

Summary of TNI NEFAP FSMO Program Changes
From the 2007 Standard to the 2014 Standard
(Rev Date: February 2, 2015)

Volume 1 Changes:

- In Section 4.2.8: The 2nd and 3rd sentences were reworded for clarification.
 - Section 4.2.8 stated: The FSMO shall establish and maintain data integrity procedures, which shall be defined or referenced in the quality manual. The term “data” used in the clause refers to field measurement data and all other recording keeping. The data integrity that documents field sampling and measurement activities shall provide assurance that a highly ethical approach to field sampling and measurement is a key component of all FSMO planning, training, and method implementation. The data integrity procedures shall include provisions for the following:
- In Section 4.2.8: Sections (e), (f), and (g) were added including provisions to be in data integrity procedures.
 - Section (e): The data integrity procedures shall be signed and dated by senior management.
 - Section (f): The data integrity procedures and the associated implementation records shall be properly maintained.
 - Section (g): The data integrity procedures shall be reviewed annually and updated by management as needed.
- In Section 4.5.5: The entire section was added to clarify “competent subcontractors”.
 - A competent subcontractor is one that, for example, complies with this TNI Standard for the work in question.
- In Section 4.13.1.4.3: The entire section was removed.
 - Section 4.13.1.4.3 stated: Access to archived information shall be documented with an access log. These records shall be protected against fire, theft, loss, environmental deterioration, vermin and in the case of electronic records, electronic or magnetic sources.
- In Section 4.13.2.1.2: The last sentence on “long duration projects” was removed.
 - Section 4.13.2.1.2 stated: or for long duration projects five (5) years from project completion.
- In Section 4.15.1: Note 4 was removed.
 - Note 4 stated: A management review includes an annual review of the FSMO’s quality manual in accordance with a documented procedure.
- In Section 5.2.2.2 (b): The reference to the 4 elements of the data integrity system and the following 4 bullets, as well as subsections i., ii., and iii.

- Reference stated: There are four required elements within a data integrity system.
 - Bullet 1 stated: Data integrity training.
 - Bullet 2 stated: Signed data integrity documentation for all FSMO employees.
 - Bullet 3 stated: In-depth, periodic monitoring of data integrity issues with confidential reporting of issues to management.
 - Bullet 4 stated: Data integrity procedures documentation
 - Subsection i stated: The data integrity procedures shall be signed and dated by senior management.
 - Subsection ii stated: These procedures and the associated implementation records shall be properly maintained.
 - Subsection iii stated: The data integrity procedures shall be annually reviewed and updated by management.
- In Section 5.3.3: A note was added for avoiding conditions that could affect results.
 - The note states: During field tests and while handling samples, personnel should avoid areas where activities or conditions may adversely affect results, such as temporarily storing samples near volatile liquids, or transporting test items between areas of high temperature contrast.
- In Section 5.3.6: This entire section including the note was removed.
 - The section stated: Ambient environmental conditions at the selected field observation location that may affect the quality of the measurements or samples shall be documented. For measurement instruments or sampling devices that require a controlled environment, the FSMO shall also document the location where the instruments or devices are used and any relevant conditions in that location.
 - The note stated: Ambient field conditions include, but are not limited to, information such as temperature, weather conditions, tides, etc. Comments about samples or conditions associated with the sample source (e.g. turbidity, sulfide odor, insufficient amount of sample collected, etc.) should also be noted.
- In Section 5.6.2.1.4: Letter (f) and letter (g) were added.
 - Letter (f) states: Data associated with an unacceptable initial or continuing instrument/equipment calibration shall be reported with appropriate data qualifiers.
 - Letter (g) states: Records of reference standard used for calibrations and reference material certificates shall be retained.
- In Section 5.6.2.2: Section 5.6.2.2.1 and its note were added, as well as 5.6.2.2.2 was added to provide ISO language that was previously missing.
 - Section 5.6.2.2.1 states: For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions

used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

- The note states: The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.
 - Section 5.6.2.2.2 states: Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).
- In Section 5.9.1: Letter (f) was added.
 - Letter (f) states: Verification of a measurement calibration using a second source
 - In Section 5.9.2: The previous wording for 5.9.2 was moved into 5.9.3 then added new language in 5.9.2 on proficiency testing.
 - Section 5.9.3 states: Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.
 - Section 5.9.2 states: The FSMO shall participate in a proficiency-testing program that is applicable to its scope of accreditation.
 - Section 5.9.2 note states: The selected methods should be appropriate for the type and volume of the work undertaken.

