State Lab Annual Submission – Assessments (Session 5371)

Presented via Adobe Connect Pro: February 5, 2015

National Assessment Summaries from Annual Submissions 20150114.pdf

Assessment Circulated: January 15, 2015

Review Uncertainties Annually

- 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
  - updated calibration certificates obtained for standards (which include updated uncertainties).

  - Sections of the Handbook 143:
    - _____
    - _____

Review Control Charts? Update Uncertainties!

- 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.

Obtain or Do Calibrations? Update Uncertainties!

- 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. (Handbook 143, Section 5.6)

Update Uncertainties? Include All Components.

- 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).

Adequate *d.f.* required to use "*k* = 2"

- Uncertainties must be based on "*k* = 2" only where there are adequate degrees of freedom (d.f.) (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).
  - Advantages of: Effective degrees of freedom (enough measurements in your control charts and standard deviation charts); Monte Carlo simulations (GUM Supplement 1)
- Q/A regarding NVLAP and *k*=2 assessments: You are NOT required to submit uncertainties at *artificial k*=2 values. You must submit *d.f.* values when submitting values that are not k=2. ILAC requires "approximately 95 % confidence intervals." NVLAP is modifying their CMCs to reflect accurate use of *k* values.

More applications and recommendations – in a few slides.

Evaluate Uncertainties to Meet Needs

- Uncertainties must be evaluated for acceptability (SOP 29, HB 143, Sections 4.4 Contract Review, and 4.7 Customer Service.)

4.3 Document Control: Review Uncertainty Documents

- 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).

4.14 Technical Audit: Evaluate Uncertainties

- 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*.

- Q/A: if there were no updated calibrations and no updates on control charts, besides the likelihood of us asking “why” no updates at all, at least make a note that values were reviewed and continue to be acceptable and include the actual review dates (that are updated each year!)

4.15 Management Review: Review Uncertainties

- 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.

Assessment: Review Uncertainties!

- This means uncertainties should be reviewed at least annually, when calibration uncertainties updated, with degrees of freedom updated as values are entered into control charts, 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. ☹ Action Item.**

- Q/A: Send in updates to OWM at any time values are to be reduced significantly (by 10 %) or wait until the next submission cycle.

Update Uncertainties for SOP 8

- *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*). ☹ Action Item.**

- Q/A: what is inappropriately small? Failing E_n on a PT just to keep uncertainties small is unnecessary on Class F weights. There is absolutely no marketing value on keeping uncertainties tiny for Class F work.

Evaluate Uncertainties for d.f. and k Values

- **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. ☹ Action Item.**

- Q/A: combining nearby *d.f.* when values pass the F-test (e.g., 10 mg and lower) – yes, no problem!
- Q/A: dealing with replicate measurements (provers, weight carts) – Val is working on a paper with Will Guthrie on this topic; it was covered at the C-RMAP.
- Q/A: GUM Supplement 1 – Monte Carlo simulations also possible!
  - See: http://uncertainty.nist.gov/ for "NIST Uncertainty Machine"
  - http://www.nist.gov/itl/sed/gsg/uncertainty.cfm for some tutorials

