

# The NEFAP Accreditation Process

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*This document is not intended to be a substitute for reading, understanding and following the TNI Field Activities Standard. Every effort has been made to ensure the accuracy of this information, but the Standard has final authority if any discrepancies are found.*

## Introduction

The NELAC Institute (TNI) has prepared a Field Activity Standard for accreditation of organizations performing environmental sampling and/or field measurements. The current (2014) Standard consists of *Volume 1 General Requirements for Field Sampling and Measurement Organizations*, and *Volume 2 General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations*. The TNI Field Standard –Volume 1 conforms to ISO/IEC 17025:2005 (E) and includes applicable clauses from that standard. Note that clauses from the ISO/IEC standard frequently contain the terms “laboratory” and “test and/or calibration” that should be substituted with the terms “field sampling and measurement organization (FSMO)” and “field sampling and/or measurement,” respectively. The TNI Field Standard is available from the TNI website ([The NELAC Institute \(TNI\)](http://www.nelac-institute.org)) and is your source for requirements on how to qualify for and maintain accreditation as an FSMO.

Within the following explanation of the accreditation process, the applicant organization is termed “FSMO,” but the term does not imply accredited status.

Note: As defined in ISO, the term “management system” means the quality, administrative and technical systems that govern the operations of the FSMO.

## Overview

The process starts with the selection of an Accreditation Body (AB) to work with. There is a link on the TNI website (<http://www.nelac-institute.org/nefap-ab.php>) to all TNI recognized NEFAP ABs. Take time to become familiar with each AB as you make your decision. Each AB has proficiency testing, traceability, measurement uncertainty, accreditation symbol and marketing requirements. All ABs are equally qualified to service NEFAP accreditation needs. Applications are found on each ABs website and conditions for Accreditation (including fees, accreditation schedule, and invoicing requirements) are up to each individual AB.

Upon receipt of a complete application, the AB will assign a qualified assessor to lead an assessment team that performs the initial assessment. The assessment team

may consist of one or more assessors depending on the number and nature of technologies that the FSMO performs. An on-site assessment will be scheduled on a date that is mutually agreeable to the AB and FSMO.

Accreditation is granted typically on a two-year cycle. The frequency of on-site assessments is left to the discretion of the AB. The FSMO is responsible for alerting the AB of any significant changes in its management system, testing abilities, or scope of services that occur at any time during the FSMO's accreditation cycle.

## **Application Process**

Requests for accreditation require submission of the following:

- A completed application form
- Supporting documents, which may include but are not limited to:
  - FSMO's Quality Manual, and information regarding compliance to Volume 1 of the TNI Field Standard
  - FSMO's Draft Scope of Accreditation, including information regarding sampling and measurement capabilities
  - Standard Operating Procedures (SOP) for each method or technology the FSMO is seeking accreditation for
  - Organizational Chart, job descriptions, summary of personnel qualifications and training records
  - Proficiency Testing data (if available)
- Payment of fees as defined by the AB

As part of its application package, the FSMO must submit a summary document of its management (quality assurance) system (see Quality/Management System below). The FSMO's management system must meet all the criteria set forth in Volume 1 of the TNI Field Standard. TNI has developed a Priority Checklist for FSMO Management Plans that can help assure the management system meets the requirements of the TNI Field Standard ([link to document on website](#)).

## **Technical Manager and Quality Manager**

FSMO's must identify the technical manager(s) and quality manager (however named) who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the management system related to quality is implemented and followed (Volume 1, Section 4.1.5 and 4.2.6).

## **FSMO Scope of Services**

As part of its application, in a summary Scope document, the FSMO must list all field sampling and measurement (FSM) services that will be accredited. The Scope document shall clearly identify each FSM service, the test or sampling method(s) including source citation(s), applicable environmental media, required equipment, required calibration supplies (if any), and special staff training/qualifications to perform the service (if any). The FSMO's management system must ensure that a procedure approval process is employed, that procedures listed in the Scope document are currently approved by FSMO management, and that the procedures provide sufficient and concise information on how to perform each FSM service. Further, approved procedures listed in the Scope document must be available to all FSMO staff within the organization. The Scope document will be the basis for office and field assessments performed by the AB.