Volume 2 Changes:

- In Section 4.2.5: Letter (g) was removed.
 - Letter (g) stated: Supervision of the applicable portions of the TNI Proficiency Testing Program.
- In Section 4.3.7.1: Section 4.3.7.1 including letters (a), (b), and (c) were removed.
 - Section 4.3.7.1 stated: For the instance of an Accreditation Body and FSMOs that are organizational units of the same department or agency of a government authority which is an accreditation body, or that have other organizational conflicts of interest, the AB shall:
 - Letter (a) stated: demonstrate by organizational structure, that the accreditation body's accreditation program manager and FSMO's technical director (however named) do not report within the same chain-of-command; and
 - Letter (b) stated: demonstrate by policies and procedures, that conflicts-of-interest do not exist; or

- Letter (c) stated: direct the FSMO to apply for accreditation through any other recognized accreditation body.
- In Section 4.5.1: Both note 1 and note 2 were removed.
 - Note 1 stated: A government accreditation body shall have the same arrangements to cover liabilities and workman’s compensation claims arising from its operations and activities as all other programs, units, divisions, bureaus, etc., in the department or agency in which the accreditation body is located.
 - Note 2 stated: A non-government accreditation body shall have appropriate coverage for liabilities and workman’s compensation claims arising from its accreditation activities.
- In Section 5.2.2: A note was added.
 - The note states: The requirements within TNI Standard “General Requirements for Field Sampling and Measurement Organizations”, Volume 1, and *ISO/IEC 17025* or *ISO 9001* could serve as the basis for a quality manual.
- In Section 5.2.4: The entire section including the note was removed.
 - Section 5.2.4 stated: The accreditation body shall have a quality manual appropriate to the type, range and volume of work performed as part of its accreditation activities and that addresses all requirements of this Standard.
 - The note stated: The requirements within TNI Standard “General Requirements for Field Sampling and Measurement Organizations”, Volume 1, and *ISO/IEC 17025* or *ISO/IEC 9001* could serve as the basis for a quality manual.
- In Section 5.4.3: This entire section was deleted including bullets (a) and (b).
 - Section 5.4.3: In lieu of section 5.4.3 section 5.3.1. was added.
 - See section 5.3.1 for details.
- In Section 5.4.4: This entire section was deleted including bullets (a) and (b).
 - Section 5.4.4: In lieu of section 5.4.4 section 5.3.2. was added.
 - See section 5.3.2 for details.
- In Section 5.7.1.2: This entire section was removed.
 - Section 5.7.1.2 stated: When applicable, the accreditation body shall use the same policies and procedures for internal audits as used by all other programs, units, divisions, bureaus, etc., in the department or agency or organization in which the accreditation body is located.
- In Section 5.8.2: Letter (m) was added.
 - Letter (m) states: Proficiency Testing Program.

- In Section 6.1.1.1: This entire section was removed.
 - Section 6.1.1.1 stated: The accreditation body shall have physical and human resources required for the operation of its accreditation program, necessary to complete action on an application within nine (9) months from the time a completed application is first received from the FSMO. This time period shall not apply if delays are caused by the FSMO responses to the accreditation process, on-site assessment or proficiency testing requirements beyond the required time limits set forth in this Standard.

- In Section 6.2.6.1: Added bullet iv
 - Bullet iv states: Be judged proficient by the accreditation body.

- In Section 6.2.6.1: Letters (b) and (c) were removed along with the associated subsections.
 - Letter (b) stated: Each assessor shall participate in at least four actual on-site assessments under the supervision of a qualified assessor (see following exception, item c).
 - Letter (c) stated: For a newly recognized accreditation body, assessors shall not be required to complete assessments under the supervision of a qualified assessor provided:
 - Subsections stated: They have completed at least four other FSMO on-site assessments; they have been judged proficient by the accreditation body; and documentation of completion of the assessments and a statement of proficiency by the accreditation body is available.

- In Section 6.2.6.2 Note 1: The reference toward the specific program was removed.
 - Note 1 reference stated: such as the CAA, RCRA, TSCA, SARA, FIFRA, CWA, CERCLA and SDWA.

- In Section 7.1.3.1: Minor grammar changes and references to the specific program were removed.
 - Section 7.1.3.1 stated: Field sampling and measurement activities may be related to regulatory programs such as the CAA, RCRA, TSCA, SARA, FIFRA, CWA, CERCLA, SDWA and CEM monitoring or may be a result of other provisions or specialty areas promulgated as a result of action by a local, state or federal authority.

- In Section 7.1.3.2.1: A section on scope was added.
 - Section 7.1.3.2.1 states: Accreditation shall be granted for Field Sampling by Matrix/Technology, and/or for Field Measurements by Matrix/Technology.
 - Section 7.1.3.2.1 note states: Accreditation may also be granted for Field Sampling/Measurement Methods, or analyte as specific to regulatory programs.

- In Section 7.1.3.2.2: The entire section was added to replace the above changes.
 - Section 7.1.3.2.2 states: The accreditation body shall make publicly available a list of scopes they are competent to assess.
 - Section 7.1.3.2.2 stated: Accreditation may be granted by Matrix (either sampling or measurement) such as: air matrices (ambient, indoor, outdoor air, point source and fugitive emissions, soil atmospheres, air monitoring, and continuous emissions monitoring); solids, including soil, sediment, sludge and solids monitoring; water, including surface, waste, drinking and groundwater; and biological samples, including, for example, whole animals, fish, shell, animal or plant tissue and microorganisms.
 - Section 7.1.3.2.2 note stated: Accreditation may also granted by Field Sampling/Measurement methods, or analyte/analyte group as specific to those programs defined previously under “Types of FSMOs” and “Types of Matrices”.

