

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.

## **Recommendations & Rationale for Recommendations**

### **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*”.

### **Risk Assessment Tool**

Given the nature of the data to be used for the assessment the Risk Ranking and Filtering (RRF) method has been selected to aid in the assessment of risks associated with a change in testing frequency.

RRF focuses on two separate risk factors, probability and severity, associated with each potential risk relevant to an issue.

### **Risk Assessment -Identification, analyses, and evaluation of potential risks**

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 following areas were identified as having risks related to a change in verification testing frequency:

**Regulatory Expectations** – the formalized requirements pertaining to control of balances should be reviewed and understood to determine the potential risk of non-compliance. Risks may vary from one market to another, it is suggested that the expectations for the most stringent market served be used for the assessment when multiple markets are involved.

**cGMP Expectations** – the unwritten expectations that are generally accepted as “standard practice” should be considered. Many times these expectations are verbally expressed by regulatory inspectors during facilities inspections. As with Regulatory expectations the assessment should be based on the most restrictive expectations

**Environment** – the potential for change in environmental factors that could affect the performance of the weighing device and potentially go unnoticed during a more prolonged test interval should be evaluated. These factors generally include static, vibration, temperature, humidity and the potential for physical disturbance.

Controls such as temperature and humidity monitoring systems in place within the work space should be considered to determine if the potential risk is mitigated or eliminated as a concern. Typically a thorough IQ should address the risk of exposure to unacceptable levels of vibration or static; however, these variables should not be overlooked. There should be procedural controls in place to evaluate the need for additional performance verification when the environmental conditions or the physical location are changed such that it is inconsistent with the IQ.

**Measurement** – the impact of loss of accuracy due to device drift should be assessed. The criticality of the weighing operations performed, i.e. standards, samples, actives, excipients, media, etc. should be considered in the assessment. As should the type of operation supported, i.e. intermediates, API or finished product. The impact of weighing inaccuracy may be lesser for an intermediate since it is tested at the API stage and again as part of the finished product.