**Volume 2 Standard Update - Summary of Suggested Changes – Draft (2/7/22)**

**Volume 2 Rev 4 includes the following:**

**ISO/IEC 17011 text**

TNI EL text with modifications for FSMO (Explanatory notes deleted by MM in this version)

**TNI FSMO 2014 text**

**November 5, 2021 Duplicate text deleted**

**December 22, 2021 Incorporated all comments received to date**

**January 26, 2022 to wording modified in text based on comments from committee**

**Blue highlight in text of standard awaiting public comment**

**Light blue text of standard modified language from source text placed in standard**

**OVERVIEW**

|  | **Original Text (FSMO Vol 2 2014)** | **Suggested Change** | **Justification** | **Public Comments** |
| --- | --- | --- | --- | --- |
| 2 | None | Add ISO/IEC 17011:2017 standard to volume 2 and renumber volume 2 to be consistent with ISO/IEC 17011:2017 | For consistency with ISO/IEC 17011:2017 AB requirements |  |
| 5 | ISO/IEC 17011:2004 (all places in the standard)  Language from ISO.IEC 17011:2004 removed from FSMO standard if duplicated or similar language. (For example FSMO 2014 6.4.1 and 6.4.2) | Updated the FSMO Volume 2 to reference ISO/IEC 17011:2017  Remove duplicate or similar language from ISO/IEC 17011 2004 | Updating to the latest ISO/IEC 17011 version  Some ISO/IEC 17011 2004 language retained if slightly different or contains different concept that the new ISO/IEC 17011:2017 |  |
| 15 | Definitions: Items 3.29, 3.30 and 3.31: Update PT definition to TNI 2016 Volume 1 Module 1 | See Red Text Item 15; Confirm terms with the Glossary Committee | Term consistency across all TNI programs. Coordinate with PT EC related to terms used in ELV1M1 and V2M2. The same definitions to be used. |  |
| 16 | FSMO 2014 7.15 lists PTPA and PTP recognized by TNI | Add language to FSMO Clause 7.15  “PT samples shall be consistent with Volume 3 and 4 of the TNI standard” | Consistency across all TNI programs |  |
| 18 | Clause 6.1.2.3 Note removed | Delete Note | Referencing attributes found in 19011:2011. Attributes are no longer defined in ISO 19011:2018 Language is from 6.2.4 ISO/IEC 17011:2004 |  |
| 67 | Volume 1 standard for the FSMO does it contain items such as denial, suspension and revocation and renewal of accreditation consistent with Volume 2 Test retained in rev 4 | 7.9.2.1.3 7.9.2.1.5, and 7.9.2.1.6 and suspension moved to 7.11.1 ( FSMO 7.9.2.1.4) | Does the standard contain anything that should be in the Volume 1 standard for the FSMO? Such as denial, suspension and revocation and renewal?  Are the FSMO 7.9.2.1.3 7.9.2.1.5, and 7.9.2.1.6 still needed with the new sections of ISO/IEC 17011:2017? Text retained in rev 4 |  |
| 37 | FSMO 2014 from ISO/IEC 17011:2004 7.2.1 | Removed 17011:2004 language | Replaced with 17011:2017 language |  |

