



NATIONAL ENVIRONMENTAL FIELD ACCREDITATION PROGRAM

PRESENTED BY
NEFAP Executive Committee
Field Activities Expert Committee



AGENDA

AM Session – 9 -12

- Field Activities Committee Meeting
 - Introduction and Action Items
 - Standard Interpretation Demo
- NEFAP Executive Committee Meeting
 - Introduction Action Items
 - Nominations, Evaluators, Finalize Working Documents
- Status of Advocacy – Jo Ann and Justin
- Program Development Status /Timeline – Marlene
- EPA Lead Program MOU – EPA representative
- PT Subcommittee Status of PTs for field program – Shawn Kassner



AGENDA

PM Session – 1:30 – 5:00

- TNI Board Perspective – Dave
- Program Checklists – Mike, Pat, Kim
- ABs perspective/ implementation – Tracy, Cheryl, and Doug, Keith
- FSMO perspective/ implementation – Justin and Dane, Pat





Field Activities Committee Charter

- The mission of the TNI Field Activities Committee is to develop specific field accreditation standards for accrediting bodies for field sampling and measurement activities by engaging industry experts in a consensus-based standards development process providing the means to improve the quality and consistency of environmental data throughout the United States.
- The committee will support these field accreditation standards with appropriate guidance materials to facilitate implementation and adoption of these standards on a national and international level.
- The committee is committed to establishing and maintaining an environment for standards development that will ensure continual improvement of field accreditation standards that are aligned with the practical constraints of sampling and field measurement as well as regulatory and industry specific requirements.



FAC Objectives

- Improve the quality and consistency of environmental data by establishing standards for activities related to environmental sampling and field measurements.
- Engage industry experts in the standards development process through targeted outreach activities to ensure the development of standards for various medias that are practical, appropriate and implement-able for organizations of varying size and structure.
- Develop consensus-based field accreditation standards that are consistent with other national and international standards , avoiding unnecessary duplication and non-value added requirements. Complete the initial phase of standards with the development of the foundational standards (competency and conformity assessment)



FAC Objectives

- Collaborate with affected stakeholders to develop a practical and functional audit system, specifically designed to assess conformance to the requirements of the standard, which utilizes existing resources and capabilities to ensure that: the required technical expertise is available; costs are minimized; and the quality and consistency of environmental data continually improves.
- Continually evaluate and establish success measures to target opportunities for improvement.
- Develop and maintain the tools (e.g., guidance documents, templates, training materials, etc.) necessary for consistent standards implementation.
- Utilize existing and future TNI infrastructure and resources to accomplish mission.





Field Activities Committee

- Introduction
- Action Items
 - Establish Expert Sub-Committee (s)
 - ✦ Stack Testing
 - Standards Interpretation Process
 - Monitor TNI FAC information on website

<http://www.nelac-institute.org/>





NEFAP Executive Committee Charter

- The mission of the NEFAP Executive Committee is to ensure the implementation of a national program for FSMO accreditation that is consistent with the TNI FSMO Standard requirements.
- The Committee will support the field accreditation program with appropriate guidance, procedures and policies to facilitate implementation of these accreditation standards on a national level.
- The Committee is committed to establishing and maintaining a program in support of the TNI FSMO standards that will ensure continual improvement of field accreditation process and which incorporate practical, effective, and clear standards of performance that are consistent with the needs of the environmental community as well as regulatory and industry specific requirements.





NEFAP Executive Committee Objectives

- Implement a national accreditation program that is consistent with the TNI FSMO standards.
- Establish adoption and formal acceptance of the program through an advocacy program including supportive contracts, communications, and direction to the stakeholders as well as input to the Field Activities Expert Committee regarding additional standards needs.
- Ensure consistent implementation by the ABs as an integral part of the recognition process, including the implementation of AB evaluation protocols, peer review processes, and an open input policy to ensure an effective forum and corrective action processes in support of all stakeholders.
- Develop field accreditation program guidance, procedures and policies that meet the needs of the environmental community as well as regulatory and industry specific requirements and are consistent with other national and international standards, avoiding unnecessary duplication and non-value added requirements.





NEFAP Executive Committee Objectives

- Collaborate with affected stakeholders to develop a national program that balances the needs and interests of all stakeholders while balancing considerations of cost; practical concerns, and the quality and consistency of environmental data.
- Continually evaluate and establish success measures to target opportunities for improvement.
- Develop and maintain the tools (e.g., guidance documents, templates, training materials, etc.) necessary for consistent standards implementation and AB recognition.
- Utilize existing and future stakeholder organizational infrastructure and resources to accomplish mission.





NEFAP Executive Committee

- Introduction
- Action Items
 - Implement SOPs
 - Nomination
 - Complete Evaluation Documents
 - ✦ Select and Train Evaluators
 - Provide information for website

<http://www.nelac-institute.org/>





TNI's NATIONAL ENVIRONMENTAL FIELD ACCREDITATION PROGRAM (NEFAP)

Presented by:
Jo Ann Boyd
Justin Brown





PREVIOUS PRESENTATIONS

- 2009 Pittcon (EPA Sponsored Symposium)
- Texas 2010 (Fortune 500 pipeline client with an audience of many FSMO's)
- 2009 Midwest Groundwater Conference
- 2010 Department of Defense EMDQ
- 2010 National Groundwater Summit





PRESENTATIONS SCHEDULED

- The 26th Annual International Conference on Soils, Sediments, Water and Energy October 18 - 21, 2010
 - Poster Presentation
- 20th Annual Quality Assurance Conference U.S. Environmental Protection Agency Region 6, Dallas, Tx October 18-22, 2010
- Industrial, Water, Waste, and Sewage Group 2010 Fall Meeting





ABSTRACTS PENDING ACCEPTANCE

- Illinois Groundwater Association – Fall 2010
- Federation of Environmental Technologists - 2010
- 2010 Midwest Groundwater Conference
- 2010 Easter South Dakota Water Conference
- 2011 (January) North American Field Conference and Expo
- *Sixth International Conference on Remediation of Contaminated Sediments* will be held in New Orleans February 7–10, 2011
- 2011 Department of Defense - EMDQ





PUBLICATIONS SUBMITTED

- Pollution and Engineering-fall publication
 - Pending confirmation/date
- WE&T
 - Pending revision/acceptance





Spread the Word!

- Advocacy done on ground level in conjunction with TNI advocacy activities
- Please let Jo Ann Boyd or Justin Brown know of any presentation opportunities, or publications that would be interested in articles





Program Development

- Work Products
 - Completed
 - In Progress





Work Completed

- 10-101 General Operating Procedure – NEFAP Board
- 10-102 Voting Procedure
- 10-103 Nominating Committee Procedure
- 10-104 Dispute Resolution SOP
- 10-105 Evaluation SOP

All voted and approved by TNI Board, TNI Policy Committee, NEFAP Board



Work in Process

- Application form
 - Second Draft completed
- Recognition Certificate
- Scope draft prepared – Is this needed?
 - Recognition Scope
- Evaluation Checklist
 - Second Draft completed
- Evaluator Training
 - To be developed and presented





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

Some AB

742 Evergreen Terrace
Springfield LG, 12345

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: _____

TNI NEFAP Executive Committee Chair





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



Miscellaneous

- Different process from ILAC/NELAP
 - Stakeholder community makes decision on recognition
 - Transparency of process
 - Registrar defined in TNI Standard FSMO V2
- Possible Central Training of Assessors
 - TNI to approve training
- Announcements and Training in August 2010
 - Justin Brown Coordinated this Session
- Advocacy
 - Talks and Papers being given by TNI FAC to promote process



AB Fees Defined

- ILAC Signatory's \$2500/ Year
 - Four ABs
- Non-ILAC Signatory \$3500/ Year
 - Two ABs
 - ✦ One completed ILAC process, not recognized (Fee may be \$2500 depending on ILAC report availability)
 - ✦ One no interest in ILAC process





