

Summary - Quality Risk Management Application to Establishment of Weighing Device Performance Testing Intervals

The quality risk management approach as applied to the evaluation of reduction of performance verification frequency illustrated in this guidance not only identifies the different risk factors to consider when performing the evaluation but also demonstrates a simple tool (depicted in tabular format) for determining how to group potential risks into low, medium, and high categories. For the purpose of this evaluation, two risk factors, probability and severity, will be examined for each perceived risk associated with the defined risk scenario. From this evaluation of individual perceived risks the cumulative risk profile associated with a potential change in frequency will be devised. Through application of a simple tool coupled with requisite background knowledge it is expected that this assessment will serve as a model to GMP sites to standardize the evaluation of changes to the frequency of weighing device performance verification testing.

The potential risks associated with decreasing the frequency of weighing device performance verification testing were derived through completion of a brainstorming exercise. The risks identified should be relevant to most weighing devices and operations.

The probability of the weighing device encountering drift during the proposed period should be based on the operating history of the device. This review should include the frequency of unscheduled maintenance over the previous two year period and the device's performance history from, minimally, the last five calibrations. If the idealized running history, respective of maintenance and calibration, is not available for a specific weighing device, the history of a like model instrument deployed under similar conditions may be used for reference.

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