FIELD SAMPLING AND MEASUREMENT ORGANIZATION

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VOLUME 1

GENERAL REQUIREMENTS FOR FIELD SAMPLING AND MEASUREMENT ORGANIZATIONS

TNI Standard

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FORWARD

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO) and circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This third edition cancels and replaces the second edition (ISO/IEC 17025:2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

- *the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;*
- *there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information, and organizational responsibilities;*
- *a definition of “laboratory” has been added (see Section 3.6).*

PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Field Activities Committee. The TNI Board of Directors wishes to thank these committee members for their efforts in preparing this Standard, as well as those TNI members who offered comments during the review process.

This Standard conforms to ISO/IEC 17025:2017(E) and includes applicable clauses from that international standard. The ISO/IEC clauses are provided *in italics.* Additional TNI text is provided in a normal font. The term FSMO (Field Sampling and Measurement Organization) is used interchangeably with "laboratory" throughout this Standard for clarity.

This Standard may be used by any organization that wishes to implement a program for the accreditation of organizations performing sampling and field measurements.

Standard Revision History

Action	Date
Final Standard Published	May 1, 2007
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Introduction

This document has been developed with the objective of promoting confidence in the operation of FSMOs*. This document contains requirements for FSMOs to enable them to demonstrate they operate competently, and are able to generate valid results.* FSMOs *that conform to this document will also operate generally in accordance with the principles of ISO 9001.*

This document requires the FSMO *to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results, and preventing negative effects. The* FSMO *is responsible for deciding which risks and opportunities need to be addressed.*

The use of this document will facilitate cooperation between FSMOs *and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures. The acceptance of results between countries is facilitated if* FSMOs *conform to this document.*

In this document, the following verbal forms are used:

- *"shall"* and "must" *indicates a requirement;*
- *"should" indicates a recommendation;*
- *"may" indicates a permission;*
- *"can" indicates a possibility or a capability.*

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey: 17025_ed3_usersurvey.

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VOLUME 1

GENERAL REQUIREMENTS FOR FIELD SAMPLING AND MEASUREMENT ORGANIZATIONS

1.0 SCOPE

This document specifies the general requirements for the competence, impartiality, and consistent operations of Field Sampling and Measurement Organizations (FSMO or FSMOs).

This document is applicable to all organizations performing FSMO *activities, regardless of the number of personnel.*

FSMO *customers, regulatory authorities, organizations, and schemes using peer-assessment, accreditation bodies, and others, use this document in confirming or recognizing the competence of* FSMOs*.*

1.1 Introduction

This Standard includes requirements applicable to those organizations engaged in ~~environmental~~ sampling and field measurement activities.

This TNI Standard is intended as an application of *ISO/IEC 17025:2017(E)*, *General Requirements for the Competence of Testing and Calibration Laboratories*. It extends *ISO/IEC 17025:2017(E)* to provide a more comprehensive framework to conduct sampling and measurement activities. The *ISO/IEC* clauses are provided in *italics*; added TNI clauses are presented in a non-italicized font. In addition, the term FSMO is used interchangeably with "laboratory" throughout the document.

Where regulatory or other requirements are applicable, these must also be included, and the most stringent competence requirements enforced.

Unless the contrary is clearly indicated, all references to singular nouns include the plural noun, and all references to plural nouns include the singular.

2.0 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99, International vocabulary of metrology — Basic and general concepts and associated terms (VIM)[1]

ISO/IEC 17000, Conformity assessment — Vocabulary and general principles

[1] Also known as JCGM 200.

3.0 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- *ISO Online browsing platform: available at https://www.iso.org/obp*
- *IEC Electropedia: available at http://www.electropedia.org/*

NOTE 1: The relevant definitions listed in the referenced ISO/IEC documents apply when using this document. Definitions related to this document, which are used differently or do not exist in the ISO/IEC references, are defined below.

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.

3.1 impartiality
presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory (3.6) or FSMO (3.11).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even- handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words “the certification body” have been replaced by “the FSMO*” in Note 1 to entry, and the word “independence” has been deleted from the list in Note 2 to entry.]*

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*

[SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words “other than appeal” have been deleted, and the words “a conformity assessment body or accreditation body, relating to the activities of that body” have been replaced by “a laboratory, relating to the activities or results of that laboratory*”.]*

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*

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.

[SOURCE: ISO/IEC 17043:2010, 3.4]

3.4 intralaboratory 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)

[SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]

NOTE 1: Proficiency testing for measurements is a means to evaluate an organization's performance for performing testing and measurements, under controlled conditions, relative to a given set of criteria, through analysis of unknown samples provided by an external source.

