Uncertainty of Measurement and Traceability of Measurement
Frequently Asked Questions (FAQs)

Webinars conducted March 11 and April 30, 2010

1. Is the Excel spreadsheet presented available for download?

   A: Yes, the workbooks are posted on the AIHA-LAP, LLC website under “Policy Modules” at the bottom of the page.

   http://www.aihaaccreditedlabs.org/PolicyModules/Pages/default.aspx

2. What do you consider "modifications" to a method? For example, in GC methods, if you use a different column, is that a modification?

   A: A modification to a method is something that changes the chemistry (different reaction), different sample preparation (change in desorbing solvents or digestion methods), or the type of detector or instrument used. Using a different column that achieves equivalent or improved separation for gas chromatography is not considered a modification.

3. What if the NIOSH method specifies a packed column and you are using a capillary column?

   A: That is an acceptable substitution.

4. Does the requirement of the uncertainty have to be incorporated into each analytical method?

   A: No. It can be incorporated into each analytical method, but that is not a requirement. The requirement to have procedures describing how uncertainty will be calculated and reported can be addressed with a single procedure, within each analytical method, or in any way a laboratory chooses as long as all requirements, including identifying contributors to uncertainty for each method or type of method are met.

5. If the client does not request uncertainty does the laboratory have to calculate the uncertainty with all analyses?

   A: No. The laboratory must have procedures and data available to calculate uncertainty of measurement, but does not need to report uncertainty unless requested by the customer.

6. So if our customers don't require a measurement uncertainty, then we don't have to calculate it for each analyte, but have to have a procedure that describes how we would calculate and report it?

   A: That is correct.

7. On PLM visual percent estimations, are there any suggestions for grouping results to configure SDs and configuring the measurement of uncertainty?

A: AIHA LAP has no specific recommendations, although observed approaches include the use ranges of such as 1 to 5%, 5-10%, >10%, etc. for grouping results to determine standard deviations.

8. How would you apply this to bulk asbestos and what would be the measurand?

   A: The measurand would be % asbestos in bulk samples. Uncertainty can be estimated using the standard deviation of replicate sample analyses and laboratory control samples, as applicable.

9. For PCM do we have to report the bias along with the MU? If yes, what quality data do we use?

   A: NIOSH 7400 includes the method for reporting uncertainty of measurement and does not require that bias is reported.

10. For PCM Samples can we use the Intralab Sr to calculate the UCL and the LCL OR do we have to use the Interlab Sr?

    A: The equations for calculation of the UCL and LCL in NIOSH Method 7400 require the use of the interlaboratory Sr values for expressing measurement uncertainty. Interlaboratory Sr can be estimated using round robin data.

11. For the Interlab Sr should we have one Sr for every range OR should we have only one Sr?

    A: The laboratory should calculate and utilize the interlaboratory Sr values for the three ranges specified in step 11 of NIOSH Method 7400 (5-20, >20-50 and >50 fibers/100fields), as applicable.

12. For PCM samples, we are using the NIOSH 7400 method (Type A approach). For this method, I understand that the measurement of uncertainty at the 95% CL is the difference between the upper confidence limit and the lower confidence limit. Is this correct?

    A: The estimation of uncertainty for a given result at a 95% confidence level would be the calculated value with a range from the lower confidence limit value to the upper confidence limit value.

13. What is the difference between analytical sensitivity and limit of detection as it applies to colony forming units on plate counts in Environmental Microbiology?

    A: This question is outside the scope of traceability and estimation of uncertainty of measurement.

14. Do stock reference cultures have to be purchased from a culture collection, such as ATCC or can they be isolates collected and identified by the laboratory?

    A: Cultures from ATCC are best, however currently, laboratories may use isolates collected and identified by the laboratory and confirmed by a second independent qualified laboratory or individual.

15. Would it suffice if a laboratory takes an internally identified reference culture and submits it to another AIHA-LAP accredited laboratory for identification and that lab comes up with the same identification?

    A: YES

16. We would like a specific example for lead in paint chips and show how you calculate uncertainty (combined uncertainty).

