfaction
    b) Reduces redundant business processes
    c) Prevents user errors
    d) Reduces cycle time
3. Reduce resource burden (Donaldson et al., 2021)
    a) Reduce redesign costs
    b) Decrease support costs
    c) Reduce training needed
    d) Reduce documentation costs

Iterative Approach to FMEA

As a process, the difference between actual and risk and the perception of risk can partly be explained by difficulties in gaining a holistic perspective of systematic assessment of the relevance and the strengths of assurance activities concerning principal risks and core business processes. Like any robust quality process (Gericke et al., 2018), FMEAs require verifying that the evidence received provides a clear view of risks to satisfy the risk oversight and governance and optimize the risk management level across all lines of defense.

FMEA Risk Priority Number (RPN) is a numerical approach for identifying and assessing the nature, validity, and interconnectivity across all lines of defense in an FMEA analysis. As an output of the FMEA analysis, according to Wu & Wu (2021), the RPN is not an end in itself. Its value is the discussion that it facilities between stakeholders beyond the functional boundaries in which they operate. An embedded integrated assurance process will promote greater collaboration between functional areas, gain collective intelligence for identifying risks as they evolve and emerge, and determine any additional assurance required.

FMEA Guidance

Failure Mode and Effects Analysis (FMEA) is a structured way to identify and address potential problems or failures and their effects on the system or process before an adverse event occurs. In comparison (Cheshmberah et al., 2020), root cause analysis (RCA) is a structured way to address problems after they occur. The basic steps for conducting an FMEA are outlined below.

Step 1. Analyze functional requirements and the effects of process parameters on failures modes

- To encourage employees, regardless of title or seniority, to support FMEA and consider the impact of task characteristics on assessment indicators, management should influence collaboration in the context of problem-solving.
- Consider incorporating FMEA to optimize the decision-making process in evaluating new strategies.

Step 2. Create a charter that will help guide the team in managing the project's scope and ensure the implemented changes reflect the FMEA findings

- To help reduce ambiguous accountability for managing a Performance Improvement Project (PIP), leadership should identify change agents who are motivated about the change and credible with their stakeholder group.
- While it can sometimes be tempting to complete FMEA in a vacuum, delegating tasks to members or committees can be an effective engagement strategy in creating and sustaining a culture of data-driven quality.

Step 3. Describe the process

- Construct a flowchart of the steps.
- Suppose such changes create the same instability and impermanence faced by most organizations. Given that transformational leadership practices seem likely to foster organizational learning (VHA National Center for Patients Safety, 2021), reasonable success through FMEA is likely that subsequently, the organization will continually refine in response to changes in its goals and the circumstances in which those goals are to be achieved.

Step 4. Identify and eliminate proposed and potential problems by executing FMEAs

- Change by definition requires creating a new system that always demands leadership.

- This step is similar to a brainstorming session where the concepts of uncertainty and ambiguity resulting from sometimes conflicting ways of framing a problem offer rich ways to formulate policies and practices that improve service delivery.
- Create an atmosphere where staff participating in the FMEA feel safe talking about dialogical learning, negotiation, and opposition (Cabanes et al., 2016). Mistakes are not a sign of incompetence. Instead, most mistakes result from a poorly designed process that "fails to anticipate sources of error and fail to build mechanisms for correction" (Wailoo et al., 2006, p. 105).
- Do not let this brainstorming session become a finger-pointing exercise (Eichorn, 2005, p. 200-201). As such, it reflects discrepancies in meanings and interpretations.
- The product must be appropriately controlled to prevent unauthorized modification and facilitate documentation.
- Selection of the failures to work on eliminating is based primarily on two factors: how likely the failure will occur and the effects of the failure (Mushiri & Mbowhwa, 2018). For each failure, the team decides:
    a) What could happen should this failure occur? (outcome)
    b) How serious would the outcome be? (severity)
    c) How often is this failure likely to occur? (probability)

Step 5. Establish a numerical ranking

- The Risk Priority Number (RPN) is a mathematical product of the numerical Severity, Probability, and Detection ratings: RPN = (Severity) x (Probability) x (Detection). The RPN prioritizes items that require additional quality planning or action (Singh et al., 2020).

Step 6. Design and implement changes to reduce or prevent problems

- According to Jiang (2019), the root cause of each failure grouped with the corresponding life phase must be identified to determine how the process should be changed. The team may need additional input from other staff members to better understand the root causes of failures and apply these processes appropriately.
- Well-designed regulations take into account the limitations of implementation and enforcement. Effective risk management means the simultaneous and targeted deployment of limited remedial resources at different system levels. Mechanisms behind induced change blindness to prevent failures (Leveson, 2016) are likely unsuccessful and refer to the "inability adequately capture the dynamic complexity and non-linear interactions that characterize accidents in complex systems" (Marais et al., 2006, pg. 1).

Step 7. Measure the success of process changes

- Concurrent with implementing action plans, mechanisms are established to gather data that will be used to measure the success of the corrective action. In one embodiment, an FMEA is to create an objective methodology of quantitative accountability for applications related to decision support, procedural performance, cost efficacy, best practices, comparative performance, and safety analytics.
- Evaluating the success of the PIP occurs after a substantial amount of organizational change is expected once the proposed implementation becomes operational (Zwikael & Meredith, 2019). All process changes will become the responsibility of the person designated to monitor the corrective actions, including reviewing data on the effectiveness of all improvement projects.

- The following criteria must be realistic and achievable to conclude the PIP has been successful:
    a) Measures of effectiveness were optimized, not maximized
    b) The change was appropriate for the organization and its members; the sufficient consensus
    c) Leaders are committed to the change

Conclusion

Uncertainty in business environments enforces business practitioners to develop tools and methodologies to consider the impact of business uncertainty to prevent derailment of business operations. In this context, innovativeness in rectifying service quality problems is essential for sustaining the business operation. Failure mode and effects analysis (FMEA) is a widely used risk assessment tool to analyze the situation, process failure, and prediction effects of factors and has been used in a wide range of organizations. The criticality of a failure mode, according to Singh et al. (2020), is traditionally established by its risk priority number (RPN), which is the product of the scores assigned to the three risk factors, which are the likeness of occurrence, and the chance of being undetected, and the severity of the effects. Ignoring the impact of these events can result in a corrective action being chosen (Wu & Wu, 2021), which will either create business losses owing to the presence of weaknesses and threats in the company or not take advantage of potential opportunities and strengths (Sutrisno et al., 2016).

Consequently, this situation requires integrating strategic assessment tools within the systemic FMEA approach that identifies errors, defects, and failures in the product management system when considering the impact of business environment factors in risk-based improvement decision-making. Although this technique may be a little time-consuming because of the involvement of various stakeholders, FMEA innovation can become a more powerful tool for the organization's safety and reliability analysis of systems, processes, designs, and services, reducing labor, time, and financial costs.

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