**PUBLIC INPUT SOUGHT**

|  | **Original Text (FSMO Vol 2 2014)** | **Suggested Change** | **Justification** | **Public Comments** |
| --- | --- | --- | --- | --- |
| 22 | Add prescriptive text to standard | 6.1.3.2.1 Before an assessor is allowed to perform unsupervised assessments for an accreditation body, the assessor shall have performed a minimum number of assessments under the supervision of an assessor whose competence has been qualified by the accreditation body. The qualified assessor shall observe the candidate assessor performing:  a) at least one assessment, for those assessors that have previous documented experience performing environmental CAB assessments; or  b) at least two assessments, for those assessors that have no documented experience performing environmental CAB assessments.  c) The supervising qualified assessor shall document his or her conclusions to the accreditation body employing the candidate assessor. The accreditation body shall use the qualified assessors’ conclusions to determine if an assessor candidate may perform unsupervised assessments or if additional supervised assessments beyond the minimum specified in this Standard are required to qualify the candidate assessor. | 6.1.3.2.1 from TNI EL standard – One member of the committee suggested that this is too specific. Should this be deleted since other parts of the standard requires the AB to define monitoring. |  |
| 23 | 6.2.5.2. and all of a and b  See attached language removed | Remove language | Relates to being impartial and is very prescriptive  Should this be removed or modified. The removed language is prescriptive. |  |
| 24 | 6.2.6 plus EL language | Modify language after public input and consistency with TNI EL | The text from the FSMO 2014 standard section 6.2.6 and the EL Volume 2 text must be streamlined. This is not technical training but technical assessment training. Technical training is defined by the AB but the assessment training is defined in the standard. The new proposed wording in the EL standard needs to be reviewed and may be used in the updated of the FSMO Volume 2. |  |
| 26 | 6.2.6.c c) Assessors shall complete Technical Training requirements for at least one technical discipline addressing sampling (grab or composite) or measurement technologies or a combination of technology and method in areas of accreditation, such as, for example: (6.2.6 FSMO 2014)  i. air matrices (ambient, indoor and outdoor air, point source and fugitive emissions, soil atmospheres, air and continuous emissions monitoring);  ii. solids, including soil, sediment, sludge and solids monitoring;  iii. water, including surface, waste, drinking and groundwater;  iv. biological samples including, for example, whole animals, fish, shell, plant or animal tissue and microorganisms.  See listing item 24 for entire text | Remove matrices presented in the FSMO section 6.2.6.c and indicate the AB will decide how competency is defined. | Do we need to list matrices in this standard. Obtain public comment. |  |
| 29 | 6.2.6.2.d Assessors Roles and Responsibilities  See item 29 language | No language changes – | Unsure where this section is the best fit. Or if it is still needed request public comment  Is it is the right place in section 6? |  |
| 31 | FSMO 2014 6.3.1 and 6.3.2  See attached language removed  See listing item 31 for entire text | Removed FSMO 2014 6.3.1 and 6.3.2 ISO.IE 17011 2004 language and FSMO Language 6.3.3.1 | Is this needed for the FSMO standard? |  |
| 34 | FSMO 2014 7.1.2 ISO/IEC 17011:2004  See attached language removed  See listing item 34 for entire text | Delete 7.1.2 ISO/IEC 17011 2004 | This is publicly available information/. Should all or part be moved to section 8.2 |  |
| 40 | FSMO 2014 7.2.1.1.3 Accreditation fee  The accreditation body shall determine the applicability, frequency, and level of any fees.  NOTE: If accreditation is sought from more than one accreditation body, each accreditation body may assess the FSMO an applicable accreditation fee. | Should this be removed? | Is this language needed? Public input requested |  |
| 53 | EL language added to 7.6.6.b. (modified) | (1) The accreditation body shall present to the CAB within thirty calendar days of the last day of the assessment a final assessment report.  (2) The assessment report shall contain the following minimum contents:   * 1. Assessment Date(s)   2. FSMO Name and Physical Address   3. FSMO ID Number (as assigned by the Accreditation Body)   4. Scope of Accreditation   5. Key FSMO Personnel (e.g., technical manager, QA officer, etc.)   6. FSMO personnel interviewed at the time of the assessment   7. For each nonconformity reported, the specific Standard citation, regulatory requirement, or CAB’s methog section where the observed laboratory activity is not in conformance   (3) If the report is not issued by the accreditation body itself, the accreditation body shall develop and implement procedures to outsource the issuance of assessment reports to conformity assessment bodies, as described in clause 6.4. | Modified EL language to FSMO and allowed flexible scope and removed analyte from scope  Comment to delete from FSMO too prescriptive  Should this be deleted from the FSMO standard? |  |
| 54 | 7.6.1 to 7.8.8.2 Blue Text to be removed or retained  See attached document for language deleted | Is this language too prescriptive and should it be removed or placed in an annex or guidance document? | Different comments from the committee seeking public input for this wording. Some of the ISO/IEC 17011:2004 language concepts are overlapping with ISO/IEC 17011:2017 |  |
| 56 | 7.11.1.2 TNI EL language added | 7.11.1.2 Subject to applicable laws, regulations and due process requirements, an accreditation body may suspend, withdraw or reduce a CAB’s accreditation if the CAB fails to meet the standards for accreditation. The CAB shall retain accreditation for the scope of accreditation, where it continues to meet the requirements of the Standard. Reasons for suspension, withdrawal or reduction shall include but are not limited to:  7.11.1.2.1 If the accreditation body finds, during the assessment, that the public interest, safety or welfare imperatively requires emergency action;  7.11.1.2.2 Failure to complete proficiency testing studies as required;  7.11.1.2.3 Failure to notify the accreditation body of any changes in key accreditation criteria as referenced in Clauses 4.2 and 7.2.1;  7.11.1.2.4 Failure to maintain a Quality System as required;  7.11.1.2.5 Failure of the CAB to employ staff that meets qualifications for education, training and experience as required.  7.11.1.2.6 Misrepresentation of any fact pertinent to receiving or maintaining accreditation;  7.11.1.2.7 Denial of entry to an accreditation body’s assessment team during normal business hours for the purpose of conducting an assessment;  7.11.1.2.8 Failure to provide documents requested by the accreditation body for review in a timeframe requested by the accreditation body prior to the assessment.  7.11.1.2.9 Failure to complete responses or corrective actions from an accreditation body’s current or past assessment report(s).  7.11.1.2.10 Failure to pay fees. | Is the EL standard language added to the FSMO to prescriptive? Public input requested |  |
| 58 | 7.9.2.1.4 Suspension | Moved to Section 7.11.1  Request input on language | What language is redundant with ISO/IEC 170111:2017 and the EL language and FSMO language |  |
| 63 | TNI EL 7.6.10 to 7.6.14 deleted | See text in attached that was deleted | Section just adds a 30 day response and review time and then goes into the weeds talking about weekends, etc. Are these sections needed? Request public input |  |
| 65 | FSMO 2014 7.9.2.1.c wording remains in the standard  Consider adding EL 7.9.4.1 modified wording | c) The initial accreditation shall remain in effect for a period of time (typically two years as determined initially by the accreditation body to accommodate applicable regulatory or government fiduciary cycles), from the initial date of notification of accreditation unless suspended or revoked by the accreditation body, or withdrawn at the written request of the FSMO to the accreditation body.  NOTE: The accreditation body should determine, after the initial period of accreditation, an accreditation cycle. This may typically be a two-year cycle.  7.9.4.1 After an initial assessment for accreditation, accreditation bodies shall perform reassessments at intervals of two years plus or minus six months. Once a CAB is accredited, accreditation bodies reserve the right to assess a CAB at any time during the accreditation cycle ~~period~~ | Should the two year cycle be stated as a requirement? Consider modified wording from TNI EL standard 7.9.4.1  Request public input |  |
| 78 | 7.14.5 Record Retention Time  Copies of all assessment reports, checklists, and FSMO responses shall be retained by the accreditation body for a period of at least five (5) years or longer, if required by the customer. ~~if required by specific state or federal laws or regulations~~. | Modify language or delete  ~~“ if required by specific state or federal laws or regulations~~.” | Await comments from the public |  |
| 79 | FSMO 2014 7.14.4 Checklists/Records  a) Accreditation bodies shall use standardized checklists for the assessment to assist in conducting a thorough and efficient assessment.  NOTE1: The use of checklists does not replace the need for assessor observations and staff interviews.  NOTE2: A checklist is not a substitute for assessor training and experience.  b) Any checklists used by the assessors during the assessment shall become a part of the permanent file kept by the accreditation body for each FSMO accredited location.  c) The assessor shall specify the requirements of any Standards for the records, documents, equipment, procedures, or staff evaluated, and record the observations that contributed to the evaluation of “No” for each assessment checklist item and document this information in the comments section or provide reference to the checklist item. | Modify language or delete | Await comments from the public |  |
| 80 | FSMO 7.15.1 applicable and available PT sample(s) from a TNI PTPA-approved PT provider for each scope of accreditation.  See full text attached item 80 and 81 | Does this require more specification in the standard or allow each AB to decide and justify. | just 1 per scope? At what interval, 1 per year? Or CAB determined?  Request public input  Should we add language to Volume 1 on performing PTs  Should we refer to TNI volume 3 and 4 for design of PTP and PTPA |  |
| 100 | EL 6.2.2.2 The accreditation body shall require assessors employed directly or under contract to affirm this commitment before they participate in their first assessment for the accreditation body or whenever the rules of the accreditation body pertaining to the accreditation of CABs change.  EL 6.2.2.3 Before conducting an assessment, an assessor shall sign statements certifying the assessor has no conflict of interest with the CAB to be assessed and provide such statements, upon request, to the CAB. | Add EL language to 6.2.2 | For consistency with TNI EL standard. Public input requested |  |
| 101 | 6.2.3.1 Accreditation bodies shall assign an adequate number of assessors to complete an assessment within a reasonable period.  NOTE: The length of an assessment is determined by the scope of accreditation of a CAB, the number of assessors in an assessment team, the size of a CAB, the number of findings encountered during the previous assessment, and the cooperativeness of the CAB staff. | Add EL language to 6.2.3 | For consistency with TNI EL standard. Public input requested |  |
| 20 | *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. (5.1.2 17011:2004)* | 5.5.1 An accreditation body shall not delegate authority for granting, maintaining, suspending or revoking a CAB’s accreditation to an outside person or body. Portions of the accreditation process may be contracted out; however, the authority to grant, maintain, suspend or revoke accreditation shall remain with the accreditation body. | From EL Volume 2 language  Is the ISO/IEC 17011:2017 5.5 and FSMO 2014 5.5 the same as this language. Is the ISO/IEC 17011:2017 language sufficient? |  |

