Forensic Technology Center of Excellence
Forensic Science Failure Mode and Effects Analysis (FMEA) Application Instructions

Version: 01.24.24

Failure Mode and Effects Analysis (FMEA) is a risk management tool that identifies and quantifies the influence of failures or potential failures in processes or activities. The application automates FMEA by evaluating the level of risk associated with an area of concern or non-conformance in forensic laboratory processes. The application calculates a Risk Priority Number (RPN) that shows the level of risk associated with a failure or potential failure and the action required to mitigate that risk. The RPN is derived from a severity, occurrence, and detection matrix, which has been customized for forensic science service providers (FSSPs). The application provides an option to export to excel to save the data or export to PDF to retain a record of the risk assessment.

When a failure has been identified, such as in a non-conformance, a root cause analysis (RCA) is commonly performed to identify the reason for the failure. Although RCA is an effective tool, it does not provide an assessment of the magnitude of risk associated with the failure. When used with RCA, FMEA provides a clearer understanding of the impact of the failure, which informs FSSPs of the actions needed to mitigate risk to an acceptable level. Ideally, FMEA is used before a failure (area of concern) to assess and mitigate risk to avoid a non-conformance. This application has been designed for use either before or after identification of a failure, providing FSSPs with a proven method to demonstrate compliance with ISO 17025:2017, Clause 8.5.

FTCOE anticipates continually refining and improving the FMEA application. Please email **ForensicCOE@rti.org** with any suggestions or comments.

To access the Forensic Science FMEA application, use the following link: https://forensiccoe.org/tool-2024-app-failure-analysis/

NOTE: This application does not store any data entered by users. Data is processed in the browser and is not saved to any server or database. If you exit the page without saving the PDF or Excel export to your local computer drive(s), you will not be able to return to retrieve a copy and will have to restart the entire process.

Follow the steps below to complete the FMEA Template:

1. Risk to be evaluated
   1.1. Use the drop-down menu to indicate whether you are evaluating risk in a “non-conformance” or “an area of concern.”
2. QA Manager (free text)
   2.1. Enter name of the Quality Assurance Manager.
3. Prepared by (free text)
   3.1. Enter the name of the individual leading the assessment if different than the name entered for “QA Manager.”
4. Incident No. (free text)
   4.1. Enter the laboratory-generated incident number, if applicable. This number is commonly used for internal tracking purposes.
5. FMEA No. (free text)

5.1. Enter the FMEA number from your laboratory's numbering system, if applicable. This is commonly a sequential number generated by your lab, which may be the same as incident number.

6. Date
   6.1. This field auto-populates with the current date. To change, either manually enter using the format (MM/DD/YYYY) or use the calendar select option.
7. Process or Activity (free text)
   7.1. Briefly describe the step in the process or activity in which you are assessing risk. The description should contain enough information for a reviewer to clearly understand the specific step in the process or activity to be assessed. For example, "an evidence custodian or other authorized staff adhering barcode labels to evidence containers when in-processing evidence." In this example, the specific step is "adhering barcode labels." If you are assessing risk in multiple steps, each step in the process or activity is evaluated separately.
8. Failure or Potential Failure (free text)
   8.1. Enter the failure or potential failure you are assessing. This field is designed to examine all possible failures. Here is where individuals directly involved in the process can help describe what could or did go wrong, such as "barcode label placed on wrong evidence." Each individual failure should be assessed separately.
9. Potential Effect of Failure
   9.1. Enter the potential outcome or result of the failure. Consider how the failure will impact the customer or end user (e.g., results do not correspond to the correct evidence). This will serve as the basis for assessing your severity of condition score. If multiple adverse outcomes are identified, complete an assessment for each.
10. Severity of Condition
    10.1. Using the drop-down menu, enter a score from 1 (negligible) to 5 (catastrophic). Use the More Info link for a description of each score. Consider the consequences of the failure on the customer or end user.
11. Likely Cause of Failure (free text)
    11.1. Briefly describe the likely cause of the failure. If an RCA has been completed, enter the root cause (e.g., multiple tasks completed at once). If there is no RCA, examine the process or activity and seek assistance from those involved in the process or activity to determine potential cause(s) of the failure. Attempt to narrow the cause to the most likely reason for the failure. Unlike an RCA, this step does not require a documented and comprehensive analysis. Use a quick "5 whys" or a similar technique to help you identify the likely causes of the failure. This will serve as the basis for assessing your occurrence of failure score.
12. Occurrence of Failure
    12.1. Using the drop-down menu, enter a score from 1 (remote) to 5 (very high). Use the More Info link for a description of each score. Consider the number of times the process or activity is performed in a day, week, or month. If evaluating risk in an area of concern, consider the potential for the failure to occur in the process or activity over a period of time. Ask "How likely is the cause of the failure to occur?"
13. Current Controls (free text)

13.1. Briefly describe the current control(s) in place to detect the failure (e.g., examiner reviews evidence prior to analysis). This will serve as the basis for assessing your probability of detection score. Consider all controls in place to prevent the failure.

14. Probability of Detection
    14.1. Using the drop-down menu, enter a score from 1 (very high) to 5 (remote). Use the More Info link for a description of each score.
15. After all scores have been entered, click submit. The application will open in a new page with your risk assessment (RPN Score), followed by a description of the magnitude of risk and actions needed, if applicable. Click on the Calculation Formula link to view the RPN calculation and the severity, occurrence, and detection matrix.
16. Corrective Action(s) (free text)
    16.1. If the RPN score is above the acceptable limit, document actions taken here. Consider additional or improved controls to lower the detection score. Consider training staff or redesigning the process to improve occurrence score. Use the "add action" button to document multiple actions.
    16.2. If the RPN score is acceptable, no entry is needed. Add any comments in the space provided. Proceed to step 19.
17. CAR/PAR
    17.1. Use dropdown menu to indicate whether a Corrective Action Request (CAR) or Preventive Action Request (PAR) has been opened. Add any comments in the space provided.
18. If corrective action was taken, click score again and repeat steps 10, 12, 14, and 15. Note: after rescoring, the application calculates and displays an RPN percent reduction. This step is repeated until RPN reaches an acceptable level or user decides to review and export to PDF or excel.
19. Click Review when complete to view the full risk assessment from the session.
20. Click Export PDF to save a PDF of your full risk assessment or export to Excel to capture data for processing.
21. Close session