

# Process Failure Mode Effects Analysis (PFMEA) (Risk Assessment)

**Purpose:** A PFMEA is a structured approach to review and analyze a process to ensure potential problems have been identified and their associated risks have been documented. The PFMEA is most useful when it is integrated into the process development cycle and is updated as the process changes.

PFMEA activities shall include:

1. Review of the process. Process flow diagrams can be the primary input to the PFMEA.
2. A multi-disciplinary team of process owners, subject matter experts, and other stakeholders examine the processes for potential failure modes and document them.
3. The effects of failures are reviewed and documented.
4. The severity of the failure is reviewed and documented.
5. The likelihood of the failure, or occurrence, is estimated.
6. The likelihood of the failure being detected is estimated.
7. The Risk Priority Number (RPN) is calculated.
8. An action plan is developed and actions may be taken depending on the RPN ranking.
9. If changes are made the RPN is recalculated to determine the effect of the change.