



Improving the Reliability of Field Operations

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What Can Be Done to Ensure Reliable Data?

Competency can be ensured by a robust accreditation scheme with a strong quality management system foundation.

- ✓ Laboratories: *ELV1, Management and Technical Requirements for Laboratories Performing Environmental Analysis*
- ✓ **Field Sampling and Measurement Organizations (FSMOs):** *FSMO V1, General Requirements for Field Sampling and Measurement Organizations*



Accreditation of Field Sampling and Measurement Organizations (FSMOs)

- ❑ Effort started in 1998 with a belief that field activities should have the same oversight as the laboratory.
- ❑ First complete TNI standard approved in 2007 and first FSMO accredited shortly thereafter.
- ❑ FSMO standard Volume 1 and 2 revised in 2014.
- ❑ Like the laboratory standard, basis is ISO/IEC 17025 with additional requirements specific to environmental sampling and field measurements.
- ❑ Like the laboratory standard, also contains requirements for Accreditation Bodies (ABs) based on ISO/IEC 17011





National Environmental Field Activities Program (NEFAP)

- ❑ The purpose is to establish and implement an accreditation program for FSMOs.
- ❑ Oversight is provided by the TNI NEFAP Executive Committee.
 - Recognition of Accreditation Bodies
 - Provide training and guidance
- ❑ Standards for the program are developed by the TNI Field Activities Expert Committee.



Major Differences Between NEFAP and NELAP

- ❑ Accreditation not required by regulations in states for sample collection.
 - Louisiana has adopted NEFAP accreditation for stack testing
- ❑ State or federal agencies do not oversee the accreditation process.
 - TNI oversees the accreditation process as implemented by the recognized ABs.
- ❑ “Umbrella” accreditation possible. (Organization, not location)
- ❑ So what ABs Accredit to this Program?
 - [ANSI-ASQ National Accreditation Board](#)
 - [American Association for Laboratory Accreditation \(A2LA\)](#)
 - [Perry Johnson Laboratory Accreditation, Inc. \(PJLA\)](#)

<https://www.nelac-institute.org/content/NEFAP/nefap-ab.php>





The TNI Field Activities Accreditation Standards

- ❑ Two Volumes = Two Standards
 - Volume 1: Requirements for FSMOs
 - Volume 2: Requirements for Accreditation Bodies





A New Approach

- ❑ New draft Standard published July 30, 2024.
 - Comment period open for 90 days.
- ❑ Move to the 2017 version of ISO/IEC 17025.
- ❑ Add much more specificity, comparable to the TNI laboratory standard, to add value.

The laboratory Quality Systems module, Module 2, is under revision to include 17025: 2017 with approval likely in 2025.



Objectives of 17025 Revision

- ❑ Align structure and content with other recently revised ISO standards
 - Other 17000-series documents
 - ISO 9001
- ❑ Focus on outcomes rather than prescriptive requirements
 - Less variety in terms used to describe required documentation
 - Elimination of some favorite terms (e.g., quality manual, quality manager, subcontracting, etc.)
 - More flexibility for laboratories
- ❑ Requirements for information systems/records more reflective of current technologies
- ❑ Many requirements are nearly verbatim from previous version, just in different places



Key Difference

3.9 laboratory

body that performs one or more of the following activities:

- testing
- **sampling, associated with subsequent testing**

FSMO: Field Sampling and Measurement Organization

body that performs one or more of the following activities:

- Testing in the field (field measurement)
- Calibration in the field (field calibration)
- Field sampling
- Field observation (field conditions related to an environmental activity)



Organization of ISO/IEC 17025

2005

1. Scope
2. Normative references
3. Terms and definitions
4. **Management requirements**
5. **Technical requirements**

2017

1. Scope
2. Normative references
3. Terms and definitions
4. **General requirements**
5. **Structural requirements**
6. **Resource requirements**
7. **Process requirements**
8. **Management requirements**





Comparison of 17025 to TNI Volume 1

17025

- General requirements
- Structural requirements
- Resource requirements
- Process requirements
- Management requirements

TNI Volume 1

- Everything in 17025 plus
 - Data integrity
 - Sampling plans
 - Sample procedures'
 - Many other changes





EXAMPLE: INSTRUMENT CALIBRATION

ISO 17025

- ❑ *The FSMO shall verify that equipment conforms to specified requirements before being placed or returned into service.*

TNI Standard

- ❑ 3 pages of specific details related to initial calibration and calibration verification, including:
 - Documentation and records
 - Acceptance criteria
 - Corrective action
 - Verification of standards
 - Etc.





