

Summary - Quality Risk Management Application:
Critical Instrument Calibration Interval Change via Risk Analysis

This document offers a risk assessment approach to document a critical instrument calibration interval change request.

Calibration frequencies for non-critical instruments, if any, can be adjusted by the maintenance team as appropriate based on instrument history and other factors. This practice has no impact to non-critical instrument interval change opportunities.

The impact of an instrument calibration failure from the standpoint of probability, severity, and detectability may be determined through the integration and factoring of multiple parameters associated with each criterion as illustrated in Tables I -III. This section will provide additional narrative description in support of the contents in each table which contain guidance on how these parameters can impact the risk of experiencing an out-of-tolerance (OOT) condition for an instrument.

Due to the dynamic nature of a work environment a ranking cannot be based solely on one factor. Rather, all influences should be considered, for example – a transmitter located in a clean, dry area that does not get washed down but at the same time operates in an unstable environment – while the transmitter may be adequately protected and isolated from dirt and dust or exposure to wash down, the vibration and shock to which it is exposed can physically fatigue components that might cause erroneous reading. In this case, the sub-category of vibration and shock will determine the environmental risk ranking for failure probability.

Human safety – Direct threat to human safety defines the most severe consequence of calibrations OOT. If an instrument reading (or alarm) is the main protection against severe or potentially fatal injury, such as breathing air, oxygen level, or lethal compounds monitor, then severity is potentially high. Depending on whether an instrument is a primary component in a safety system, or part of a redundant system, will determine the severity of this risk.

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