January 14, 2015 (*Amended February 5, 2015 for Graph on 5 gal standard deviations.*)

Technical Memorandum for: State Weights and Measures Metrologists

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Subject: National Assessment Summaries from Annual Submissions – September to December 2014.

Introduction

This document provides a national overview and feedback for State weights and measures laboratories related to materials submitted for annual review by OWM as part of the Laboratory Recognition Program associated with NIST Handbook 143. During the 2014 end-of-year review, special emphasis was placed on technical and administrative evaluation of two sections of the published criteria: 1) compliance with OWM training requirements (Section 5.2); and 2) evaluation of submitted uncertainties (5.4.6).

Background

Annual submissions are requested each year through an annual submission memorandum that is sent to all laboratories during the first two weeks of August. Each year, specific items are requested for review prior to issuing certificates of metrological traceability and special technical assessments are done of all materials in key areas. Laboratories are notified in advance what the special assessments will cover and training on those topics is generally provided to enable continual improvement and/or success in complying with Handbook 143 requirements. The published requirements in Handbook 143 include those of ISO/IEC 17025 and other OWM administrative and technical requirements.

The annual submissions are sent to OWM in the submission cycle between October 1 and November 15. For 2014, the cycle was extended to November 30, due to the late Combined Regional Measurement Assurance Program (C-RMAP) training session which included review of and planning for laboratory proficiency tests.

During the 2015 submission cycle, laboratories were notified that special assessments of the laboratory Quality Management Systems and Proficiency Tests (follow up, corrective actions, and planning) will be conducted. Training will be provided during the 2015 RMAP meetings and through webinars.

OWM Training Compliance

Since 2011, all of the OWM metrology seminars have been updated – replacing the core of Basic, Intermediate, and Advanced seminars with a Fundamentals of Metrology, Mass, Volume, and Advanced Mass seminars. Laboratory Auditing Program (LAP) problems have been assigned to State weights and measures metrologists since the 1960's to provide demonstration of competency and application of concepts in their own laboratories. LAP problems were also updated with the 2011 training transition.

During the 2014 review of submission materials, attention was focused on “training gaps” and specific feedback was provided regarding missing LAP problems.

In addition, during the 2014 C-RMAP training session, it was noted that when OWM replaced the training requirements that are published in Table 2 of Handbook 143, it didn’t acknowledge the completion of training and LAP problems prior to the new course structure as satisfactory. At this time, the Table 2 has been updated and now specifically states that both the published version (2007) and the updated version of Table 2 are valid as evidence of training compliance, with some exceptions related to the failure to complete LAP problems within designated time limits. The updates also specifically state that there are time limits to completing the new LAP problems due to several ongoing issues – 1) laboratory management need to ensure that time is available for newly trained metrologists to apply concepts from the Fundamentals of Metrology course to the documents, processes, and procedures to their own laboratories, and 2) metrologists need to prioritize completing the Fundamentals of Metrology LAP problems. In the case of the Advanced Mass Seminar, a longer time line is allowed; however, failing to immediately apply the measurement processes and concepts from the Advanced Mass seminar results in quickly losing application ability due to the complexity of the material and often requires undue support from OWM staff and/or subsequent re-attendance at an Advanced Mass seminar.

The “original” Basic and Intermediate LAP problems were required with those courses, for OWM to recognize those staff as “approved signatories” to sign calibration certificates at the levels designated in Handbook 143. As such, staff who did not successfully complete those problems are not recognized as “approved signatories” for the laboratories. At this time, staff who did not complete the Basic LAP problems are being asked to complete the newer Fundamentals of Metrology LAP problems (better application for the laboratory and they can serve as a technical audit) by December 31, 2015. Staff who failed to complete the Intermediate Seminar LAP problems must complete them by December 31, 2015. Staff who previously completed the Advanced Mass seminars and no Advanced LAP problems will not have the laboratory Recognized for work at the Mass Echelon I level (to provide either internal or external calibrations) until such problems are completed.

