

# Transparent and Open Recognition of Accreditation Bodies

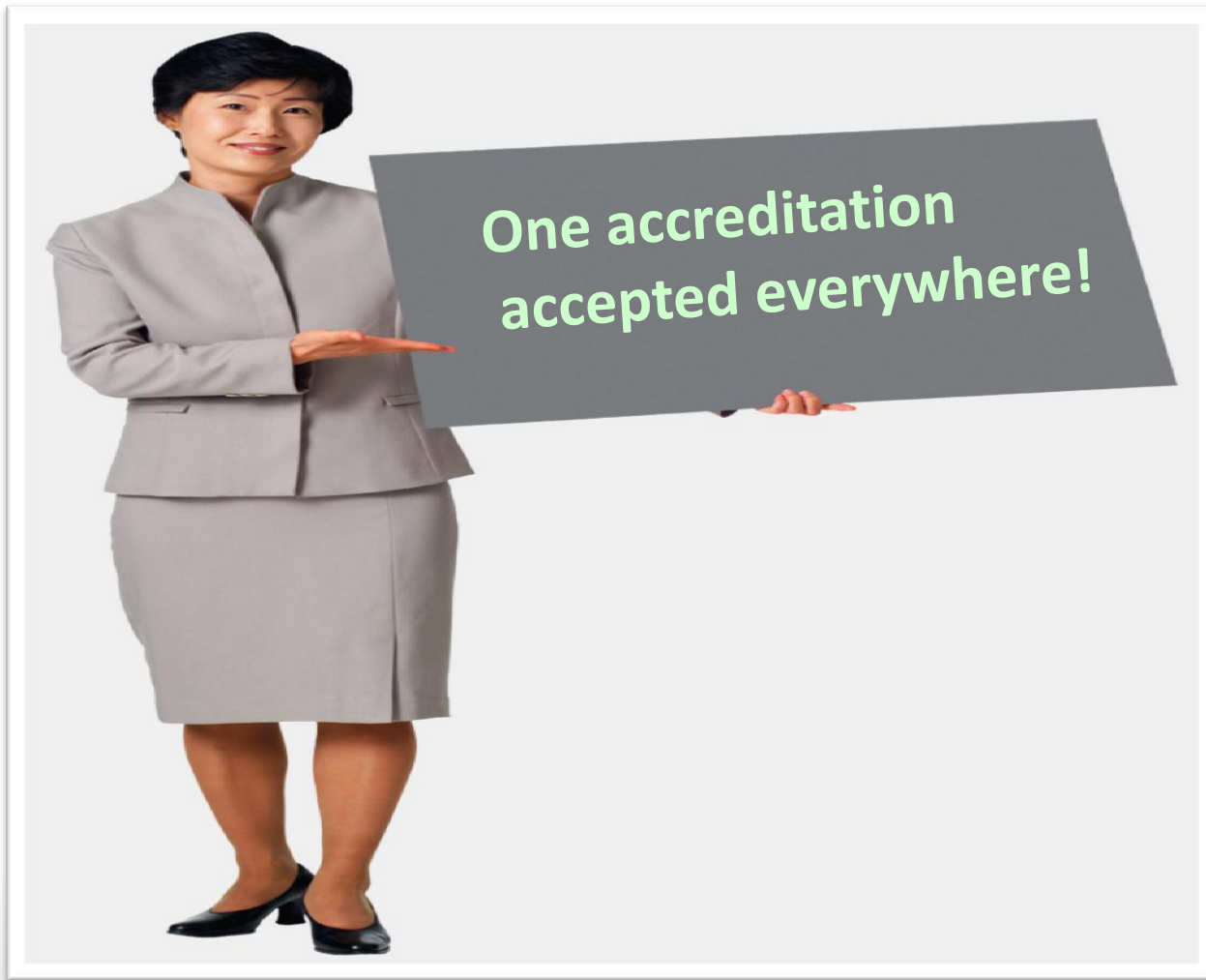
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# Outline

- Current recognition arrangements
- Open/transparent process
- Maintain confidentiality and monopoly issues for U.S.
- NEFAP model

# Current Goal

- **The Dream of Many!**



# Accreditation

- *Accreditation is the independent evaluation of conformity assessment bodies against recognized standards to carry out specific activities to ensure their impartiality and competence. Through the application of national and international standards, **government, procurers and consumers can have confidence in the calibration and test results, inspection reports and certifications provided.***

*Accreditation bodies are established in many countries with the primary purpose of ensuring that conformity assessment bodies **are subject to oversight by an authoritative body.***

(Source: ILAC website)