**Retained FSMO Language 2014 and ISO.IEC 17011:2204 (Deleted language in attached)**

|  | **Original Text (FSMO Vol 2 2014)** | **Suggested Change** | **Justification** | **Public Comments** |
| --- | --- | --- | --- | --- |
| 3 | FSMO-V2-ISO-Rev .2.0 (header of each page) | Changed the number of Volume 2 to the FSMO-V2-ISO-2017 or follow TNI naming of Volumes | To update the number of the document as the latest version of ISO/IEC 17011:2017 and the additional TNI FSMO requirements |  |
| 6 | Added note to ISO/IEC 17011:2017 definition for Conformity Assessment Body (3.4) | NOTE 2: This module is concerned with conformity assessment bodies (CAB) commonly known as Field Sampling and Measurement Organization (FSMOs) that perform environmental activities. | Defining the FSMO as a CAB  Modified language from EL standard |  |
| 9 | Retain definitions from FSMO V2 2014 for 3.22 to 3.24, 3.26 to 3.28  Other definitions from ISO/IEC17011:2017 added  See retained FSMO definitions item 9 attached | For consistency with FSMO program  Delete all definitions from ISO/IEC 17011:2004 from the FSMO standard and add only the FSMO language to the ISO/IEC 17011:2017 definitions | Retain the definitions from FSMO Standard 2014 to Volume 2 |  |
| 28 | 6.2.5.2 NOTE Rules defined by the accreditation body should include ethics policies and compliance requirements. | Modify language “Rules defined by the accreditation body shall include ethics policies and compliance requirements.” | Changed to a requirement |  |
| 58 | FSMO 7.9.2.1.4 b.ii. the FSMO cannot continue to sample or measure or report data in the affected areas of accreditation, during the period of suspension; | 7.9.2.1.4.b. ii the FSMO cannot continue to provide accredited sample or measure or report data in the affected areas of accreditation, during the period of suspension | Clarify language to indicate cannot provide accredited work |  |
| 83 | *NOTE: Those accreditation bodies that are signatories to a mutual recognition arrangement may refer to the obligations of the mutual recognition arrangement in their policies. (5.2.1 17011:2004)* | Modify note NOTE: Those accreditation bodies that are signatories to a mutual recognition arrangement may refer to the obligations of the mutual recognition arrangement in their policies. | Delete reference to ISO/IEC 17011 2004 5.2.1 |  |
| 88 | FSMO 2014 5.3.1 and 5.3.2  The accreditation body shall maintain in hard copy, electronic media or other means, a controlled document or documents describing its environmental FSMO accreditation program including: *(5.3.1 FSMO 2014)*  a) at a minimum, all information required of an FSMO to acquire and maintain accreditation through the accreditation body; and *(5.3.1 FSMO 2014)*  b) additional documentation requirements as described in Sections 4.6, 6.2 and 7.1.2 of this Volume. *(5.3.1 FSMO 2014)*  The accreditation body shall review such documents annually. *(5.3.2 FSMO 2014)*  a) A written record of this review shall be readily available. *(5.3.2 FSMO 2014)*  b) When the review of such document or documents reveals that the accreditation body’s FSMO accreditation program has changed or is otherwise different from the accreditation program described in such documents, the document or documents shall be updated within thirty (30) calendar days of completion of the review. *(5.3.2 FSMO 2014)* | Moved to Section 9.3 | Place in proper locations in ISO.IEC 17011 2017 |  |
| 89 | *ISO 9000:2000, Quality management systems — Fundamentals and vocabulary. ISO/IEC 17000:2004, Conformity assessment — Vocabulary and general principles. VIM:1993, International vocabulary of basic and general terms in metrology, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.* | ISO/IEC Guide 99, International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM, latest edition), may also be used as a reference. (JCGM 200-2008) | Updated reference to current version. Adopted ISO/IEC 17011:2017 for the ISO/IEC 17000 reference and updated the VIM reference in the FSMO standard to the EL standard (current reference) |  |
| 90 | *The structure and operation of an accreditation body shall be such as to give confidence in its accreditations. (4.2.1 17011:2004)* | Language retained and moved to section 5.1 | Not stated in 1701l:2017 so added to the standard in Section 5.1 |  |
| 91 | *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. (5.1.2 17011:2004)* | Language retained and moved to section 5.5 | Not stated in 1701l:2017 so added to the standard in Section 5.5 |  |
| 92 | FSMO 5.2.2 NOTE: 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. | Move to 9.2.1 | Statement related to management system was in Section 5 of ISO/IEC 17011:2004 which is not section 9 |  |
| 93 | Internal audits shall include a review and effectiveness assessment of the accreditation body’s quality manual *(5.7.1.1 FSMO:2014* | Move to 9.7.1 | Statement related to internal audit was in Section 5 of ISO/IEC 17011:2004 which is not section 9 |  |
| 94 | NOTE: The frequency of internal audits, normally at least once per year, should not be less than once every twenty-four (24) months if augmented (to demonstrate effective management systems) by alternate-year-audit by external agents. *(5.7.2 FSMO:2014)* | Moved to 9.7.3 | Statement related to internal audit was in Section 5 of ISO/IEC 17011:2004 which is now section 9 |  |
| 95 | *6.1.1.The accreditation body shall have a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time) having the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed. (6.1.1 17011 2004)* | Retain in section 6.1.1 | Language not found in ISO./IEC 17011:2017 |  |
| 96 | 6.1.2.1 *The accreditation body shall require all personnel to commit themselves formally by a signature or equivalent to comply with the rules defined by the accreditation body. The commitment shall consider aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with CABs to be assessed. (6.1.4 17011 2004)*NOTE: Rules defined by the accreditation body should include ethics policies and compliance requirements. See Clause 6.2.5.2, Note 3. (6.1.4 FSMO 2014) | Move to section 6.1.2.1 | Language not found in ISO./IEC 17011:2017 |  |
| 97 | 6.1.2.3 *The accreditation body shall ensure that assessors and, where relevant, experts (6.2.4 17011 2004*  *a) are familiar with accreditation procedures, accreditation criteria and other relevant requirements, (6.2.4 17011 2004*  *b) have undergone a relevant accreditation assessor training, (6.2.4 17011 2004*  *c) have a thorough knowledge of the relevant assessment methods, (6.2.4 17011 2004*  *d) are able to communicate effectively, both in writing and orally, in the required languages, and (6.2.4 17011 2004*  *e) have appropriate personal attributes. (6.2.4 17011 2004* | Move to section 6.1.2.3 | Language not found in ISO./IEC 17011:2017 |  |
| 98 | *6.1.2.7 The accreditation body shall make clear to each person concerned the extent and the limits of their duties, responsibilities and authorities. (6.1.3 17011 2004)* | Move to section 6.1.2.1 | Language not found in ISO./IEC 17011:2017 |  |
| 99 | *6.1.3.1 The accreditation body shall describe for each activity involved in the accreditation process:*  *a)  the qualifications, experience and competence required, and*  *b)  initial and ongoing training required. (6.2.1 17011 2004)*  *The accreditation body shall establish procedures for selecting, training and formally approving assessors and experts used in the assessment process. (6.2.2 17011 2004)*  *The accreditation body shall identify the specific scopes in which each assessor and expert has demonstrated competence to assess. (6.2.3 17011 2004)* | Move to section 6.1.3.1 | Language not found in ISO./IEC 17011:2017 |  |
