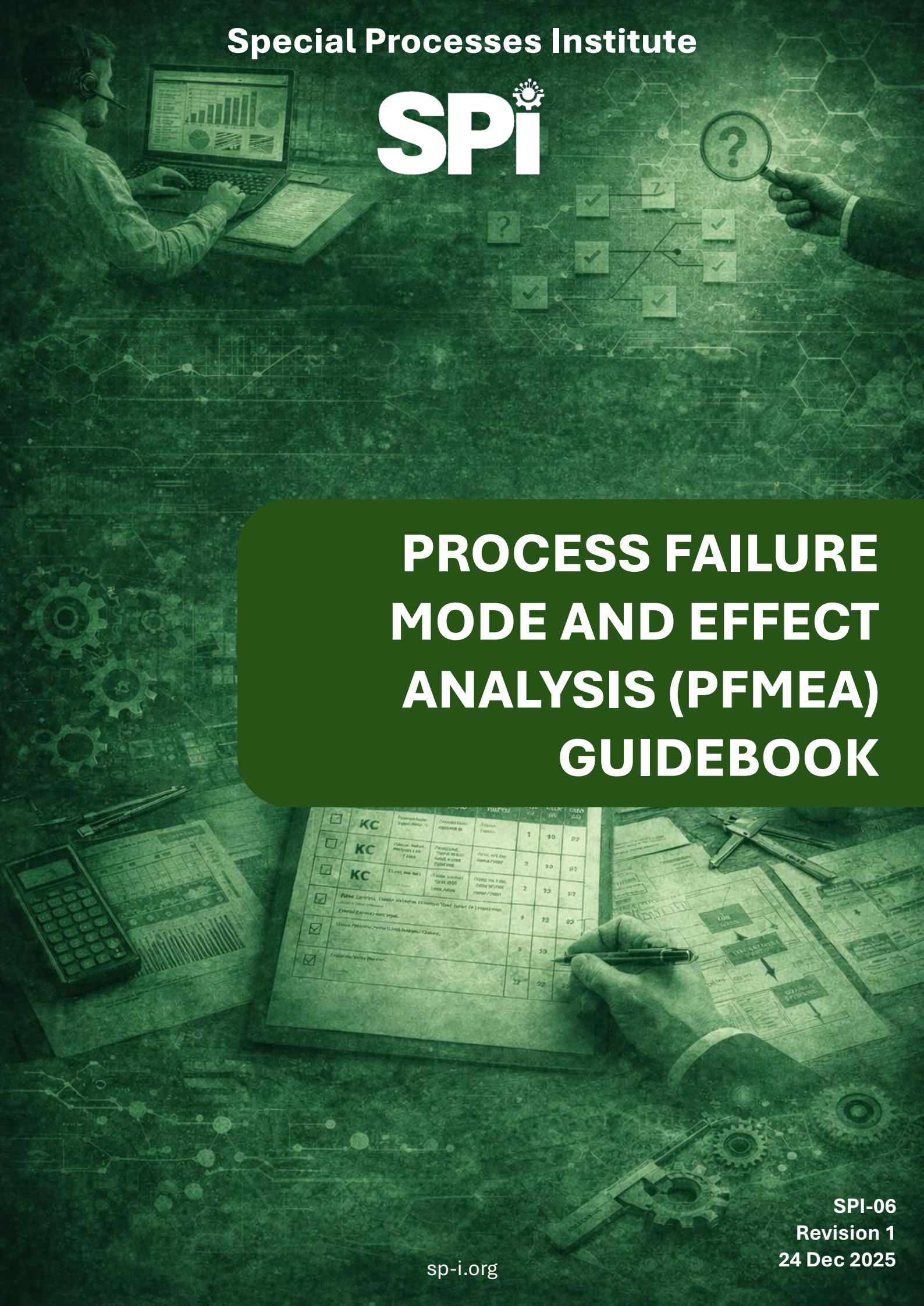
Special Processes Institute

SPI

PROCESS FAILURE MODE AND EFFECT ANALYSIS (PFMEA) GUIDEBOOK



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PFMEA Guidebook

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1. Introduction

1.1. Purpose

The purpose of this guidebook is to provide a clear, structured and practical framework for the effective application of Process Failure Mode and Effects Analysis (PFMEA). It is intended to improve consistency, quality and effectiveness of process risk identification, assessment, mitigation and prevention.