Failure to complete the problems may result in requirements for retraining with the new series of seminars, limited potential to expand the laboratory Scope for additional measurement areas, or not meeting pre-requisites for subsequent training; in all cases, failure to complete the problems can have a training/career limiting impact.

Summary and Requirements:

- Staff who completed the core training courses and Laboratory Auditing Program (LAP) problems prior to the transition of training courses in 2011, continue to fully meet the requirements of Handbook 143 (2007).
- Staff who completed core training courses prior to the 2011 transition, and who have not completed LAP problems, must complete them by December 31, 2015 or OWM may require

attendance at the new core courses. The older version of LAP problems will not be accepted after December 31, 2015.

- Staff who complete the new series of courses with Fundamentals, Mass, and Volume, only have one set of LAP problems – Fundamentals of Metrology LAP problems. The new problems require proficiency tests in both mass (SOP 8 or better) and volume (SOP 18 or better), plus technical assessments of the laboratory in fundamental areas. Problems must be completed within one year, or retraining may be required. The problems can serve as technical assessments that can also be submitted as evidence of technical assessments during the annual review cycle.
- Staff who complete the Advanced Mass seminar (old or new) have two years to complete the Advanced LAP problems or refresher training may be required (two year deadline is effective as of 2015 and beyond; for attendees prior to 2015 (2011 was the last Advanced Mass class prior to 2015), problems are due by December 31, 2015 or refresher training is required).
- Proficiency testing at the level of service to be provided on the Scope is an ongoing competency requirement in addition to training and LAP problems; nothing has changed regarding completion of successful proficiency test requirements.

Uncertainty Evaluations

Updating Uncertainties on an Annual Basis

Uncertainties should be updated based on review of control charts that are done real time and at least annually (leading to updated process standard deviations) and based on updated calibration certificates obtained for standards (which include updated uncertainties).

Supporting information for this statement:

1. Laboratories must periodically review their control charts (real-time and periodically) to ensure standards and processes are within control limits and to detect trends (SOP 9, 17, 20, 30 and HB 143, Section 5.9). All new balances or processes will have new standard deviations and updated uncertainties. When we see new balances or processes, we expect to see updated uncertainties.
2. Laboratories must obtain or perform calibrations of the laboratory standards according to calibration intervals published in GMP 11 (as modified and tailored for the laboratory) and/or adopted in the laboratory Quality Manual or Quality Management System; many working standards need to be calibrated on an annual basis. Some of the baseline intervals are "annual" unless you have modified and adopted them in your laboratory and have data to support the modifications. When we see updated calibration certificates, we expect to see updated uncertainties.
3. Tying items 1 and 2 together, the data from the measurement assurance (1) supports the calibration intervals (2). Both items 1 and 2 provide input to updating laboratory uncertainties. Uncertainties must take into account all components, and if following recognized procedures, using those components is considered to satisfy this requirement (5.4.6.2, Note 2).
4. Uncertainties must be based on "k = 2" only where there are adequate degrees of freedom (SOP 29). Otherwise the uncertainties are based on degrees of freedom or effective degrees of

freedom, where the coverage factor, *k,* is updated based on obtaining additional observations and degrees of freedom as the measurements are implemented throughout the year (all measurement SOPs and SOP 29).

5. Uncertainties must be evaluated for acceptability (SOP 29, HB 143, Sections 4.4 Contract Review, and 4.7 Customer Service.)
6. Document control requirements also specify a periodic review and approval process. Uncertainty tables are a laboratory document (in many cases either Appendix E, referenced by GMP 11 or 13, or are included as a portion of the Quality Manual and Associated Appendices).
7. During an annual internal audit or technical audit, you might find "uncertainties continue to be acceptable" rather than needing to update them, in which case, the review or audit should be noted in the uncertainties file with evidence that the assessment was done and all values found to be acceptable.
8. The Management Review is typically covered once every 12 months (and is an annual requirement of OWM and NVLAP submissions). As a part of the Management Review, items that are related to reviewing and/or updating uncertainties might include but not be limited to: a) acceptability of procedures; b) outcome of recent internal audits; c) corrective and preventive actions; d) results of proficiency tests (with failed P_n assessments); e) customer feedback; f) complaints; g) recommendations for improvement; and h) review of quality control activities.