Timeline

Date	Step
August - September	Finalize application form, checklist, Preparation for evaluator training, train evaluators
August	PT FSMO Subcommittee forwards information on Lead PT in soil, paint and dust wipes to PT Board for approval
August to February	PT providers request scope extension to accreditation
September	AB Applications made to TNI NEFAP Executive Committee for review
October 15, 2010	Application from ABs accepted – Announcement made on TNI website of ABs with acceptable applications. FSMOs may apply to ABs with acceptable applications. (Other ABs can be added as received, reviewed and accepted)
January 2011	Announce AB meeting initial application review – TNI meeting in January 2011
October 15, 2010	FSMO applications received by ABs
October to March	Perform witness assessment (evaluators observe AB assessor perform FSMO assessment)
October to March	Perform on-site evaluation or review documentation as per procedure
April 2011	Announce AB recognition TNI website
After February 2011	PTs available for FSMOs using field techniques (e.g. XRF) as required by LQSR 3.0. Other PTs for FSMOs to be developed as identified.
On-going	Follow Evaluation SOP for process after recognition Add other ABs with applications received after October 1, 2010 as soon as recognition process completed.

Great Group



But in the end !!

*Sometimes we
struggled to reach
consensus!!*



Special Thanks

**Ilona
Taunton**



We could not be this far
without her assistance and
support!!!



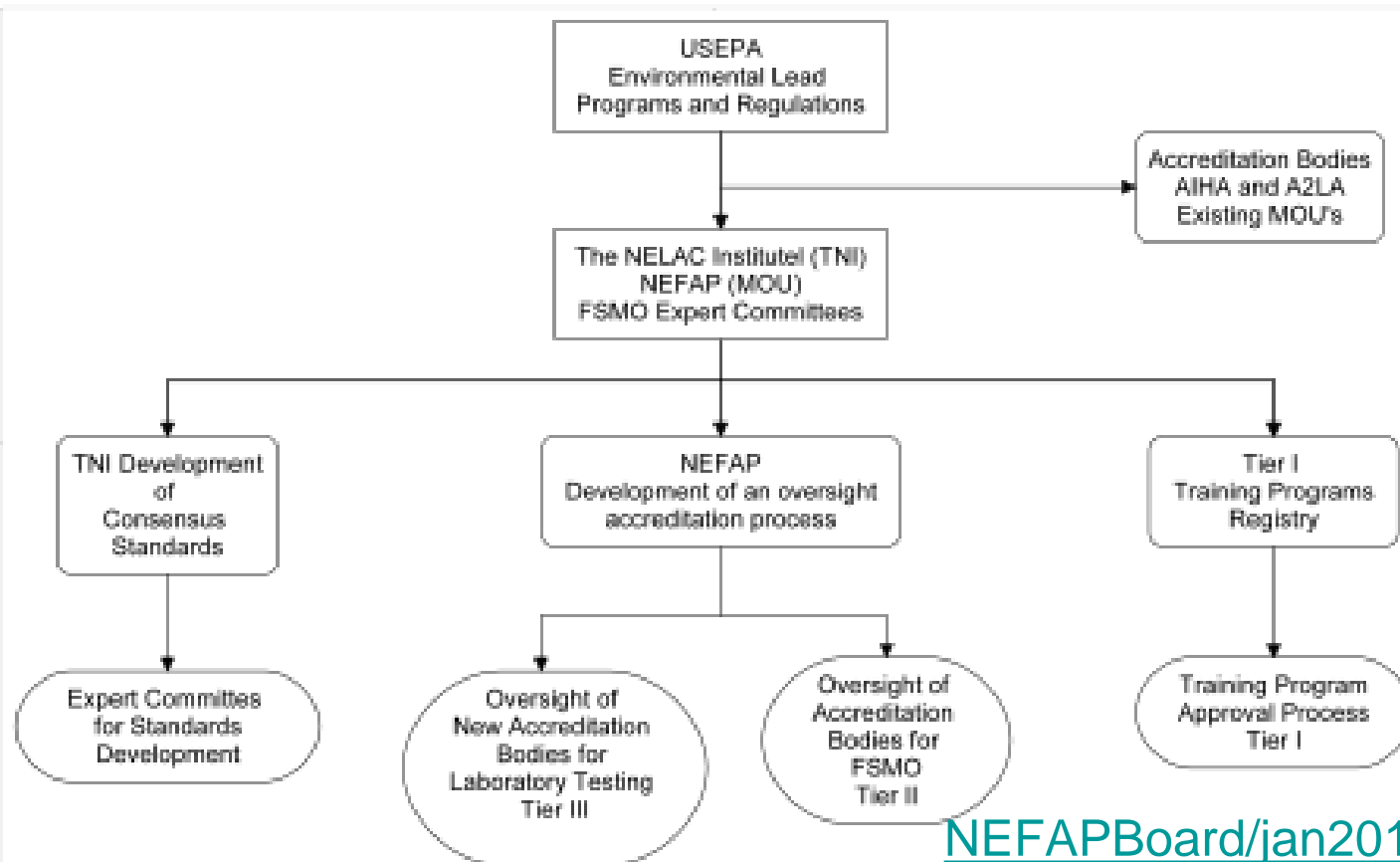


EPA TNI MOU

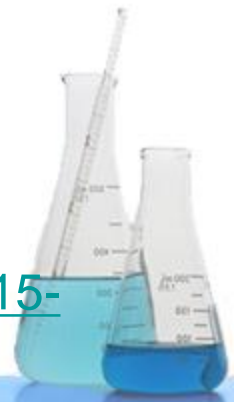
- EPA MOU signed by TNI
- EPA leading Lead PT subcommittee
 - Many issues related to policies resolved
- FAC to support EPA MOU with expert committee input
- Need more outreach to help EPA ensure accreditation process is understood (Abatement contractors)



Lead Program Process



[NEFAPBoard/jan2010/Tier II Accreditation Process Final 1-15-10.doc](#)



- Paul Cestone, EPA
 - Chair of PT FSMO Subcommittee





Lead in Paint, Soil, & Dust FOPT Subcommittee Update

Shawn Kassner, ERA, Senior Product Specialist

Stacie Metzler, Hampton Roads Sanitation District, QA Manager



Areas to cover

- Subcommittee Specifics
- What have we been up to!
- Where are we now!
- What's next!





Subcommittee Formed

□ Subcommittee Purpose

- “To develop PT acceptance criteria for lead in soil, paint films, and dust. This will be used for analysis of PTs in the field using field equipment. In addition, the subcommittee will evaluate the applicability of TNI Standard Volume 3 for this purpose.”





Subcommittee Members

Member	Affiliation
David Binstock	Research Triangle Institute
Paul Cestone (Chair)	US Environmental Protection Agency
Ty Garber	Wibby Environmental
William (Bill) Gutknecht	Research Triangle Institute
Shawn Kassner	Environmental Resource Associates
Mary Anne Latko	American Indust. Hygiene Assoc.
Benjamin Lim	US Environmental Protection Agency
Stacie Metzler	Hampton Roads Sanitation District
Marlene Moore	Advanced Systems, Inc.
Cheryl Morton	American Indust. Hygiene Assoc.
Natasha Mugambwa	American Indust. Hygiene Assoc.
Jack Paster	Radiation Monitoring Devices
John Pesce	Environmental Training Institute
Eugene Pinzer	US Housing&Urban Develop, OHHLHC
Randy Query	American Assoc for Laboratory Accred.
Christopher Rucinski	Resource Technology Corp
Eric Smith	Test America, Inc.
Ilona Taunton	The NELAC Institute
Kenn White	Environ Svcs Consult & Contractor
Erik Winchester	US Environmental Protection Agency
Stephen Williams	Thermo Fischer Scientific





Subcommittee Activities

- The SSAS FOPT Subcommittee began working on the table in February 2010.
- The Subcommittee started by reviewing and implementing the TNI SOP # 4-001 Rev 3.0, the Calculation of Acceptance Limits for Chemical, Radiochemical and Microbiological Components of Proficiency Tests.





