The following table summarizes the changes that the Field Activities Committee is recommending for **Volume 1: General Requirements for Field Sampling and Measurement Organizations (2014) (FSMO V1 2014). The new standard will incorporate 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.**

The table is divided into three sections:

1. New concepts recommended by FAC (Item # 1-14)
	* The language shown in the table is not intended as final language but should be viewed as conceptual.
2. Additional ideas still under development (Item # 15-19)
3. New Concepts added due to the incorporation of the new ISO language (ISO/IEC 17025:2017) (Item # 20-36)
	* **Please note, the ISO language cannot be changed. However, any comments on how these requirements can be implemented is appreciated.**
	* **The full text of ISO/IEC 17025:2017 will be incorporated into the final FSMO standard. Only the new ideas are shown in this section of the table.**

| **Item #** |  | **Suggested Changes** | **Justification** | **Comments** |
| --- | --- | --- | --- | --- |
|  | **NEW Concepts recommended by FAC** |
| *1* |  | Add language to the Preface explaining that the term FSMO is covered by the term “Laboratory” as in this standard.  | Prevent confusion to readers looking for sampling terms at the beginning of the document and only finding “laboratory”.  |  |
| *2* |  | 3.6 LaboratoryConsider expanding the definition of laboratory (where sampling is concerned) to also include samples collected only for field observation (pH, temp, residual chlorine, dissolved oxygen, visual opacity (air permit requirements). Also consider including observations made when a sample is not technically collected (groundwater (GW) elevation measurements) | In section 3.6, the Laboratory definition specifies “…sampling, associated with subsequent testing or calibration.” This lacks the specificity necessary to capture all sampling activities conducted by FSMOs.  |  |
| *3* |  | Add terms to Section 3 that are specific to FSMO activities.* Mobile Lab
* Field Activity
* Field Equipment
* Representative sample
* ?
 | 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  |  |
| *4* |  | Move FSMO V1:2014 5.2.1 NOTE 1 to a requirement by adding the following to 6.2.3This shall also include any certifications or licenses required. | Provides additional clarification/detail to new ISO/IEC 17025:2017 Section 6 language |  |
| *5* |  | Add new sub-section to Section 7 on Planning to add details to the sampling plan requirements. The following are suggestions that have been made as potential additions to this standard. It has been noted that the language below may be too detailed. The committee is specifically seeking feedback on the level of detail that should be included. Prior to initiating a sampling event, a written sampling plan will be generated detailing the requirements and project. A sampling plan will detail sampling event(s) with specifications for the sampling event(s). The sampling plan should be as complete as possible before arriving on the sample site included such information as sampling devices and number of sample increments and size. If the sampling plan is a repeat event, based on a contract with a client, there should be a project plan with the information that will stay consistent.The sampling plan shall address factors to be controlled to ensure the representativeness of the sample(s) collected.Factors such as storage, environmental conditions, heterogeneity of the batch or sample, all must be considered and addressed in the sampling plan. Any deviation from the standard sampling process, or addition to the sampling plan must be documented in detail and shall be included in the final report and, whenever possible, linked to the final results of the planned target analytes.Sampling and Analysis Plan* Request for Sampling or record of Client Contract
* Analyses requested
* If applicable, standing or individual subcontract agreements by the sampling and analysis laboratories
* Sampling schedule and transport schedule
* Personnel assigned to sampling and transport
* Location of Monitoring Site or Sampling Population
	+ Whenever possible, the location shall be documented as specifically as possible with address, GPS/GIS information, location in applicable buildings, and/or permanent landmarks.
	+ The sampling plan shall contain diagrams or maps whenever written information may not be enough to historically reconstruct the sampling or monitoring event.
* Orientation/Expected Configuring of Sampling Population
* Target Analytes to be Sampled
* Sampling or Monitoring Matrix and Sub-Matrix, if applicable
* Applicable SOPs for type of monitoring or sampling and matrix/submatrix
* Appropriate sampling design considerations, statistical methods or calculators used for sampling design
* List of necessary equipment
 | New language to improve the standard. |  |
| *6* |  | Add a new item 6.2.5 g) Personnel Safety and Security * 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 shall consider the nature of the samples and the areas from which they are collected.
* 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.
 | New language to improve the standard. |  |
| *7* |  | Add a new section 6.3.6 “Sample Integrity and Transport” * The laboratory must have detailed procedures on maintaining custody and sample integrity during transport. These procedures should take into consideration sample preservation according to the target analytes and reference analysis methods, controlling temperature, and other environmental factors.
* Containers for sample transport must be designed to prevent damage, contamination, spillage, or commingling of the sample during transport. The required container for sampling should be appropriate for the sample matrix and the tests required.
* Samples shall be identified by labeling or marking the sample container. This identification system must provide for traceability back to the sample location and when it was collected.
 | New language to improve the standard. |  |
| *8* |  | Add new sub-sections to 6.4 specifically pertaining to field equipment6.4.xx The laboratory shall have procedures ensuring that field equipment (whether owned or rented) shall be properly inspected and verified to be in good working condition prior to the beginning of each working day, protected against environmental conditions during use, and properly decontaminated between uses. * Records of instrument calibration or verification shall be maintained by the FSMO.