1.2. Risk Management

PFMEA is a preventive risk management tool, not a problem-solving activity. When used correctly, it reduces the likelihood of nonconformities, escapes and reactive corrective action.

1.3. Scope

This guide defines a PFMEA methodology aligned with AS13004. It applies to:

- New Product Introduction (NPI)
- Process changes (material, method, measurement)
- Process transfers or industrialisation
- Process improvement activities
- Root-cause driven PFMEA updates
- All processes not just special processes

2. Quality Requirements

2.1. Relationship to Quality Standards

PFMEA supports compliance with:

- AS13004 – PFMEA and Control Plans
- AS9100 – Risk-based thinking and process control
- AS9145 – APQP and PPAP.

3. Key Characteristics (KCs)

3.1. What are Process Key Characteristics?

In simple terms, a Process Key Characteristic is something about how the process is carried out—not the product itself—that, if it drifts out of control, increases the risk of defects or failures downstream.

3.2. What Makes a Characteristic "Key"

A process characteristic is considered key when:

- It has a strong influence on a Critical or Key Product Characteristic
- It is linked to high-risk failure modes identified through tools like FMEA
- It cannot be fully verified or corrected by final inspection alone
- Loss of control could result in nonconformance, rework, scrap, or safety risk

3.3. Examples of Process Key Characteristics

Depending on the industry, PKCs might include:

- Temperature, time, or current in a heat treatment or plating process
- Torque applied during assembly
- Mixing ratios or dwell times in chemical processes
- Software parameters controlling automated equipment
- Sequence or method of operation where order matters

These are different from product characteristics (such as dimensions or coating thickness), which describe what the product is, whereas PKCs describe how the product is made.

3.4. Relationship to Risk Management

PKCs are often derived directly from **high-risk items in a Process FMEA**. By controlling the process characteristics that drive risk, organisations reduce the likelihood of defects rather than relying on inspection to catch them later.

4. Associated Documents

A PFMEA does not exist in isolation and should never be reviewed or maintained as a standalone document. Its effectiveness depends on strong alignment with a set of associated documents that together describe how the process is designed, controlled and executed. These documents must be consistent with one another and reflect the process as it is performed, otherwise the PFMEA quickly becomes detached from reality and loses its value as a risk management tool.

4.1. Process Flow Diagram

The Process Flow Diagram provides the structural backbone for the PFMEA by defining the sequence of process steps, interfaces, decision points and hand-offs. The PFMEA should directly follow this flow, with each failure mode clearly linked to a specific step in the process. Any change to the process flow, whether through added steps, removed activities, or altered sequencing, should trigger a review of the PFMEA to ensure that new risks have not been introduced and existing risks remain valid.

4.2. PFMEA

The PFMEA itself captures the structured assessment of process risk, documenting potential failure modes, their effects, causes and the actions taken to reduce risk. However, the PFMEA only describes what the risks are and how they are being managed at a high level. It relies on other documents to define how controls are implemented in practice.

4.3. Control Plan

The Control Plan translates the outcomes of the PFMEA into operational controls. Key characteristics, process parameters, monitoring methods and reaction plans identified as necessary through the PFMEA must be reflected in the Control Plan. This document ensures that risk reduction actions are embedded into routine production rather than remaining theoretical. Any disconnect between the PFMEA and the Control Plan is a strong indicator that risk controls may not be effectively implemented.

