



Accreditation of Environmental Testing Labs by a Non-Governmental Accreditation Body (NGAB) – How is this Different from a State Accreditation?



Operational and Advocacy Issues Impacting
the Environmental Laboratory Industry

NEMC 2018

Topics

- Who is A2LA
- What is Accreditation
- What is Mutual Recognition
- ISO 17011
- Accreditation Process
- Benefits and Shortcoming of NGAB Accreditation



Who is A2LA

- Established in 1978
- Largest U.S. multi-discipline Conformity Assessment Body (CAB) Accreditation system
 - **More than 2800 accreditations granted**
- Fifth largest system in the world
- Non-profit and non-governmental
- First lab accredited was an environmental lab 35 years ago and remains with us to this day!



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What is Accreditation

- “third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks” (*ISO/IEC 17000*)
- Key phrases
 - competence
 - specific.... tasks



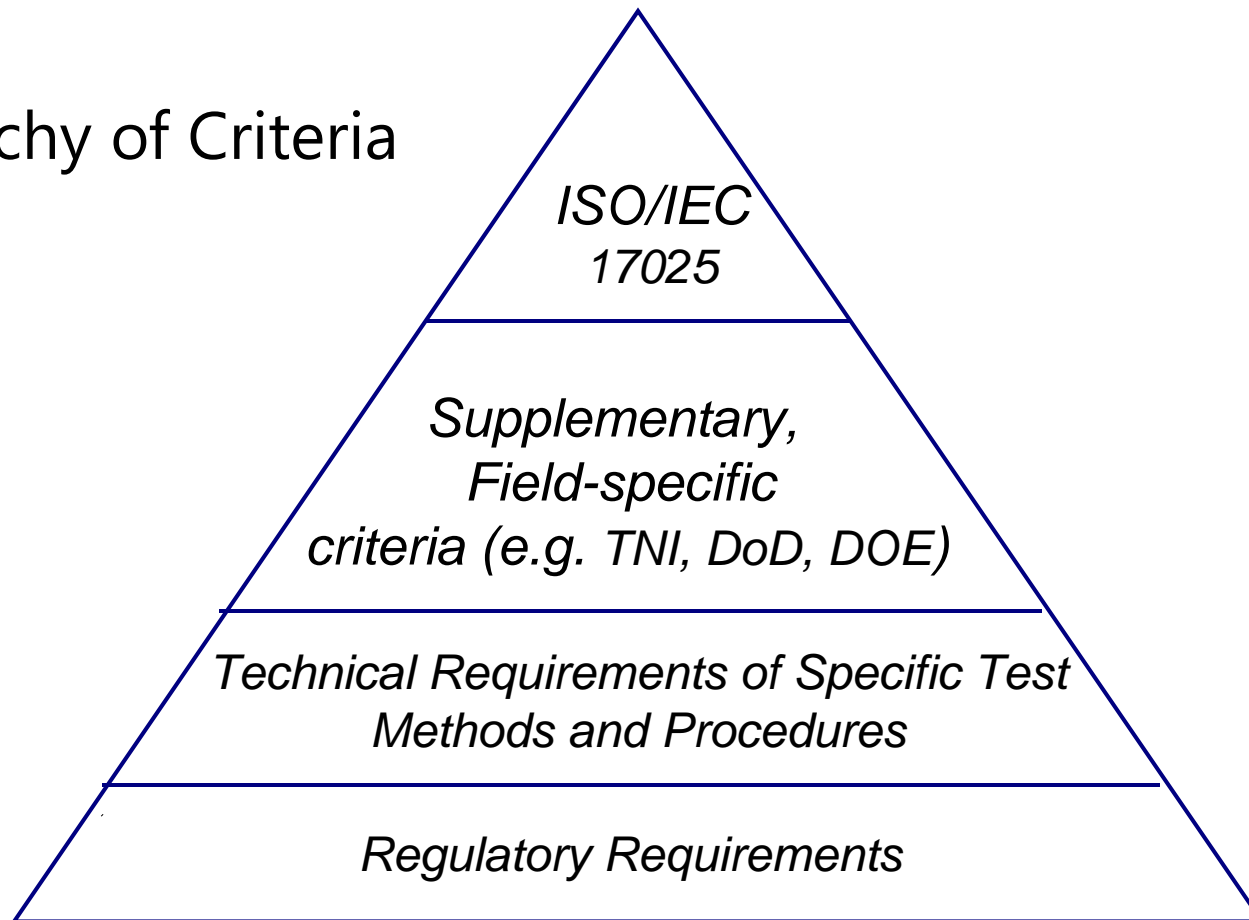
What is Accreditation

- Technical competence (specific tasks)
- Integrity
- Transparency
- Fairness
- Scope of Accreditation
 - products; types of test parameters types of inspections; matrices
 - measurement techniques, range, accuracy
 - test specification; test method



What is Accreditation

Hierarchy of Criteria



The Bottom Line

- Does the laboratory “say” what they do?
 - Do they have written documents (policies, procedures, arrangements) that meet the requirements of ISO 17025?
- Does the laboratory “do” what they say?
 - Are they in compliance with their own management system and ISO 17025?
- And can they “prove” it with their records?
 - From training records to standards preparation to work books to customer reports to audit reports and everything in between.