This means uncertainties should be reviewed at least annually, degrees of freedom updated, coverage factors updated if needed, and they must be updated when they will be reduced (by any amount for NVLAP) and when there are significant changes (i.e.,, 10 % change in standard deviations).

2014 Annual Assessment:

- 64 % of the laboratory submissions in 2014 included updates from the 2013 submission.
- 36 % of the annual submissions did not include updates and did not include a note that the uncertainties were reviewed in any way.

Updating Uncertainties for SOP 8, Modified Substitution

The P_n assessment was included in the 2008 Uncertainty Template for laboratories to use – to prevent failures in PTs due to uncertainties not meeting requirements for maximum permissible errors (tolerances). Training on additional components and approaches to be included in SOP 8 calibrations was begun in 2010 due to the number of proficiency test (PT) failures where the normalized precision test (P_n) was excessively small and normalized error (E_n) values failed due to inappropriately small uncertainties. Ongoing training on SOP 8 is covered in the Mass Metrology Seminar. SOP 8 was updated in 2012 and again in 2014 and includes specific components that are to be included in uncertainty calculations. Since 2008, failures on PTs have steadily decreased through correctly calculated and updated uncertainties.

2014 Annual Assessment:

- 82 % of the laboratory submissions in 2014 (or earlier) included updates to comply with SOP 8 uncertainty components.
- 18 % of the annual submissions still do not comply with SOP 8 uncertainty components (and the laboratories have adopted and regularly use SOP 8 – thus are *non-compliant* and *corrective action is required*).

Evaluating Uncertainties for Degrees of Freedom and Normalized Precision

SOP 29 for calculating uncertainties was updated in 2012 to include effective degrees of freedom and appropriate use of degrees of freedom to select a suitable coverage factor, *k*. This approach has been a part of the *Guide to the Expression of Uncertainty in Measurements* (GUM) since 1993. Laboratory Quality Management Systems and Calibration Certificates have specified or referenced adoption of the GUM for many years. Having adequate number of degrees of freedom in the measurement assurance system will ensure that a *k* value of 2 may be selected and used. Mathematical modifications of standard deviations to provide an equivalent standard deviation are NOT approved GUM methods. Training on selecting appropriate coverage factors has been conducted since the early 1990's; however, training on effective degrees of freedom has been covered more recently in the 2013 RMAPs, 2014 C-RMAP, and other training seminars and webinars. Handbook 143 requires adoption of the GUM methodology.

The ILAC Policy, *ILAC-P14:12/2010, ILAC Policy for Uncertainty in Calibration* specifies that the GUM must be followed and that an "approximate 95 % confidence interval must be reported." However, it does not require "*k = 2.*" Laboratories must report the appropriate coverage factor to meet an approximate 95 % confidence interval; this is usually 2 only if there are adequate degrees of freedom in the measurement process (Laboratories accredited by ILAC signatories are required to comply at this time).

2014 Annual Assessment:

- Only 43.2 % of the laboratories have incorporated references to degrees of freedom and use of suitable *k* values to obtain an approximate 95 % confidence interval to comply with the GUM and SOP 29 and ILAC policies.
- 56.8 % of the laboratories have yet to update uncertainties to comply with these requirements.

Evaluation of P_n Failures

As noted earlier, P_n assessments were included in the 2008 Uncertainty Template for laboratories to use to prevent failures in PTs due to uncertainties not meeting requirements for maximum permissible errors (tolerances). Appropriate preventive or corrective actions must be taken to meet the maximum permissible error (tolerance) requirements of the Handbook 105-series standards and Handbook 44 Fundamental Requirements to support legal metrology and to prevent PT failures from.

