The following table summarizes the changes that the Field Activities Committee made to **Volume 1: General Requirements for Field Sampling and Measurement Organizations (2014) (FSMO V1 2014). The new standard incorporates all the language from ISO/IEC 17025:2017. The references shown correlate to ISO/IEC 17025:2017.**

**Please provide feedback (questions, concerns, additional suggestions) for these items in the Comments column. Consideration should be given to both the concepts being incorporated and the appropriate level of detail for the new standard.**

| **Item #** | **Original Text (FSMO Vol 1 2014)** | **Changes Made** | **Justification** | | **Comments** | |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | TNI language | Change “shall” to “must” in TNI text. | TNI directive. | |  | |
| 2 | None | Added ISO/IEC 17025:2017 standard to Volume 1 and renumbered Volume 1 to be consistent with ISO/IEC 17025:2017 | For consistency with ISO/IEC 17025:2017 requirements. | |  | |
| 3 | ISO/IEC 17025:2005 (all places in the standard)  Language from ISO/IEC 17025:2005 removed from Volume 1 FSMO Standard if duplicate or similar language. | Updated the Volume 1 FSMO Standard to reference ISO/IEC 17025:2017.  Remove duplicate or similar language from ISO/IEC 17025:2005. | Updated to the latest ISO/IEC 17025 version.  Some ISO/IEC 17025:2005 language was retained if slightly different or contained different concept. Any retained language is noted as 2005 language. | |  | |
| 4 | **New** | 1.0 In addition, the term FSMO is used interchangeably with “laboratory” throughout the document.  3.0 NOTE 2: The term “laboratory” was left in the ISO/IEC definitions in clauses 3.1 through 3.9 but  note that “FSMO” is used interchangeably with “laboratory” throughout the document. | Prevent confusion to readers looking for sampling terms at the beginning of the document and only finding “laboratory”. | |  | |
| 5 | ***NEW*** *ISO/IEC 17025:2017*  *Definition: 3.2 Complaint* | Added clarification to 3.2: NOTE: TNI recognizes that *ISO/IEC 17000:2017 Clause 8.7* has a similar definition that is not standard specific to a laboratory or FSMO: *expression of dissatisfaction, other than appeal (8.6), by any person or organization to a conformity assessment body (4.6) or an accreditation body (4.7), relating to the activities of that body, where a*  *response is expected* | To clarify the definition | |  | |
| 6 | **3.14 Matrix**  The substance upon which a measurement is made or from which a sample is collected.  The matrix include the physical, chemical, biological, and radiological characteristics of  the substance. | Added Clarification to 3.12: NOTE: Example matrices:  Air and Emissions: Whole gas or vapor samples including those contained in flexible or  rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor  that are collected with a sorbant tube, impinger solution, filter, or other device.  Aqueous: Any aqueous sample excluded from the definition of Drinking Water or  Saline/Estuarine. Includes surface water, ground water, effluents, and TCLP or other  extracts.  Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant  material. Such samples must be grouped according to origin.  Chemical Waste: A product or by-product of an industrial process that results in a matrix  not previously defined.  Drinking Water: Any aqueous sample that has been designated a potable or potential  potable water source.  Non-Aqueous Liquid: Any organic liquid with <15% settleable solids.  Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source  such as the Great Salt Lake.  Solids: Includes soils, sediments, sludges and other matrices with >15% settleable solids. | To clarify the definition | |  | |
| 7 | **3.4 FSMO** Field Sampling and Measurement Organization See Clause 1 | ***3.11* Field Sampling and Measurement Organization (FSMO)**  *body that performs one or more of the following activities:*   *testing*   *calibration*   *sampling, associated with subsequent testing or calibration*   field observation (field conditions related to an environmental activity)   recording of measurements conducted by field instrumentation or subjective  observations related to sampling or other field activities.  *Note 1 to entry: In the context of this document, “*FSMO *activities” refer to the three*  *above-mentioned activities.*  NOTE 2: The fourth and fifth items expand the ISO/IEC 17025:2017 definition to  incorporate additional activities appropriate for field operations.  NOTE 3: “FSMO” is equivalent to “laboratory” (3.6). | To clarify the definition | |  | |
| 8 | **3.6 Preservation:** The physical, chemical, and/or radiological treatment of a sample to prevent the gain or loss of target analytes before analysis. Filtration, refrigeration, and addition of chemical reagents are examples of preservation techniques. | **3.15 Preservation**  Any conditions under which a sample/s is kept in order to maintain chemical, physical, and/or biological integrity prior to analysis. | To clarify the definition | |  | |
| 9 | **3.7 Management System:** See ISO/IEC 17025:2005(E) Clause 1.4, Note 1and Clause 4.2. | **3.16 Quality Management System**  A framework that includes the organization’s commitment to producing reliable and  trustworthy data, its system for ensuring proper documentation of data quality, and its  processes for constant improvement in operations.  [SOURCE: *Laboratory Accreditation Makes a Difference - Data You Can Rely On*, The  NELAC Institute, October 2020, modified.]  NOTE: The term “Quality Management System” is equivalent to “Management System”. | To clarify the definition | |  | |