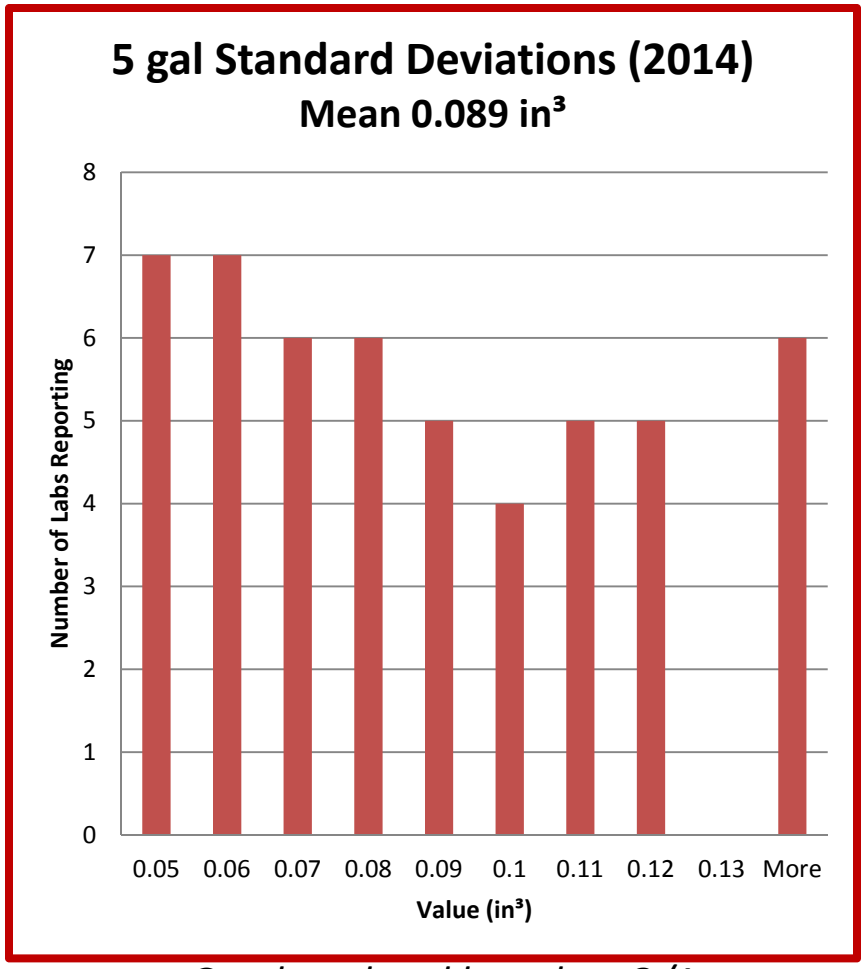
Evaluation of P_n Failures

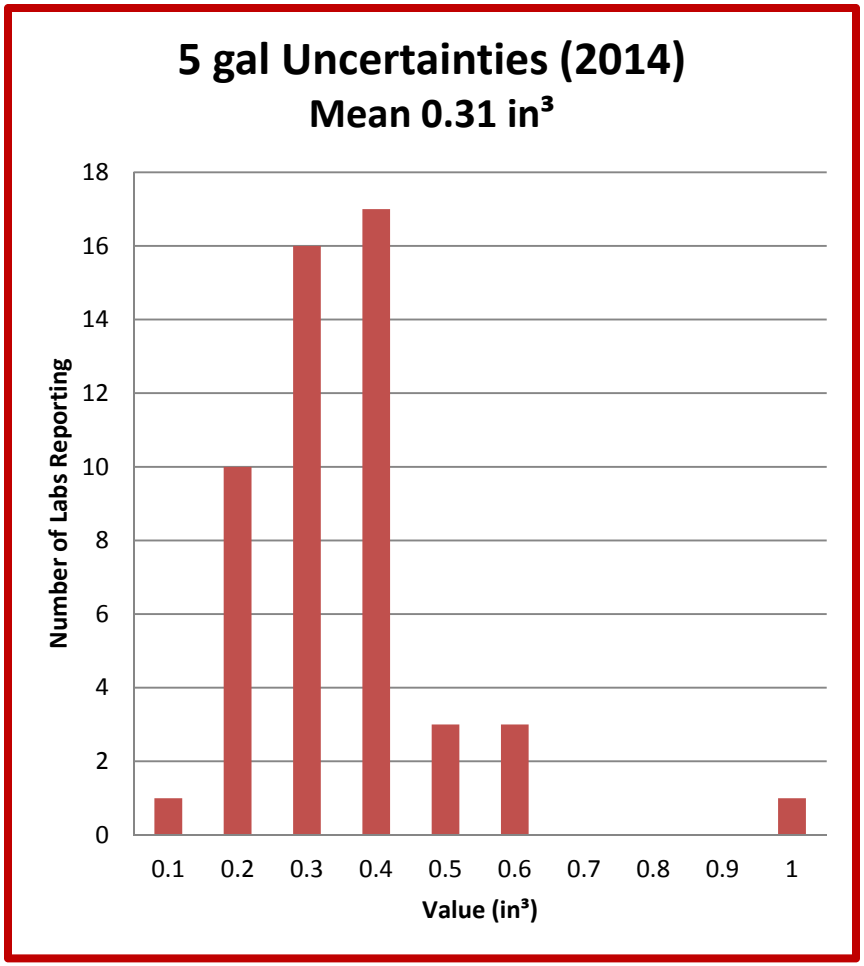
- **Some labs are assessing uncertainties using P_n, assessing with extra classifications and/or tolerances, noting failures and taking actions. Good job! ☺**
- **Some labs are not using the template and have not incorporated P_n assessments, or are using the template and have failures with no notes, assessments, comments or actions. Action required. ☹ Action Item.**