2014 Annual Assessment:

There are numerous examples of P_n failures in submitted uncertainty tables without comment or corrective actions being noted in the uncertainty tables, in the technical audits, or in the Management

Reviews. In fact, in those cases where the laboratory has not used the Uncertainty Template, there is no P_n assessment at all. Any failures noted anywhere in a laboratory assessment must have appropriate corrective actions noted with plans in place to perform and assess the corrections. In most cases where these failures have been identified (Volume measurements will be covered separately), the laboratory Scope has been modified accordingly. In a number of cases, these actions have impacted the available services to customers, resulting in complaints to the laboratory, to laboratory management, and to other government representatives, including NIST staff.

5 gallon Sampling of Uncertainty Data

A sampling of 5 gallon data was conducted to evaluate standard deviations and final uncertainties. There is a graph showing the spread of the data below. Of interest, only 18 % of the laboratories have noted whether the data includes 3 inch necks, 4 inch necks, and whether this data is separated or combined to determine the uncertainties. Unexpectedly, 82 % of the uncertainty data at 5 gal included no notes whatsoever on neck or graduation sizes. Given that typical standard deviations of those who have submitted data for both, show a standard deviation for 3 inch necks that is about 66 % of the standard deviation for 4 inch necks, this data should be collected and separated in the laboratory (to minimize uncertainties for 3 inch neck test measures) by using multiple check standards where possible.

Laboratories with data at the minimum or maximum ends of the spectrum on these graphs should conduct investigations to further assess the reasonableness and suitability of their standard deviations and uncertainties (*You are flagged in our analysis tables!*).

Excel analysis of the data is shown in these tables, with four graphs following.

Table 1. 5 gal Uncertainty and Standard Deviation Data.

Uncertainties		**Standard Deviations**	
Mean	0.311366667	Mean	0.089416546
Standard Error	0.019291195	Standard Error	0.007455772
Median	0.29	Median	0.077847
Mode	0.23	Mode	0.12
Standard Deviation	0.137766686	Standard Deviation	0.053244861
Sample Variance	0.01897966	Sample Variance	0.002835015
Kurtosis	7.632819632	Kurtosis	4.614990899
Skewness	2.070156479	Skewness	1.724255233
Range	0.84	Range	0.289
Minimum	0.1	Minimum	0.011
Maximum	0.94	Maximum	0.3
Sum	15.8797	Sum	4.560243852
Count	51	Count	51

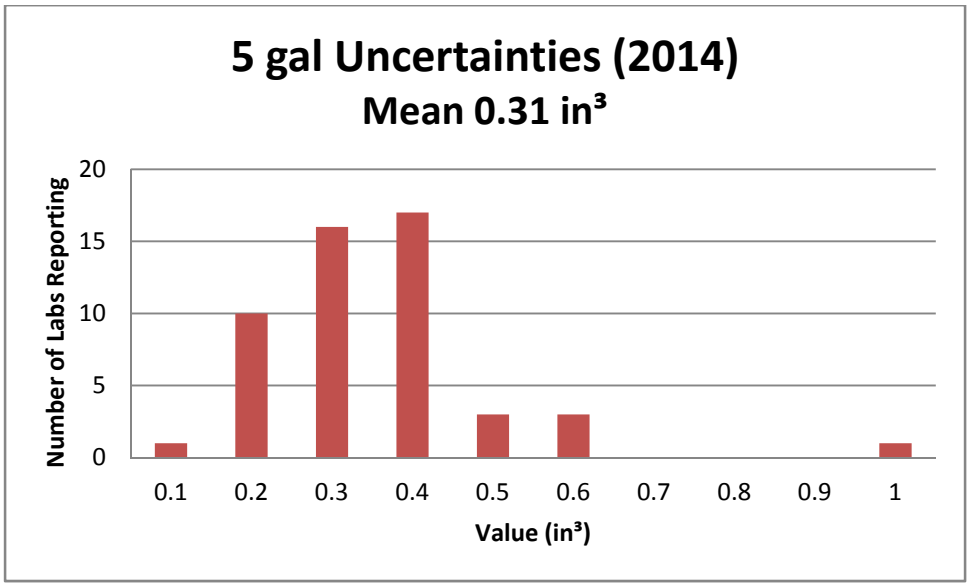

Figure 1. 5 gal Uncertainty Histogram.