# Agreement on Standard

- Laboratories have one standard worldwide!
- ISO/IEC 17025 – foundation for accreditation
- Added requirements and clarifications come from
  - Regulation
  - Data user
  - Standards
  - Accreditation bodies
- Consistency of these additional requirements is often contradictory for analyzing the same media
- The additional requirements is most often where inconsistencies are derived in the current testing marketplace

# Current Models

- Accreditation/certification schemes
  - Accreditation of conformity assessment bodies (CAB) that certify, test or inspect
    - EnergyStar – EPA
    - Telecommunication Bodies (TCB) – FCC
    - Food Safety – GFSI - Public/Private Organizations Cross Economies
    - Many, many others
- Recognition schemes
  - Recognition via peer evaluation of accreditation bodies
    - ILAC – government and private sector ABs
    - TNI NEFAP – government and private sector ABs
    - TNI NELAP – government ABs
    - Others – NACLA - government and private sector ABs

# International Accreditation Forum

- *The primary purpose of IAF is to establish **Multilateral Recognition Arrangements (MLA)** between its accreditation body members in order to contribute to the freedom of world trade by eliminating technical barriers to trade.*

(Source: IAF website)

- Recognition of accreditation bodies by accreditation bodies.
  - Evaluation performed by AB personnel or contractors
  - Recognition granted by ABs that are signatories

# International Laboratory Accreditation Cooperation (ILAC)

- *Accreditation bodies, that have been **evaluated by peers as competent**, sign arrangements that enhance the acceptance of products and services across national borders, thereby creating a framework to support international trade through the removal of technical barriers.*
- *Global recognition of laboratories and inspection facilities via the ILAC Arrangement, thus facilitating acceptance of test, inspection and calibration data accompanying goods across national borders.*

(Source: ILAC website)

- Recognition of accreditation bodies by accreditation bodies.
  - Evaluation performed by AB personnel
  - Recognition granted by AB's that are signatories



# NACLA

- *NACLA is unique in that it is the only cooperation in which regulators and specifiers play an active role in the formulation of evaluation criteria including review and approval of accreditation bodies.*

(Source: NACLA website)

- Recognition of accreditation bodies by non-ABs
  - Evaluation performed by personnel trained to perform evaluations
  - Recognition granted by NACLA based on evaluation information
    - Lack of openness in process resulted in concerns several years ago

# National Environmental Field Accreditation Program (NEFAP)

- One of the The NELAC Institute (TNI) Programs.
- This program has developed and implemented a transparent and open recognition process for ensuring accreditation bodies implement the TNI FSMO standard in a uniform manner.
- Administered by the NEFAP Executive Committee
- Balance of membership – No one interest dominates
  - Accreditation bodies
  - Field Sampling and Measurement Organizations
  - Others (Users, regulators, etc.)



# NEFAP

- Input on the recognition process by all stakeholders
- Executive Committee developed and adopted the following
  - Criteria
    - TNI FSMO Standards Volume 1 and 2;
    - TNI PT Standards Volume 3 and 4
  - Evaluation Process (SOP 5-105 August 2010)
  - Recognition Process (SOP 5-105 – revision expected August 2012)
  - Agreement signed with TNI on use of Seal and commitment to implement standard
    - TNI NEFAP agreement



# NEFAP Evaluation

- The process developed by NEFAP for the accreditation of field sampling and measurement organizations
  - Defined in 2007 TNI FSMO Volume 2 standard (rev 0.1)
  - Application by AB to TNI evaluation coordinator
  - Application processed and Evaluation Team selected
    - Qualification for team members specified by NEFAP EC
  - Lead Evaluator performs document review
    - Nonconformances, concerns, comments presented to AB
    - Nonconformances accepted and corrective action plan accepted
    - Preliminary recognition granted
  - Technical evaluator performs witness of the AB assessor(s) performing an assessment of an FSMO (includes going to field)
  - Evaluation Report prepared by Lead Evaluator

# ILAC and Non-ILAC ABs

- Evaluation SOP 10-105 Appendix F
- ILAC conformance to ISO/IEC 17011
  - Reduce redundancy by TNI
  - Participate as observed in ILAC evaluation
  - Demonstrate conformance to TNI standard
- Non-ILAC – must demonstrate conformance
  - ISO/IEC 17011
  - TNI Standard
- All must be observed doing assessment to TNI standard (witness evaluation) for scope of program

# Third Party Programs

- Accepted by building onto existing recognitions
- ILAC MRA signatories have received preliminary approval
  - Document review completed that demonstrates conformance to TNI FSMO Volume 2
- Next Steps
  - Must obtain FSMO application and be observed performing an assessment
  - Evaluation process completed
  - Contract signed with TNI = Recognition Granted