- In Section 7.2.1.1.1: Letter (d) and bullet (i) were reworded, bullet (ii) was deleted, number 1 and 2 (subsets of bullet iii) were deleted, letter (h) was deleted, letter (i) was deleted, and letter (k) was reworded.
 - Letter (d) stated: a scope of accreditation including:
 - Bullet (i) stated: field sampling and field analytical methods for which accreditation is being requested;
 - Bullet (ii) stated: a complete listing of sampling and measurement methods employed including analytes to be; and
 - Number 1 stated: The accreditation body shall have in place a procedure for mutually selecting and agreeing, with the FSMO, the field sampling and measurement locations and sampling/measurement personnel for observations in accordance with the scope of the requested accreditation.
 - Number 2 stated: The accreditation body shall have in place a procedure for selecting field sampling and measurement locations that provide a representative sampling of such locations and a representative sampling across field sampling and analytical methods and FSMO locations, such that all activities are assessed within an agreed timeframe not to exceed three accreditation cycles.
 - Letter (h) stated: job description summaries of management and supervisory positions responsible for field sampling and measurement activities, with reporting relationships between positions;
 - Letter (i) stated: job description summaries of field sampling and measurement positions, with reporting relationships between positions;
 - Letter (k) stated: copies of the results of the previous three proficiency testing samples/programs if applicable;

- In Section 7.7.5: Letter (l) was added.
 - Letter (l) states: Proficiency Monitoring Plan which describes how the FSMO will demonstrate and/or measure proficiency, and shall include any available records.

- In Section 7.8.1.1: Language was added to letter (a), minor changes were made to the note, minor changes were made to (b), letter (c) was reworded for clarity, and letter (e) was deleted.
 - Letter (a) states: The assessment team shall use specific documentation in its reporting of deficiencies (e.g., a checklist). All deficiencies shall include a specific reference(s) to a clause in the relevant assessment standards, a clause in a method, a section or clause in the FSMO's own management system documentation, or to an accreditation body's own policies/procedures.
 - The note stated: The issues under i and ii above, at the discretion of the accreditation body, may or may not be subjects of or become issues for discussion at the closing conference, however, the assessor must continue to gather the information necessary to complete the assessment process.
 - Letter (b) stated: The assessment report shall be presented to the FSMO within thirty (30) days of the last day of the on-site assessment.
 - Letter (c) stated: The accreditation body shall allow the FSMO thirty (30) days after receipt of the report to provide a corrective action plan on any identified deficiencies to the accreditation body. An extension to this third-day period may be agreed if possible enforcement actions have been indicated.
 - Letter (e) stated: If a second corrective action plan is found unacceptable, the accreditation body shall consider denial of initial accreditation or re-accreditation status (see Clause 7.9).

- In Section 7.9.2.1.2: The entire section was significantly reworded.
 - Section 7.9.2.1.2 although significantly reworded doesn't necessitate explanation. The vast majority of the content is the same but additional information was added.

- In Section 7.9.2.1.3: Letter (c) was reworded, as well as letter (i).
 - Letter (c) stated: Failure to successfully analyze and report applicable proficiency testing samples within a twelve month period;
 - Letter (i) stated: Denial of entry during normal business hours for on-site assessment.

- In Section 7.9.2.1.4: Letter (c) was reworded, as well as letter (i).
 - Letter (c) stated: Reasons for suspension shall include:
 - Letter (i) stated: Failure to successfully complete applicable proficiency testing studies within any interim accreditation period (twelve months), failure to complete at least one applicable PT sampling program during the accreditation period (typically two years) and failure to maintain a two out of three passing record on applicable PT studies, or failure to demonstrate the required degree of competency in the absence of applicable and available PT programs.

- In Section 7.9.2.1.5: Within (b) subsection (ii), (iv), and (v) were deleted.

- Subsection (ii) stated: if after being suspended due to failure of two consecutive proficiency testing samples, the FSMO's analysis of the next proficiency testing study results in a further failed proficiency test study. Revocation shall apply only to each affected accredited scope of accreditation;
- Subsection (iv) stated: failure to participate in the ongoing proficiency testing program (if applicable and available) or maintain a two out of three passing PT record
- Subsection (v) stated: submittal of proficiency test sample results generated by another FSMO as its own;
- In Section 7.15.1.2: Letter (a) was deleted.
 - Maintains a quality manual that meets the requirements of Clause 5 of this Standard to demonstrate sampling and measurement procedure competency.
- In Section 8.2.5: The entire section was removed.
 - Section 8.2.5 titled (Enforcement) stated: An accreditation body shall take any enforcement actions independently. The enforcement component of the accreditation authorities shall be based on explicit values, or principles, with which all participants concur including:
 - The program is equitable to all participants;
 - The rules are well publicized;
 - The program needs of the participating regulatory agencies shall be upheld; and
 - The due process rights of participating FSMOs shall be protected.

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.