## **FSMO Assessment**

As noted above, a date mutually agreeable to the AB and FSMO is selected. Additionally, ABs reserve the right to perform unannounced on-site assessments for just cause. In order to maintain accreditation, the FSMO must allow the assessor(s) access during normal business hours. Additional detail on assessment procedures can be found in Volume 2 of the TNI Field Standard.

## **Opening Conference**

Upon arrival at the agreed assessment location, the lead assessor will introduce him/herself and any team members. The assessors will meet with the FSMO's authorized representative and staff members invited to the opening conference. The lead assessor will explain the purpose of the assessment and assessment process. The overall assessment agenda and schedule will be confirmed. During the Opening conference the assessors will typically:

- Introduction and identification of each assessor along with their qualifications and areas of responsibilities
- Review the purpose of the assessment and the schedule of activities
- Identify the Standards used by the assessors in judging the compliance status of the FSMO
- Verify information on FSMO's application
- Indicate which records of services will be examined
- Examine the roles and responsibilities of key managers and staff

- Address Confidential Business Information (CBI) concerns
- Identify location, time and services to be assessed at the field site(s)
- Review special requirements that the FSMO may have (*e.g.*, requirements related to health and safety or field-site security)
- Allow management/office staff to ask questions necessary to understand the assessment process and events that will follow the assessment
- Discuss how non-conformances will be handled
- Identify tentative time and location for the closing conference
- Review the post assessment timeline
- Request a general tour of the facility

### **Quality/Management System Review**

The lead assessor will review the implementation of the FSMO's quality/management system policies and procedures. This phase of the assessment, which typically will take place in a conference room setting, will include a thorough review of the FSMO's records related to document control, corrective actions, internal audits, etc. Typically this portion of the assessment is attended by the FSMO's Quality Manager (however named) as well as the personnel responsible for the various activities in the TNI Field Standard.

### **Records and Data Review**

The scope of records and data review includes FSMO documents and a vertical audit of a particular sample from field collection, to field measurements, to the final laboratory reporting of analytical results (if any). The field records and data review will vary widely depending on the FSM service(s) being assessed. Assessments are a sampling exercise – while it is not possible for an assessor to review every record of every method, the assessor will make an effort to review an appropriate sampling of records related to field activities. In general however, all data will be evaluated by an assessor from its rawest form to determine method compliance and scientific defensibility.

The minimum essential areas that shall be reviewed during the assessment include the following and records will be examined for each area:

- Adherence to published test methods and internal standard operating procedures;
- Observed field sampling and measurement practices;
- Verification of implemented, functional quality manual elements;

- Personnel – experience, training and demonstration of competency records;
- Physical facilities – accommodation and environment;
- Sampling and measurement equipment and reference materials;
- Measurement traceability and calibration;
- Associated field records and data reductions;
- Subcontracting of sampling or measurement activities;
- Outside support services;
- Records of preventive, corrective actions and complaint resolution;
- Records of Proficiency Testing (if applicable);
- FSMOs annual management review and
- Proficiency Monitoring Plan which describes how the FSMO will demonstrate and/or measure proficiency, and shall include any available records.

## **Staff Interviews**

Information on FSMO personnel and their qualifications (education, training and FSM experience) should be on file in the office and made available to assessors for review. The assessors will verify through interviews with office and field personnel that the staff have the appropriate qualifications and are performing their duties as reported and are knowledgeable of the procedures for which they are responsible.

Staff members should be:

- qualified and competent to perform assigned FSM services
- familiar with the FSMO management system and follow its guidelines
- understand the Scope of FSMO services and especially the SOP's for services they perform
- follow specific QA\QC requirements of project work plans

## **Quality/Management System**

The following are important elements of the quality/management system that will be assessed:

### *Document Control*

The FSMO shall maintain copies of all written, printed, and electronic records, including but not limited to sampling, field measurements, laboratory results for samples, calibration results, and instrument repairs for the period required by its client contract, or longer if required by applicable regulatory program. These records must be made available to assessors during the on-site assessment.

