Summary of the NELAP Accreditation Council Meeting

February 3, 2014

The NELAP Accreditation Council (AC) met at 1:30 pm EDT on Monday, February 3, 2014, for another of its quarterly series of assessor conversations. Attendance was not taken, except to note that FL, LA DEQ, MN, TX and VA, plus OK, had representatives present, as well as ACLASS, Analytical Excellence, Dade Moeller, Dynamic Technology Solutions, Shepherd Technical Services, Sims & Associates and Wade Consulting.

The AC's Vice Chair, Paul Bergeron of LA DEQ, introduced Susan Wyatt of MN as the moderator of the discussion, and Kelly Black of Neptune and Co., as the presenter for the topic of Assessing Certified Reference Materials.

The content of the PowerPoint slides used in Kelly's presentation is provided in Attachment 1. Images of the particular reference material labels that Kelly used are unavailable, but at least one of the certificates was prepared so that it could "almost" be misunderstood to be actually "certified" even though it actually never made that claim. One way to help determine the accuracy of the labelling is to check the scope of accreditation for the provider, on the provider accreditor's website. Another important issue, again illustrated in the absent certificates, is to determine whether "certified reference material" purchased from a second vendor or supplier is actually from a separate manufacturing batch than the original CRM, and not just a sub-lot supplied by a re-seller.

Kelly had to leave the call at the end of the presentationbut Mitzi Miller of Dade Moeller agreed to answer additional questions. The primary issue discussed was that the 2009 TNI ELSS does not have an explicit requirement for Guide 34 accreditation in V1M2 §5.6, and that a "note" in that section indicates that it does not apply. Several individuals believe that the requirement for certified reference materials absolutely ought to apply to environmental laboratories.

Attachment 1

What to Expect on CRM Certificates
Presented to the NELAP Accreditation Council Assessor Call, February 3, 2014,
by Kelly Black of Neptune and Company, Lakewood, Colorado

1 -- When are CRMs Needed?
- Reference Material use is usually associated with calibration of instrumentation
- Reference materials shall, where possible, be <u>traceable</u> to SI units of measurement, or to certified reference materials.

2 -- How do you know you've got a CRM?
- Check before ordering
- Confirm after receipt
  - The certificate should tell you all you need to know!

3 -- ISO Guide 34: 2009
- The reference material producer must provide a certificate for certified reference materials.
- The contents of those certificates must comply with the requirements of ISO Guide 31.

4 -- ISO Guide 31: 2000
- CRM certificates should contain all the information which is essential to its use.
"Without the certificate, the material, however costly its production, is valueless."
ISO Guide 31: 2000

5 -- Certificate Requirements
- Name of responsible organization and certifying officer
  - Company name, physical address
  - Telephone number, fax number
  - email address, if available
  - Name and signature of certifying officer
    - accepts responsibility for CRM

6 -- Certificate Requirements
- Document Title
  - "Certificate of Analysis"
  - "Certificate of Measurement"
  - etc.
  - Provisional certs discouraged
  - Multiple certs per batch discouraged

7 -- Certificate Requirements
- Name and description of material
  - Type of material
  - Content of material
  - Physical description
  - Provide sufficient information to avoid misuse of the material

8 -- Certificate Requirements

- CRM "code", batch number, and date
  - Unique code that identifies the CRM
  - Batch number
  - These may be combined into one code by some reference material producers
  - Date of certification

9 -- Certificate Requirements
- Intended use
  - Primary intended use of the CRM
  - Secondary intended uses may be mentioned
  - Not intended to limit use
  - Examples: for calibration of instruments, for validation of methods, for preparation of internal reference samples

10 -- Certificate Requirements
- Instructions for use and safety
  - Examples:
    - Acceptable temperature range for storage and use
    - Solvents and mixing procedures, as appropriate
    - Exposure to light limitations
    - Subsampling protocol
  - MSDS (SDS)
    - Included directly or by reference

11 -- Certificate Requirements
- Homogeneity
  - Quantified level of homogeneity
  - Minimum subsample for which homogeneity is valid
  - Procedure to "homogenize" prior to use

12   Certificate Requirements
- Stability
  - Quantitative degree of stability (G34)
  - Period of validity with starting date
  - Statement that stability is monitored
  - Assurance of notification in case of loss of stability
  - Equation for use of instable material (e.g., radionuclides)

13 -- Certificate Requirements
- Certified values
  - VALUE
    - method of establishing value
    - interim values if multiple methods used
  - UNCERTAINTY
    - based on GUM
    - method for establishing uncertainty
  - TRACEABILITY
    - ideally to SI or NMI

14 -- Certificate Requirements

- Uncertified values
  - Other characteristics of the material measured during production of the CRM
  - Clearly identify as uncertified
  - E.g., weight, pH, unintended analytes, etc.

15 -- Example Certificates
- Six different certificates were displayed as examples of the variability in format and also to show that a non-Certified Reference Material may actually be issued with a certificate that closely resembles a CRM, only not claiming manufacture in compliance with ISO Guide 34

16 -- Certificates Summary
- CRM certificates should:
  - Provide sufficient info to avoid misuse
  - Provide contact information for the responsible party
  - Provide clear traceability info
  - Show current accreditation info
- RM certificates should not imply certification