    A: A specific example for lead in paint chips and how uncertainty can be calculated is included in the Chemistry example Excel workbook on the AIHA-LAP website. Example Chemistry Measurement Uncertainty Calculations

17. Aren't you assuming that the CV is linear through all concentrations when you are pooling them? Don't you have to test for linearity first?

    A: When pooling CV, you are making an assumption that CV is relatively constant throughout the concentration range that is pooled. If CV varies significantly with different concentration levels of the measurand, then several estimations of uncertainty at differing concentration levels is more appropriate.

18. For estimating uncertainty using Type A, the policy requirement allows use of LCS QC data to estimate the combined uncertainty (5.4.3, and p. 10 of 18, 5.3.2.3.1, Guidance Document), since control charted LCS data is a source of long term uncertainty that have gone through every sample prep, environmental conditions, personnel, instrument, etc. Therefore, is it acceptable to use the single sample standard deviation from this control chart to satisfy the estimate of overall uncertainty? In other words, is it correct to say we don't need to estimate each component of uncertainty separately and then combine them into one overall uncertainty using type A method if we use the sample standard deviation from control chart?

    A: The LCS may include the only significant sources of uncertainty, but the laboratory must make this determination. Other sources can include the uncertainty of reference materials used for calibration standard preparation and/or preparation of the LCS. If you are dealing with solid samples, then sub-sampling can be a significant contributor. An evaluation similar to that described in the guidance document and presented in the example Excel workbooks is required. In many circumstances, the LCS incorporates all significant contributors to uncertainty.

19. If you use type A method, do we need to calculate combined uncertainty? or just use LCS RPD?

    A: You need to evaluate contributions to uncertainty and calculate combined uncertainty taking into consideration these contributors. If all contributors are not accounted for by the LCS RPD (such as reference material uncertainty), then these contributors must be considered by calculating the combined uncertainty.

20. If we can use the control chart sample standard deviation to estimate the overall uncertainty requirement, what do SD1, SD2, etc represent in 5.3.2.5.1, "Calculate the Combined Uncertainty" formula? Is this formula just if we are using type B method?

    A: This is applicable to both the Type A and Type B method. When using the Type A method, SD1, SD2, SD3… may represent the standard deviation of the LCS, the standard deviation of the reference materials used, and the standard deviation of replicate analysis of sub-samples

(of solid samples). If significant (i.e. greater that 1/3 of the largest SD), these SDs must be combined using the formula provided to calculated a combined uncertainty.

21. Do you have a recommended method for testing the linearity? If so, could you include that test and examples of where you would break the CVs into groups on your spreadsheets?

    A: AIHA-LAP has no recommended method for testing linearity.

22. Are there other contributions to uncertainty (e.g., pipetting, dilution, etc)? Are these negligible?

    A: The contribution from pipetting is taken into account by laboratory control sample, since it is treated in the same manner as a customer sample. For dilutions, there may be an additional contribution if the laboratory is routinely diluting customer samples, but not diluting laboratory control samples. The additional contribution from dilution can be determined via gravimetric evaluation of the dilution process.

23. Does the combined uncertainty equation (square root sum of squares) only contain random error components or can it contain systematic errors as well?

    A: The type A approach generally includes primarily random error components, but may also include some systematic errors (such a differences in instruments and/or analysts).

24. Mettler Toledo's calibration certificates for balances indicate that Mettler is ISO 9001:2000 registered, but not ISO/IEC 17025 accredited. Will the site assessors consider this to be the same or will we need to find another supplier of this service?

    A: Mettler Toledo does offer ISO/IEC 17025 accredited calibration services for balances. The laboratory must order this type of service and obtain a calibration report that includes the required elements of section 5.2 of the AIHA-LAP Traceability of Measurement Policy.

25. What are the calibration/verification criteria for syringes?

    A: The calibration/verification of syringes is not addressed by the AIHA-LAP Traceability of Measurement Policy.

26. Verification daily when used for balances?

    A: Verification of balance calibration is required daily when used (each day of use).