NOTE 2: Proficiency testing for sampling is a means to evaluate an organization's performance for collecting samples under controlled conditions relative to a given set of criteria, through sampling of a well-defined source.

3.6 laboratory

body that performs one or more of the following activities:

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

Note 1 to entry: In the context of this document, "laboratory activities" refer to the three above-mentioned activities.
NOTE 2: "Laboratory" is equivalent to "FSMO" (3.11).

3.7 decision rule

rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

3.8 verification

provision of objective evidence that a given item fulfils specified requirements.

EXAMPLE 1: Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2: Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3: Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration.

Note 2 to entry: The item may be, for example, a process, measurement procedure,

material, compound, or measuring system.

Note 3 to entry: The specified requirements may be, for example, that a manufacturer's specifications are met.

Note 4 to entry: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

Note 5 to entry: Verification should not be confused with calibration. Not every verification is a validation (3.9).

Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

[SOURCE: ISO/IEC Guide 99:2007, 2.44]

3.9 validation

verification (3.8), where the specified requirements are adequate for an intended use.

EXAMPLE: A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.

[SOURCE: ISO/IEC Guide 99:2007, 2.45]

3.10 Field Activity(ies)

Testing, calibration, measurements, observations, or sampling performed outside of the confines of the FSMO's permanent control.

***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).

3.12 Matrix

The substance upon which a measurement is made or from which a sample is collected.

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.

3.13 Measurement

The process or result of determining, by comparison to a standard, the dimensions, quantity, capacity, or other characteristic of a measurand.

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.

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.

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".

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.

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 is recognized by TNI to accredit and monitor the performance of TNI PTPs.

4.0 General requirements

4.1 Impartiality

4.1.1 FSMO *activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.*

4.1.2 The FSMO *management shall be committed to impartiality.*

4.1.3 The FSMO *shall be responsible for the impartiality of its* FSMO *activities and shall not allow commercial, financial or other pressures to compromise impartiality.*

4.1.4 The FSMO *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* FSMO *with a risk to impartiality.*

NOTE: A relationship that threatens the impartiality of the FSMO *can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.*

4.1.5 If a risk to impartiality is identified, the FSMO *shall be able to demonstrate how it eliminates or minimizes such risk.*

4.2 Confidentiality

4.2.1 The FSMO *shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of* FSMO *activities. The* FSMO *shall inform the customer in advance of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the* FSMO *and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.*

4.2.2 When the FSMO *is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.*

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 FSMO*. The provider (source) of this information shall be confidential to the* FSMO *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 FSMO*'s behalf, shall keep confidential all information obtained or created during the performance of* FSMO *activities, except as required by law.*

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.

5.0 Structural requirements

5.1 The FSMO *shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its* FSMO *activities.*

NOTE: For the purposes of this document, a governmental FSMO *is deemed to be a legal entity on the basis of its governmental status.*

5.2 The FSMO *shall identify management that has overall responsibility for the* FSMO*.*

5.3 The FSMO *shall define and document the range of* FSMO *activities for which it conforms with this document. The* FSMO *shall only claim conformity with this document for this range of* FSMO *activities, which excludes externally provided* FSMO *activities on an ongoing basis.*

5.4 FSMO *activities shall be carried out in such a way as to meet the requirements of this document, the* FSMO's *customers, regulatory authorities and organizations providing recognition. This shall include* FSMO *activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.*

5.5 The FSMO *shall:*

a. define the organization and management structure of the FSMO*, its place in any parent organization, and the relationships between management, technical operations and support services;*

b. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of FSMO *activities;*

c. document its procedures to the extent necessary to ensure the consistent application of its FSMO *activities and the validity of the results;* and

d. (ISO/IEC 17025:2005(E), Clause 4.1.5.k) ensure that all personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

[SOURCE: ISO/IEC 17025:2005(E), Clause 4.1.5.k.]

5.6 The FSMO *shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:*

a. implementation, maintenance and improvement of the management system;

b. identification of deviations from the management system or from the procedures for performing FSMO *activities;*

c. initiation of actions to prevent or minimize such deviations;

d. reporting to FSMO *management on the performance of the management system* and any need for improvement;

e. ensuring the effectiveness of FSMO *activities*;

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.

5.7 FSMO *management shall ensure that:*

a. communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;

b. the integrity of the management system is maintained when changes to the management system are planned and implemented.