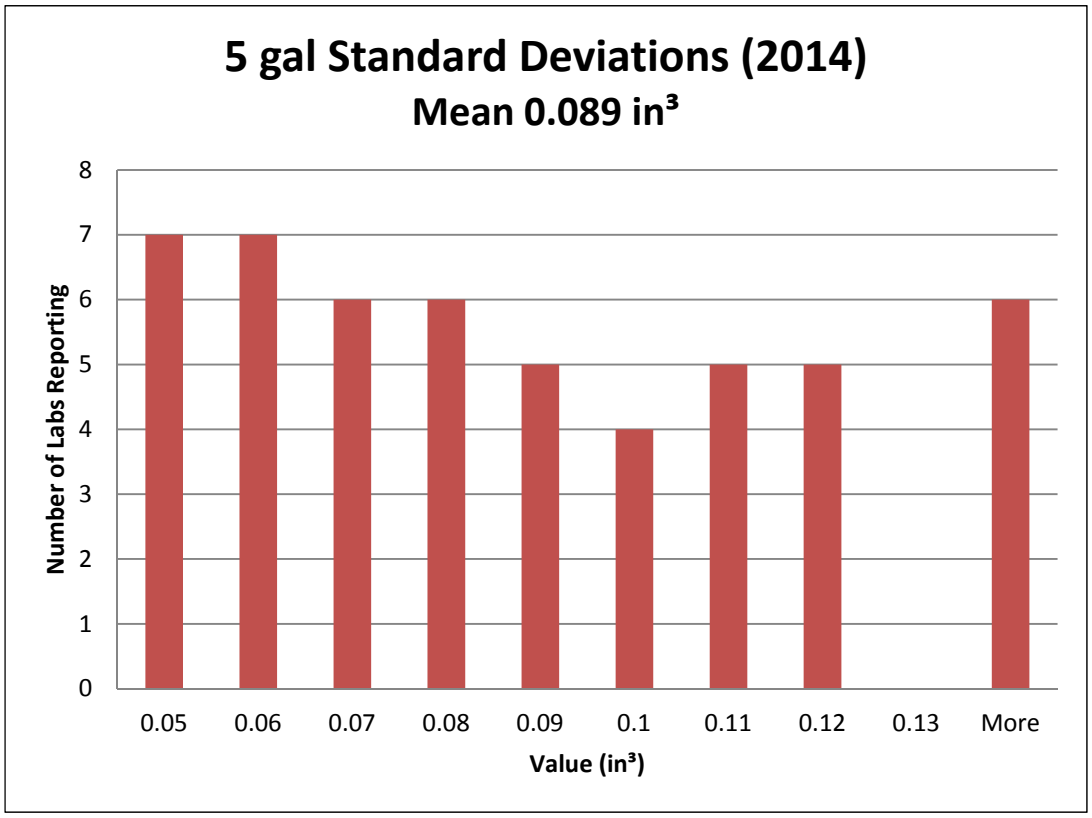

Figure 2. 5 gal Standard Deviation Histogram.

