

**Outline of Proposed Changes with Justification for TNI Environmental
Laboratory Sector Standard, Volume 2 Module 1, “General Requirements
for Accreditation Bodies Accrediting Environmental Laboratories”
Draft Standard, November 17, 2020**

I. General Changes to Overall Standard

1. General requirements for the Accreditation Body in Module 1 and the specific laboratory on-site assessment requirements in Module 3 now combined into one module.
Justification: Improvement to the Standard and requested by the NELAP Accreditation Council and the volunteer NELAP AB Evaluators group.
2. The recently-revised international standard for accreditation bodies in ISO/IEC 17011:2017(E) incorporated.
Justification: Improvement to the existing International Standard and to this Standard for environmental testing laboratory accreditation bodies
3. Additional TNI normative language specific for environmental testing laboratory accreditation bodies retained or revised for improvements, and then moved into the appropriate sections of the Standard.
Justification: Improvements to the Standard; substantial re-write needed for handling parking lot issues (left unresolved since year-2007), standard interpretation requests, and previous NELAC and TNI Standards.
4. Some requirements now deemed redundant, obsolete, or no longer needed proposed for elimination.
Justification: Improvements to the Standard to eliminate outdated and obsolete requirements and practices (inclusive of the former ISO/IEC 17011 2004-version Standard).

II. Summary of ISO/IEC 17011:2017(E) Key Concepts for Accreditation Bodies

1. Common Structure with other conformity assessment standards, including for testing laboratories.
Justification: Improvements to the Standard; ease for presentation of respective requirements for Structure, Resources, Process, Information, Management System, and other General requirements.
2. Common Elements for Impartiality, Confidentiality, Handling Complaints, Handling Appeals, Competence, and Management Systems
Justification: Improvements to the Standards; alignment with international norms and expectations.
3. Accreditation Cycle, Assessment Program, Assessment Plan, and Assessment Techniques
Justification: Improvements to the Standard; emphasis on results rather than process.

III. Major Issues Identified and Resolved During Consensus Standard Development

1. Competence of laboratory assessors (Sections 6.1.2.9 and 6.1.3)
Justification: Improvement to the Standard; clarity and purpose achieved for education, experience, training, qualification, and monitoring.
2. Timelines for post-assessment activities (Sections 7.6.6(b)(1), 7.6.7.1, 7.6.8.1, and 7.6.10-7.6.14)
Justification: Improvement to the Standard; compromise on requirements for issuing reports, reviewing corrective actions, and making accreditation decisions.
3. Confidential and Publicly Available Information (Section 8, entire section)
Justification: Improvements to the Standard; alignment with international norms between accreditors and testing laboratories; clarification of how to handle confidentiality with the requirements for public records access.
4. Risk Assessment and Mitigation (Sections 4.4.6-4.4.9, 7.4.5-7.4.6, 7.9.3, and 7.10.1)
Justification: Improvements to the Standard and alignment with international norms; assurance of competent yet consistent unbiased process for laboratory accreditation activities.