| 10 | **3.8 Sampling:** See ISO/IEC 17025:2005(E) Clause 5.7.1, Note 1. | **3.17 Sampling**  The process of obtaining a representative portion of a matrix, substance, material or product suitable for analysis or measurement, according to a documented method. | To clarify the definition | |  | |
| 11 | **3.11 Proficiency Testing (PT):** A means of evaluating an organization’s performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by a Proficiency Testing Provider (PTP | **3.18 TNI Proficiency Testing Provider (PTP)**  An organization accredited as a Conformity Assessment Body by a TNI-recognized  Proficiency Testing Provider Accreditor (PTPA) to operate a TNI- compliant PT Program.  A PTPA is an organization that | To clarify the definition | |  | |
| 12 | **NEW** | Added terms:  **3.10 Field Activity(ies)**  Testing, calibration, measurements, observations, or sampling performed outside of the  confines of the FSMO’s permanent control.  **3.14 Mobile Facility**  A portable enclosed structure with necessary and appropriate accommodation and  environmental conditions, within which testing is performed by competent personnel. A  defined space that is not fixed at one location, operating under the control of a defined  quality management system (3.16).  NOTE: Examples include but are not limited to trailers, vans, and skid-mounted  structures configured to house testing equipment and personnel. | Additional terms need to be added specific for FSMO activities. The TNI Field Activities Task Force prepared some draft language that can be used as guidance | |  | |
| 13 | Removed:  **3.10 Validation: See ISO/IEC 17025:2005(E) Clause 5.4.5.1.**  **3.11 Environmental Sampling**  Equivalent to “Sampling.” See Clause 3.3.  **3.12 Field**  Any location where work is performed outside of the legal entity’s facility (e.g. FSMO  location).  **3.13 Field Sampling**  The process of obtaining a representative portion of an environmental matrix suitable for FSMO or field measurement  **3.20 Proficiency Testing Provider Accreditor (PTPA)**  An organization that is approved by TNI to accredit and monitor the performance of  Proficiency Testing Providers.  **3.21 Chain of Custody Form**  Record that documents the possession of the samples from the time of collection by a  FSMO to receipt in a testing FSMO. This record generally includes: the number and  types of containers, the mode of collection, the collector, time of collection, preservation,  and requested analyses. The form is a tracking form. The term does not represent  evidentiary collection. | Removed |  | |  | |
| 14 | 4.2.8 The FSMO shall establish and maintain data integrity procedures, which shall be defined or referenced in the quality manual. The term “data” used in this clause refers to samples and results of field measurements and all other records related to the quality of those samples and results. The data integrity procedures 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:  a) data integrity training provided as an element of new-hire employee training and during refresher training at least annually;  b) formal commitment to data integrity procedures signed by all FSMO employees;  c) confidential reporting of data integrity issues to senior management;  d) in-depth periodic review of data to verify its integrity and compliance with data integrity procedures;  e) the data integrity procedures shall be signed and dated by senior management;  f) the data integrity procedures and the associated implementation records shall be properly maintained; and  g) the data integrity procedures shall be reviewed annually and updated by management as needed. | **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, 2) data integrity  training, 3) periodic in-depth data monitoring, and 4) data integrity investigation.  4.3.2 Data Integrity Procedures  4.3.2.1 The data integrity procedures must, at a minimum, address the  following:  a. requirements to act impartially and to refrain from  inappropriate practices;  b. frequency of data integrity training;  c. topics to cover in data integrity training;  d. frequency and a schedule of items to be reviewed for  conducting periodic in-depth data monitoring;  e. process for confidential reporting of data integrity concerns  within the FSMO and a process whereby FSMO management  is informed of the issues;  f. requirements that management ensures no retaliation,  coercion or intimidation of employees reporting concerns or  potential issues;  g. information on performing a detailed data integrity  investigation; and  h. records required for training, in-depth data monitoring,  reported data integrity concerns, and data integrity  investigations.  4.3.3 Data Integrity Training  Data integrity training must be provided as a formal part of new employee  orientation and must also be provided on an annual basis for all current  employees. The FSMO must have records demonstrating when staff participate  in data integrity training and that they understand their obligations related to data  integrity. A record of the topics covered in the data integrity training must be  provided to all attendees. Data integrity training must include the following:  a. organizational mission and its relationship to the critical need for honesty;  b. the relationship of FSMO-generated data to public health concerns and the need for known and documented quality;  c. review of data integrity procedures;  d. how and when to report data integrity issues;  e. requirements for keeping analytical records;  f. requirements for reporting qualified data;  g. requirements to refrain from improper, inappropriate, and prohibited actions  (NOTE: Examples of prohibited actions are found in Annex C.1); and  h. potential consequences of engaging in improper, inappropriate or  prohibited actions:  i. Immediate termination  ii. Debarment  iii. Civil or criminal prosecution  4.3.4 Management Responsibilities  4.3.4.1 The data integrity procedures must be authorized and dated by  management.  