| 102 | 7.1.1.2 General Applicability  a) Accreditation shall apply to the FSMO (organization) and not to any one individual or group of individuals within an organization.  b) Accreditation shall be granted as follows:  i. an Umbrella Accreditation: To a parent FSMO operating under a single common Management system (e.g., at a corporate or divisional level), and providing field sampling and measurements across various jurisdictions from multiple non-contiguous fixed-based locations; or  ii. an Individual Accreditation: To a single fixed-base FSMO entity or to each non- contiguous entity of a parent FSMO, each with its own management system, providing sampling and measurements across various jurisdictions.  c) The accreditation body shall determine whether a FSMO qualifies for an umbrella accreditation or for an individual accreditation, taking into account the presence or absence of a common management system, ownership/management, technical oversight, and scope of accreditation as detailed in the FSMO accreditation application.  NOTE 1: FSMO activities, whether from a fixed or mobile base, that encompass multiple field sampling and measurement locations, do not require separate accreditations.  NOTE 2: A mobile sampling and measurement unit, operating under the FSMO management system, does not require a separate accreditation.  7.1.3 Accreditation Applicability 7.1.3.1 Types of FSMOs and Applicability  Accreditation shall apply to those FSMOs engaged in environmental field sampling and/or measurement activities (for example, research, development, monitoring and regulatory compliance) and reporting under federal, state, and local (mandated or not) testing programs, or for other purposes.  NOTE: Field sampling and measurement activities may be related to regulatory programs or may be a result of other provisions or specialty areas promulgated as a result of action by a local, state or federal authority.  7.1.3.2 Scope of Accreditation  7.1.3.2.1 Accreditation shall be granted for Field Sampling by Matrix/Technology, and/or for Field Measurements by Matrix/Technology.  7.1.3.2.2 The accreditation body shall make publicly available a list of scopes they are competent to assess. | Move to section 7.1 | Retain language from FSMO 2014 |  |
| 103 | * + - * 1. An accreditation body shall require a FSMO-seeking accreditation to complete and submit a formal application package to the accreditation body to include:  1. legal name and contact mailing address; 2. billing address (if different from 2); 3. name and address of owner(s) if privately held; 4. a scope of accreditation including:   i. field sampling and field measurement technologies for which accreditation is being requested;  ii. address(s) of all FSMO entities under the scope of the accreditation, and address(s) of the field sampling and measurement locations, if applicable, for selection of on-site assessment observations.  e) name and contact information of the responsible person(s) and or quality assurance officer, however named;  f) normal hours of operation for each FSMO entity included in the Scope;  g) a description of the FSMO type (for example, commercial, federal, hospital or health care, state, academic institute, public water system, public wastewater system, industrial/industry with discharge permits, mobile, consulting or engineering firm);  NOTE: Documentation of representative individual field sampling and measurement personnel along with their qualifications and any applicable personal certifications will be examined by the accrediting body during on site assessments (see 7.7.3).  h) a summary of mobile units, listed by function, that are integral to field sampling and measurement activities and are employed by the FSMO facilities being considered for accreditation;  i) a description of the FSMO’s Proficiency Testing (PT) program, and copies of the results of the proficiency testing performed, if applicable; and  j) other documents as requested by the accreditation body or approved assessment team.  k) Examples of documents that shall be provided include those related to the quality manual and evidence of its application across the FSMO locations.  l) Examples of documents that may be requested include representative standard operating procedures, work instructions, copies of calibration and maintenance records, field notebooks/records, internal or external quality audits, corrective/preventive action reports, organization charts, etc.  m) Examples of documents that verify the implementation of Section 5.9.1 of ISO/IEC 17025 and the Volume 1 TNI FSMO Standard. | Moved to section 7.2.1 | Retain language from FSMO 2014 |  |
| 104 | 7.2.2 *ISO/IEC 17011:2004(E), Clause 7.2.2*  *a) a description of the conformity assessment services that the CAB undertakes, and a list of standards, methods or procedures for which the CAB seeks accreditation, including limits of capability where applicable;*  *b) a copy (on paper or in electronic form) of the quality manual of the CAB, and relevant associated documents and records, such as information on participation in proficiency testing as described in 7.15, where applicable.* | Added to Section 7.2.2 | Language not found in ISO/IEC 17011:2017 |  |
| 105 | 7.3.3 The accreditation body shall document the procedure for conducting an internal audit of its ability to assess a FSMO (CAB) and document the audit results. | Move to section 7.3.2 | Retain language from FSMO 2014 |  |
| 107 | 7.5.4.1 Upon request, the accreditation body shall provide the FSMO with all forms and records pertaining to the assessor team member’s credentials and qualifications, including certification of freedom from conflicts of interest that may impact the assessors’ objectivity and impartiality. Such information shall be provided to the FSMO management even if the request is made after the conclusion of the on-site visit.  7.5.8.2 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. | Moved to 7.5.2 | Retain FSMO 2014 language |  |
| 110 | NOTE: Other relevant information may include documentation or practices that demonstrate conformity to TNI Field Sampling and Measurement Sector Volume 1, General Requirements for Field Sampling and Measurement Organizations.  7.9.2.1 Types of Accreditation 7.9.2.1.1 Initial accreditation  a) When the accreditation body has determined the FSMO has completed all of the requirements for accreditation as given under the FSMO Volume I Standard, the accreditation body shall issue to the FSMO an official certificate of accreditation including:  i. an official signature from the accreditation body;  ii. a clear indication of the effective dates of accreditation;  iii. name and address(s) of the FSMO and all its entities covered by the scope of accreditation;  iv. the scope of the field sampling and/or field analytical methods subjected to accreditation; and  v. any addenda or attachments (also considered as official documents).  b) The accreditation body shall issue the FSMO a separate certificate for each different or change in scope of accreditation. Each certificate shall:  i. note that continued accredited status depends on successful ongoing participation in the program;  ii. urge a customer to verify the FSMO’s current accreditation standing;   1. be reissued if an accredited FSMO changes its scope of accreditation, subject to meeting any new accreditation requirement. | Move to 7.7.6 | Retain FSMO 2014 language |  |
| 111 | 7.9.2.1.3 Denied accreditation Reasons to deny an initial application shall include:  a)  failure to submit a completed application;  b)  failure to pay required fees;  c)  failure to successfully demonstrate competency ;  d) failure to respond to an assessment report from the on-site assessment with a corrective action report within the required thirty (30) calendar days after receipt of the assessment report;  e) failure to implement the corrective actions detailed in the corrective action report within the time frame as approved by the accreditation body;  f) failure to implement a management system and quality manual as defined in Clause 5 of this Standard;  g) failure to pass the on-site assessment(s) as specified in Clause 7.7 of this Standard;  h) misrepresentation of any fact pertinent to receiving or maintaining accreditation; and  i) denial of access during normal business hours for an on-site assessment.  7.7.5.1.10 failure to provide documents requested by the accreditation body for review in a timeframe requested by the accreditation body prior to the assessment.  NOTE1: Denied means to refuse to accredit ,in total or in part, a FSMO applying for initial accreditation or resubmission of an initial application.  