27. Do we need training records for personnel performing outside calibrations, such as thermometers and balance masses?

    A: AIHA-LAP requires that external calibrations are performed by ISO/IEC 17025 accredited calibration laboratories. When such laboratories are used, the accreditation is sufficient evidence of competence and the AIHA-LAP accredited laboratory is not required to maintain training records of outside personnel.

28. If you have weights calibrated, is in-house balance calibration in accordance with 17205 acceptable?

A: Yes, in-house calibration is acceptable provided the laboratory follows acceptable procedures, calculates and reports uncertainty, and maintains training records for staff. This is discussed in section 5.2.2.1 of the AIHA-LAP Guidance on Traceability of Measurement.

29. Therefore, after the initial balance certification and as long as no "service" is performed and because any pure calibration is optional - is the ISO/IEC 17025 accreditation really required for this type of calibration activity?

    A: External calibration is not required for balances.

30. Do we need to use ISO/IEC 17025 accredited providers of chemical supplies and equipment? For Example Thomas Scientific or Olympus?

    A: The appropriate accreditation for chemical suppliers is accreditation as a reference material producer to ISO Guide 34 in conjunction with ISO/IEC 17025. Equipment suppliers are not required to have any accreditations unless they are performing external calibrations of equipment.

31. What do you do when you determine an outside calibration service is not traceable to NIST as claimed on their certificate?

    A: If the service is not accredited to ISO/IEC 17025 and does not provide traceability, then this service does not satisfy AIHA-LAP traceability requirements.

32. We do many analyses of our own products which would never be available as CRMs. How will we meet the requirement for traceability?

    A: Section 5.3 of the AIHA-LAP Traceability of Measurement Policy (and further expanded in the guidance document) addresses when traceability to certified reference materials is not available. Under such circumstances, agreement with the customer regarding the use of alternate reference materials can satisfy AIHA-LAP requirements.

33. We only do verifications of calibrations and use ISO 17025 vendors for calibration. Do we need to calculate MU's on the verifications?

    A: Estimates of uncertainty of measurement do not need to be calculated for verifications; however, acceptance limits are needed.

34. We use Mettler Toledo for the calibration of our balances. Mettler Toledo is accredited by A2LA in accordance with ISO/IEC 17025:2005. Can we use their services?

    A: Yes, provided a calibration report that includes the required elements of section 5.2 of the AIHA-LAP Traceability of Measurement Policy is provided.

35. Are we responsible for the validity of reference material certificates? If the supplier "lies" or misstates the information are we as laboratories responsible to verify each certificate's validity?

    A: It is the laboratory's responsibility to use a competent supplier of reference materials where possible.

36. How do you establish traceability for neat materials (i.e., organics)?

A: A certificate from a manufacturer stating the percent purity +/- some value is currently acceptable. It is helpful to show how the percent purity was determined. For mixtures, the providers may have accreditations.

37. How does one establish traceability to the SI? For example, does traceability to a specific NIST standard provide traceability to the SI?

    A: Yes, because NIST reference standards are traceable to SI. To clarify, this is not full traceability for all NIST reference materials. There is full traceability; for reference standards (mass, length, and temperature), but not for all reference materials (SRM, CRM, and reference materials).

    Refer to the guidance documents on the website as there is a large section discussing reference materials and levels of acceptability.

38. It may be interesting to look at examples of certificates for SRMs and/or secondary reference materials. Note that examples are available from the NIST website.

    A: The AIHA-LAP Guidance and Traceability of Measurement has a section regarding reference materials and contact information for locating such.

39. You mention requirements for glassware (non class A). What are the requirements for class A glassware used in critical measurements?

    A: Class A glassware has published uncertainties associated with volume. Laboratory calibration or verification is not required unless the glassware has been subject to abnormal use (such as very high temperatures).

40. Regarding the example certificate for the thermometer from Calibration Corporation, if it complies with ISO/IEC 17025, doesn't it comply with AIHA-LAP? I'm wondering why you'd use this calibration report if it wouldn't be applicable.

    A: The certificate presented in the second webinar is acceptable as it includes an ILAC signatory AB logo, measurement results and associated uncertainty of measurement.