Subcommittee Activities

- The subcommittee was provided with the last 2 years worth of data, collected by AIHA from EPA's NLLAP program, to statistically analyze.
- The proficiency testing scheme for AHIA NLLAP studies slightly different than TNI studies.





Subcommittee Activities

- Data from AIHA was statistically analyzed following the procedures outlined in the TNI Standards.
- The statistical analysis was summarized & presented to the subcommittee for their review.





Subcommittee Activities

- The statistical analysis from the TNI SOP 4-001 Rev 3 was performed on the NLLAP study data for each matrix.
- The resulting data and plots were then presented to the subcommittee.





Subcommittee Activities

- The subcommittee then reviewed relevant data to the performance of XRF instrumentation:
 - Environmental Technology Verification Program Case studies.
 - US-HUD Guidelines and the protocols from the Environmental Lead Proficiency Analytical Testing Program (ELPAT)
 - Various documents for the operation & calibration of XFR instruments.





Subcommittee Activities

- Many policy issues & questions were raised during the review of the data & documentation.
- A supplemental meeting was held to gather everyone's ideas & concerns.
- The data gathered will be forwarded to the expert committee that is being formed within NEFAP.





Subcommittee Activities

- Current Meeting Activities:
 - Reviewing the fixed limits & regression equations for each matrix

 - Reviewing the appropriate concentration ranges in each of the matrixes





Subcommittee Activities

- Current Meeting Activities:
 - Approved the concentration range & acceptance criteria for Lead in Paint, Soil & Dust wipes.
 - Working on the review of sample design requirements



What's Next?

- Development of a draft FOPT table for review by the PT Executive Committee
- Review & gather documentation developed during this process to provided to the PT Executive Committee





TNI Board Perception of NEFAP





- * The Board Envisioned Accreditation for Non-Laboratory Programs During It's First Strategic Planning Session. NEFAP Fits Into the Original Strategic Plan
- * The NEFAP Model Does Not Rely On Implementation By Governmental Bodies, With Their Regulatory Restrictions And Limited Resources. Its Success Depends Instead On The Needs Of The Industry
- * Pleased with the General Direction that NEFAP is Taking.
- * They have been impressed with the Speed of NEFAP's Infrastructure Development
- * NEFAP's Development Progress has Pushed the TNI Board to make the administrative changes Necessary to Accommodate the NEFAP Structure in the Organization (ex. By-Laws Changes)
- * There are always Underlying Concerns About Self Funding





NATIONAL ENVIRONMENTAL FIELD ACCREDITATION PROGRAM ACCREDITATION BODY EVALUATION CHECKLIST

PRESENTED BY
MICHAEL W. MILLER
PATRICK CONLON
KIM WATSON



INTRODUCTION

- Field Sampling and Measurement Organizations (FSMO) Accreditation Bodies (ABs) need to be evaluated to the TNI FSMO Standard Volume 2 (ISO/IEC 17011 & Specific FSMO Requirements)
- NEFAP is tasked with evaluating the ABs
- FSMOs Need to be accredited to the TNI FSMO Standard Volume 1 (ISO/IEC 17025 & Specific FSMO Requirements) by evaluated ABs



INTRODUCTION

□ TYPES OF AB Initial Evaluations:

- ABs Currently Holding ISO/IEC 17011 Recognition (ILAC)

The initial evaluation will be for the TNI-FSMO specific requirements of Vol. 2

- ABs not seeking ISO/IEC 17011 Recognition and Government ABs

The initial evaluation will be for the ISO/IEC 17011 requirements and the TNI-FSMO specific requirements of Vol. 2



INTRODUCTION

- The NEFAP Board has adopted SOP 105 for the recognition of the ABs.
- The SOP details the application, documentation review, on-site evaluation of AB, witnessing AB on-site assessment of FSMO, reporting requirements, AB responses and the recognition of the AB
- The NEFAP AB evaluation checklist is a key part of the evaluation process





NEFAP AB

Evaluation Checklist

- The NEFAP Checklist Sub-committee presents an initial draft for comment.
- The checklist is in Excel
- The checklist has a row for every assessable requirement in the standard
- Non assessable Portions of Standard need for clarity are “Gray Bar”
- Use of the Checklist:
 - AB to assure that all required documents and records are available for submission and inspection;



NEFAP AB

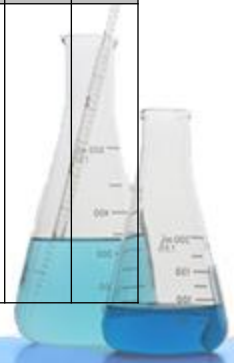
Evaluation Checklist

- NEFAP Evaluators to assure that all required documents and records have been submitted with the application. Also, documents and records are compliant with the Standard;
- NEFAP Evaluators to assure that all required documents and records are being implemented during the onsite of the AB, and
- NEFAP Evaluators to record the witnessing of the AB assessment of an FSMO.



NEFAP AB Evaluation Checklist Examples

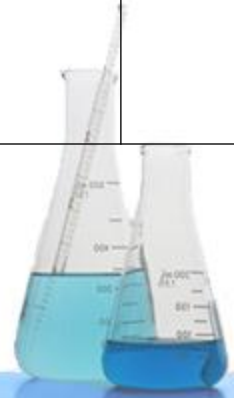
4.0	ACCREDITATION BODY				
4.1	Legal Responsibility (ISO/IEC 17011:2004(E), Clause 4.1)				
4.1	The accreditation body shall be a registered legal entity.				
4.1	NOTE: Governmental accreditation bodies are deemed to be legal entities on the basis of their governmental status. Where the governmental accreditation body is part of a larger governmental entity, the government is responsible for identifying the accreditation body in a way that no conflict of interest with governmental CABs occur. This accreditation body is deemed to be the "registered legal entity" in the context of this International Standard.				
4.1.1	An accreditation body shall seek recognition for its accreditation activities from an applicable registrar or other standards setting authority that shall use this Standard as the basis for granting recognition.				





NEFAP AB Evaluation Column Headers

		Yes	No	N/A	DELETE	Reference Document (list procedure or record where information is found, if applicable)	QUESTIONS FOR OFFICE EVALUATION	FLAGGS
Section	<p>Does the AB comply with this section? Note: Cover in a Quality Systems document or SOPs. Have records to comply or documentation (CAB) or FSMO</p>							
with Volume 1								





Additional Column Headers for NEFAP Comm. Review

□ KEY FOR FLAGS

- X = NON ASSESSABLE (*THIS TO BE CHANGED TO NOT EVALUATED*)
- INSTR = INSTRUCTION VALUE, MAY WANT
- C-DOC = DOCUMENTATION VERIFICATION, MUST BE PERFORMED AS PART OF DOCUMENT REVIEW. IMPLEMENTATION OF DOCUMENTATION VERIFIED IN OFFICE AND/OR AT WITNESS FSMO ASSESSMENT BY AB IN CHECKLIST
- ASSESS = REQUIRES OBSERVATION OR INTERVIEW WITH STAFF. REQUIRES OFFICE AND/OR WITNESS OF FSMO ASSESSMENT (*THIS TO BE CHANGED TO EVALUATE*)