What is ILAC

- International Laboratory Accreditation Cooperation
- The international authority on laboratory accreditation, with a membership of accreditation bodies and affiliated organizations throughout the world. It's role is to:
 - Maintain a mutual recognition arrangement (MRA) among accreditation bodies to facilitate trade and to eliminate the need for duplicate accreditations
 - Develop and maintain state-of-the-art accreditation practice
 - Assist developing accreditation systems throughout the world



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ILAC Membership

- 139 member bodies representing:
 - 80 countries (98% of global GDP)
 - 65 full member MRA signatories, 50 countries (7 from USA)
 - Over 30,000 accredited laboratories (13% from USA)
 - 23 associate accreditation bodies (1 from USA)
 - 20 affiliate accreditation bodies (3 from USA)
 - 26 stakeholder associations (6 from USA)
 - 4 regional cooperation bodies
 - 1 national coordination body



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Vision of ILAC

- Once accredited, accepted everywhere



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Mutual Recognition Arrangement (MRA) among Accreditation Bodies

- The fundamental purposes of the ILAC MRA are:
 - A laboratory accredited by one MRA partner has equivalent competence to a laboratory accredited by the other partners.
 - Enables promotion of acceptance of accredited results by all other partners in their respective spheres of influence.
 - Reduces duplicate testing and duplicate accreditations.



MRA Requirements

- Compliance with ISO/IEC 17011 using ISO/IEC 17025
- Demonstration of competence through rigorous
 - peer evaluation
- Periodic performance through proficiency testing
- Regular re-evaluations



NGAB Recognition

- Similar to peer evaluation under ILAC
- Assessed by TNI evaluators to TNI standard volume 2:
**GENERAL REQUIREMENTS FOR ACCREDITATION BODIES
ACCREDITING ENVIRONMENTAL LABORATORIES (WITH ISO
17011)**
- Responded to any findings
- Gained recognition January 16, 2017



A2LA Accreditation Process

- Application
- On-Site Assessment Deficiencies
- Proficiency Testing
- Accreditation Decisions
- Annual Review
- Reassessment/Renewal of Accreditation



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Application For Accreditation

- Provide specific information on your laboratory
- Select appropriate Field of Testing (Environmental)
- ISO/IEC 17025:2005 Checklist that also includes the TNI standard requirements.
- Submit quality manual
- Attach a technical staff matrix



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Application For Accreditation

- Application date
 - Attests to when laboratory is ready for assessment
 - Earliest date deficiencies should be written
- Agree to set of conditions
 - Cooperate with A2LA
 - Comply with requirements for accreditation and policies
 - Inform A2LA about changes in laboratory status and key staff
- Send in the accreditation fee



On-Site Assessment

- Agree on proposed assessor
- Assessor conducts document review
 - Quality manual, system and technical procedures
- Schedules assessment
- Pre-assessment considerations
- Conducts assessment
 - Assessor Report with Deficiency Report



Assessment Criteria

- ISO/IEC 17025:2005 and A2LA Policies
- Specific Field/Program Criteria-TNI/DoD/DOE
- Laboratory's Management System
- Technical Requirements of Methods
- Customer Specifications-QAPP



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Deficiencies

- Definition
 - “any nonconformity to accreditation requirements”
- Including:
 - inability to perform a test or calibration
 - policies and procedures don't conform to ISO/IEC 17025
 - laboratory hasn't completely documented or implemented required policies and procedures
 - laboratory doesn't conform to additional A2LA policies and program requirements
- Laboratory expected to
 - correct deficiencies
 - submit report to A2LA within 30 days
 - 4 months maximum for new laboratories



Proficiency Testing

- Laboratories required to participate in “relevant and available” PT programs



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Accreditation Decisions

- Three parts to becoming accredited:
 - Fact finding by assessor
 - A2LA review of lab's corrective actions
 - Final decision by Accreditation Council
 - At least 3 volunteer "peer experts"
 - Required vote = at least 2 positive votes
 - no negatives



Annual Review

- Accreditation is granted for 2 years

- After 1st year of accreditation, each new laboratory:
 - Pays annual fees
 - Undergoes a one-day surveillance visit
 - Confirms laboratory is still in compliance
 - Demonstrates that the management system is still in place

- Normal annual review:
 - Pay annual fees
 - Submit internal audits and management review



Reassessment & Renewal

- Full on-site reassessment every 2 years
- Submittal of completed checklists, staff matrix, fees, etc.
- On-site assessment
- Response to deficiencies / Corrective actions
- Accreditation Council or A2LA Staff



Benefits of NGAB Accreditation

- Can cover multiple sets of requirements in one assessment (ISO, DoD, DOE, NELAP, etc.)
- Competition in the marketplace - Multiple NGABs to choose from
- Demonstrated competence of assessors through experience and training with an exam along with ongoing monitoring
- State resources can be redirected from assessing to focusing on issues of compliance




Reciprocity


- There are states that will not accept NGAB accreditation
- Due to regulations stating the accreditation (especially of Drinking Water) must be a government function



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