Additions from the TNI Field Activities Committee (Scope)

- ❑ 1.0 Clarifies it applies to any organization conducting sampling or field measurements.
- ❑ 1.1 Clarifies that regulations or other state/Federal requirements supersede the requirements in this Standard.

Note: Throughout the Standard, FSMO and/or laboratory are used in the proper context.





Additions from the TNI Field Activities Committee (Definitions)

- ❑ 3.5 – proficiency testing: Separate notes for sampling and measurement
- ❑ 3.10 – 3.18: New Definitions
 - Field Activities
 - Field Sampling and Measurement Organization
 - Matrix
 - Mobile Facility
 - Preservation
 - Proficiency Test Provider
 - Quality Management System
 - Sampling





Additions from the TNI Field Activities Committee

(4 - General Requirements)

□ 4.3 - Data Integrity

4.3.1 The FSMO must establish and maintain a documented data integrity system that includes the following four elements:

- 1) data Integrity procedures (4.3.2),
- 2) data integrity training (4.3.2),
- 3) periodic in-depth data monitoring (4.3.4), and
- 4) data integrity investigation (4.3.5).





Additions from the TNI Field Activities Committee

(5 - Structural Requirements)

- ❑ 5.5 Added “ensure that all personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.”
- ❑ 5.6(g) Revised to emphasize Quality Assurance





Additions from the TNI Field Activities Committee

(6 - Resource Requirements)

- 6.2.1 Added notes about demonstration of capability.
- 6.2.5(g) Added language to address security and safety concerns.
- 6.3.2 Added language relative to records of sampling.
- 6.3.6 Added language to specify the staff member that will evaluate and communicate observations to facilities and environmental conditions.
- 6.4.13/14/15 Added language about representative sampling, decontamination, and contamination concerns



Additions from the TNI Field Activities Committee (6 - Resource Requirements) Continued

- ❑ 6.4.2 and 6.4.3 Added language relative to calibration of equipment used for field measurements, both attended and unattended.
- ❑ 6.4.4 Extensive revisions related to an initial calibration for field measurements.
- ❑ 6.4.5 Added a Note to clarify use of equipment in multiple locations.
- ❑ 6.4.7 Extensive revisions related to verification of an initial calibration for field measurements.
- ❑ 6.6.1(d) Added language relative to competency of contractors.





Additions from the TNI Field Activities Committee

(7 - Process Requirements)

- ❑ 7.1.7.1 Revised language to improve customer communication.
- ❑ 7.3 Revised to emphasize even more the need for a sampling plan and appropriate sampling methods with a reference to Annex C.
- ❑ 7.4 Added Notes to clarify that the procedures apply to field activities.
- ❑ 7.5 Revised to clarify handling and documentation of field records.





Additions from the TNI Field Activities Committee

(7 - Process Requirements) Continued

- ❑ 7.7.1 (l) Added language related to QC samples.
- ❑ 7.7.2 Added language to require use of an accredited PT provider.
- ❑ 7.8.2 Added paragraphs o-t on additional requirements for reports.
- ❑ 7.10.4 New section allowing reporting of qualified data.





Additions from the TNI Field Activities Committee

(8 - Management Requirements)

- 8.4.3 New section relating to transfer of ownership.



Additions from the TNI Field Activities Committee (Annex C - Informative Annex)

- Implementation Examples
- C.1 General
- C.2 Data Integrity
- C.3 Demonstration of Capability and Competence
- Sampling Plan
- Sample Method

Non-mandatory guidance to assist FSMOs in implementing the standard.



STRENGTHS OF THE TNI STANDARD

- ❑ Uses ISO 17025 quality system approach;
- ❑ Adds specificity to improve clarity and help with consistency for FSMO assessments;
- ❑ Allows flexibility in meeting requirements;
- ❑ Represents best professional practice;
- ❑ Allows for multiple Accreditation Bodies to implement consistently; and
- ❑ Includes data integrity component missing from 17025.



Summary

- ❑ NEFAP - The only independent national or international program to accredit field sampling and measurement organizations.
- ❑ Benefits to FSMOs in becoming accredited
 - Increase data reliability
 - Reduce risk
 - Reduce cost
 - Marketing advantages
- ❑ NEFAP Future Vision
 - Continue education on the standard and market NEFAP value
 - Increase recognized ABs and FSMOs
 - Increase regulator recognition of the program





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