4.4. Work Instruction

Work Instructions provide the detailed, step-by-step guidance that operators follow to perform the process correctly. They are the primary means by which PFMEA-driven controls reach the shop floor. If a failure mode has been identified as high risk, the corresponding preventive or detection measures should be clearly visible in the work instructions through defined methods, settings, checks, or cautions. Operator involvement in PFMEA development helps ensure that work instructions are practical, clear and aligned with real operating conditions.

4.5. Inspection Plans

Inspection Plans define how and when verification activities take place to confirm that the process and product meet requirements. These plans should directly support the detection controls identified in the PFMEA and referenced in the Control Plan. Where inspection is relied upon to manage risk, the inspection method, frequency and acceptance criteria must be capable of detecting the failure mode with the assumed level of effectiveness.

4.6. Summary

Together, these associated documents form a closed loop of risk management. The process flow defines what happens, the PFMEA analyses what could go wrong, the control plan defines how risks are controlled, work instructions ensure consistent execution and inspection plans verify effectiveness. Maintaining alignment across these documents is essential to ensuring the PFMEA remains a living, effective tool rather than a disconnected compliance exercise.

5. PFMEA Approach to Risk

5.1. Incorrect Approach to Process Risk

Common ineffective practices include:

- Completing PFMEA as a paperwork exercise
- Copying PFMEAs without process understanding
- Focusing only on RPN thresholds
- Treating PFMEA as static documentation
- Performing PFMEA as an individual or without operator or SME involvement

- Using a PFMEA to create a process from scratch without an existing, accurate Process Flow Diagram
- Not producing a control plan or work instruction from the PFMEA

These behaviours lead to undetected risks and repeated escapes.

5.2. Correct Approach to PFMEA

An effective PFMEA:

- Is developed by a cross-functional team
- Is based on actual process knowledge
- Focuses on prevention before detection
- Is living documentation, updated with learning
- Links directly to the Process Flow Diagram (PFD) and Control Plan with traceability.

5.3. Risk Assessment

Essentially, an FMEA (Failure Modes and Effects Analysis) is a structured risk assessment of a process, product, or system that focuses on identifying what could go wrong and evaluating the potential consequences of those failures. The FMEA is developed collaboratively by relevant stakeholders, who systematically brainstorm and document possible failure modes at each step of the process.

5.4. Prevent and Detect

For each identified risk, the team records the potential effects, root causes and the prevention and detection controls that are already in place. The level of risk is then assessed, typically by considering factors such as severity, likelihood of occurrence and ability to detect the failure. Where risks are determined to be unacceptably high, additional actions are defined and documented to eliminate the failure mode where possible, or otherwise to reduce its likelihood or improve its detectability.

6. The PFMEA Process (Six-Step Model)

The PFMEA methodology follows six disciplined steps.

6.1. Step 1 – Review and Define the Process

6.1.1. Understand the Process Completely

PFMEA Step 1 establishes the foundation for the entire analysis. If the process is not clearly understood and consistently defined, the PFMEA will quickly become inaccurate, disconnected from reality and of limited value. The intent of this step is to ensure that everyone involved shares a common and accurate understanding of how the process actually operates, rather than how it is assumed to operate based on documentation alone.

6.1.2. Define the Scope

At this stage, the process under review must be clearly defined in terms of its scope and boundaries. This includes understanding where the process starts and ends, what products or services are included and how the process interfaces with upstream and downstream activities. A well-defined scope prevents important risks from being missed and avoids the PFMEA becoming unfocused or overly broad.

6.1.3. Walk the Process

The process should then be reviewed in its actual sequence, using available process flows, work instructions, route cards, or control plans as a reference. The emphasis is on understanding the process step by step, in the order it is performed, including inspections, hand-offs, decision points and any rework or looping that may occur. This review must be validated against real operations by observing the process and engaging directly with operators and supervisors. Informal steps, workarounds, or variations between shifts and equipment are often revealed at this point and should be captured, as they represent real sources of risk.

6.1.4. Existing Controls

For each step of the process, it is important to understand what goes into the step, what comes out of it and what controls currently exist. Inputs may include materials, information, equipment settings, tooling, or environmental conditions, while outputs describe the condition of the product or the records generated. Existing controls such as parameter limits, in-process checks, automation, or error-proofing mechanisms provide the baseline for later evaluation of risk.