### *Control of Nonconforming Work*

The FSMO management system must show its policy(s) and procedures to respond to instances when FSM work or results do not conform to client's requirements. The management system must contain procedures to recognize customer complaints, to allow staff to inform management of nonconforming work, to determine causes and assess appropriate corrective actions, to implement those actions, and to audit the actions to determine the effectiveness of the actions.

### *Personnel*

An FSMO may appoint one or more managers to administer its management system. The FSMO must identify its manager(s) responsible for implementing its management system, and its staff that will provide FSM services. The organization must describe its requirements of training and experience for each position that may manage or perform FSM services. Managers must be full-time employees of the FSMO and may be listed as manager for only one FSMO.

A technical manager who is absent from work for a period of time exceeding 15 consecutive calendar days shall designate another full-time FSMO staff member, meeting the qualifications of a technical manager, to temporarily perform his function. If a technical manager's absence exceeds 35 consecutive calendar days, the AB administrator must be notified in writing. The FSMO must also maintain training and experience records for staff managing/performing FSM services. The AB will inspect these records during assessments.

### *Methods and Method Validation*

The FSMO should use appropriate methods (SOPs) for FSM services offered to its clients. The FSMO may adopt widely-accepted procedures, such as provided by ASTM, US EPA and US Army Corps of Engineers, or may adopt its own procedures. As explained in Volume 1-Section 5.4, methods developed by the FSMO must be validated and should provide, where appropriate, estimates of the sampling or measurement uncertainty. The FSMO is responsible for assuring its methods are current and that its SOPs are readily available to its FSM staff.

### *Equipment*

The FSMO may use its own equipment or equipment provided by others. Regardless of source, the FSMO is required to maintain records that show all equipment used for FSM services was appropriate for the work, was properly calibrated and maintained, and was operated by properly trained staff. During the assessment, the AB will review FSMO's records of equipment calibration, maintenance and use, as well as assess equipment calibration and use at the field site(s).

### *Sampling*

Per the TNI Field Standard, “sampling” is a defined procedure to obtain a portion of an environmental medium suitable for testing such that the test result is representative of the whole. The FSMO is responsible for developing a site-specific and client specific sampling plan that meets client objectives, is appropriate for the media of concern and test method(s), that provides representative samples, and that controls to the extent practical environmental factors that would affect the validity of test results. Each sampling plan must ensure documentation of sampling purpose, sampling method(s), sampling conditions, unique sample identifiers, sampling location(s) and sampling time(s), and sufficient information to allow data users to assess the validity and representativeness of the test results.

### *Reporting the Results*

The FSMO must report results of its FSM services accurately, clearly, objectively, and in accordance with requirements of the test method(s). FSMO reports must provide all information necessary for interpretation of the results, particularly unique sample identifiers, sample location and time, sampling methods, and discussion of sampling or testing anomalies that may affect the validity and representativeness of the results. Reports that contain results obtained from subcontractors must clearly identify those results.

### **Field Audit**

Prior to the field audit, the FSMO and Assessor will work together to identify FSM services to be assessed at the active field site(s). In the absence of available client work, the FSMO staff may be required to provide a demonstration of selected FSM services. The FSMO will identify suitable site(s) and schedule for the AB’s assessors to travel to the field site(s) and conduct the required assessments. The FSMO should assure that the field team(s) are aware of the AB’s intention to assess and the schedule. At least one day in advance of each site assessment, the FSMO must confirm with its field team(s) and the AB that the FSM services to be assessed will occur as planned. The FSMO is responsible for providing PPE and site-specific hazard warnings to assessors during site visits.

