



ANSI-ASQ National Accreditation Board / ACLASS

# ISO Guide 34 for Environmental Labs - - NEMC 2012

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# Related ISO Technical Standards

- ISO/IEC 17025 – Calibration and Testing Labs
- ISO/IEC 17020 – Inspection Bodies
- ISO/IEC 17043 – Proficiency Testing Providers
- **ISO Guide 34 – RMPs**
- ISO Guide 65 – Product Certification



# ISO Guide 34:2009

- “General requirements for the competence of Reference Material Producers”
- Replaced 2000 version – REMCO not CASCO
- Important to understand it as a Standard and NOT a Guide, despite its title
- Built on ISO 17025 framework, but does not incorporate all 17025 elements
- Carries a large burden to educate the technical community about its use / value



# Distinguish Reference Standard from Reference Material

- VIM definition 5.6: A **reference standard (RS)** (also called reference measurement standard) is defined as “*measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location.*”



## ... vs a Reference Material

- VIM definition 5.13: A **reference material** (RM) is defined as “*material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.*” (may be **qualitative** or **quantitative**)



# Value / Need for RMs and Guide 34 Accreditation

- Needed for **confidence** in many elements :
  - Identification
  - Quantitation
  - Metrological traceability
  - Measurement uncertainty



# Example Applications of RMs for Environmental Laboratories

- Establishing identity and concentrations of analyzed analytes
- Establishing traceability of analytes
- Instrument calibration for analysis of analytes
- Establishing test uncertainty for determining analytes
- Performing method validations
- Assuring QC and QA for analyses via IC's, LCS, spikes, etc.



# Categories of Reference Materials

- Category A -- Chemical
- Category B -- Biological and Clinical
- Category C -- Physical
- Category D -- Engineering
- Category E -- Other - unique





# Subcategories of Chemical RMs

- Metals
- Inorganic
- Organic (including foodstuffs)
- Environmental
- Health & Industrial Hygiene
- Engine Wear
- Analyzed Gases
- Forensic RMs
- Ion Activity (pH, conductivity)



# Subcategories of Biological RMs

- Most categories related to Clinical (medicine)
- Bacteriology and Mycology
- Virology
- Forensic materials (hair, fiber, blood)
- Other (DNA and other biological materials)



# Subcategories of Physical RMs (for Environmental Labs)

- RMs for Optical Properties (spectral, uv)
- RMs for electrical and magnetic properties
- RMs for frequency
- **RMs for Radioactivity**
- RMs for thermodynamic (temperature)
- RMs for physico-chemical (density, viscosity)



# Distinction between RMs and CRMs

- RM is the general category
- CRM is a sub-category with the most detail, traceability and uncertainty defined
- ISO Guide 34 Scopes of Accreditation need to have clear distinctions on these RM / CRM



# Definition / Distinction of a CRM

- **VIM definition 5.14:** A certified reference material (CRM) is defined as a *“reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.”*



# CRM Definition directly from Guide 34

- reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability



# CRM Uncertainty

- Builds on ISO 17025 uncertainty for assaying the “property values” of the RM
- Adds 3 key new uncertainty sources to  $U_{CRM}$ 
  - Homogeneity – package to package
  - Short-term stability (shipping)
  - Long-term stability (shelf-life)
- Follow ISO Guide 35 for details and examples



# ISO Guide 34 Requirements NOT in ISO 17025

- Many related to subcontractors / collaborators
- Determination of “property values”
- Details on Certificates of Analysis
- Production planning and execution
- Homogeneity and Stability requirements
- CRM uncertainties and traceability
- Follow ISO Guide 31 and Guide 35





# ISO 17025 Requirements NOT Automatic in ISO Guide 34 Accreditations

- Possible to be an RMP and have NO LAB !!
  - ...but key list of responsibilities detailed
- Many subcontracted functions permitted not otherwise allowed in 17025 schemes



# Priorities for RM/CRM Traceability for Accredited Laboratories

- Highest priority is always using a RMP accredited to ISO Guide 34 or a NMI or DI
- Need to acknowledge that many accredited RMPs do NOT produce many CRMs
- Need to be cautious that sourcing RMs from an accredited RMP may yield RMs and not CRMs (may not be on their Scope of Accrn)



# Status of International RMP Accreditations and ABs

- APLAC currently has an MRA for RMP accreditations with 5 approved AB's
- Several other AB's starting an RMP accreditation program
- Europe in the EA has multiple AB's approved as RMP accreditors but no MRA as yet
- IAAC has RMP accreditations by multiple AB's but no MRA as yet
- No ILAC Mark used as yet



# Final Thoughts

- Key role of Reference Materials in a great many testing and calibration and inspection areas
- All relate to maintaining confidence in the technical analysis and operations and reports
- Accreditation to ISO Guide 34 a key component
- Large educational challenge to us all to help contribute and build this confidence



# ANSI - ASQ National Accreditation Board



- Laboratories – ISO/IEC 17025
- Inspection Bodies
  - ISO/IEC 17020
- RMPs – ISO Guide 34  
(Reference Materials)
- PT Providers – ISO/IEC 17043
- Product Certifiers
  - ISO Guide 65
- Government Programs:
  - DoD ELAP, EPA Energy Star, CPSC Toy Safety, NRC, NST IPV6, US Navy
- Training Programs



- Accreditation for ISO/IEC 17025 forensic test laboratories and ISO/IEC 17020 forensic test agencies
- Academic Programs
- Workshops and Training



- Certification Bodies
  - ISO/IEC 17021
- Accreditation for Management System Certification Bodies:
  - ISO 9001 (QMS)
  - ISO 14001 (EMS)
  - TS 16949 (US Automotive) etc.