NEFAP AB Evaluation Checklist Example 2

4.2	Structure							X
4.2.1	ISO/IEC 17011:2004(E), Clause 4.2.1							X
4.2.1	The structure and operation of an accreditation body shall be such as to give confidence in its accreditations.							ASS ESS
4.2.2	ISO/IEC 17011:2004(E), Clause 4.2.2							X
4.2.2	The accreditation body shall have authority and shall be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation.							ASS ESS
4.2.3	ISO/IEC 17011:2004(E), Clause 4.2.3							X
4.2.3	The accreditation body shall have a description of its legal status, including the names of its owners if applicable, and, if different, the names of the persons who control it.							C- DOC



NEFAP AB Evaluation Checklist Example 3

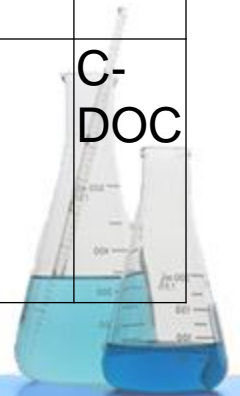
4.2.6	ISO/IEC 17011:2004(E), Clause 4.2.6							x
4.2.6	The accreditation body shall have access to necessary expertise for advising the accreditation body on matters directly relating to accreditation.							C-DOC & ASSESS
4.2.6	NOTE: Access to the necessary expertise may be obtained through one or more advisory committees (either ad-hoc or permanent), each responsible within its scope.							INSTR



NEFAP AB Evaluation Checklist

Example 4

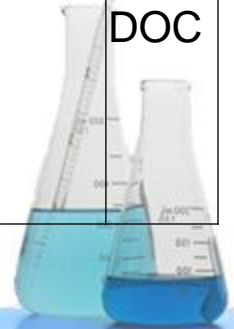
5.3	Document Control (ISO/IEC 17011:2004(E), Clause 5.3)							X
5.3	The accreditation body shall establish procedures to control all documents (internal and external) that relate to its accreditation activities. The procedures shall define the controls needed:							C- DOC
5.3 a)	to approve documents for adequacy prior to issue,							C- DOC
5.3 b)	to review and update as necessary and re-approve documents,							C- DOC
5.3 c)	to ensure that changes and the current revision status of documents are identified,							C- DOC
5.3 d)	to ensure that relevant versions of applicable documents are available to personnel, subcontractors, assessors and experts of the accreditation body and CABs at points of use,							C- DOC



NEFAP AB Evaluation Checklist

Example 5

6.2.6	Basic On-Site Assessment Personnel Qualifications and Training							X
6.2.6.1	Qualifications							X
6.2.6.1	An assessor shall be qualified by the accreditation body prior to conducting an assessment.							C-DOC
6.2.6.1 a)	Each assessor shall complete or comply with the following:							X
6.2.6.1 a)i.	Sign a statement before conducting an assessment certifying that no conflict of interest exists;							C-DOC
6.2.6.1 a)ii.	Provide any supporting information as required by the accreditation body. Failure to provide this information makes the proposed assessor ineligible to participate in the assessment program; and							C-DOC



Next Steps

- NEFAP Exec Comm. review and edit draft;
- Resolve Standard interpretation problems with Field Activities Comm.;
- Post on TNI web site;
- Prepare final version for NEFAP evaluators.
- Date checklist must be ready for use Sept. 1





General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations Volume 2

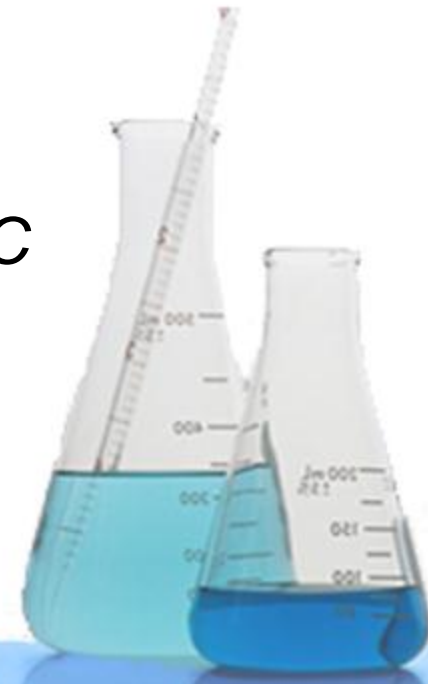
August 10, 2010





Presenters

- **Tracy Szerszen, President/Operations Manager**
Perry Johnson Laboratory Accreditation, Inc.
- **Keith Greenaway, Vice President**
ACLASS
- **Cheryl Morton, Director**
AIHA Laboratory Accreditation Programs, LLC
- **Doug Leonard, President**
Laboratory Accreditation Bureau

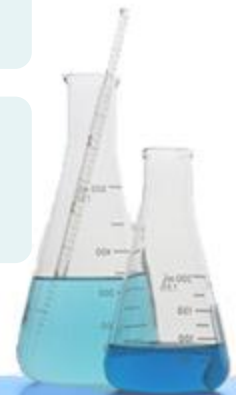
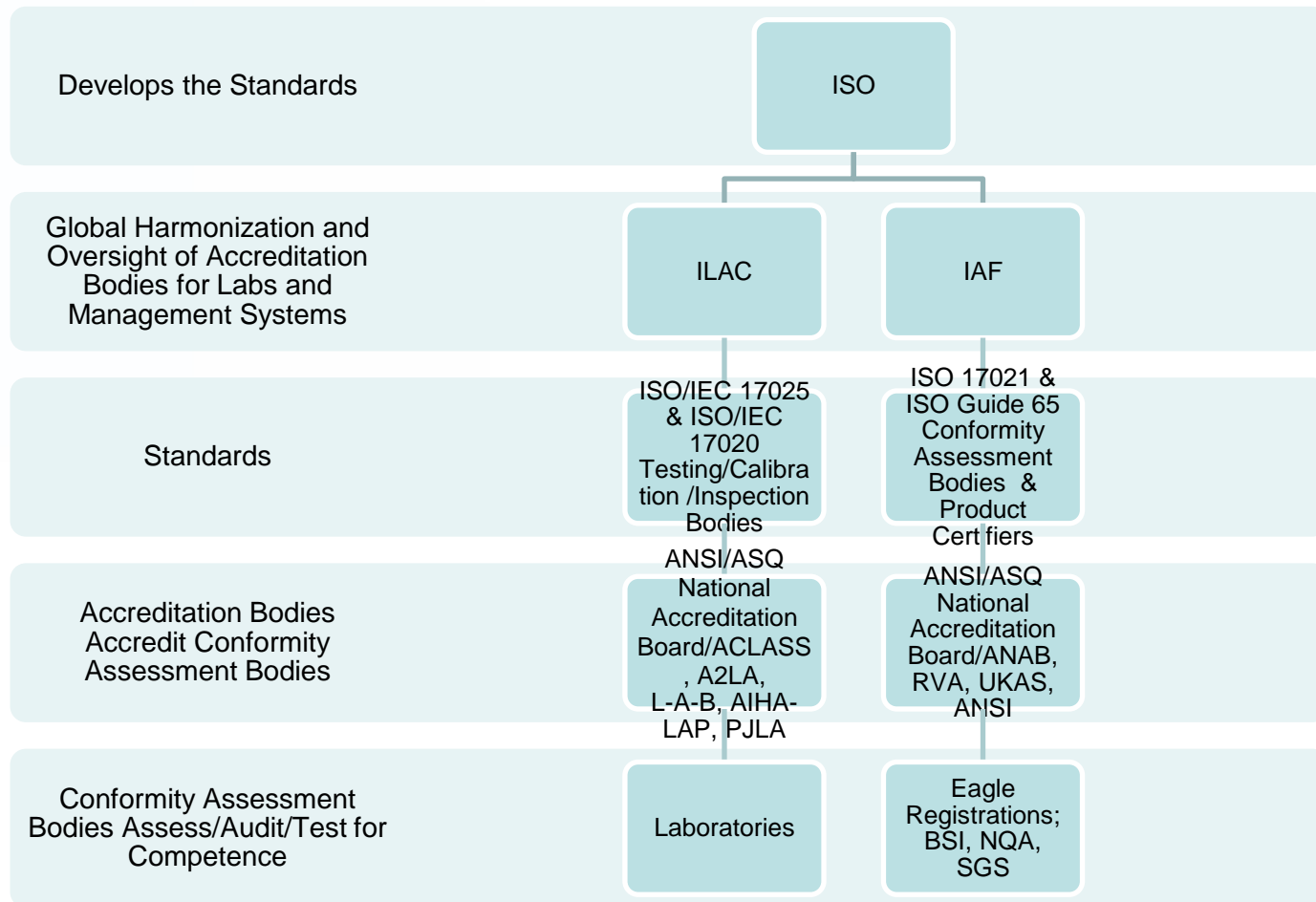