NOTE 2: The accreditation body should not deny the FSMO’s accreditation without the right to due process as set forth by the accreditation body.  7.9.2.1.5 Revoked accreditation  a) The accreditation body may revoke a FSMO’s accreditation, in part or in total, for failure to correct the deficiencies as identified during the assessment, Clause 7.7 of this Standard and for failure to correct the reasons for being suspended. Accreditation shall be retained by the FSMO for those matrices, field sampling or measurement/ analytical methods where it continues to meet the requirements of the FSMO Volume I Standard.  b) Reasons for revocation, in part or in total, shall include:  i. failure to submit an acceptable corrective action report, in response to an assessment report and failure to implement corrective action(s) related to any deficiencies found during an assessment. The FSMO may submit two corrective action reports within the time limits specified in Clause 7.8;  ii. failure to respond with a corrective action report within the required thirty (30) calendar days;  iii. failure to participate in an applicable and available PT program, or required competency demonstration;  iv. misrepresentation of any material fact pertinent to receiving and maintaining accreditation;  v, denial of entry during normal business hours for an assessment;  vi. conviction of charges relating to the falsification of any report relating to a sampling or measurement activity; or  vii. failure to remit the accreditation fees, if applicable, within the time limit as established by the accreditation body.  NOTE 1: Revocation means the in part or total withdrawal of a FSMO’s accreditation by the accreditation body. After correcting the reason/cause for revocation and satisfying any legal remedies, the FSMO may reapply for accreditation.  NOTE 2: The accreditation body should not revoke the FSMO’s accreditation without the right to due process as set forth by the accreditation body.  7.9.2.1.6 Renewal or continuation of accreditation.  The accreditation body shall:  a) Notify the FSMO that its accreditation status may be suspended or revoked upon receipt of information that the FSMO has failed to maintain, revise, or replace any of the key FSMO management system components or as specified elsewhere in Sections 7.9.2.1.4 and 7.9.2.1.5 of this Standard unless the FSMO has notified the accreditation body of any changes in key accreditation criteria within thirty (30) calendar days of the change. This written notification includes, but is not limited to, changes in the FSMO ownership, locations, key personnel, and major sampling and measurement methods or instrumentation.  NOTE 1: The accreditation body may approve transfer of the FSMO’s accreditation when the legal or ownership status of the FSMO changes with no impact on the components of accreditation.  NOTE 2: The accreditation body, at its discretion, may impose a ”transfer fee” and/or require a follow up assessment to verify any effects on continued FSMO compliance with the FSMO Volume I Standard.  b) maintain all records on FSMOs, associated with accreditation parameters, for a minimum of five (5) years unless otherwise designated for a longer period by regulation or regulatory authority.  c) ensure traceability of the FSMO’s accreditation number(s) or FSMO ownership changes for a minimum of five (5) years. | Move to section 7.7.6 | Retain FSMO 2014 language and add EL language from 7.7.5.1.10 into this section |  |
| 114 | 7.9.2.1.4 Suspended accreditation  a) An accreditation body may suspend an FSMO’s accreditation in total or in part. Accreditation shall be retained by the FSMO for those areas where it continues to meet the requirements of the FSMO Volume I Standard.  b) The accreditation body shall inform the FSMO that, if suspended:  i. the FSMO shall not have to reapply for accreditation if the cause(s) for suspension is corrected within six (6) months after written notification of the suspension (the effective date);  ii. the FSMO cannot continue to provide accredited sample or measure or report data in the affected areas of accreditation, during the period of suspension (  iii. the FSMO’s suspended accreditation status for any impacted area shall change to accredited when it demonstrates to the accreditation body that it once again complies with the FSMO Volume I Standard; and  iv. the FSMO's accreditation shall be revoked in total or in part if the FSMO fails to correct the causes of suspension within six (6) months after the effective date of the suspension.  NOTE 1: Suspension means the temporary removal of a FSMO’s accreditation for a defined period of time, not to exceed six (6) months. The purpose of suspension is to allow a FSMO time to correct deficiencies or an area of non-compliance with the FSMO Volume I Standard.  NOTE 2: The accreditation body should not suspend the FSMO’s accreditation without the right to due process as set forth by the accreditation body.  c) Reasons for suspension include failure to continue to meet the requirements of accreditation including, but not limited to:  i. failure to successfully demonstrate ongoing competency;  ii. failure to notify the accreditation body of any changes in key accreditation criteria required to maintain accreditation; as per Clause 8;  iii. failure for cause based on information made available to and verified by the accreditation body;  iv. failure to maintain a Quality manual (see TNI Standard Volume 1, General Requirements for Field Sampling and Measurement Organizations);  v. failure to employ staff that meet the qualifications for education, training and experience as required; and  vi. a finding by the accreditation body during an assessment that the public interest, safety or welfare imperatively requires such emergency action. | Move to after 7.11.1 and modified FSMO language in blue | Retain FSMO 2914 language and modify the language to allow reporting of information and performing work but not claiming accreditation during suspension |  |
| 115 | 7.13.2 *ISO/IEC 17011:2004(E), Clause 7.13.2 The accreditation body shall make decisions to suspend and/or withdraw accreditation when an accredited CAB has persistently failed to meet the requirements of accreditation or to abide by the rules for accreditation.*  *NOTE: The CAB may ask for suspension or withdrawal of accreditation.*  7.13.3 *ISO/IEC 17011:2004(E), Clause 7.13.3 The accreditation body shall make decisions to reduce the scope of accreditation of the CAB to exclude those parts where the CAB has persistently failed to meet the requirements for accreditation, including competence.*  *NOTE: The CAB may ask for reduction of its scope of accreditation.* | Move to 7.11.3 | Retain ISO/IEC 17011:2004 language and FSMO language |  |
| 118 | 7.10.1.1 The accreditation body shall also have documented standard operating procedures for dealing with complaints and disputes arising from denial, suspension or revocation of FSMO accreditation, or from users of the services of the FSMO or for any other matters impacting accreditation status.  7.10.1.2 The accreditation body shall have a documented policy or procedure for resolving conflicts regarding interpretation of standards that arise between the accreditation body and a FSMO and shall:  a) communicate the final consensus interpretation of the Standard to the relevant FSMO, and  b) make the consensus interpretation available and easily accessible to other interested parties. 7.10.1.3 Due Process  As a matter of course, the accreditation body shall document in writing and clearly communicate to the FSMO any decisions and supporting information, such as citations from this Standard and/or the FSMO Volume I Standard, impacting the FSMO accreditation status.  NOTE: Regardless of the language in this Standard concerning actions such as denial, suspension and revocation of accreditation, a FSMO is always entitled to the right of due process. Due process rights are delineated in the appropriate state laws and regulations. Since these laws and regulations may vary from state to state, FSMO’s seeking accreditation are encouraged to become familiar with the specific laws and regulations governing due process. | Moved to after 7.13.1 | Retain FSMO 2014 language |  |
| 119 | *NOTE: Those accreditation bodies that are signatories to a mutual recognition arrangement may refer to the obligations of the mutual recognition arrangement in their policies. (5.2.1 17011:2004)* | Move to after 9.1.2 | Retain FSMO 2014 language |  |