6.1.5. Process Owner

Clarifying who is responsible for performing each step, who sets or verifies critical parameters and who responds when something goes wrong is also a key part of this stage. Lack of clear ownership often leads to inconsistent execution and delayed response to issues, which in turn increases process risk.

6.1.6. Output

When PFMEA Step 1 is carried out thoroughly, the result is a realistic and agreed representation of the process as it is actually performed. This ensures that subsequent PFMEA steps are built on accurate information, enabling meaningful identification of failure modes and effective risk reduction actions.

- Develop or review the Process Flow Diagram (PFD)
- Identify all operations and key steps
- Confirm process scope and boundaries
- Ensure operation numbering is consistent
- If the PFMEA feels too large, the scope is too large.

6.2. Step 2 – Identify Potential Failure Modes

6.2.1. In what ways could this process step go wrong?

Step 2 focuses on systematically identifying how each step of the defined process could fail to perform its intended function. Building on the accurate process definition established in Step 1, this stage asks the fundamental question: “In what ways could this process step go wrong?” The intent is not to assign blame or assume poor performance, but to anticipate realistic breakdowns in the process before they result in defects, escapes, or adverse outcomes.

- Ask: How can this process fail to meet requirements?
- Consider material, method, machine, measurement, environment and people
- Use lessons learned, NCR data, escapes and prior PFMEAs
- Document failure modes in technical, requirement-based terms

Examples:

- Feature over tolerance
- Incorrect material
- Surface finish nonconforming

6.2.2. Clear, Specific and Observable

A potential failure mode describes the manner in which a process step fails to meet its requirements or intended purpose. This may involve doing the wrong thing, failing to do something required, doing it at the wrong time, or doing it inconsistently. Failure modes should be described in clear, specific and observable terms that reflect what could actually happen in normal operations, rather than vague or generic statements.

6.2.3. Collaboration

Identifying meaningful failure modes requires collaboration with those who understand the process in practice. Operators, technicians, engineers and quality personnel all bring different perspectives and their combined experience helps uncover issues that may not be evident from documentation alone. Historical data such as nonconformances, rework records, scrap reports, audit findings and customer complaints are also valuable inputs, as they highlight failures that have already occurred and could reasonably occur again.

6.2.4. Process Focus

At this stage, the focus remains on the process, not the product effects or root causes, which are addressed in later PFMEA steps. Each failure mode should be directly linked to a specific process step and expressed in a way that makes it clear what aspect of the process is not functioning as intended. Overly broad failure modes reduce the effectiveness of the PFMEA, while overly narrow or speculative ones can distract from real risks. The aim is to strike a balance that reflects credible, process-based failures.

6.2.5. Relevant and Actionable

Care must be taken to ensure that failure modes reflect the process as it actually operates, including variations, manual interventions, handovers and reliance on human judgement. Common PFMEA weaknesses often arise when idealised or “paper” processes are analysed instead of real-world conditions. By grounding failure modes in observed practice and known issues, the PFMEA remains relevant and actionable.

6.2.6. Output

When carried out effectively, Step 2 produces a comprehensive and realistic set of potential failure modes that form the basis for assessing effects, causes and risk in subsequent PFMEA steps. This step is critical in ensuring that the PFMEA serves as a proactive risk management tool rather than a theoretical exercise.

6.3. Step 3 – Identify Effects of Failure

Objective: Understand the impact of each failure mode. Effects should be considered at:

- Next process step
- Higher-level assembly
- End product
- End customer or regulatory impact

6.3.1. What Happens If That Failure Occurs?

PFMEA Step 3 focuses on understanding the consequences of each potential failure mode identified in the previous step. At this stage, the question shifts from how the process could fail to what happens if that failure occurs. The purpose is to clearly describe the impact of a failure, regardless of how often it might occur or how easy it may be to detect.