Purpose

- Provide overview of AB(s) operations and processes including the requirements outlined in ISO 17011:2004 and the Specific FSMO Accreditation Body Requirements Volume 2
- Provide insight on how AB(s) will apply these particular requirements to FSMO(s)



ILAC/IAF Overview



ILAC/IAF Overview





Section 4.0 Accreditation Body Requirements

- 4.1 Legal Responsibility
 - Should be registered as a legal entity
 - May be government or private organization
 - Should be a recognized AB (i.e. NEFAP, ILAC)
- 4.2 Structure
 - Competent staff to give confidence in its accreditations being offered (Top Mgt, Technical Mgt Support, Access to Tech. Expertise) and for making accreditation decisions (granting, maintaining, reducing, suspension and withdrawing of accreditation)





Section 4.0 Accreditation Body Requirements

4.3 Impartiality

- AB(s) should be organized and operated to safeguard impartiality
 - ✦ Balance of interested parties (Boards, Committees)
 - ✦ Staff should be free from undue pressure that could compromise impartiality
 - ✦ Independent decision making on accreditation
 - ✦ Avoid offering the same accreditation services as those being accredited and consultancy services

4.4 Confidentiality

- AB should ensure records obtained remain confidential throughout the organization



Section 4.0 Accreditation Body Requirements

4.5 Liability and Financing

- AB should have arrangements to cover liabilities arising from its activities
- Financial resources should be demonstrated including a description of its sources of income

4.6 Accreditation Activities

- AB(s) should clearly define accreditation activities offered
- Adopt relevant application and guidance documents
- Establish procedures for extending its activities to include:
 - ✦ Resources, Additional Guidance Documents, Selection and Training of Assessors and AB staff



Section 5.0 Management

- 5.1-5.2 Management System
 - AB(s) should maintain a quality management system to continually improve its effectiveness in accordance to standard requirements
 - ✦ Define documents, policies and objectives
 - ✦ Quality Manual and associated documents
 - ✦ Ensure procedures are established and communicated
 - ✦ Review the effectiveness of the management system



Section 5.0 Management

- 5.3-5.4 Document Control and Records
 - Procedures should exist to control documents including: approval, review and updating, revision status, availability to staff, legible, control obsolete documents, safeguard confidentiality
 - Procedures should exist for identification, collection, indexing, accessing, filing, storage, maintenance and disposal of its records and to define retention time periods (may be based on contractual agreements)*FSMO Accreditation 5 -Year Period*



Section 5.0 Management

- 5.5-5.6 Nonconformities and Corrective Actions/Preventive Actions
 - AB(s) should have procedures to identify nonconformities, take appropriate corrective action including avoiding reoccurrences of the nonconformity
 - AB(s) should identify opportunities for improvement and take preventive action to avoid nonconformance
 - Results should be recorded and analyzed for effectiveness



Section 5.0 Management

- 5.7 Internal Audits (Once per year)
 - AB(s) should have procedures for conducting internal audits to verify its conformity to particular international or national standards
- 5.8 Management Review (Once per year)
 - AB(s) should conduct a management review to ensure continuing adequacy and effectiveness
- 5.9 Complaints
 - AB(s) should have a procedure for dealing with complaints





Section 6.0 Human Resources

- Personnel Requirements (assessment staff, assessors and technical expertise)
 - AB(s) should have personnel competent to support their accreditation program
 - AB(s) should define competency requirements and training needs of, staff, assessors and technical expertise and ensure that on-going training is conducted
 - *Personnel should be in place and ready to conduct accreditation of an FSMO within 9-months from receiving the application





Section 6.0 Human Resources

- Personnel Requirements-Staff
 - *In addition to the management representative, AB(s) should identify personnel to manage the FSMO program. These individuals shall:
 - ✦ Be an employee of the AB
 - ✦ Have the technical expertise to:
 - ◆ Plan and manage the FSMO matrix specific program
 - ◆ Coordinate various facets of the FSMO program w/ territory, state and federal non-government AB(s) as applicable
 - ◆ Provide input on the technical competency and performance of contractors or employees involved with the accreditation process



Section 6.0 Human Resources

- Personnel Requirements-Assessors
 - *Assessors should be qualified by the AB prior to conducting any FSMO assessment. This includes the following:
 - ✦ *Professional experience and hold at least a Bachelors degree in a scientific discipline or have equivalent experience in environmental sampling and measurement
 - ✦ *Participate in at least 4 actual on-site assessments under the supervision of an experienced qualified assessor





Section 6.0 Human Resources

- Personnel Requirements-Assessors Cont'd
 - Note- for newly recognized AB(s), assessors will not be required to complete supervised assessments as long as:
 - ✦ They have completed at least 4 other FSMO on-site assessments
 - ✦ They have been judged competent by the AB and
 - ✦ Documentation is available for the completion of the assessments along with a statement of proficiency from the AB





Section 6.0 Human Resources

- Assessor Training Course Requirements
 - *Complete a Basic Training course approved by the AB that includes the requirements of the FSMO standard, includes on-going changes or adoption of applicable regulations, standards and sampling and measurement methods and technologies
 - *Complete a Technical Training course for at least one technical discipline addressing sampling or measurement technologies: (air, solids, water or biological samples)



Section 6.0 Human Resources

- On-Going Training of Assessment Staff
 - *Assessors should complete annual refresher training in order to gain:
 - ✦ Familiarity with relevant regulations, accreditation procedures and requirements
 - ✦ Thorough knowledge of assessment methods and documents, data reporting, analysis and reduction techniques and procedures
 - ✦ Working knowledge w/ specific sampling and measurement techniques and associated preservation sampling procedures
 - Assessment training can be conducted by the AB, assessor bodies or other approved entities



Section 6.0 Human Resources

- On-site Monitoring of Assessment Staff
 - AB(s) should ensure the satisfactory performance of assessment staff
 - *On-site monitoring of assessment staff should be conducted at least once over a 3-year period (Note- 17011 clause 6.3.2) “ unless there is sufficient supporting evidence that the assessor is continuing to perform competently” does not apply to the FSMO accreditation program. All assessment staff needs to monitored on-site.



