



Laboratory Accreditation Body Expert Committee

Carl C. Kircher, PhD, Chair

Forum on Laboratory Accreditation

Washington, DC

August 10, 2017



Agenda

Welcome and Introductions

Update on Activities Since Houston

Discussion of Revising Volume 2

Outline Based on Draft ISO/IEC 17011

Discussion of Specific Issues Considered for Inclusion

Comments and Additional Issues from Participants

Adjourn





Committee Membership

- Carl Kircher, Chair
- Nilda Cox, Vice Chair
- William Batschelet
- Oommen Kappil
- Catherine Katsikis
- Marlene Moore
- Mei Beth Shepherd
- Aurora Shields

Associate Members:

- Yumi Creason
- June Main
- Bill Ray
- Donna Ruokonen

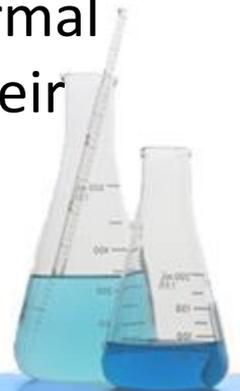
Program Administrator -
Lynn Bradley





Activities Since Houston

- Discussion of Comments from Participants in LAB session in Houston
 - Topics primarily concern remote assessments
 - Cannot be addressed until language of final 17011 revisions are available
 - All comments in public sessions will be noted in “response to comments” spreadsheet, from meeting minutes.
 - Individual responses will not be provided, as with formal comments, but ALL comments will be tracked and their disposition recorded, including today’s session



Plan for Revision of Volume 2

Concept

- TNI ELS V2M1 will be merged with V2M3
 - Completed draft already prepared
 - TNI additional language was discussed in Houston
- Resulting V2M1 will be reorganized per revised ISO/IEC 17011 International Standard for Accreditation Bodies
 - New 17011 language will be addressed in next draft

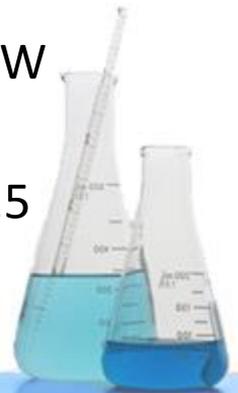
Outline Based on 17011

- Scope
- Normative References
- Terms and Definitions
- General Requirements
- Structural Requirements
- Resource Requirements
- Process Requirements
- Information Requirements
- Management System Requirements
- Annex A: Required Knowledge and Skills for Functions in the Accreditation Process



Topics for Possible Inclusion

- ❑ Assessing all methods versus selected methods for drinking water and other fields, at initial and subsequent on-site assessments (subject of a SIR and also a policy currently before LASEC)
- ❑ How to assess different Fields of Accreditation
- ❑ Accreditation of “prep methods” and accommodating the varied approaches by Accreditation Bodies (ABs)
- ❑ Using technologies as the basis for PT samples and Fields of Proficiency Testing (FoPT) tables
- ❑ Assessing laboratory accreditation scopes by matrix/method/analyte (by governmental and nongovernmental ABs)
- ❑ What to do about PT requirements for scopes where there are no approved PT providers (such as Biological Tissues as a matrix and DW Asbestos)
- ❑ NELAP policy on AB conformance to the current V2M3, Section 6.3.5 (current ISO/IEC 17011, Clause 7.5.6)





Topics for Possible Inclusion, cont'd

- Allowance to grant interim accreditation status to laboratories
- Allowance to extend deadlines in any standard through which timeframes are specified
- Requirement for the laboratory to seek NELAP Primary Accreditation in the state in which it resides, if that state has a Recognized NELAP AB for the fields of accreditation requested
- Allowance for NELAP Recognized ABs' personnel to perform accreditation functions for each other
- Process for expanding the scope of recognition for each NELAP AB to offer as Primary Accreditation to applicant laboratories
- Communication policy to allow advance notice to other recognized NELAP ABs of cost increases or other changes in the AB's program
- Policy on secondary accreditation to mobile laboratories
- Generic accreditation application form that will be used or acceptable to all recognized ABs



Topics for Possible Inclusion, cont'd

- Requirements on the content and frequency for updating information to LAMS (the National Database) on NELAP-accredited labs
- Policy on secondary accreditations (scope of accreditations)
- Timeframes for ABs to require of laboratories to complete corrective actions to non-conformances identified during on-site assessments
- Policy outlining qualifications and credentials needed for contract assessors or ALL AB assessors
- Scope of Accreditation definitively defined (at a minimum) as matrix – method (technology?) – analyte (or analyte group, or not at all?)
- Minimum requirements for training courses to train and qualify assessors (and accreditation decision-makers?)

- Are there others?





Additional Discussion as Time Permits

Topics TBD

For further information, contact:

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