Sampling: 5 gal (units in^3)

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

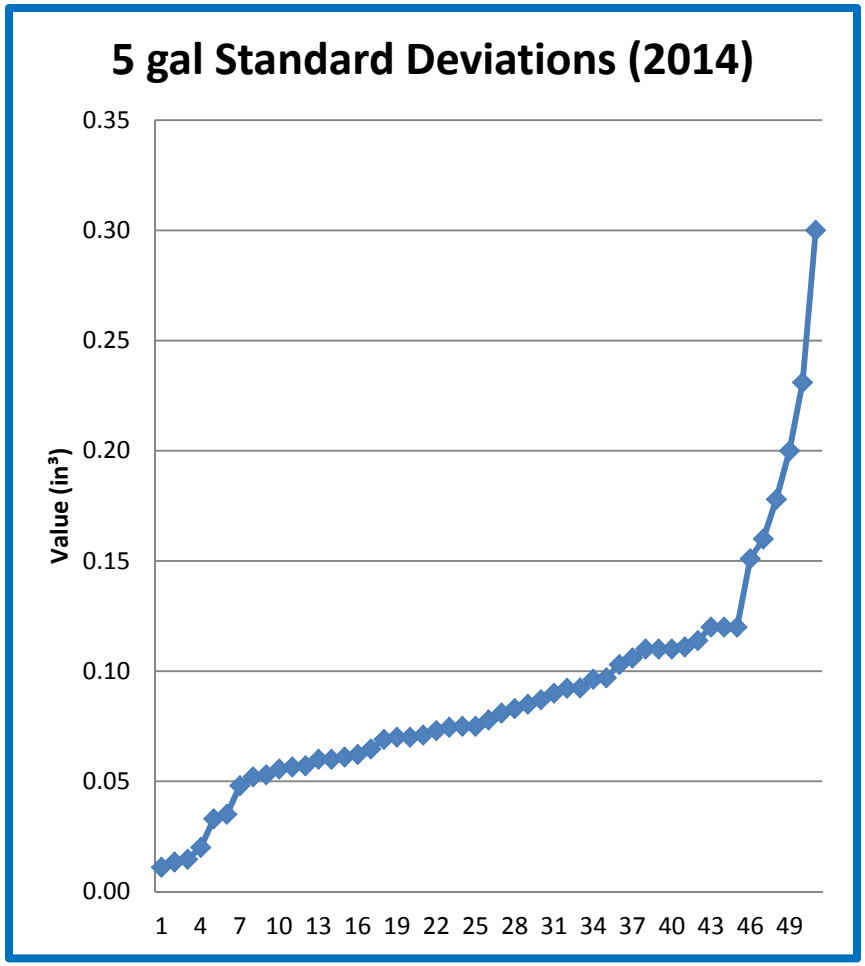
Sampling: 5 gal (units in^3)