6.4.xx All equipment necessary to take a consistent representative sample shall be identified prior to the sampling event.6.4.xx The lab shall have written procedures for cleaning and decontamination of field sampling equipment.* These procedures must effectively eliminate carryover by removing any analyte of interest regardless of concentration of the analyte.
* 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. |  |
| *9* |  | Add language at 7.2.1.3 requiring that the sampling methods meet the needs of the data user. | New language to improve the standard. |  |
| *10* |  | Add directions regarding how to validate a sampling method at 7.2.2.1 | New language to improve the standard. |  |
| *11* |  | Develop and add language regarding statistical sampling design methods and requirements at 7.3.1 | New language to improve the standard |  |
| *12* |  | Consider adding a section in 7.3 regarding the Selection of Sampling Scheme along the lines of the following –1. The FSMO shall have procedures relating to Representativeness of the Sampling Design, if required by the client or regulation. Specific procedures for collecting representative samples are to be determined in consideration of several attributes of the products and production methods:
	1. Homogeneity – A sample is more likely to accurately represent the production batch if the material is homogenous (i.e., well mixed). Mixing or other homogenization steps help to homogenize the product before sample collection.
	2. Physical Form – Production batches will vary in physical form (e.g., liquids, solids), density, and viscosity. Physical form can affect homogeneity, homogenization steps, and sample collection methods. For example, liquid products can be homogenized by stirring. Grinding and other methods described further below can be used to homogenize solid products.
	3. Quantity – Because production batches may vary in scale (i.e., volume or weight), varying numbers or sizes of samples may be required to promote representativeness.
	4. Frequency/Timing – the timing of the collection of a representative sampling shall vary depending on the population being targeted.
2. Planning the type of sampling method shall take into consideration the following:
	1. Statistical Design to a Confidence Interval
	2. Risk-Based
	3. Incremental
	4. Grab
	5. Composite
	6. Time Composite
 | New language to improve the standard |  |
| *13* |  | Add a definition of complaint to the Section 3(Section 7.9 does not provide a definition))From ISO/IEC 17000 8.7 “expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or an accreditation body relating to the activities of the body where a response is expected” OR expression of dissatisfaction by an person or organization to a FSMO or an accreditation body or TNI relating to the activities of the FSMO where a response is expected. (This should be placed in the definitions sections and not in this section.) | New language to improve the standard.Definition of complaint shall be clearly defined by laboratory (there is often not complaint records because no one knows what a “complaint” is…..also, front-line employees (samplers) are often the ones receiving complaints but least trained on them.  |  |
| *14* |  | Add language at 7.11.6 regarding requirements regarding the review of field records. | New language to improve standard |  |
|  | **Additional ideas still under development** |
| *15* |  | Sampling activity planning – additional requirements (, least to most contaminated sampling, on-site storage/ preservation, decontamination, waste disposal / waste disposal plan, awareness of impacts from environmental conditions (rain, wind, etc.)) |  |  |
| *16* |  | Training / certification / experience of field personnel |  |  |
| *17* |  | Demonstration of capability requirement |  |  |
| *18* |  | Scopes of accreditation |  |  |
| *19* |  | Modules for specific areas (emerging markets, CLP, matrix specific, food, NPDES, drinking water, stormwater, organics, inorganics, stack, etc.) |  |  |
|  | **New Concepts added due to the incorporation of the new ISO language** |
| *20* | **ISO/IEC 17025:2017****3** | Added new requirements from ISO/IEC 17025:2017Use 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) |  |
| *21* | **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 |  |
| *22* | **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 |  |
| *23* | **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 |  |
| *24* | **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 |  |
| *25* | **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 |  |
| *26* | **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 |  |
| *27* | **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 |  |
| *28* | **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 |  |
| *29* | **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 |  |
| *30* | **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 |  |
| *31* | **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 |  |
| *32* | **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 |  |
| *33* | **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 |  |
| *34* | **ISO/IEC 17025:2017****8.5** | Added new requirements from ISO/IEC 17025:2017Introduce 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 |  |
| *35* | **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 |  |
| *36* | **ISO/IEC 17025:2017****8.9** | Added new requirements from ISO/IEC 17025:2017New 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 |  |