Should Reference Material Providers, Including NMIs, be Accredited?

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NEPTUNE AND COMPANY

Presentation Overview

- Definition of Accreditation
- Requirements of Accreditation
- Accreditation Process Overview
- Benefits of Accreditation

What is Accreditation?

'**Independent evaluation** of conformity assessment bodies against recognized standards to ensure their impartiality and competence to carry out specific activities, such as tests, calibrations, production of reference material, inspections and certifications.'

Accreditation Requirements…

- ISO Guide 34 – General requirements for the competence of reference material producers
- ISO Guide 30 – Reference Materials – Selected terms and definitions
- ISO Guide 31 – Reference Materials – Contents of certificates and labels
- ISO Guide 35 – Reference Materials – General and statistical principles for certification
- ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories

Accreditation Process

- Application
- Assessment Planning and Preparation
- Onsite Assessment
- Post Assessment Activities including Corrective Action Response Review
- Evaluation of Assessment Package by the Accreditation Council
- Accreditation!

Who Benefits from Accreditation…

- Reference Material Producers
- Users
- Specifiers
- General Public

Accreditation Benefits...

- Reference Material Producers
  - Provides a Credential
  - Regular, objective “check-up”
  - Increased productivity
  - International recognition and acceptance
  - Staying on “cutting edge”
  - Improved performance

Accreditation Advantage

- Accreditation bodies required to publish/maintain directory of accredited organizations - which includes the organization's contact information and scope for materials available
- Further means of promoting services to potential clients
- With MRA's, opens the door for international recognition
- Facilitates acceptance of data in international market
- Many users routinely specify accreditation for suppliers services

Accreditation is important for Reference Material Providers (RMP), even for national metrology institutes(NMI's), to ensure the consistency of:

- Uncertainties
- Homogeneity
- Stability

Uncertainties

ISO Guide 34:2009 5.16.2 An important aspect of establishing the property values of the reference material being produced is an assessment of their uncertainties.

- GUM (ISO/IEC Guide 98-3)
- ISO Guide 35

Uncertainties

Is your CRM **MISSING** uncertainty values?

Do you know **HOW** the uncertainty values were calculated? "+/- 5%" ???

Do you know if **ALL** the variables were included?

- Production, homogeneity, transportation, storage.

Is the CRM **FIT** for purpose?

- Laboratories often perform additional analytical work to achieve the needed uncertainty for a CRM where the uncertainty values were either missing or too variable.

Homogeneity

Aliquots are often taken from CRMs to generate calibration and other standards for laboratory use.

- Is each aliquot homogeneous / equivalent?
- Is the minimum sample size for the level of homogeneity stated on the Certificate of Analysis?

Homogeneity

ISO Guide 35:2006 5.13 Assessment of homogeneity is always required…
…Although the measurement values do not have to be communicated to customers, the degree of homogeneity (e.g. expressed as maximum between bottle variation) shall be indicated in the documentation accompanying the reference material.

Homogeneity

Not knowing the volume of the CRM required to meet the stated level of homogeneity, could cause internal quality samples to be out of control.

Stability

Stability

ISO Guide 34:2009 5.14.2 The stability of the reference material shall be assessed…. in accordance to **ISO Guide 35**.

ISO Guide 35:2006 8.4 Stability monitoring

Monitoring should be envisaged during the lifetime of the CRM. … As these mechanisms are highly unpredictable, it is necessary to monitor the stability.

Stability

Stability is the ability of a reference material, when stored under specified conditions, to maintain a stated property value within specified limits for a specified period of time.

Example:

- A lab found an organochlorine pesticides SRM from an NMI had Aldrin instability.
- The laboratory notified the NMI.
- The NMI issued a letter stating that Aldrin had decreased in concentration by 30%.

Stability

Critical laboratory impact

- Calibration standards diluted from this CRM have been incorrect for an unspecified timeframe.
- Any subsequent analyses related to the calibration is invalid for an unspecified timeframe.
- Traceability??

Accreditation Benefits…

- General Public
  - Stimulation of higher standards of quality which leads to:
    - more consistently reliable data
    - more effective health and safety regulations
    - more consistent product quality

Should RMPs, including NMIs, be accredited?

Accreditation and adherence to ISO Standards generates CRMs with:

- Verified with validated methods
- Uncertainties calculated consistently
- Ensured to be homogeneous to a specified level
- Stability, not only verified, but with continual monitoring
- Standardized information on certificates

Questions?

Thank you!

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