6.3.2. What is Actually Affected?

An effect of failure is the outcome experienced by the customer, the next process, or the organisation when a failure mode is realised. These effects should be described in terms of what is actually affected, such as product performance, fit, function, safety, compliance, delivery or cost. Where applicable, effects should be traced through the process chain to show how an issue at one step may propagate downstream before it is discovered.

6.3.3. Description of Effects

The description of effects should be written from the perspective of the most serious credible consequence. A single failure mode can have multiple effects and it is important to capture the worst-case impact, particularly where safety, regulatory compliance, or customer satisfaction could be compromised. Even if a failure is unlikely or well controlled, its effect still needs to be understood and documented accurately.

6.3.4. Failure Impact Focus

At this stage, the analysis should remain independent of existing controls or detection methods. The focus is on the inherent impact of the failure itself, not on whether it will be caught later. Conflating effects with detection or causes weakens the PFMEA and can lead to underestimated risk ratings in subsequent steps.

6.3.5. Specific Effects

Clear and specific descriptions are essential. Vague statements such as “poor quality” or “process issue” do not convey the real significance of a failure. Instead, effects should explain what actually goes wrong and for whom, whether that is an internal operation, an external customer, or a regulatory body. Where relevant, both immediate effects and longer-term consequences should be considered.

6.3.6. Output

When Step 3 is performed thoroughly, the output enables consistent and meaningful severity assessment in the next stage of the PFMEA. By clearly understanding the potential impact of each failure mode, organisations can prioritise risks appropriately and focus improvement efforts where they matter most.

6.4. Step 4 – Risk Evaluation

6.4.1. Effects Evaluated in Terms of Risk

PFMEA Step 4 is where the identified failure modes and their effects are evaluated in terms of risk. This step brings structure and prioritisation to the PFMEA by assessing how severe the effect of a failure would be, how likely the failure is to occur and how likely it is that the failure would be detected before it reaches the customer or the next process. The combination of these three factors provides a relative measure of risk that helps determine where action is required.

6.4.2. Severity

Severity reflects the seriousness of the effect should the failure occur. It is assessed based on the impact of the failure alone, without considering any controls that may exist to prevent or detect it. Severity therefore remains constant unless the effect itself changes and it should be rated with particular care where safety, regulatory compliance, or critical product performance is involved. Even rare failures must be treated as high risk if their consequences are severe.

- Impact of the failure effect
- Ranked 1–10
- Independent of controls
- Severity ≥ 9 requires design authority review

6.4.3. Occurrence

Occurrence considers how frequently the failure mode is expected to happen. This rating should be based on evidence wherever possible, such as historical process data, nonconformance trends, scrap rates, or field returns, rather than subjective judgement alone. Where data is limited, informed engineering judgement may be used, but assumptions should be realistic and reflect actual process behaviour rather than ideal conditions.

- Likelihood of the cause occurring
- Influenced by prevention controls
- Ranked 1–10

6.4.4. Detection

Detection evaluates the ability of current controls to identify the failure before it escapes the process. This includes in-process checks, inspections, monitoring systems, automation and error-proofing measures. A low detection rating indicates a high likelihood that the failure will be caught, while a high detection rating reflects weak or unreliable detection methods. Detection should be assessed based on the effectiveness of the control, not its presence.

- Likelihood the failure will be detected before escape
- Influenced by detection controls
- Ranked 1–10

6.4.5. Risk Priority Number

Once severity, occurrence and detection have been assigned, they are combined to produce a risk value, often expressed as a Risk Priority Number. While the numerical result helps to rank risks, it should not be treated as an absolute measure. High-severity risks should always receive attention, even if their overall score appears moderate due to low occurrence or strong detection. The purpose of the calculation is to support prioritisation, not to replace engineering judgement.

- RPN = Severity × Occurrence × Detection
- RPN is a prioritisation tool, not a decision threshold.