Section 6.0 Human Resources

- Personnel Records of Assessment Staff
 - AB(s) should maintain records to demonstrate competency of assessment staff
 - ✦ Name, address and position
 - ✦ Education qualifications
 - ✦ Work experience and experience conducting assessments
 - ✦ Training in Mgt Systems and Conformity Assessment Activities
 - ✦ *Number of assessments completed*
 - ✦ *Date of most recent updating of record*



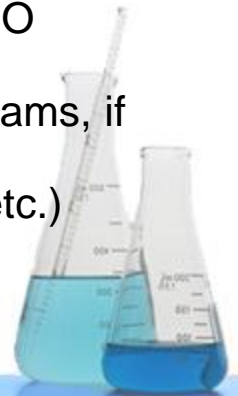
Section 7.0 Accreditation Process

- Accreditation Body Responsibilities to CABs/FSMOs etc.
 - Provide details on its accreditation process and requirements for accreditation
 - Provide information of accredited organizations
 - Provide organizations details on the AB(s) complaint, dispute or appeal process
 - Provide information on the AB(s) means of financial support
 - Provide information on related bodies if applicable
 - *FSMO specific accreditation criteria should be made available including the types of matrices accreditation can be granted for (i.e. air, solids, water or biological samples)



Section 7.0 Accreditation Process

- Applying for Accreditation
 - Application Packages should be detailed enough to capture relevant information of the CAB/ FSMO
 - ✦ Legal name, address and description of any relationships with larger corporate entities
 - ✦ Name and contact information of responsible person for the program
 - ✦ Normal hours of operation for each FSMO entity included in the scope
 - ✦ A description of the FSMO type (i.e. commercial, federal, hospital, industrial/industry with discharge permits)
 - ✦ Job description summaries of management and supervisory positions responsible for field site and sampling activities
 - ✦ Job description summaries of field site sampling and measurement positions with reporting relationships between positions
 - ✦ A summary of mobile units, listed by function that are integral to field sampling and measurement activities and are employed by the FSMO facilities to be considered for accreditation]
 - ✦ Copies of results of previous three proficiency testing samples/programs, if applicable
 - ✦ Other documents requested by the AB (quality manual, SOPs, WI, etc.)





Section 7.0 Accreditation Process

- Application Package Cont'd
 - ✦ *The scope of accreditation including:
 - ◆ Field sampling and analytical methods
 - ◆ A complete listing of sampling and measurement methods employed including analytes
 - ◆ Addresses of all FSMO entities under the scope of accreditation and address of all of the field sampling and measurement locations if applicable for selection of on-site assessment observations
 - ❖ AB (s) should have a procedure in place for mutually agreeing with the FSMO on locations and personnel to be observed to sufficiently assess the scope of accreditation
 - ❖ AB (s) should have a procedure in place to ensure that the sampling process of locations captures a thorough representation of field site activities and analytical methods within an agreed timeframe *Not to exceed three accreditation cycles*





Section 7.0 Accreditation Process

- Determining Assessment Time/Fees
 - Based on information required in application package:
 - ✦ Number of sampling sites, field site sampling technicians, matrices
 - ✦ FSMO(s) may be provided with either an Umbrella Accreditation or Individual Accreditation depending on the structure (to be determined during application stage)
 - ✦ Each AB may have different fees or assessment schedules/cycles, but are all equivalent in regards to following the TNI standard and 17011



Section 7.0 Accreditation Process

- Selection of the Assessor/Scheduling of the Assessment
 - AB(s) will ensure a competent team is selected and will provide the FSMO with their credentials
 - FSMO(s) have the right to object to an assessment team. This should be provided in writing to the AB.
 - AB(s) will confirm assessment dates, details with the FSMO.





Section 7.0 Accreditation Process

- Preparation of the Assessment
 - Discussion with the FSMO in regards to site availability/security, safety issues
 - AB(s) are required to have procedures in place to address compliance with regulatory or FSMO requirements (i.e. security clearances, site access, on-site identification, safety briefings, site emergency procedures, use of safety equipment)
 - A review of additional documents not submitted with the application package
 - Assessment Plan (start times, sites to be witnessed)
 - Submission of the assessment checklist to the FSMO
 - Completion of confidentiality forms (assessment information or for national security reasons)
 - AB(s) have the right at any time to cancel the assessment if they have sufficient evidence that the FSMO is not prepared for accreditation



Section 7.0 Accreditation Process

- On-site assessment
 - Opening Meeting (Confirmation of the scope, locations, introduction of assessment team, identification of FSMO processes, personnel, discussion of any concerning procedures related to business confidential information, review of safety requirements)
 - Review of accreditation standards
 - Time and place of closing meeting
 - ◆ Assessors will not sign any waiver of responsibility on the part of the FSMO for injuries incurred
 - ◆ The AB will request that the FSMO provide safety gear and instructions for safe use



Section 7.0 Accreditation Process

On-site assessment of FSMO staff

- Interview and on-site witnessing of sampling either at fixed site or field locations
- To ensure competency of staff for the scope of accreditation (procedures, calculations, quality control, data reductions, transfer and reporting, SOPs, standard methods)
- Pertinent records of the assessment should be collected
- Adherence to the TNI Standard, including 17025 and any additional AB requirements





Section 7.0 Accreditation Process

□ Assessment Conclusion

- Closing Meeting (discussion of the assessment, review of findings, AB post assessment process, process for disputing findings, final report distribution times)
- An interim report will be provided to the FSMO and to the AB
- Final reports will be provided to the FSMO within 30-days of the last day of the assessment once an interim report is reviewed and agreed upon by the FSMO and AB
- Reports should include:
 - ✦ Details of the Assessment team, assessment #, location, date
 - ✦ Statement of the objective of the assessment
 - ✦ Identification of the FSMO participants involved
 - ✦ Summary of the FSMO adequacy to the related standards
 - ✦ Summary of findings
 - ✦ Summary of existing conditions of FSMO for future assessment planning



Section 7.0 Accreditation Process

- Corrective Action Closure Requirements
 - FSMO(s) will be granted 30-days from the date the final report is released to submit a corrective action plan to address findings
 - AB(s) should respond to the FSMO within 30-days of receiving the FSMO(s) corrective action plan in regards to acceptability
 - Follow-up assessments may be required depending on the severity of the findings. These visits must be completed within 180 days after the submission of the FSMO(s) corrective action plan
 - Failure to submit corrective action on-time may cause a delay in the recommendation of accreditation or reassessment of the FSMO



Section 7.0 Accreditation Process

- Granting of Accreditation
 - AB(s) are required to make a final decision to grant accreditation
 - Typically through the use of independent committees, technical support etc.
 - Review of assessment material, corrective action responses, assessment report



Section 7.0 Accreditation Process

- Issuance of the Accreditation Certificate
 - Certificates should include:
 - ✦ Identity and logo of the AB, Official Signature from AB
 - ✦ Unique identity of the FSMO (name, address and unique entities of the FSMO)
 - ✦ Unique accreditation number
 - ✦ The effective date of the accreditation
 - ✦ The scope of the field sampling or analytical methods (i.e. air, water, soil, biological samples and associated methods)
 - ✦ Any addenda or attachments



Section 7.0 Accreditation Process

- Issuance of the Accreditation Certificate
 - Certificates should include:
 - ✦ Statements that accreditation status depends on successful on-going participation in the program
 - ✦ Statements to urge customers to verify the current accreditation status
 - ✦ Revision levels as appropriate (i.e. scope expansions, reductions etc.)
 - Certificate Validation Period
 - ✦ Certificates are typically valid for 2-years from the initial accreditation date
 - ✦ For interim accreditations certificates should only be issued for a 12- month period



Section 7.0 Accreditation Process

- Denied Accreditation
 - AB(s) may deny accreditation for the following reasons:
 - ✦ Failure to submit completed application
 - ✦ Failure to pay fees
 - ✦ Failure to successfully analyze and report applicable PT samples within a 12 month period
 - ✦ Failure to implement corrective action within required timelines
 - ✦ Failure to implement a system in accordance to the specified standard
 - ✦ Misrepresentation of any facts pertinent to receiving or maintaining accreditation
 - ✦ Denial of entry during normal business hours for an on-site assessment
 - If accreditation is denied AB(s) should require the FSMO to wait 6 months before reapplying



Section 7.0 Accreditation Process

- Suspension of Accreditation
 - AB(s) may suspend an FSMO's accreditation in total or in part for the following:
 - ✦ Failure to complete PT studies within 12 months
 - ✦ Failure to complete at least 1 PT sampling program during the accreditation period (2 years)
 - ✦ Failure to meet a two out of three passing record on applicable PT studies
 - ✦ Failure to notify the AB of any changes in key accreditation activities
 - ✦ Failure to meet the standard requirements
 - ✦ Receipt of a finding that the public interest, safety or welfare imperatively requires such emergency action
 - FSMO cannot continue to conduct sampling for any area under suspension
 - FSMO have 6-months to correct the reason for suspension without being charged any additional fees or forced to reapply. After 6-months the certificate will be revoked by the AB.