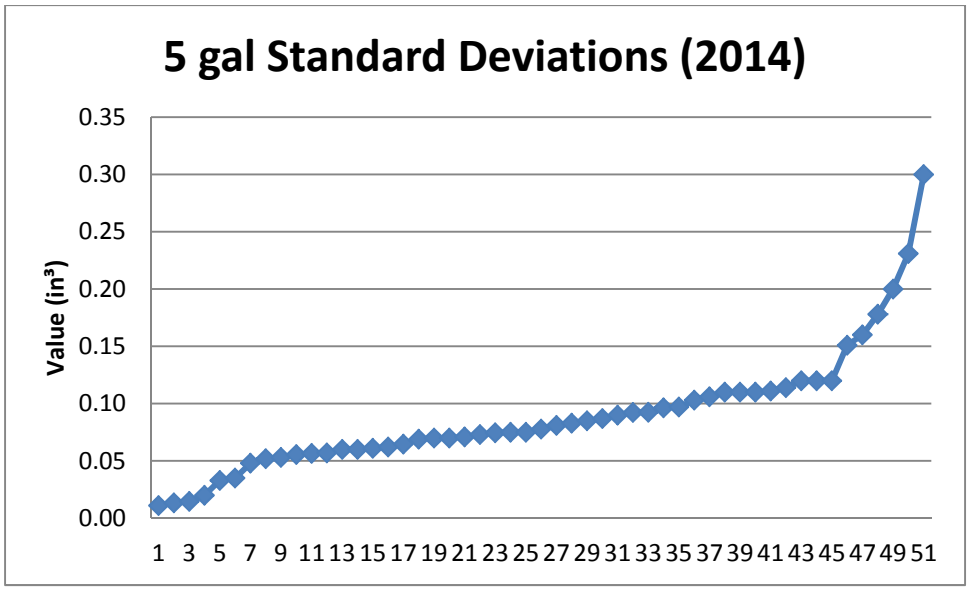

Figure 3. 5 gal Standard Deviation Line Graph - Sorted.

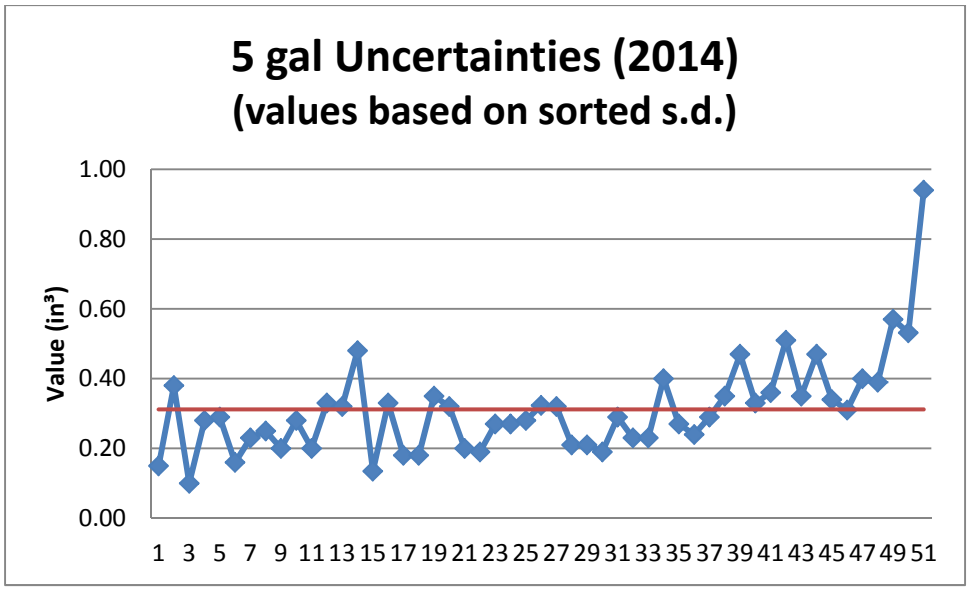

Figure 4. 5 gal Uncertainty Line Graph - Sorted by Standard Deviation.

P_n Assessments for Volume

Laboratories have approached dealing with normalized precision assessments in a number of ways, primarily due to the absence of published guidance and direction in handling failures. In the past, PTs were assessed using either 1) uncertainties must be less than 1/3 of the tolerance in Handbook 105-3 (which is not a published requirement) or 2) uncertainties must be less than 1/3 of the smallest applicable tolerance in Handbook 44, and 3) during 2014, all volume PTs were assessed by the following equation (which is effectively: Unc < Tolerance, for a 1:1 relationship which will be used in the future):

$$P_n = \frac{3 * Uncertainty}{3 * Tolerance} < 1$$

The following approaches were observed in the 2014 submissions:

- Not performing a P_n assessment at all (Either by eliminating P_n assessments or by failing to complete the templates).
- Including the P_n assessments with failures noted and no preventive action or corrective action noted, or basically saying "no one else can do any better, so we're going to leave it as is."
- Comparing uncertainties to tolerance in Handbook 105-3 with a 1:1 ratio (uncertainty must simply be less than the tolerance stated in the Handbook of 0.58 in³).
- Comparing uncertainties to 1/3 of the tolerance given in Handbook 44 (uncertainty must be less than 1/3 of the acceptance tolerance of 3 in³, or less than 1 in³).
- Also used is multiplying the tolerance of Handbook 105-3 by 3 to get a value of 1.74 in³ for comparison with the standard P_n assessment.