6.4.6. Output

When carried out correctly, Step 4 provides a clear and rational basis for deciding which risks require action and which are acceptable. It ensures that resources are focused on the most significant threats to quality, safety and compliance and it sets the stage for defining effective risk reduction actions in the subsequent PFMEA step.

6.5. Step 5 – Define and Implement Risk Reduction Actions

6.5.1. Practical Improvement

PFMEA Step 5 focuses on actively reducing the risks identified during the evaluation stage by defining and implementing appropriate actions. At this point, the PFMEA moves from analysis into practical improvement, with the objective of lowering risk to an acceptable level rather than simply documenting it. The emphasis is on preventing failures wherever possible, rather than relying on detection after the event.

6.5.2. Preventive Measures

Risk reduction actions should be driven by the results of the severity, occurrence and detection ratings, with particular attention given to high-severity failure modes. Actions may aim to eliminate the failure mode entirely, reduce the likelihood of its occurrence, or improve the ability of the process to detect the failure before it causes harm. Preference should always be given to preventive measures that improve process capability or robustness, as these provide more sustainable risk reduction than inspection alone. Priority order:

1. Eliminate the failure mode
2. Reduce occurrence (prevention controls)
3. Improve detection (automated preferred)

6.5.3. Effective Actions

Defining effective actions requires a clear understanding of the process and its constraints. Actions must be realistic, technically sound and proportionate to the level of risk. They should be clearly described, assigned to a responsible owner and supported by a defined timescale for implementation. Vague or generic actions weaken the PFMEA and often result in little or no real improvement.

6.5.4. Implementation

Implementation is a critical part of this step and should not be assumed simply because an action has been recorded. Risk reduction measures must be integrated into the process through updated work instructions, control plans, training, tooling, equipment settings, or system changes, as appropriate. Where changes affect

how the process is controlled or monitored, associated documentation should be updated to ensure consistency and sustainability.

6.5.5. Verification of Effectiveness

Once actions have been implemented, their effectiveness must be verified. This involves confirming that the intended reduction in occurrence or improvement in detection has been achieved and that no new risks have been introduced. The PFMEA should then be updated to reflect the revised ratings, reinforcing its role as a living risk register rather than a static record.

6.5.6. Output

When Step 5 is applied effectively, the PFMEA becomes a powerful tool for continual improvement. It ensures that identified risks lead to tangible action, strengthens process control and helps prevent failures before they reach the customer or impact compliance.

6.6. Step 6 – Re-evaluate Risk

6.6.1. Confirmation of Risk Reduction Effectiveness

PFMEA Step 6 closes the improvement loop by reassessing risk after defined actions have been implemented. The purpose of this step is to confirm whether the risk reduction measures have been effective and to determine whether the residual risk is now acceptable. Without this re-evaluation, the PFMEA becomes a record of intentions rather than evidence of effective risk management.

6.6.2. Review Focus

At this stage, the focus is on reviewing the same failure modes using updated information from the changed process. Severity is revisited only if the effect of the failure has fundamentally changed, which is relatively uncommon. In most cases, the impact of a failure remains the same and any reduction in risk is achieved through lowering the likelihood of occurrence or improving the ability to detect the failure earlier and more reliably.

- Re-score Occurrence and Detection
- Severity remains unchanged unless design changes
- Update PFMEA, Control Plan and Work Instructions

6.6.3. Objective Evidence

Re-evaluation should be based on objective evidence wherever possible. This may include process capability data, monitoring results, audit outcomes, trial runs, or early production feedback. Assumptions that a risk has been reduced simply because an action was completed should be avoided. The question being answered is not whether the action was implemented, but whether it has genuinely changed the behaviour or control of the process.

6.6.4. Additional Improvement

If the revised risk level remains unacceptably high, further action is required. In some cases, this may indicate that the original action was insufficient or incorrectly targeted, while in others it may reflect inherent limitations of the process that require more fundamental changes. The PFMEA should capture these outcomes and drive additional improvement rather than closing the issue prematurely.