# Recognition Process Change

- In 2011 during the evaluation process
  - Evaluation SOP required the NEFAP Executive Committee to review all AB documents and vote on recognition
  - PROBLEM IDENTIFIED
    - Confidentiality
    - U.S. Trade requirements
  - SOP 5-105 required a major update – Vote to be taken later today
    - In process since February 2011
    - Establish Recognition Subcommittee of the NEFAP EC
    - Members agreed to by the NEFAP EC
    - The NEFAP Recognition Subcommittee reviews the Evaluation Team objective evidence of findings to:
      - (1) assure it is unbiased
      - (2) demonstrates a consistent interpretation of the standard and
      - (3) is complete (demonstrates all elements of TNI FSMO Volume 2 are performed by the AB for assurance the FSMO implementation TNI FSMO Volume 1.

# Recognition Subcommittee

- Composition:
  - Must be a TNI Member in good standing
  - Must be impartial to the evaluation for recognition
  - Must sign the conflict of interest statement.
  - Does not have to be a current member of the Executive Committee but must have the following credentials :
    - Must be familiar with TNI NEFAP program and its standards and NEFAP procedures by acknowledging having read the current documents
    - Must have TNI-recognized training on the NEFAP process with documentation of completing the training (e.g.; an overview of the NEFAP evaluation and assessment program)
- Tasks:
  - Review the Evaluation Team observations and objective evidence on the Evaluation Performed of the designated AB
  - Provide a Decision on the Recognition of the AB for conformance to the TNI NEFAP requirements
  - Submit a letter on the decision to the AB, EC, Executive Committee and TNI Board of Directors.



# Accreditation Bodies

- Applications received January 2011
- Evaluators training March 2011
- Assessor training
  - Part 1 – Webinar April 2011 – ongoing
  - Part 2 – Illinois March 2012
  - Maryland May 2012
- Evaluation steps
  - Document Review July 2011
  - Preliminary Recognition August 2011
  - Witness May 2012 On-going

**Recognition complete:**

**Expected October 2013**

Certificate of  
*NEFAP Recognition*  
The National Environmental Field Activities Program  
Recognizes:

**Some AB**

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as being compliant with the accreditation body requirements of  
the TNI FSMO Standard and is hereby recognized to accredit  
field sampling/ measurement organizations in accordance with this standard.



Effective Date: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Date of Last On-site Evaluation: \_\_\_\_\_

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TNI NEFAP Executive Committee Chair

# NEFAP Assessment

- The process for accreditation of field sampling and measurement organizations (FSMOs) developed by the TNI standards development organization's field activities committee.
- TNI FSMO standard –Volume 1 (rev 0.1)
  - Applicable to all types of field sampling and measurement
  - Single site organization
  - Multiple site organization
  - Mobile laboratories included in this standard
    - Different from the 2003 NELAC standard
    - Addresses unique operations of mobile testing (not addressed in 2009 TNI Environmental Laboratory standard)

# Contractual not Regulatory

- Users of FSMO services place in contract the following:
- This statement in a contract requires the FSMO to produce a certificate and scope of accreditation to demonstrate the accreditation was granted.

***“Sampling and field measurements must be performed by a FSMO accredited by a TNI recognized accreditation body.”***

- Provides assurance of consistent implementation of the TNI standard and ensure the competency of the AB to perform the accreditation

# ABs Accepting Applications

ACCLASS

[WWW.ACLASSCORP.COM](http://WWW.ACLASSCORP.COM)

American Association for Laboratory  
Accreditation

[WWW.A2LA.ORG](http://WWW.A2LA.ORG)

Laboratory Accreditation Bureau

[WWW.L-A-B.COM](http://WWW.L-A-B.COM)

Perry Johnson Laboratory Association

[WWW.PJLABS.COM](http://WWW.PJLABS.COM)

# Open and Transparent

- Different process from ILAC/NELAP
  - Stakeholder community representatives makes decision on recognition
  - Transparency of process
  - Impartiality with declared conflicts vetted at meetings
- Maintains confidentiality of the ABs and FSMOs
- Central Training of Assessors
  - TNI to approve training in future
- Input from all stakeholders on process and standards
  - Minutes of all meetings published
  - Comments welcomed at all NEFAP EC and FAC meetings
  - Standards revision are underway now!
  - Procedures are always open to revision in order to improve process
- Adoption of a continuous process improvement program!

# The End



- Thank you