4.3.4.2 Management must annually review data integrity procedures and  update them when needed.  4.3.4.3 FSMO management must provide a procedure for confidential  reporting of data integrity issues in their FSMO. A primary element of  the procedure is to assure confidentiality and a receptive environment  where all employees may privately discuss ethical issues or report  items of ethical concern without repercussions.  4.3.5 Investigations  4.3.5.1 All investigations resulting from data integrity issues should be  conducted in a confidential manner until they are completed.  4.3.5.2 These investigations must be documented and include any  notifications made to clients receiving any affected data. need for known and documented quality; | Enhance Data Integrity Ethics a core TNI value and align with QMS | |  | |
| 15 | 5.2.2.1 The FSMO shall have sufficient personnel with the necessary education, training, technical knowledge, and experience for their assigned functions. | Removed | Already a requirement in 5.5 | |  | |
| 16 | NEW | 5.6  f. Supervising all processes, to include sample preparation, instrument calibration, sample collection, sample analysis, quality control, identification, quantitation, and reporting; and  g. appointing quality management with the necessary authority and responsibility to:  i. function independent from FSMO operations for which they have quality  assurance oversight;  ii. evaluate data objectively and perform assessments without outside (e.g.,  managerial) influence;  iii. have documented training and/or experience in quality assurance/quality  control procedures and the FSMO’s management system;  iv. have a general knowledge of the analytical methods for which data review is  performed;  v. coordinate internal audits;  vi. notify FSMO management of deficiencies in the management system; and  vii. monitor corrective actions. |  | |  | |
| 17 | *NEW* | *6.2.1* NOTE: Written policies or procedures may demonstrate conformance to this requirement. | Provides additional clarification/detail to new ISO/IEC 17025:2017 Section 6 language | |  | |
| 18 | *NEW* | 6.2.3 NOTE: A demonstration of capability may be used to demonstrate competence for a field test. An observation or witness of technique by a trainer may be more appropriate for sample collection activities. Additionally, these observations may be combined with internal audit activities. Examples of demonstration of capability can be found in Annex C.2. | Provides additional clarification/detail to new ISO/IEC 17025:2017 Section 6 language | |  | |
| 19 | *5.3.1* NOTE: Field personnel should document sampling and measurement conditions that may affect the quality of results including, but not limited to, air temperature, ambient conditions, weather conditions, tides, stream stage, etc. Descriptions of sample conditions (e.g. turbidity, odor, less than optimal sample quantity, etc.) should also be noted. | 6.3.2.1 Facilities and environmental conditions that affect the quality of  results must be recorded  6.3.2.2 Descriptions of sample conditions (e.g. turbidity, odor, less than  optimal sample quantity, etc.) must also be recorded. | Clarified language | |  | |
| 20 | **NEW** | Added a new item 6.2.5 g)  The FSMO shall include safety and security as a component in planning the sampling event and any concerns or additional measures as required by the client.   * 1. The FSMO must include safety and security as appropriate in planning the sampling event and any concerns or additional measures as required by the client.   Note: FSMO Personnel should take precautions necessary to protect the safety of the personnel involved in sampling and the security of the samples. Procedures concerning safety should consider the nature of the samples and the areas from which they are collected, as well as equipment involved. This may include vehicle operation. | New language to improve the standard. | |  | |
| 21 | **NEW** | Added language:  6.3.6  The person responsible for evaluating and communicating observations related to facilities and environmental condition requirements must be specified. | New language to improve the standard. | |  | |
| 22 | **NEW** | Added language:6.4.13 All equipment necessary to take a consistent, representative sample must be identified prior to the sampling event.6.4.14 The FSMO must have written procedures for cleaning and decontamination of field sampling equipment that reduce contamination to the level specified for the project. 6.4.15.1 These procedures must be validated initially and at any time the procedure, materials, or analyte of interest change, or there is evidence of contamination in samples. | New language to improve the standard. | |  | |
