Guidance Number: 89

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

	located in a controlled but unmonitored area with no protections from disturbance; detection of changes to environment and physical condition of the device are dependent on operators. There is a history of infrequent (one per month) temperature and/or humidity excursions in the area where the weighing device is kept or the area is controlled but not monitored. **Measurement** – the weighing device has failed to meet tolerances once during the past five calibrations and/or exhibited data (special cause) outside of 3σ of the overall mean obtained for the targeted mass during the assessment period (30 data points). **Business** – schedule has limited flexibility and less than two weeks of inventory exists for order fulfillment. The proposed verification testing interval is approximately the same as the typical batch/lot cycle time.	repeat of operations (1-5) and result in additional costs due to labor and materials. Failure could result in the need to conduct a limited number of product recalls.
High (5)	**Regulatory** - a formal requirement exists for daily performance verification testing. **GMP** – it is standard industry practice to conduct daily performance verification testing. **Environment** – device is located in a uncontrolled/unmonitored area with no protections from disturbance; detection of changes to environment and physical condition of weighing device are dependent on operators. There is a history of frequent (one per week) temperature and/or humidity excursions in the area where the	**Regulatory/GMP** – likely to result in a FDA-483 or major observation during a regulatory inspection. **Measurement** –accuracy of weighing activities not assured. **Business** – issue resolution will require repeat of operations (5+) and result in significant costs due to labor and materials. Failure could result in the need to conduct periodic recalls of impacted batches/lots.

	weighing device is kept or the area is uncontrolled/unmonitored and the environmental history is unknown. **Measurement** – the weighing device has failed to meet calibration tolerances more than once during the past five calibrations and/or periodic unexplained verification test failures during the assessment period (30 data points). **Business** – schedule has no flexibility and is typically adheres to a just-in-time model for order fulfillment. Additionally, proposed verification testing interval is longer than typical batch/lot cycle time.	

The tool is applied to the risks identified and a Risk Score is calculated using the values assigned for probability and severity.

Probability x Severity = Risk Score

Risk Acceptance

After the Risk Score has been calculated for the individual potential risks it must be assessed versus an evaluation matrix to determine the acceptability of the existing risk or conversely, identify the need for reduction of the risk through implementation of controls, where possible. The evaluation matrix is to be devised based on a site's willingness to accept different levels of risk (determined prior to conducting ranking of the various risks). Table 2 and the related Interpretation section represent an example evaluation matrix.

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.