**Added EL language or modified from proposed New draft standard**

|  | **Original Text (FSMO Vol 2 2014)** | **Suggested Change** | **Justification** | **Public Comments** |
| --- | --- | --- | --- | --- |
| 1 | Removed proposed TNI EL Volume 2 section 6.1.2.9.1 and 6.1.2.9.2 and 6.1.2.9.3 with the revised language here. | See Red text for language in Sections 6.1.2.9.1 and 6.1.2.9.2 and 6.1.2.9.3 for new language for FSMO AB assessors | Allows ABs to define the requirements for competency and requires the AB to justify how commensurate experience is evaluated by the AB. Defines the training and on-going training needed for assessors |  |
| 7 | Added language to ISO/IEC 17011:2017 definition for scope of accreditation (3.6)  Field of accreditation not defined the same in NEFAP and NELAP language from the TNI EL standard removed from FMSO V2 | (Also called Field of Accreditation) | Language used in TNI EL Volume 2 added to FSMO standard but the definition for field of accreditation is not used in Volume 2 so definition not required for field of accreditation  Should this be retained for consistency with EL standard? |  |
| 19 | None | At end of 5.7 add  NOTE: In the case of an accreditation body within a government department or entity, top management refers to the management of the organizational unit (and not the department or entity) having authority and responsibility for the accreditation program | From EL Volume 2 language on what to consider for the government agency management |  |
| 47 | Add language to FSMO 7.6.3 from EL standard – Change to a note | 7.6.3.1 NOTE: If the assessment plan is not followed, the assessment report should document any changes and should include justification for those changes. | Changed to a note from the EL standard and removed shall to should |  |
| 48 | Add language to FSMO 7.6.3.3 from EL standard | 7.6.3.3 It is possible that If during an assessment, the assessor or the CAB become aware of previously unforeseen conflicts of interest. When this happens, the ~~assessment team leader~~ ~~lead~~ team leader or designate shall consult with the accreditation body, as soon as practicable, to determine how to proceed. The accreditation body shall take action to ensure that the assessment can proceed without compromising its integrity and impartiality or shall request that the assessment team terminate the assessment. ~~If it is necessary to appoint a new assessment team, the accreditation body shall appoint it as soon as practicable without jeopardizing the CAB's request for accreditation.~~ | Modify the EL wording to meet the FSMO requirements. The wording with a line strike is to be removed from the final standard. |  |
| 50 | Add language to FSMO 7.6.4 from EL wording from 7.6.4.1 | 7.6.4.1 During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information must be carefully documented since further action may be necessary. In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team shall present such information to the accreditation body for appropriate action(s). These issues, at the discretion of the accreditation body, may or may not be subjects or issues at the closing conference. ~~However, the assessor shall continue to gather the information necessary to complete the accreditation assessment.~~ | Modify the EL wording to meet the FSMO requirements. The wording with a line strike is to be removed from the final standard. |  |
| 52 | EL Language added to 7.6.6.a | (2) Attendance at the closing conference shall be documented. | Provides clear statement of requirement |  |
| 62 | TNI EL 7.6.8.2 wording added | The accreditation body shall require the CAB’s implementation of each corrective action to be due as specified in the submitted corrective action plan or as specified in the accreditation body’s policy. | Specific requirement for the AB to require implementation of corrective action Delete TNI EL 7.6.8.1 since this is covered in ISO/IEC 17011 section 7.6.8 and in the TNI EL standard 7.6.8.2. |  |
| 70 | TNI EL 7.7.5.1.10 considered and retained | 7.7.5.1.10 failure to provide documents requested by the accreditation body for review in a timeframe requested by the accreditation body prior to the assessment. | Clearly states the reason for denial that is not included in the FSMO items |  |
| 71 | Note added after 7.8.3  And wording added to 7.8.3.d for matrix and technology/method | NOTE: In the context of the TNI's FSMO standards only clause 7.8.3(d) and (h) are applicable. Clause 7.8.3(e) is applicable to Volume 4 in the TNI standard.  7,.8.3.d *d) for testing laboratories (including medical laboratories):*  *- materials or products tested;*  Matrix  *- component, parameter, or characteristic tested;*  *- tests or types of tests performed and, where applicable, the techniques, methods, and/or equipment used.*  Technology / Method | Clarifies the ISO.IEC 17011:2017 items that are applicable to FSMO  7.8.3.h is for the sampling activities of the FSMO  Analyte not added to 7.8.3.d as in the TNI EL standard. But added matrix, technology/method to this clause. |  |
| 106 | None | **Add 7.5.2** NOTE: . Accreditation bodies should inform CABs of a cancellation of an assessment as soon as feasible. | Consistency with TNI EL standard |  |
| 108 | None | 7.6.2.1 Attendance at the opening conference shall be documented | Consistency with TNI EL standard |  |
| 109 | None | 7.7.5.2 No CAB’s accreditation shall be denied without the right to due process. | Consistency with TNI EL standard |  |
| 112 | None | Add after 7.9.3 from EL standard NOTE: “Other assessment techniques” may include review by the accreditation body of internal audit reports and managerial reviews or continuing demonstration of corrective actions, or proficiency testing performed by the CAB. | Consistency the TNI EL standard |  |
| 113 | None | Add after 7.9.5 NOTE: Examples of changes may include changes in the CAB's ownership, key personnel, location, and scope of accreditation. | Consistency the TNI EL standard |  |
| 116 | None | Add Note after 7.12.1: NOTE: An independent person, or group of persons, may consist of another group within the accreditation body organization whose responsibility is to handle investigations and appeals. Alternatively, the matter can be addressed by an external group of peers called together for this purpose, and following a documented policy and procedure consistent with this Standard and agreed upon by all participants. | Consistency with TNI EL standard |  |
| 117 | None | Add Note after 7.13.1\_ NOTE: An independent person, or group of persons, may consist of another group within the accreditation body organization whose responsibility is to handle investigations and appeals. Alternatively, the matter can be addressed by an external group of peers called together for this purpose, and following a documented policy and procedure consistent with this Standard and agreed upon by all participants. [*.* | Consistency with TNI EL standard |  |