| 23 | **5.5.3** NOTE: This Standard applies to measurements made and samples collected with equipment operated by attending staff, as well as to measurements made and samples collected discretely, continuously or at intervals by unattended equipment. | 6.4.2.1 Note: Equipment for attended or unattended measurements at a selected observation point must be capable of maintaining calibration throughout the range of environmental conditions that occur during the period of measurements. | Clarified language to improve the standard. | |  | |
| 24 | 5.5.6.1 Equipment for field sampling and measurement that are by necessity portable may be used in multiple locations under variable environmental conditions. The FSMO shall establish and maintain procedures for selection, identification, preparation, calibration before use, during use, and maintenance of its field- equipment. | Added 6.4.5 NOTE: Equipment for field sampling and measurement that are of necessity portable may be used in multiple locations under variable environmental conditions. Processes for selection, identification, preparation, calibration before use, during use, and maintenance of its field equipment should be considered. | Clarified language to improve the standard. | |  | |
| 25 | 5.6.2.1.4 Instruments/equipment used for environmental sampling and field measurement activities shall be calibrated (where applicable) prior to use. The following items are essential elements of initial instrument/equipment calibration:  a) The details of the initial instrument/equipment calibration procedures including calculations, integrations, acceptance criteria, and associated statistics shall be documented.  b) Sufficient raw data records shall be retained to permit reconstruction of the initial instrument/equipment calibration (e.g., calibration date, method, instrument/equipment ID, analyte(s) being calibrated, calibrator’s initials or signature, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument/equipment responses to concentration).  c) Criteria for the acceptance of an initial instrument/equipment calibration and calibration verification shall be established. The criteria used shall be appropriate to the calibration technique employed.  d) If the initial instrument/equipment calibration or applicable calibration verification results are outside established acceptance criteria, corrective actions shall be performed and all associated samples reanalyzed if possible.  e) When continuing calibration checks are needed to maintain confidence in the calibration status of the instrument/equipment, these checks shall be carried out according to a defined procedure.  f) Data associated with an unacceptable initial or continuing instrument/ equipment calibration shall be reported with appropriate data qualifiers.  g) Records of reference standard used for calibrations and reference material certificates shall be retained. | 6.4.4.1 The following items are essential elements of initial  instrument/equipment calibration:  a. The details of the initial instrument/equipment calibration  procedures including calculations, integrations, acceptance  criteria and associated statistics must be documented.  b. Sufficient raw data records must be retained to permit  reconstruction of the initial instrument/equipment calibration  (e.g., calibration date, method, instrument/equipment ID,  analyte(s) being calibrated, identity of the calibrator, standards  used, reference material certificates, concentration and  response, calibration curve or response factor, or unique  equation or coefficient used to reduce instrument/equipment  responses to concentration).  c. Criteria for the acceptance of an initial instrument/equipment  calibration must be established. The criteria used shall be  appropriate to the calibration technique employed.  d. If the initial instrument/equipment calibration is outside  established acceptance criteria, corrective actions must be  performed, and a new initial instrument/equipment calibration  performed.  e. The initial calibration must be verified against an independent  standard obtained from a second manufacturer, or from a  second lot obtained from the same manufacturer, prior to use  for analysis of samples. Criteria for the acceptance of the  independent standard must be established. If the independent  standard is outside established acceptance criteria, and  corrective actions must be performed. | New language to improve the standard. | |  | |
| 26 | **NEW** | 6.4.7.1 The following items are essential elements of calibration verification:  a. The details of the calibration verification procedures including  calculations, integrations, acceptance criteria and associated  statistics must be documented.  b. Sufficient raw data records must be retained to permit  reconstruction of the calibration verification (e.g., calibration  date, method, instrument/equipment ID, analyte(s) being  calibrated, identity of the calibrator, concentration and  response, calibration standards used, reference material  certificates).  c. Criteria for the acceptance of a calibration verification must be  established. The criteria used shall be appropriate to the  calibration technique employed.  d. When calibration verification is needed to maintain confidence  in the calibration status of the instrument/equipment, these  checks must be carried out according to a defined procedure.  If frequency is not addressed in a given method, calibration  verification must be performed | New language to improve the standard. | |  | |