OWM will be standardizing the approach for PTs in volume transfer so that "the uncertainty must be less than the tolerances of NIST Handbook 105-3" (Gravimetric volume calibrations will need to be much smaller and likely still reviewed against 1/3 Handbook 105-3 tolerance requirements).

E.g., at 5 gal, Uncertainty < 0.58 in³. The P_n equation for volume transfer will now be as follows:

$$P_n = \frac{\text{Uncertainty}}{\text{105-3 Tolerance}} < 1$$

This approach necessitates that provers routinely be adjusted as close to Zero error as possible to ensure that the Fundamental Considerations of NIST HB 44, Appendix A, 3.2 are met, providing the maximum allowance for error by the user of the volumetric device.

Action Item: Laboratories need to take appropriate corrective actions to modify P_n equations in their Uncertainty tables.

10 lb Sampling of Standard Deviation and Balance Data

A sampling of 10 lb data was conducted to evaluate standard deviations and final uncertainties. In the past there were numerous laboratories that did not have a balance with sufficient resolution to perform internal calibrations of working standards at the 10 lb level and that barely met the requirements for meeting Class F tolerances in Handbook 105-1. There is a table and graph showing the spread of the data below. There were 41 labs reporting, with 11 Sartorius balances and 30 Mettler balances. While only one laboratory at each end of the standard deviation spectrum was flagged as a concern, all of the standard deviations will enable meeting uncertainty requirements for Class F (10 lb tolerance: 450 mg) though 7 laboratories may not meet higher levels of work.

Table 2. 10 lb Standard Deviations.

10 lb Standard Deviations	
Mean	4.371361025
Standard Error	1.416146709
Median	1.68
Mode	1.3
Standard Deviation	9.067763316
Sample Variance	82.22433155
Kurtosis	24.37129953
Skewness	4.641491578
Range	54.47608841
Minimum	0.064
Maximum	54.54008841
Sum	179.225802
Count	41

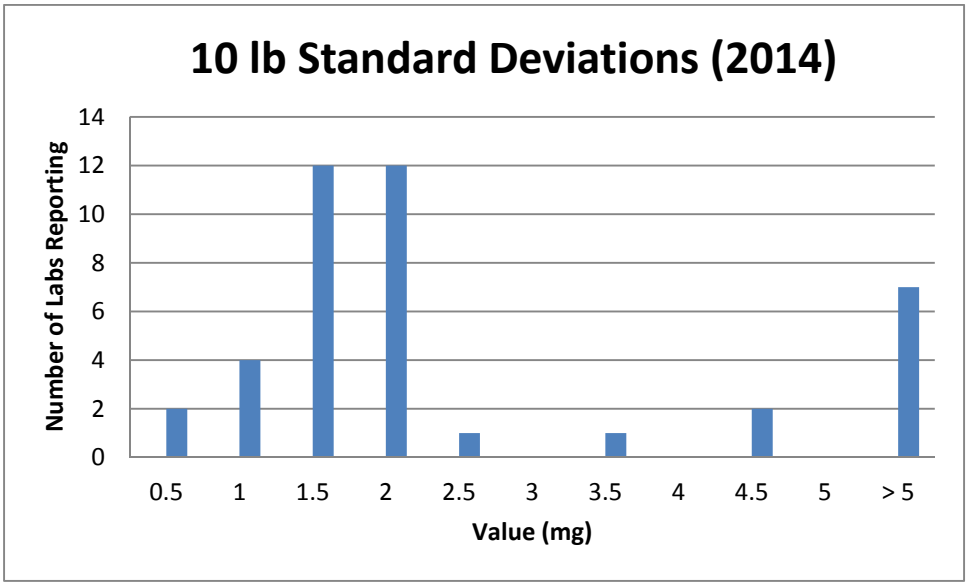

Figure 5. 10 lb Standard Deviations (2014).