**MISCELLANEOUS**

|  | **Original Text (FSMO Vol 2 2014)** | **Suggested Change** | **Justification** | **Public Comments** |
| --- | --- | --- | --- | --- |
| 4 | Removed the forward from ISO/IEC 17011:2017 since the introduction addresses the use of this standard for FSMO | Removed ISOIEC 17011:2017 forward | The introduction addresses the use of this standard for FSMO ABs. and it is covered in the introduction. |  |
| 8 | Added note to ISO/IEC 17011:2017 definition for Accreditation Scheme (3.8) | NOTE 2 to entry: For The NELAC Institute's FSMO standard, the accreditation scheme requirements include Volume 1, "General Requirements for Field Sampling and Measurement Organizations" and Volume 2, "General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations." | Added the reference to the TNI  FSMO standards as another scheme |  |
| 10 | **Sampling:** See (*ISO/IEC 17025; 2005(E), Clause 5.7.1, NOTE 1*): | Removed definition for Sampling 3.32 | Reference is incorrect now and Field sampling is defined in the FSMO Standard (def 3.24) |  |
| 11 | **Measurement:** The process or result of determining, by comparison to a standard, the dimensions, quantity, capacity, or other characteristic of a measurand. (Remove 3.33 from FSMO V2 2014))\_ | process of experimentally obtaining one or more **quantity values** that can reasonably be attributed to a **quantity (JCGM 200:2008)**  NOTE1 Measurement does not apply to **nominal properties.**  NOTE2: NOTE1Measurement implies comparison of quantities and includes counting of entities.  NOTE 3 Measurement presupposes a description of the quantity commensurate with the intended use of a **measurement result,** a **measurement procedure,** and a calibrated **measuring system** operating according to the specified measurement procedure, including the measurement conditions. | Definition revised in the VIM (200-2008) the new language if from the current VIM |  |
| 12 | **Finding:** An assessment conclusion referenced to an accreditation standard and supported by objective evidence that identifies compliance with and/or a deviation from an accreditation standard requirement. | Removed the definition for finding (3.25 Section needs renumbering) (from FSMO 2014 standard) | Term used in ISO/IEC 17011 is non-conformance |  |
| 13 | Retain Flexible Scope definition | None | TNI EL V2 removed flexible scope from the definitions from ISO/IEC 17011:2017 but this allowed in the FSMO scope of accreditation |  |
| 14 | Retaining the ISO/IEC 17011:2017 language for Consultancy | Removed language from the TNI EL standard related to consultancy being a paid service only.  Removed the allowance for a government agency or the assessor to provide consultancy or recommendation to a CAB. | ILAC MLA signatories are not allowed to do consulting. This allowance is not suitable for the NEFAP AB at this time. |  |
| 17 | **3.4  Accreditation Certificate *(ISO/IEC 17011:2004(E), Clause 3.4):*** *Formal document or a set of documents, stating that accreditation has been granted for the defined scope.*  **3.18  Surveillance *(ISO/IEC 17011:2004(E), Clause 3.18):*** *Set of activities, except reassessment, to monitor the continued fulfillment by accredited CABs of requirements for accreditation.*  *NOTE: Surveillance includes both surveillance on-site assessments and other surveillance activities, such as the following:*   1. *enquiries from the accreditation body to the CAB on aspects concerning the accreditation;* 2. *reviewing the declarations of the CAB with respect to what is covered by the accreditation;* 3. *requests to the CAB to provide documents and records (e.g. audit reports, results of internal quality control for verifying the validity of CAB services, complaints records, management review records);* 4. *monitoring the performance of the CAB (such as results of participating in proficiency testing).* | Remove | ISO/IEC 17011:2004 definition no longer listed in ISO/IEC 17011:2017 – Terms no longer used in ISO.IEC 17011:2017  Surveillance removed from ISO/IEC 17011:2017 |  |
| 21 | Human Resources (Title section 6) | Resource Requirements | ISO/IEC 17011 2017 title for section 6 changed |  |
| 30 | Removed EL language from Combined standard | 6.1.3.7 The accreditation body shall maintain records for assessing and monitoring for all assessors | This is covered in other parts of ISO.IEC 17011:2017 |  |
| 32 | EL 6.4.1.1 Portions of the accreditation process may be contracted out; however, the authority to grant, maintain, suspend or revoke accreditation shall remain with the accreditation body. | EL language removed from combined standard | Redundant language removed  Covered in 5.5.1 |  |
| 33 | Expert Roles and Responsibilities (6.2.7 FSMO 2014)  The accreditation body shall identify experts capable of performing specific tasks within assessment teams based on their education, training, technical knowledge, skills and experience. See *ISO/IEC 17011:2004(E) Clauses 6.2.1* through *6.2.4.*  NOTE 1: Experts perform specific and limited tasks within assessment teams by witnessing FSMO activities within the expert’s field of competence and reporting to the lead assessor. See *ISO/IEC 17011:2004(E) Clause 6.1.3.*  NOTE 2: Experts have the same ethical responsibilities as all other personnel associated with the accreditation body. See *ISO /IEC 17011:2004(E) Clause 6.1.4*. | Delete language from standard | Covered in 6.1.2.3 redundant language |  |
| 35 | FSMO 7.9.2.1 b The accreditation body shall issue the FSMO a separate certificate for each different or change in scope of accreditation. Each certificate shall:  Iii be returned to the accreditation body upon loss of accreditation. A certificate that has simply expired does not need to be returned; and | Delete language 7.9.2.1.b.iii | Language implies paper certificates issued which is not required in ISO/IEC 17011:2017 – May be electronic or paper |  |
| 36 | EL 7.2.1 NOTE 1:Accreditation Bodies may require additional information about the conformity assessment body in the formal application.  NOTE 2: The applicant conformity assessment body could be a mobile laboratory as well as a conformity assessment body in a fixed location. | Delete EL Language | Language not needed in FSMO standard since duplicate with other sections |  |
| 38 | FSMO 2014 7.2.1.1.2 Personnel Qualifications  See attached language removed | Remove language | Text not needed due to language in other parts of the ISO/IEC 17011 standard requiring the AB to obtain information from the CAB (See definition and applicability sections ) |  |
| 39 | FSMO 2014 7.2.1.1 Components of Accreditation | Removed header name | Language not needed since 17011 section Is about application. Initial application from FSMO language retained for consideration |  |
| 41 | FSMO 2014 7.3.4 “The accreditation body shall initiate processing of completed applications for accreditation in the chronological order that the applications were received.” | Removed language | This is too restrictive since location and scope play a factor in processing. Other factors such as location, availability of personnel would have to come into the process not just the order applications are received. This is unrealistically restrictive |  |
| 42 | 7.4.7.1 At a minimum, the assessment plan and the assessment activities at the conformity assessment body's location(s) must include all analytes and test methods for which the conformity assessment body seeks to obtain or maintain accreditation for regulated drinking water contaminants, for compliance with the United States Environmental Protection Agency's Safe Drinking Water Act. | EL 7.4.7.1 not added to standard | The reason not added: since the FSMO does not accredit to analyte and the SDWA does not specify any requirements for field sampling (at tap or from source) or testing (pH Cl2). |  |
| 43 | FSMO 7.5.1, 7.5.2 and 7.5.3 (ISO 17011:2004) Note in 7.5.2  See attached text | Removed from standard | Presented in 17011:2017 in 7.2.5 and 7.4.1 Delete note in 7.5.2 since this is covered in the definitions of technical expert |  |
| 44 | FSMO 7.5.4 to 7.5.8 (ISO 17011:2004) and FSMO 2014 7.5.8.1 See 44 language | Removed from standard | Presented in 17011:2017 in 7.4.4 through 7.4.9 and 7.5.8.1 since this is handled in 7.4.6, 7.4.7 and 7.4.8 |  |
| 45 | FSMO 7.5.9 (ISO 17011:2004) and FSMO 2014 7.5.9.1 and 7.5.9.2 See 45 language | Removed from standard | Presented in application and contract. Remove reference to on-site assessment. Covered in ISO/IEC 17011:2017 for notification of the CAB |  |
