Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
Application of Quality Risk Management to performance checks for weighing devices such as balances and scales is intended to provide a tool for determining the acceptability of decreasing the frequency of verifying the performance of a weighing device from the current frequency (e.g. daily) to an alternative schedule.

This guidance document is applicable to weighing devices used in all aspects of operations. The phrase "performance verification" is representative of testing conducted using certified, traceable weights representing the upper and lower ends of the established working ranges for a specific weighing device. Performance verification typically includes determination of accuracy (a weighing device's ability to accurately determine the mass of a weight having a certified mass) and linearity (accuracy across the established working range of the device). The term "weighing device" refers to any instrument whose purpose is to render a mass determination of material placed on its weighing surface or pan. The term "weighing device" will be used universally throughout this document to refer to weighing instruments regardless of the mechanism or technology employed, i.e. analytical balances, top loading balances, comparators, floor scales, etc.

This document provides guidance in assessing the risks associated with increasing the interval between executions of performance verification testing on a weighing device. Consideration will be given to the following factors:

- Regulatory requirements and cGMP's
- Application of the weighing device (how used)
- Performance Verification History (accuracy and linearity of the specific weighing device)
- Maintenance/Calibration History of the specific weighing device
- Environmental Conditions to which the weighing device is exposed, and
- Business Considerations

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.

Risk Question
In this case the proposed change drives the creation of the risk question. Our risk question becomes, "*what are the potential risks associated with changing the frequency of weighing device performance verification testing from the current schedule (e.g. daily) to an alternate, longer period*".

Table 1. Probability and Severity Ranking Scales

Risk Level	Probability	Severity
Low (1)	**Regulatory** - no formal requirement exists for daily performance verification testing. **GMP** – there is no industry accepted practice for weighing device performance verification testing. **Environment** – weighing device is located in a controlled, monitored area with sufficient protection from vibration or other physical disturbance; changes would readily detected. The history of the area where the device is kept is monitored and shows no recorded temperature and/or humidity excursions. **Measurement** – the weighing device or device of similar make/model has met all tolerances during the past five calibrations and all verification data falls within 3σ of the overall mean obtained for the targeted mass during a the assessment period (30 data points). **Business** – schedule is flexible and ample inventory exists for order fulfillment. The revised verification interval is shorter than typical batch/lot cycle time.	**Regulatory/GMP** – Not likely to result in more than a discussion point during a regulatory inspection. **Measurement** – high level of confidence in measurements since device performance conforms to tolerances, demonstrating acceptable accuracy across the weight range employed during routine use. **Business** – issue can be overcome without conducting repeats or discarding goods. No impact to schedule or customer supply. All failures would be caught prior to release of impacted batches/lots.
Medium (3)	**Regulatory** - no formal requirement exists for daily performance verification testing. **GMP** – it is considered an industry standard to conduct daily performance verification testing. **Environment** – weighing device is	**Regulatory/GMP** – may result in a comment or a FDA-483 observation during a regulatory inspection. **Measurement** – moderate level of confidence in measurements performed on the weighing device. **Business** – issue resolution will require

Table 2. Risk Score Evaluation Matrix:

↑ Increasing Probability				
	5	5	15	25
	3	3	9	15
	1	1	3	5
		1	3	5
		Increasing Outcome Severity →		

Interpretation:

- Scores 1-3 are low risk
- Scores 5-9 are moderate risk
- Scores 15-25 are high risk

Risk Control

For those risks that are deemed to exceed the site's risk acceptance threshold mitigation must occur before proceeding forward with a change in the frequency of performance verification testing. Only when all risks are reduced to meet the site's pre-defined acceptance threshold should the process proceed forward. This should be confirmed via re-application of the tool for risks that were the subject of mitigation efforts.

Risk Review

When all risks are judged to comply with the pre-establish risk acceptance level the documentation should be routed for approval to the impacted system owner and the Site Quality Authority. The documentation package should contain all documented aspects of the Quality Risk Management process. Implementation of the proposed change in frequency cannot proceed until all approvals are obtained. The risk assessment process should be repeated any time a change is introduced that impacts the practice, e.g. change in regulations pertaining to weighing practices or performance of weighing devices.

A mechanism for ongoing monitoring of the weighing device's performance should be devised and implemented after adoption of the revised performance testing frequency.

The retention period of the assessment summary document should, minimally, be equal to the period of use of the revised verification testing frequency.