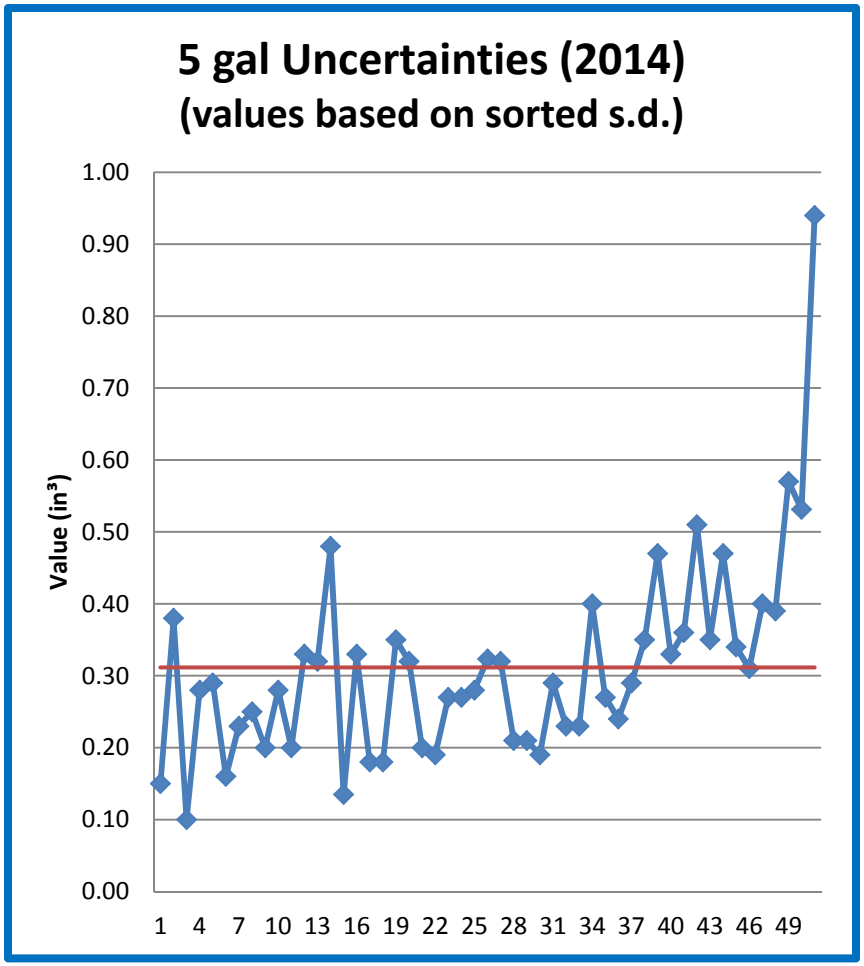




Graph updated based on Q/A.

Sampling: 5 gal (units in^3)





P_n Action Item (for *nearly* everyone)

- OWM standardizing P_n for volume transfer
  - The uncertainty must be less than the tolerances of NIST Handbook 105-3
  - Gravimetric volume calibrations will need to be much smaller; e.g., 1/3 Handbook 105-3 tolerances
- The P_n equation for volume transfer will be:

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

- At 5 gal, Uncertainty < 0.58 in³
- Action Item: Laboratories need to take appropriate corrective actions to modify P_n equations in their Uncertainty tables. **(Only 4 labs are doing this already.)**

- Q/A: HB 44 requires uncertainty less than 1/3 the tolerance (Fundamental Considerations) and according to HB 130, all states have adopted HB 44. HB 44 tolerance on 5 gal draft for RMFD is 3 in³ for acceptance tolerance; or 1 in³. We are not using this value anymore. Just use Unc < HB 105-3 (0.58 in³).

Not specially assessed this year but…. friendly advice coming here….

- Q/A regarding Volume Uncertainties.

- SOP 19 was updated in 2013 with documented uncertainty budget tables.
- SOP 14 for gravimetric calibration SHOULD BE significantly smaller than volume transfer!

- (Mean value for gravimetric uncertainties at 5 gallons is around 0.12 in^3, or about 1/3 of volume transfer uncertainties.)

SEE SOP 19 and Volume Seminar.

Identify and characterize uncertainty sources. (3.2)