| 27 | **NEW** | ***6.6 Externally provided products and services***  *6.6.1*  d. The FSMO requesting external services related to sampling or testing, must ensure the use of a competent FSMO or laboratory that meets applicable client, statutory and regulatory requirements for performing the work. | New language to improve the standard. | |  | |
| 28 | **4.7.1** *NOTE 2: Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.* | Added Language:7.1.7.1 Communication with the customer, must be maintained throughout the work. The FSMO must inform the customer of any delays or major deviations in the performance of the tests and/or calibrations. | Clarified language to improve the standard. | |  | |
| 29 | **NEW** | Added language: 7.3.1.1 A documented sampling plan must be implemented prior to initiating the event detailing the requirements of the project.  7.3.1.2 The sampling plan must consider risk.  NOTE 1: Refer to Annex C.3 for considerations in preparing a sampling plan.  NOTE 2: The same plan may be reused for repeat sampling events such as quarterly monitoring. | Provides additional clarification/detail to new ISO/IEC 17025:2017 | |  | |
| 30 | 4.13.2.1.1 The technical records to be maintained shall include the chain of custody form of transferred samples.  4.13.2.1.2 All records shall be retained for a period as specified by the client or regulatory authority or in the absence of such specificity  4.13.2.2.1 All records, except those which are generated by automated data collection systems or equipment, shall be recorded directly and promptly, and signed by the person responsible for producing | Clarified language 2/24/77.5.1.1 All records must be retained for a defined period. This period must not be less than five years from the generation of the last entry. If the client or regulatory authority specifies a longer retention time, the FSMO must retain records for the longer period.7.5.1.2 7.5.1.2 All records, except those which are generated and retained by automated data collection systems or equipment, must be recorded directly and promptly, and signed by the person responsible for producing the records. Handwritten records must be made legibly in permanent ink. A peer review of these records must be completed and documented as soon as practicable. If it is not feasible to complete a peer review, the justification for this shall be noted and the originator must review their work. This review must be documented. | Clarified language to improve the standard | |  | |
| 31 | **5.10.2** l) results for any applicable field blanks, spikes, duplicates, and confirmation samples. | 7.7.1 added  l. other quality control samples such as blanks, surrogates, laboratory  control samples, post spikes, method of standard additions, Look at  module 4 for anything else that might be missing. | Clarified language to improve the standard | |  | |
| 32 | 5.9.2 The FSMO shall participate in a proficiency testing program that is applicable to its scope of accreditation. | Added 7.7.2.1 An accredited TNI Proficiency Testing Provider or a proficiency testing provider accredited to ISO/IEC 17043:2023 must be used where available. | Clarified language to improve the standard | |  | |
| 33 | 5.6.2.1.4 f) Data associated with an unacceptable initial or continuing instrument/ equipment calibration shall be reported with appropriate data qualifiers. | 7.8.2.1  r. Data associated with an unacceptable initial calibration or  independent standard verification must only be reported if  reanalysis is not possible, and then only if the data is reported  with appropriate data qualifiers, where applicable or allowed by the regulatory program or customer.  s. Data associated with an unacceptable calibration verification, if reported, must be reported with appropriate data qualifiers.  t. Data associated with quality control failures, if reported, must be reported with appropriate data qualifiers. | Clarified language to improve the standard | |  | |
| 34 | **NEW** | Added language:  7.8.5 g information required by the sampling method or plan | New language to improve the standard | |  | |
| 35 | **NEW** | Added 7.10.4 When allowed by program or client, nonconforming results may be reported with data qualifiers or a case narrative when reanalysis is not possible. | New language to improve the standard | |  | |
| 36 | **NEW** | Added language:8.4.3 The FSMO must have a plan to ensure that the records are maintained or transferred according to the clients’ instructions in the event that the FSMO transfers ownership or goes out of business. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning FSMO records must be followed. | New language to improve the standard. | |  | |
| 37 | **NEW** | Added New Annex C  **C.1 General**  This annex provides additional non-mandatory information to help the FSMO implement  the Standard. Topics covered include Data Integrity, Demonstration of Capability and  Competence, Sample Planning and Sample Method.  **C.2 Data Integrity:**  The FSMO should not engage in any prohibited actions. The following are  examples of such actions:  **C.2.1** Field Measurement  a. fabricating, falsifying, or misrepresenting data, including creating data for an analysis  that was not performed or for a sample that was not collected or sampled (dry lab);  b. using external analysts, equipment, and/or FSMOs to perform analyses when not  allowed by contract, or intentionally concealing such use;  c. recording improper date/time, including resetting the internal clock on an instrument  to make it appear that a sample was analyzed within a compliant time frame, or  recording a false date/time or changing a date/time to make it appear that required  times were met;  d. unwarranted manipulation of samples or analytical conditions, including unjustified  dilution of samples, field filtration, or changing the instrument conditions for sample  analysis from the conditions used for standard analysis;  e. unwarranted manipulation of software, including forcing calibration or QC data to  meet acceptance criteria, removing software operational codes indicating analyst  manipulation of results, changing LIMS parameters to avoid displaying appropriate  qualifiers, inappropriately subtracting background, or improperly manipulating the  baseline;  f. turning off, or otherwise disabling, electronic instrument audit/tracking functions;  g. misrepresenting or misreporting QC samples;  h. substituting previously generated analyses for a non-compliant calibration or QC  analysis to make it appear that an acceptable analysis was performed;  i. failing to prepare or analyze method blanks, the laboratory control sample (LCS), and  when required matrix spikes, in the same manner that samples were prepared or  analyzed; e.g., using dedicated labware, instrumentation, or FSMO space for the  preparation or analysis of QC samples, analyzing QC samples outside of required  analytical time frames, using additional instrument blanks or increased rinse times  before or after QC sample analysis when not similarly applied to field samples;  j. tampering with QC samples and results, including over/under spiking and adding  surrogates after sample extraction;  k. deleting or failing to record QC data outside acceptance criteria to conceal the fact  that calibration or other QC analyses were outside acceptance criteria;  l. performing improper manual integrations, including peak shaving, peak enhancing, or  baseline manipulation to meet QC acceptance criteria or to avoid nonconforming  work;  m. concealing a known sample problem;  n. removing failed QC analyses from the record of a sequence;  o. purposely excluding known QC failures from the case narrative;  p. observing out-of-compliance equipment conditions, then adjusting the equipment into  compliance and recording only the compliant observation;  q. recording the temperature of the surface of an ice pack rather than the temperature  of a representative sample container;  r. failing to report a known improper action to the appropriate FSMO or client, or to an  appropriate government official; or  s. reporting data for regulatory purposes from a modified method that fails to adhere to  all regulatory and statutory requirements.  **C.2.2** Field Sampling  a. not collecting samples at the specified location  b. not preserving samples in the field as required.  c. Manipulation of samples (e.g., diluting samples)  d. use of incorrect sampling techniques  e. observing out-of-compliance equipment conditions, then adjusting the equipment into  compliance and recording only the compliant observation;  f. failing to report a known improper action to the appropriate FSMO or client, or to an  appropriate government official.  g. misrepresenting field QC samples  h. Fabricating, falsifying, or misrepresenting sampling data (e.g, time of collection,  location, etc.)  **C.3 Demonstration of Capability or Competence**  Demonstration of capability or competence may be achieved by:  **C.2.1.** For competence in field measurements:  a. acceptable performance of a blind sample or proficiency testing sample.  b. acceptable performance of at least 4 samples prepared containing the  analyte(s) in an appropriate quality system matrix. . The FSMO should  determine the acceptable limits for precision and accuracy prior to analysis.  c. a documented process of reviewing QC samples performed by an analyst or  groups of analysts relative to the QC requirements of the method, FSMO,  SOP, client specifications, and/or this Standard. This review can be used to  identify patterns for individuals or groups of analysts and determine if  corrective action or retraining is necessary;  d. if a) through d) are not technically feasible, then analysis of real-world  samples with results within a pre-defined acceptance criterion (as defined by  the FSMO or method) should be performed.  **C.2.2** For competence in sampling techniques:  a. Acceptable performance of the collection of quality control blank (reagent  grade water), preservation and transportation with subsequent analytical  results below a pre-defined limit for specified analytes as defined by FSMO.  b. Objectively documented conformance to with procedure(s) .. An example  could ibe successful completion of a pre-determined checklist observed and  recorded by a qualified professional.  c. Credentials for specific sampling techniques.  **C.4 Sample Planning**  The following should be addressed, as appropriate, when preparing a sample plan:  a. The number of samples required including any quality control samples.  b. Sampling schedule and transport schedule.  c. Identification of assigned test method requirements. This should include any required  test methods, target analytes, reporting limits or action levels, units for reporting and  accreditations.  d. Identification and contact information for subcontractors and a copy of the  subcontract agreement.  e. Procedure for communicating subsequent testing requirements to subcontractors.  f. Identification of the sampling methods used for each matrix.  