| 46 | EL 7.6.3.2 The assessment team shall provide or make available the following types of documents before a scheduled announced assessment or before the conclusion of the CAB assessment:   1. Notice of Announced Assessment: an appointment letter, electronic mail message or a published schedule informing the CAB about an upcoming assessment and identifying members of the assessment team with sufficient time to allow for potential objections from a CAB to members assigned to the assessment team.   b) Assessment Appraisal Form: a document used by the accreditation body to obtain feedback from CABs about the adequacy and the effectiveness of the assessment process, including the performance of the assessment team. [from V2M3, 6.5] | Not added to FSMO standard | unannounced assessments are not part of the FSMO standard |  |
| 49 | EL wording from 7.6.3.4 Assessment team members shall have the authority to conduct interviews with any or all CAB staff. | Do not adopt EL language | Wording not needed since the sampling process and agreement with the AB requires adequate sampling and cooperation based on risk to the AB |  |
| 51 | EL language 7.6.6.(1) considered. “The accreditation body shall be considered to have satisfied this requirement by having the assessment team ~~may~~ provide a preliminary written or oral report at the closing meeting. Final determinations of findings are subject to the approval of the accreditation body”. | Not added to standard | 17011:2017 requires the AB to leave the Non-conformities in writing |  |
| 55 | 7.11.1.1 Suspension shall not exceed six months or the period of accreditation, whichever is longer. The purpose of suspension is to allow a CAB time to correct nonconformities. | Remove language | Is the EL standard language added to the FSMO to prescriptive |  |
| 57 | EL 7.7.5.1.8 language considered for addition but not added | 7.7.5.1.8 misrepresentation of any fact pertinent to receiving or maintaining accreditation | Duplicate with 7.9.2.1.3 h in FSMO standard |  |
| 59 | TNI EL 7.6.6.d wording not added | d) If additional nonconformities are identified after the assessment is concluded, these nonconformities shall be communicated to the laboratory in writing. | Duplicate language item is covered in (c) |  |
| 60 | TNI EL 7.6.7.1 wording not added | The accreditation body shall develop procedures for the review and approval of assessment reports. If the accreditation body finds that any portion of the report issued to the conformity assessment body requires amendment, the accreditation body shall issue an amended report to the conformity assessment body and explain why an amended report is being issued. Issuing an amended report does not reset the timeline for a conformity assessment body to provide a plan of corrective action, as required in clause 7.6.8.1, for the portions of the report that are not amended. | item is covered in ISO/IEC 17011:2017 7.6.6.c |  |
| 61 | TNI EL 7.6.8.1 modified wording and added and then deleted | The accreditation body shall require the CAB to provide to the accreditation body a plan of corrective action to address nonconformities in the assessment report within thirty calendar days from its receipt. The accreditation body shall require the CAB to provide the date for implementation of corrective action as part of the response. | Delete TNI EL 7.6.8.1 since this is covered in ISO/IEC 17011 section 7.6.8 and in the TNI EL standard 7.6.8.2. |  |
| 64 | TNI EL note after 7.7.6 deleted | NOTE: An accreditation body would not be required to accept or recognize the primary accreditation of the CAB if the accreditation body has a legal action that precludes the accreditation body from granting any accreditation to a particular CAB for a specific scope of accreditation.” | FSMO program does not define primary AB so note is not applicable |  |
| 66 | FSMO 2014 section 7.9.2.1.2 Preliminary accreditation and note at the end of this clause  See text | Delete language related to preliminary accreditation | Preliminary accreditation is not applicable in the ISO/IEC 17011:2017. This language was from the 2003 NELAC standard. So All reference to preliminary accreditation is removed from Rev 4 |  |
| 68 | ISO /IEC 17011:2004 FSMO 2014 7.9.3 and 7.9.4  Text removed and presented in attached | Delete text | Remove 17011:2004 7.8 language |  |
| 69 | TNI EL 7.7.5.1.8 considered and deleted | misrepresentation of any fact pertinent to receiving or maintaining accreditation | Text removed see covered in item 7.9.2.1.3.h in the FSMO language related to denial |  |
| 72 | 17011:2014 language in FSMO 7.9.5 | Deleted ISO/IEC 17011:2014 | Delete FSMO 2014 Clause 7.9.5 covered in 7.8 of ISO/IEC 17011:2017 |  |
| 73 | TNI EL 7.9.4.2 considered  All requirements specified in clauses 7.4 through 7.6 (inclusive) shall apply to reassessments, including the requirement in clause 7.4.7.1 to comply with the Safe Drinking Water Act.” | Deleted | SDWA not applicable to this standard since it is not regulated by EPA |  |
| 74 | TNI EL language considered 7.11.1. 1 to 7.11.1.6  See text item 74 | Deleted EL: language | Covered in ISO/IEC 17011:2017 7.9.4 |  |
| 75 | 7.12.1 Extending the Scope of Accreditation The accreditation body may grant a request for an extension of the scope of accreditation from the FSMO provided the FSMO completes or complies with all relevant clauses of the FSMO Volume I Standard and as agreed with the accreditation body. Failure to complete or comply with these elements shall be cause for denying the scope extension as specified in Clause 7.9 of this Standard.  7.12.2 Changes in Accreditation Scope An accreditation body may approve a FSMO’s application to add an analyte or sampling/ measurement method to its scope of accreditation by performing a data review without an on-site assessment.  The addition to the scope of accreditation via a data review of PT performance, if applicable, or other measure of competency demonstration, quality control performance, and written standard operating procedure shall be at the discretion of the accreditation body, but shall be in accordance with a defined written policy.  NOTE: An addition of a new technology or test method requiring specific equipment may require an on-site assessment at the discretion of the accreditation body, in accordance with a defined written policy. | Delete FSMO language | Delete FSMO 2014 7.12.1 and 7.12.2 since covered in ISO/IEC 17011:2017 7.10 |  |
| 76 | TNI EL 7.13.3.considered  NOTE: A governmental accreditation body following its regulatory or statutory due-process administrative procedures is considered to meet this requirement. | Delete EL language | Delete Note since not applicable to the FSMO ABs |  |
| 77 | FSMO 7.14.1 to 7.14.3  See item | Delete language | Redundant language with 17011:2017 |  |
| 81 | FSMO 7.15.1  *NOTE: Guidelines on operation and selection of proficiency testing and related definitions exist in ISO/IEC Guide 43-1 and ISO/IEC Guide 43-2.* | Delete these notes in PT section or revise to be consistent with EL standard | Quality manual is it still needed and update reference to PT program as defined in the TNI Volume 3 and 4 |  |
| 82 | ISO/IEC 17011:2004 FSMO 8.1 to 8.3  See language | Deleted in entirety | Duplicate of what is required in the contract with the CAB and what does the report on the policy change by the CAB  Obligations of the CAB (ISO/IEC 17011:2004, Clause 8.1) Section removed since the obligations are now found in the requirements of the agreement ISO/IEC 17011 Section 4.2 |  |
| 84 | ISO/IEC 17011:2017 FSMO 9.5 9.6 and 9.7 - add language | The procedure must identify the records to be maintained by the AB to demonstrate the above requirements are met. | Standard does not indicate records are required |  |
| 85 | ISO/IEC 17011:2017 FSMO 5.6  *The accreditation body shall establish procedures to identify opportunities for improvement and to take preventive actions to eliminate the causes of potential nonconformities. The preventive actions taken shall be appropriate to the impact of the potential problems. The procedures for preventive actions shall define requirements for: (5.6 17011:2004)*  *a)  identifying potential nonconformities and their causes,*  *b)  determining and implementing the preventive actions needed,*  *c)  recording results of actions taken, and*  *d)  reviewing the effectiveness of the preventive actions taken****.*** | Remove language | Duplicate with 9.6 of ISO/IEC 17011:2017 |  |
| 86 | EL 8.1.5 considered  “Accreditation bodies shall have documented procedures for processing and evaluating claims made by CABs of confidential business information (CBI) referencing applicable laws and regulations, the procedures a CAB shall follow to make a claim, the parties that will determine the validity of the claim, and the appeals process to be invoked when a CAB disagrees with the disposition of a claim.” | Removed | ISO/IEC 17011:2017 requires confidential information. CBI is not applicable to IAF/ILAC ABs  Confidentiality is a requirement of ISO/IEC 17011:2017 8.1 |  |
| 87 | 17011:2004 5.8.2. inputs to management review  17011:2004 5.8.3 outputs | Remove | Remove *17011 2004*  language found in 17011:2017 9.8.2 nd 9.8.3 |  |