Miscellaneous Observations of Uncertainty Tables

- *Failing to Match Application (Appendix B-D) – Problem:* In 2013, a little over 60 % of the laboratory submissions FAILED to ensure that the Appendix B Scope exactly matched the uncertainties that were submitted. Immediate corrective action was required in 2013 prior to issuing 2014 certificates. There were still laboratories with follow up corrective action on this

issue this year. Failing to ensure that the application matches uncertainties is cause for additional action on the part of the laboratory, additional review time for NIST, often causes delays, and will likely cause additional reviews for further errors and problems. Some corrective action is needed.

- *Failing to Use the Template (or Derivation) – both Improvements and Problems:* The Uncertainty Template has been posted and available to all laboratories since 2008. The use of the template has resulted in improved consistency, greater ease in matching the Scope with the application, appropriate identification of corrective action, and ease and time-savings during reviews. Expanding on the template to include columns for k values and degrees of freedom, plus additional columns for P_n assessments for additional classes of standards have further improved the use and application in the laboratories. Even with laboratory developed spreadsheets, as long as they follow the general model and approach as the template, the advantages are still present. In several cases, failing to follow the templates has caused inconsistencies in application of the adopted SOPs, mismatching with the Scope, inadequate data being available for review, additional follow-ups required, not providing adequate calculations for technical reviews, and errors in the Scope on the laboratory Recognition certificates. Some corrective action is needed.

- *Non-SOP Based "Creative" Uncertainty Components – Problem:* If a laboratory claims to adopt the NIST SOPs, it is expected that the uncertainties will include the uncertainty components published as part of the procedure or documented evidence that certain items are insignificant. Many SOPs were updated between 2012 and 2014 – many uncertainty tables need to be updated for consistency and compliance with the SOPs. Corrective action is needed.

- *Using Multiple Files – One for each Measurement Parameter – both Improvements and Problems:* Some laboratories have taken the template and combined it with the laboratory Scope, lists of standards, calibration intervals, and traceability hierarchies for each measurement parameter. This is good and keeps everything needed as evidence to support traceability assessments in one place. However, using the Uncertainty Template, one copy for each measurement parameter where only one worksheet of many is used (and none of the rest are deleted) takes additional time to review and requires additional document management in the laboratory, which is not efficient. If you want to use a single worksheet from the template workbook for a given measurement area, get rid of all of the extra worksheets that have no data and rename the remaining worksheet(s) appropriately! In fact, there have been cases where extra parameters have been embedded in a workbook that is named for a different parameter. Some corrective action is needed.

- *Inadequate Degrees of Freedom – Problem:* The measurement SOPs all provide guidance on suitable measurement assurance. All of the control chart or measurement assurance procedures (SOP 9, 17, 20, 30) provide guidance on how much data is essential. As has been

noted in the past (See NISTIR 6969, SOP 30, 2003 edition), the laboratory needs to have 7 to 12 points to create and initial chart and statistics and have 25 to 30 points for calculating valid uncertainties. In reviewing control charts during the annual submission review process in 2010, many laboratories were provided feedback regarding having too few points to even create valid control charts, let alone valid uncertainties. Based on training and guidance that has been provided, there should be at least 25 to 30 degrees of freedom on every measurement parameter in the laboratory. Fewer than 7 points, and that measurement parameter or range may come off the Scope if/when we catch it. There are some laboratories who have inserted the current number of degrees of freedom, are using correct k values, but really do not have adequate numbers of data points or effective degrees of freedom to validate their uncertainties. Corrective action is needed.

- *Explanations Tabs and Notes in the Uncertainty Tables – Good:* A number of laboratories have inserted extra worksheets for explanation of codes and methods that are used in the Uncertainty files. A number of laboratories have inserted extra comments and review dates into the uncertainty tables. These are examples of "best practices" and are encouraged.