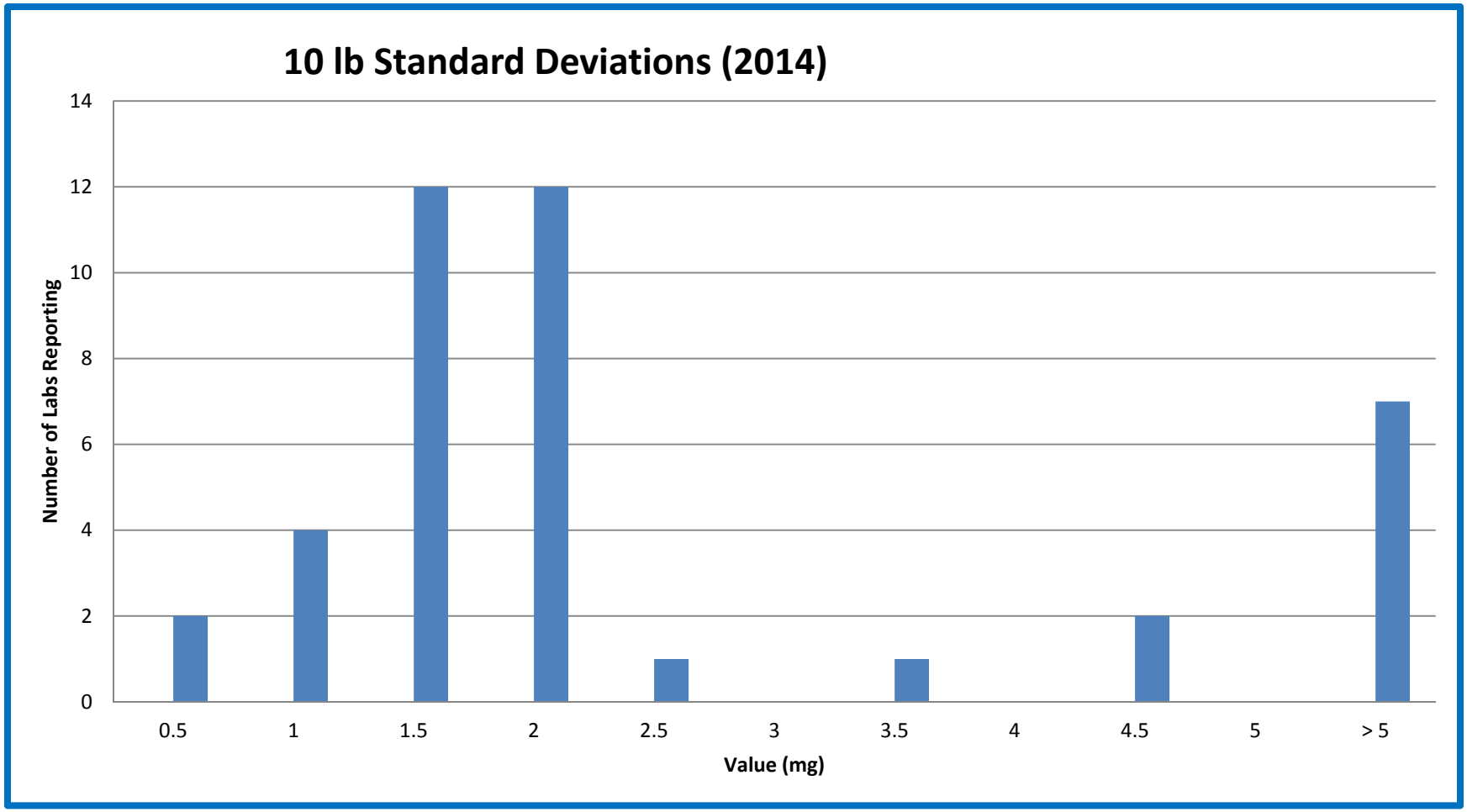
Document the Uncertainty Budget Table

Uncertainty Component Description	Symbol	Source	Typical Distribution
Uncertainty of the standard (5.1)	u_s	Calibration report; may be multiplied or added based on dependencies	Rectangular or Normal divided by coverage factor
Accepted standard deviation of the process (5.2)	s_p	Control chart, standard deviation chart	Normal
Uncertainty or uncorrected error associated with a neck calibration (5.3)	u_n	From experimental data	Rectangular
Ability to read the Meniscus in S (5.4)	u_m	None if using a slicker-plate type standard; GMP 3	Triangular
Ability to read the Meniscus in X (5.4)	u_m	GMP 3	Triangular
Water temperature (S) (5.4)	u_{ts}	Consider accuracy, resolution, and gradients	Rectangular
Water temperature (X) (5.4)	u_{tx}	Consider accuracy, resolution, and gradients	Rectangular
Cubical Coefficient of Expansion on S (5.4)	u_{CCE}	5 % to 10 % (EURAMET CG-21)	Rectangular
Cubical Coefficient of Expansion on X (5.4)	u_{CCE}	5 % to 10 % (EURAMET CG-21)	Rectangular
Uncertainty of bias or drift of standards (5.2)	u_b	From control chart	Rectangular
Uncertainty of drain time	u_d	From experimental data	Normal

Sampling: 10 lb (units mg)

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

Sampling: 10 lb Standard Deviations



Additional Problems (and Best Practices)

1. ***Failing to Match Application (Appendix B-D) – Problem:* Action Item.**
2. *Failing to Use the Template (or Derivation) – both* ***Improvements*** *and* ***Problems:* Action Item.**
3. ***Non-SOP Based "Creative" Uncertainty Components – Problem:* Action Item (review SOP updates!)**
4. ***Using Multiple Files – One for each Measurement Parameter: Improvement Action***
5. ***Inadequate Degrees of Freedom – Problem:* Action Item.**
6. ***Explanations Tabs and Notes in the Uncertainty Tables – Good***

Thank you!

Applications!

Corrective Actions!