g. Appropriate sample handling procedures necessary to protect the integrity of the  sample including proper containers, minimum sample material quantity required,  storage conditions, physical or chemical preservation required, and holding times.  h. Any procedures or requirements related to the field sampling process to prevent  cross-contamination including decontamination, order of sample collection, or  segregation during storage.   1. Identification of personnel responsible for shipping or transport to subcontractor.   j. Identification of potential environmental conditions that may impact sample validity  and mitigation procedures for identified risks.  k. Process for identifying, recording, and reporting sampling plan or sampling method  deviations to the client.  l. A copy of the client contract or a summary of all contractual requirement related to  sample collection and analysis.  m. Procedure for sample identification and labeling.  n. Requirements and procedure for field sample custody tracking and sample storage.  o. Personal Protective Equipment (PPE) requirements and other safety requirements.  p. Site or client required training or certifications.  q. Site information including address, point of contact, and any access instructions  required.  r. Identification of any associated regulatory requirements.  s. Contingency plans for unforeseen circumstances.  **C. 5 Sampling Method**  The Sampling method should include the following as applicable:  a. homogeneity and any homogenization steps that may be necessary due to the  physical form or matrix.  b. Seasonality or other timing considerations that may impact the representativeness.  c. The specific location or process for identifying each selected sample source.  d. Whenever possible, the location is documented as specifically as possible with  address, GPS/GIS information, location in applicable buildings, and/or permanent   1. landmarks. | New language to improve standard | |  | |
|  | **New Concepts added due to the incorporation of the new ISO language** | | | | | | |
| *38* | **ISO/IEC 17025:2017**  **3** | Added new requirements from ISO/IEC 17025:2017  Use of "or" in the document implies "and" as well per the ISO Directives.  New terms added to ISO/IEC 17025:2017   * (3.1) Impartiality - presence of objectivity * (3.2) Complaint - expression of dissatisfaction by any person or organization to a laboratory (3.6), relating to the activities or results of that laboratory, where a response is expected * (3.3) Interlaboratory comparison - organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions * (3.4) Intra-laboratory Comparison - organization, performance and evaluation of measurements or tests on the same or similar items, within the same laboratory (3.6), in accordance with predetermined conditions * (3.5) Proficiency Testing - evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (3.3). * (3.6) Laboratory - body that performs one or more of the following activities: Testing, calibration, and sampling associated with subsequent testing or calibration. * (3.7) Decision Rule - rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement | | Adoption of ISO/IEC 17025:2017 for FSMO (See other changes to clarify these terms based on FSMO V1 2014 standard) | |  | |
| *39* | **ISO/IEC 17025:2017**  **4.1**  **Impartiality** | Added new requirements from ISO/IEC 17025:2017   * (4.1.4) The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality. * (4.1.5) If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *40* | **ISO/IEC 17025:2017**  **4.2 Confidentiality** | Added new requirements from ISO/IEC 17025:2017   * (4.2.3) Information about the customer obtained from sources other than the customer (e.g., complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source. * (4.2.4) Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *41* | **ISO/IEC 17025:2017**  **5.0**  **Structure** | Added new requirements from ISO/IEC 17025:2017   * (5.3) The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *42* | **ISO/IEC 17025:2017**  **6.4**  **Equipment** | Added new requirements from ISO/IEC 17025:2017   * (6.4.13) Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:   + (f) documentation of reference materials, results, acceptance criteria, relevant dates, and the period of validity;   This requirement was in the 2014 FSMO standard but was stated differently. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *43* | **ISO/IEC 17025:2017**  **6.6**  **Externally provided supplies and services** | Added new requirements from ISO/IEC 17025:2017   * (6.6.2) The laboratory shall have a procedure and records for:   + (a) defining, reviewing, and approving the laboratory’s requirements for externally provided products and services;   + (d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers. * (6.6.3) The laboratory shall communicate its requirements to external providers, for:   + (c) competence, including any required qualification of personal;   + (d) activities that the laboratory, or its customer, intends to perform at the external provider's premises. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *44* | **ISO/IEC 17025:2017**  **7.1**  **Review of requests** | Added new requirements from ISO/IEC 17025:2017   * (7.1.3) When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g., pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *45* | **ISO/IEC 17025:2017**  **7.3 Sampling** | Added new requirements from ISO/IEC 17025:2017 – These were already listed in the FSMO 2014 standard.   * (7.3.3) The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:   + date and time of sampling;   + data to identify and describe the sample (e.g., number, amount, name);   + identification of the equipment used;   + deviations, additions to or exclusions from the sampling method and sampling plan. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *46* | **ISO/IEC 17025:2017**  **7.5 Technical Records** | Added new requirements from ISO/IEC 17025:2017   * (7.5.2) The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *47* | **ISO/IEC 17025:2017**  **7.7 Ensuring the validity of results** | Added new requirements from ISO/IEC 17025:2017   * (7.7.1) The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:   + (b) use of alternative instrumentation that has been calibrated to provide traceable results;   + (c) functional check(s) of measuring and testing equipment;   + (i) review of reported results;   + (j) intra-laboratory comparisons;   + (k) testing of blind sample(s). * (7.7.2) The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:   + participation in interlaboratory comparisons other than proficiency testing. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *48* | **ISO/IEC 17025:2017**  **7.8 Reporting** | Added new requirements from ISO/IEC 17025:2017   * (7.8.1.1) The results shall be reviewed and authorized prior to release. * (7.8.2.2) The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g., the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received. * (7.8.6.1) When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule. * (7.8.6.2) The laboratory shall report on the statement of conformity such that the statement clearly identifies:   + the decision rule applied (unless it is inherent in the requested specification or standard). | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *49* | **ISO/IEC 17025:2017**  **7.9 Complaints** | Added new requirements from ISO/IEC 17025:2017   * (7.9.2) A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints. * (7.9.3) The process for handling complaints shall include at least the following elements and methods: * (a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; * (c) ensuring that any appropriate action is taken. * (7.9.4) The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint. * (7.9.5) Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome. * (7.9.6) The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question. * (7.9.7) Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *50* | **ISO/IEC 17025:2017**  **7.11 Control of Data** | Added new requirements from ISO/IEC 17025:2017   * (7.11.1) The laboratory shall have access to the data and information needed to perform laboratory activities. * (7.11.3) The laboratory information management system shall:   + (e) include recording system failures and the appropriate immediate and corrective actions. * (7.11.4) When laboratory information management systems are managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *51* | **ISO/IEC 17025:2017**  **8.1 Management System** | Added new requirements from ISO/IEC 17025:2017   * (8.1.1) The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard and assuring the quality of the laboratory results. In addition to meeting the requirements of clauses 4 to 7 of this International Standard the laboratory shall implement a management system in accordance with Option A or Option B. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *52* | **ISO/IEC 17025:2017**  **8.5** | Added new requirements from ISO/IEC 17025:2017  Introduce the concept of risk-based thinking.  Management system includes actions to address risks and opportunities. This is a new section in ISO/IEC 17025:2017   * (8.5.1) The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:   + (a) give assurance that the management system can achieve its intended results;   + (b) enhance opportunities to achieve the purpose and objectives of the laboratory;   + (c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;   + (d) achieve improvement. * (8.5.2) The laboratory shall plan:   + (a) actions to address these risks and opportunities;   + (b) how to:     - integrate and implement the actions into its management system;     - evaluate the effectiveness of these actions. * (8.5.3) Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results. | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *53* | **ISO/IEC 17025:2017**  **8.7** | * Added new requirements from ISO/IEC 17025:2017   The term Root Cause Analysis is no longer present since there could be several causes. Identify the level of the cause necessary to mitigate the risk.  Change or addition to standard:  (e) update risks and opportunities determined during planning, if necessary; | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |
| *54* | **ISO/IEC 17025:2017**  **8.9** | Added new requirements from ISO/IEC 17025:2017  New input items added to Management Review (8.9.2)   * (a) changes in internal and external issues that are relevant to the laboratory; * (b) fulfilment of objectives; * (d) status of actions from previous management reviews; * (k) effectiveness of any implemented improvements; * (m) results of risk identification;   New output items added (8.9.3)   * (a) the effectiveness of the management system and its processes * (b) improvement of the laboratory activities related to the fulfilment of the requirements of this document * (c) provision of required resources * (d) any need for change | | Adoption of ISO/IEC 17025:2017 for FSMO | |  | |