### *Equipment and Testing Supplies:*

Assessors will observe and confirm that appropriate equipment, calibration materials, and supplies are available at the field site to perform the FSM services. Specifically assessors will check that:

- Equipment is in good working order, maintained on a regular basis and documentation of calibrations is kept
- All calibration materials are within expiration date, labeled properly and

- handled according to manufacturer's instructions
- Project work plan and SOPs are readily available to field staff at the site
- Field staff are properly documenting their assigned FSM services and results

### **Assessment Team Debriefing**

At the conclusion of the assessment, the assessor(s) will require a brief (typically one or two hour) period to privately compile their final report. A copy of this report, including a list of any deficiencies, will be provided to the FSMO before the assessor(s) depart.

### **Closing Conference**

Upon completion of the assessment, the assessment team will conduct a closing conference with the FSMO representative and invited staff members. The purpose of this exit briefing is primarily to inform the FSMO of assessment results and provide the opportunity to FSMO staff to ask questions about the findings, including deficiencies, if any, and their basis. The assessor will also review next steps in the accreditation process, including procedures for responding to deficiencies through the FSMO's corrective action process and required time frames.

Final determinations concerning the number, nature and extent of assessment findings shall be made by the AB after reviewing the reported findings. A final assessment report will be issued within 30 days encompassing all relevant information concerning the FSMO's accreditation status and conformance with the TNI Volume 1 Field Standard.

## **Post Assessment**

### **Corrective Action**

A corrective action plan is due 30 calendar days from the receipt of the finalized assessment report. The corrective action plan shall include the action the FSMO will implement to correct each deficiency and the time period required to complete the corrective action. Corrective actions must be completed in compliance with Volume I Section 4.11 of the TNI Field Standard. The FSMO shall submit records to the AB that include the results of the root cause analysis for each deficiency as well as objective evidence of the effectiveness of corrective actions taken.



The AB will respond to the action noted in the corrective action plan within 30 calendar days of receipt. If the corrective action plan (or a portion) is deemed unacceptable to remediate the deficiency, the FSMO shall have an additional 30 days to submit a revised corrective action plan.

Upon successful closure of deficiencies (as determined by the AB), the FSMO will be moved forward in the process to achieve final accreditation. No FSMO will have their accreditation denied, suspended, or revoked without due process as described in Volume 2 Section 7 of the TNI Field Standard.

### **Follow-up Assessment**

Follow-up assessments may be necessary when a major change occurs in FSMO personnel, equipment, or Scope of Services. Follow-up assessments may also be conducted to determine whether the FSMO has corrected deficiencies or to determine the merit of a formal appeal by the FSMO. Determination of the need for a follow-up assessment will be decided on a case-by-case basis by the assessment team assigned to the FSMO. The final decision to perform a follow-up assessment will be made by the AB administrator based on the assessment team's recommendation. Any follow-up assessment that might warrant downgrading the FSMO's accreditation status shall be completed and reported within 180 calendar days after the follow-up assessment.

### **Extending/Changing Scope of Accreditation**

Per Volume 2 Section 7.12 of the TNI Field Standard, an FSMO may extend/change the scope of its accreditation. The FSMO must provide the AB with documentation that its Management System and Scope of Services have been revised as necessary to include the proposed change(s) in services. Typically, the AB will schedule an on-site assessment of the proposed new services. However, at its discretion, the AB may approve an FSMO's application to extend/change the scope of accreditation by performing a data review, without performing an on-site assessment. The AB has a defined written policy for doing this. Data review may include but not be limited to PT performance (if applicable), a measure of competency demonstration, quality control performance and a written SOP.

### **Notification and Reporting Requirements**

The FSMO shall notify the AB administrator, in writing, of any changes in key accreditation criteria within 30 calendar days of the change. This written notification includes but is not limited to changes in FSMO ownership, changes in top management or key personnel (including the technical manager(s) and quality

manager (however named)), changes in key management system policies, key staff resources, Scope of FSM services, and other issues that reasonably might affect the FSMO's ability to fulfill the requirements of accreditation. Unless the FSMO notifies the AB that such disclosures are CBI, such updates are public record.

### **Retention of Accreditation Records**

FSMO records associated with accreditation shall be maintained for a minimum of five years, unless otherwise required for a longer period in another regulation or authority.