# Risk Management Techniques to Identify and Control Laboratory Error Sources Implementation Guide

Implementation Guide
EP18-Ed2-IG

## Introduction

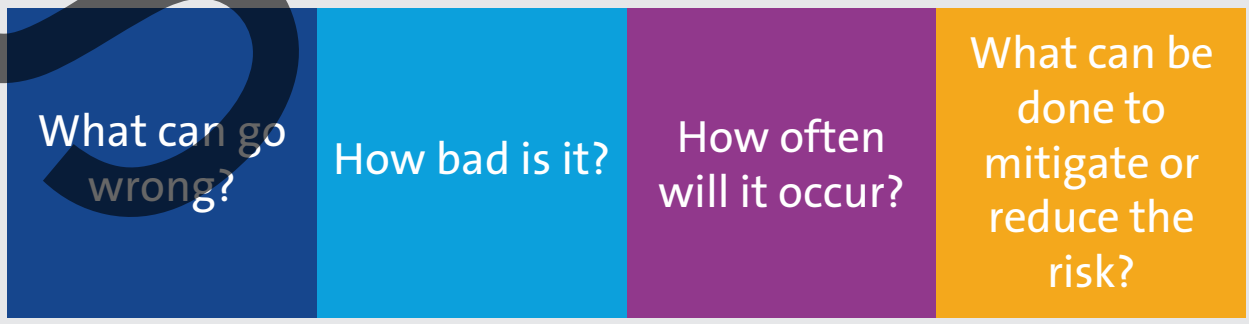
This implementation guide describes the minimum procedures necessary for a medical laboratory to identify and control laboratory error sources using risk management techniques. These instructions focus on the failure modes and effects analysis (FMEA) technique. Other options are included in CLSI documents EP18[1] and EP23™.[2]

**IMPORTANT NOTE:** This implementation guide is not intended for use by a test developer to determine error sources for a new commercial or laboratory-developed test. Instead, test developers should use CLSI document EP18[1] for guidance on determining error sources. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

## Overview of the Risk Management Process

Diagnostic devices are extremely diverse in their technology, design, and function. Every test system is subject to hazards or hazardous situations during the preexamination, examination, and postexamination testing stages. The relative importance and likelihood of these failures vary with the device, the sample, the user, and the environment. In addition, a high level of variability exists in terms of skill and knowledge level among end users. The number of potential and observed failures can be large, making it important to prioritize efforts to reduce risk. Some failures are almost certain to cause patient harm, whereas a result that must be repeated but is not time sensitive only raises cost. With the classification of severity of harm and probability (or frequency) of occurrence, the importance of failures can be prioritized. The risk management process can help identify possible failures, their severity, and the likelihood they will occur. With this information, their importance can be prioritized, and measures to reduce the risk can be implemented.

The risk management process asks the following questions:



Once the table is completed, all applicable quality monitoring should be implemented at the frequencies specified in the FMEA table. The QMS data and information should be reviewed periodically to ensure all sources of failure are identified and managed at an acceptable rate.

## General Considerations When Conducting a Failure Modes and Effects Analysis

When conducting an FMEA, the laboratory should:

- Set reasonable goals that are quantitative, measurable, and realistic. A goal of "zero" failures is not valid because the possibility of error always exists. Risks should be reduced as low as is reasonably practical.
- Be as conservative as possible when determining potential failures.
- Avoid multiple entries in a row. For example, if multiple causes are listed for a particular failure, it is unclear which control measures apply to which cause. To prevent possible confusion, the failure and each cause should be listed on a separate line.
- Take into account different types of control measures or corrective actions. Failures can be prevented, detected, or recovered from, and the mitigation strategy should be selected based on effectiveness and resource constraints.

## Failure Modes and Effects Analysis Table

The FMEA table contains four major areas.

| Potential Source of Failure | Criticality | Controls | Validation |
|---|---|---|---|

These four areas can each be subdivided as described below.

### Potential Sources of Failure

| Potential Source of Failure | | | |
|---|---|---|---|
| Step or Component in Which Failure Occurs | Description of Failure | Cause of Failure | Effect of Failure |

This portion of the FMEA table includes:

- **Step or Component in Which Failure Occurs:** This column includes the process step or product component that contains the failure, eg, sample acquisition, reagents, calibration.
- **Description of Failure:** This column includes a short description of a failure that could occur, ie, the answer to "What can go wrong?".
- **Cause of Failure:** This column includes the root cause of the failure, ie, the event or activity that causes the failure, eg, incorrect storage temperature that causes the reagent to degrade.
- **Effect of Failure:** For any failure, a cascade of downstream events is possible. For example, incorrect storage temperature causes reagent degradation that leads to an incorrect result. The incorrect result can lead to a delayed or missed diagnosis, or a delayed or missed treatment, which can lead to patient harm.