Section 7.0 Accreditation Process

- Revocation of the Accreditation Certificate
 - AB(s) may revoke an FSMO's accreditation in total or in part for various reasons (see previous suspension process)
 - FSMO(s) will be required to reapply for accreditation once the reason or cause for revocation is resolved



Section 7.0 Accreditation Process

- Appeal Process
 - AB(s) shall have a procedure for the handling of disputes and appeals, conflicts or complaints and procedures for resolving such conflicts
 - Results should be communicated to the FSMO



Section 7.0 Accreditation Process

- Maintaining Accreditation-Reassessment and Surveillance
- Reassessment to be conducted at least every two-years
 - Similar to initial accreditations with the experience gained through initial accreditation taken into account
- Surveillance assessments could take place in between the AC and RA depending on the stability of the FSMO
 - Less comprehensive than accreditations
 - Could be triggered from the results of previous assessments, complaints and instability of the system
 - Depends on AB(s) accreditation cycle requirements



Section 7.0 Accreditation Process

- Extension of Accreditation
 - Changes in scope (expansion of analyte or sampling measurement method)
 - ✦ Could be completed without an on-site review
 - ✦ Addition of new technology or test method requiring specific equipment will require an on-site visit



Section 7.0 Accreditation Process

- Proficiency Testing Requirements
 - AB(s) should ensure FSMO(s) are participating and achieving favorable results within a defined time period in order to grant accreditation and that they continue to meet these requirements once accreditation is granted
 - If an appropriate PT program is not available then the AB should consider other evidence that demonstrates FSMO competency





Section 8.0 Responsibilities of the AB and the FSMO

- Obligations of the FSMO(s)
 - Commit fully to the requirements set fourth by the AB
 - Assist by providing accommodation and cooperation in order for the AB to fulfill accreditation requirements
 - Provide information and documents as necessary
 - Arrange witness activities
 - Appropriately claim accreditation for activities accredited by the AB
 - Pay fees as determined and agreed upon between both parties
 - Inform the AB of any significant changes within the organization that could affect the accreditation



Section 8.0 Responsibilities of the AB and the FSMO

- Obligations of the AB
 - To make information publicly available about the FSMO's accreditation status (name and address, issue and expiration dates, scopes granted)
 - Provide FSMO suitable ways to obtain traceability of measurement results
 - Inform FSMOs of international arrangements engaged in (i.e. ILAC, APLAC)
 - Provide notice of any accreditation requirements



Section 8.0 Reference of accreditation and use of symbols

- AB(s) allowing FSMO(s) to utilize their accreditation symbol on reports should have a policy governing such use
- Proper use of accreditation symbols should be assessed during each assessment to ensure:
 - accreditation language or symbols are being used only for items included on the accreditation certificate
 - Language is not misleading
 - That the accreditation language or symbols are not being used in any way to imply that a product, process or system or person is approved by the AB
- Suitable action should be taken by the AB to deal with incorrect use of accreditation language or symbols



Additional AB Requirements

- ILAC Requirement Documents
 - Policy on Measurement Traceability
 - Policy on Proficiency Testing Requirements
 - ILAC MRA Mark Requirements (If utilized)
 - ✦ No significant impact on FSMO(s) since the requirements included in Volume 2 exceed the requirements in our policies
 - ✦ However, FSMO(s) should be aware of any additional requirements set fourth by their AB as they will be assessed to these during their accreditation



AB Implementation

- ABs involved in developing FSMO program
- Third party approach means that ABs will generally be operating the same way and will be compliant with ISO/IEC 17011 and TNI Standard
- ILAC important not only because of ISO requirements but because it is based on global peer recognition system
 - U.S. ABs have conducted peer reviews of each other's operations and this will continue
 - U.S. ABs already accrediting to ISO 17025:2005
- TNI Standard is based on 17025:2005 making it easier for ABs to accredit FSMOs



AB Implementation

- Many ABs in the U.S. already working with government specifiers
 - A2LA, AIHA-LAP, PJLA each have MOUs with EPA to accredit lead laboratories under the LQSR
 - PJLA and LAB accredit DOD laboratories

- AB differences in implementation
 - Timing
 - Focus (for AIHA-LAP, LLC, focus on LQSR)
 - Additional Requirements (as approved by TNI)

- FSMOs will have to decide which AB works best for their operations in selecting an AB





Field Sampling and Measurement Organizations

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Environmental Monitoring
and Technologies, Inc.

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**Environmental Measurement
Symposium
Washington, D.C.
August 2010**





Field Sampling & Measurement Organization “FSMO”

Organizations engaged in environmental sampling for laboratory analysis and/or field measurement (analysis) using field based analytical technologies performed in the field *outside of a fixed-laboratory or outside of an enclosed structure which meets the requirements of a mobile laboratory .*



Environmental Data Quality Cannot
Be Guaranteed Unless There Are
Quality

Standards for All Steps of the
Sample

**“The Quality of the Data Can Only
Collection and Analysis Process
be as Good as the Quality of the
Sample”**





The Sampling & Analysis

Dichotomy

* Laboratory Operation/Accreditation Requirements

- Accreditation Required to Produce Regulatory Data
- Specific Quality System (ISO 17025)
- Internal and External Assessment
- Proficiency Testing

* FSMO Requirements

- Absence of Regulatory Oversight for Accreditation
- Accreditation Unnecessary (No Licensing)
- Quality System Not Required for General Operations
- Assessments Rarely Performed for Field Operations
- Less Rigorous Standards for Field Data Generation





FSMO Responsibilities

Implementation of Management System

- ❑ **Management system in place to ensure proper oversight of monitoring and sampling program**
 - ✦ Maintain clear lines of responsibility
 - ✦ Qualified supervision of field activities
 - ✦ Maintain data integrity procedures

- ❑ **Record Control**
 - ✦ FSMO will need a record control policy in place to ensure proper collection, storage, identification, and retention

- ❑ **Internal Auditing Program**



FSMO Responsibilities

Implementation of Fundamental Quality Systems

- ❑ **Collection of representative sample based on project specifications**
 - Based on consultant input
 - Project Plan
 - Client requirements
 - Adheres to all applicable regulatory requirements



FSMO Responsibilities

□ Personnel

- Have sufficient personnel with necessary education, training, technical knowledge and experience.
- Up-to date training
 - ✓ Documentation of training courses

□ Data Integrity - Read and Understand System

- Training
- Signed documentation of understanding
- In-depth periodic monitoring of data integrity issues
- Documentation of data integrity procedures

□ Employee Documentation

- Ensure employee training file contains read and understand of all recent methods and SOP's employed in the field



FSMO Responsibilities

- ❑ Accommodation and Environmental Condition
 - ✓ **All sampling will be done between months of March and September. All sampling will be conducted in Key West.**



FSMO Responsibilities

❑ Accommodation and Environmental Condition

- Documentation of ambient/ field conditions
- Be aware of surroundings
- Document location of sampling devices

❑ Method Documentation

- Documentation of methodology employed and any deviation of method used

❑ Equipment

- Equipment should be appropriate for the sampling conditions and methodology required
- Documentation of selection, Identification, Prep, Use, and Maintenance of equipment