6.6.5. Ongoing Process monitoring and review

Once the risk has been reduced to an acceptable level, the PFMEA should be updated to reflect the final ratings and the current state of process control. This ensures the document remains an accurate representation of residual risk and supports ongoing process monitoring and review.

6.6.6. Output

When carried out properly, Step 6 reinforces the PFMEA as a living document and a continuous improvement tool. It provides confidence that risks have not only been identified and addressed, but also effectively controlled, supporting consistent quality, safety and compliance over time.

Objective: Confirm risk reduction.

7. Behavioural Expectations

Effective PFMEA requires:

- Cross-functional ownership
- Operator involvement
- Evidence-based scoring
- Focus on system weaknesses
- Avoidance of blame or assumptions

8. Document Review

8.1. When to Review

PFMEA shall be reviewed:

- At NPI milestones
- After process changes
- Following escapes or major NCRs
- Periodically during production
- For process improvement activities
- In conjunction with the linked process flow diagram, control plan and work instructions to ensure the system is relevant and control plans and work instruction address identified risks and have not drifted.

8.2. A Common and Avoidable Mistake

The PFMEA is a living risk register and must not be treated as a static form. A common mistake is to review the PFMEA in isolation, without reference to associated or derived documentation and without the involvement of stakeholders in the process. When this happens, PFMEAs often become disconnected from actual shop-floor operations and, as a result, provide little or no practical value.

9. Summary

9.1. Effective PFMEA

Effective PFMEA relies as much on behaviour and mindset as it does on tools and documentation. When treated purely as a paperwork exercise, PFMEA quickly loses its effectiveness and becomes disconnected from real process risk. The value of PFMEA comes from how people engage with it and how honestly and rigorously risks are explored and addressed.

9.2. Cross-Functional Ownership

Cross-functional ownership is essential to achieving a balanced and accurate assessment. PFMEA should not be created or maintained by a single function in isolation. Engineering, quality, production, maintenance and other relevant disciplines all contribute different perspectives on how the process operates and where it is vulnerable. Shared ownership helps ensure that risks are fully understood and that proposed actions are practical and supported.

9.3. Collaboration

Meaningful operator involvement is equally critical. Operators and technicians work with the process every day and often have the clearest insight into where things go wrong, where workarounds exist and where controls are weak or unreliable. Their involvement helps ground the PFMEA in reality and prevents it from being based solely on assumptions or idealised process descriptions. It also increases buy-in and consistency in how controls are applied on the shop floor.

9.4. Evidence Based Decision Making

Scoring within the PFMEA must be based on evidence wherever possible. Severity, occurrence and detection ratings should reflect actual data such as nonconformance trends, scrap rates, audit findings, or process capability, rather than optimism or personal opinion. Where data is limited, professional judgement may be used, but the rationale should be clear and defensible. Evidence-based scoring improves consistency and credibility, particularly during audits or external reviews.

9.5. PFMEA Focus

The focus of PFMEA should always be on weaknesses in the process or system, not on individual performance. Failures are rarely the result of a single person's actions and are more often driven by unclear instructions,

inadequate controls, poor interfaces, or unrealistic expectations. By concentrating on systemic issues, PFMEA supports sustainable improvement rather than short-term fixes.

9.6. Quality Culture

Finally, PFMEA must be conducted in a quality culture that avoids blame and untested assumptions. Assigning fault or speculating without evidence discourages open discussion and hides real risks. A constructive, objective approach encourages honest input and leads to more effective identification and reduction of risk.

9.7. Output

When these behavioural expectations are met, PFMEA becomes a collaborative and proactive tool that strengthens process control, supports continual improvement and delivers real value beyond compliance.

9.8. Further Information and Resources

Additional information and a range of downloadable resources, including supporting documents including a PFMEA template and reference material, can be accessed at: https://sp-i.org/downloads.html

10. Document Revision Control

Rev	Date	Change	Author
1	24 Dec 2025	Established the Process Failure Mode and Effects Analysis Guidebook	Konrad Burgoyne

sp-i.org
email@sp-i.org