FSMO Responsibilities

❑ Measurement Traceability - Calibrations

- Special calibration procedures may be required for unattended equipment and may include maintenance
- Calibrate equipment prior to use (and original and interesting concept)
- ✓ Documentation of calibration procedures including calculations, integrations, and acceptance criteria
- ✓ Sufficient raw data records to allow for reconstructing of initial calibration
- ✓ Document criteria for acceptance of initial calibration
- ✓ Documentation of corrective actions
- ✓ Documentation of continuing calibration checks



FSMO Responsibilities

❑ Sample Collection

- Documented sampling plan and procedures for sampling must be in place (site specific or sample specific)
- Document and record all deviations from sampling plan
- Documentation of sampler, environmental conditions, and site plans (diagrams)
- Documentation of sampling location, collection time, conditions, equipment used, and sampling methodology



FSMO Responsibilities

- ❑ **Handling of Test and Calibration Items**
 - Procedures for sample transportation, receipt, handling, protection, storage, and transfer of custody
 - Procedure for documentation of non-conformance with procedures, sampling plans, SOP's



FSMO Responsibilities

□ Reporting Results

- Field Form/ Chain of Custody should include:
 - ✓ Type of sample (grab/composite)
 - ✓ Matrix (Aqueous, Solid, etc..)
 - ✓ Contact information (including phone number)
 - ✓ Results of field blanks, spikes, duplicates, or confirmation samples
- Test reports
 - ✓ Documentation of deviations, additions, and exclusions from method or sampling plan (ie. Environmental conditions)
 - ✓ Statement of compliance
 - ✓ Opinions and Interpretations
 - ✓ Date and location of sampling including any diagrams, sketches, or photographs
 - ✓ Reference sampling plan and procedures used



FSMO Responsibilities

□ Reporting Results (cont'd)

- Reports of Sampling - When FSMO transfers sample to independent laboratory
 - ✓ Unique sample identification
 - ✓ Adequate information concerning times (preservation extraction, etc...)
 - ✓ Methods
 - ✓ Preservation
- Reports of Monitoring instruments
 - Indication of raw data or adjusted for sensor calibration drift or foul



- ❖ Presentation represents broad summary of standard requirements
- ❖ Not meant as audit preparation but an overview of what types of things would be in an accreditation audit
- ❖ Standard allows for relative ease of implementation for both large and small FSMO's





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FSMO Compliance with ISO/IEC 17025

**Patrick Conlon
Senior Quality Assurance Chemist
Environmental Standards, Inc.**

**Environmental Measurement
Symposium
Washington, D.C.
August 2010**



Agenda

- General and Technical Requirements
 - Personnel
 - Document Access and Control
 - PT Testing
- Discuss application of a corporate QMP through use of a “*Systematic Planning Process.*”
- Frequently Asked Questions?





Personnel Requirements

- Adequate documented training and supervision for Sampling Crews
- Job descriptions, qualifications, and training for the Sampling Crews are equally important to that of technical staff.
- QA function must extend over the field sampling processes.



SOPs and Document Control

- As with any technical Standard Operating Procedure (SOP), field sampling SOPs must be readily accessible in the areas where the activities are performed.
- As with any technical SOP, field sampling SOPs must be clearly controlled in the areas where the activities are performed.
- As with any controlled document, the assessor should be able to clearly determine which are the current controlled documents, the document history, and when they were last reviewed.



Proficiency Testing Samples?

- Proficiency testing (PT) not clearly required except where data is used for compliance reporting.
- Regardless, PTs can serve a value part of the QC program and demonstrate measurement performance and accuracy.
- Whenever possible, whole aqueous PTs and SRMs that are similar matrices to the samples being tested are preferred.



Proficiency Testing Samples?

- Proficiency testing (PT) samples demonstrate a organizations proficiency to analyze specific compounds of concern.
- Periodic analysis of PT samples can provide an on-going check to determine if proficiency is maintained.
- Single-blind and double-blind samples are used as an effective QA/QC tool.
- Performance Testing as a Best Practice





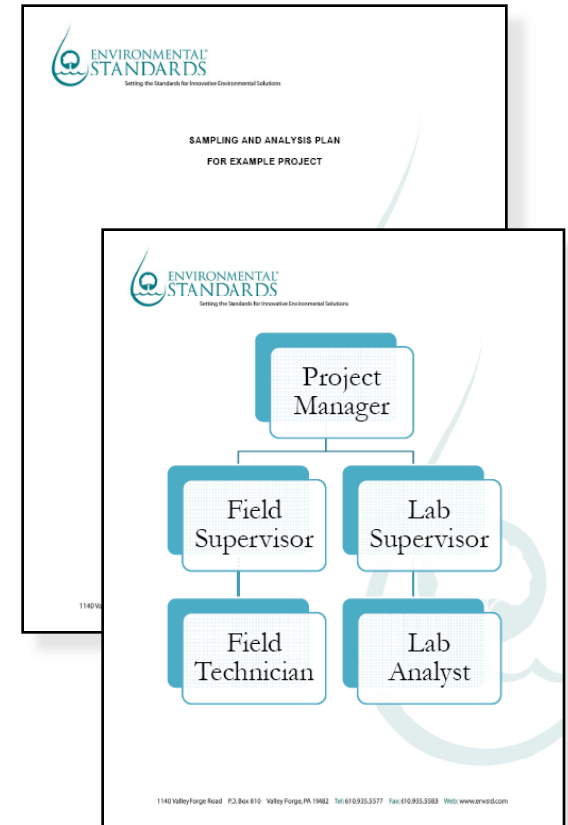
Data Validation

- Although not specifically mentioned in the FSMO guidelines, data validation serves to demonstrate compliance with completeness and accuracy of sample collection and field documentation.
- FSMO should be involved with formalized documented corrective actions as a result of validation finding that affect their activities.
- Data collected for critical measurement or for program compliance should be validated.



Standardized Process for QAPPs and SAPs

- When applicable, Project Plans, QAPPs, and SAPs should comply with ISO requirements for form and content.
- Except when required otherwise by the client, program, or regulatory authority, project plans should follow a standardized and documented “*Systematic Planning Process*”
- In effect it is appropriate to have an SOP for writing project plans and SAPs, *etc.*
- UFP-QAPP good Starting Point





Frequently Asked Questions

Q: How is FSMO accreditation different from traditional mobile laboratory accreditation?

A: FSMO accreditation allows for the accreditation of a broad range of sampling activities, which are not specifically covered by traditional laboratory accreditation.



Frequently Asked Questions

Q: How do I demonstrate an individual's capability for sampling activities?

A: When analysis is not involved, demonstration of capability is accomplished through training documentation along with acceptable sampling practices witnessed and documented by senior technical or QA staff.





Frequently Asked Questions

Q: My company has five locations from which field sampling activities are managed. Would each of these need to be accredited separately?

A: Not necessarily. If all of the locations are operating under a common set of quality system documents, they may be accredited as an overall organizational system. This standardization and overall conformance must be readily determined through the documentation.





Frequently Asked Questions

Q: All of my company's field sampling programs are site- and project-specific with their own specific QAPPs. Would each of these need to be accredited separately?

A: When the FSMO can demonstrate that individual projects are all governed by the organization's Quality Management System, the overarching quality management system may be the basis for FSMO accreditation. A specific project may be audited as part of the FSMO accreditation to demonstrate conformance of projects to the overall quality system requirements.





Frequently Asked Questions

Q: Will FSMO accreditation eliminate project-specific audits by a client or agency having oversight?

A: No. FSMO accreditation and project-specific oversight would, however, be complementary. FSMO accreditation would provide general assurance of compliance with ISO guidelines and requirements whereas project-specific oversight would provide assurance of compliance with the project requirements and assurance that the overall standards are being met for the specific project.



Contact Information



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