6.0 Resource requirements

6.1 General

The FSMO *shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its* FSMO *activities.*

6.2 Personnel

6.2.1 All personnel of the FSMO*, either internal or external, that could influence the* FSMO *activities shall act impartially, be competent and work in accordance with the* FSMO's *management system.*

NOTE: Written policies or procedures may demonstrate conformance to this requirement.

6.2.2 The FSMO *shall document the competence requirements for each function influencing the results of* FSMO *activities, including requirements for education, qualification, training, technical knowledge, skills, and experience.*

6.2.3 The FSMO *shall ensure that the personnel have the competence to perform* FSMO *activities for which they are responsible and to evaluate the significance of deviations. This shall also include any certifications or licenses required.*

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.

6.2.4 The management of the FSMO *shall communicate to personnel their duties, responsibilities, and authorities.*

6.2.5 The FSMO *shall have procedure(s) and retain records for:*

a. determining the competence requirements;

b. selection of personnel;

c. training of personnel;

d. supervision of personnel;

e. authorization of personnel;

f. monitoring competence of personnel.

NOTE: Including documentation of training requirements.

g. The FSMO must include safety and security as appropriate in planning the sampling event and include any concerns or additional safety 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.

6.2.6 The FSMO *shall authorize personnel to perform specific* FSMO *activities, including but not limited to, the following:*

a. development, modification, verification, and validation of methods;

b. analysis of results, including statements of conformity or opinions and interpretations;

c. report, review and authorization of results.

6.3 Facilities and environmental conditions

6.3.1 The facilities and environmental conditions shall be suitable for the FSMO *activities and shall not adversely affect the validity of results.*

NOTE: Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the FSMO *activities shall be documented.*

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.

6.3.3 The FSMO *shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.*

6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:

a. access to and use of areas affecting FSMO *activities;*

b. prevention of contamination, interference or adverse influences on FSMO *activities;*

c. effective separation between areas with incompatible FSMO *activities.*

NOTE: During field tests and while handling samples, personnel should avoid areas where activities or conditions may adversely affect results, such as temporarily storing samples near volatile liquids, or transporting test items between areas of high temperature contrast.

6.3.5 When the FSMO *performs* FSMO *activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.*

6.3.6 The person responsible for evaluating and communicating observations related to facilities and environmental condition requirements must be specified.

6.4 Equipment

6.4.1 The FSMO *shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus) that is required for the correct performance of* FSMO *activities and that can influence the results.*

NOTE 1: A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.

NOTE 2: ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.

6.4.2 When the FSMO *uses measurement equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.*

6.4.2.1. 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.

6.4.3 The FSMO *shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.*

6.4.3.1 Special calibration procedures may be necessary for measurements made by unattended equipment. The FSMO must establish and

maintain procedures for servicing unattended equipment at appropriate intervals in time in order to identify and quantify calibration drift. Measurement results that may be affected by calibration drift must be evaluated for usability based on specific acceptance criteria.

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

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.

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

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.

6.4.6 Measuring equipment shall be calibrated when:

— *the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or*

— *calibration of the equipment is required to establish the metrological traceability of the reported results.*

NOTE: Types of equipment having an effect on the validity of the reported results can include:

— *those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;*

— *those used to make corrections to the measured value, e.g. temperature measurements; and*

— *those used to obtain a measurement result calculated from multiple quantities.*

6.4.7 The FSMO *shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.*

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 at a level to ensure that drift is minimized.

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded, or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The FSMO *shall examine the effect of the defect*

or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.

6.4.11 When calibration and reference material data include reference values or correction factors, the FSMO *shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.*

6.4.12 The FSMO *shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.*

6.4.13 Records shall be retained for equipment which can influence FSMO *activities. The records shall include the following, where applicable:*

a. the identity of equipment, including software and firmware version;

b. the manufacturer's name, type identification, and serial number or other unique identification;

c. evidence of verification that equipment conforms with specified requirements;

d. the current location;

e. calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

f. documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;

g. the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;

h. *details of any damage, malfunction, modification to, or repair of, the equipment.*

6.5 Metrological traceability

6.5.1 The FSMO *shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.*

NOTE 1: In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".

NOTE 2: See Annex A for additional information on metrological traceability.

6.5.2 The FSMO *shall ensure that measurement results are traceable to the International System of Units (SI) through:*

a. *calibration provided by a competent* FSMO*; or*

NOTE 1: FSMO*s fulfilling the requirements of this document are considered to be competent.*

b. *certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or*

NOTE 2: Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

c. *direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.*

NOTE 3: Details of practical realization of the definitions of some important units are given in the SI brochure.

6.5.3 When metrological traceability to the SI units is not technically possible, the FSMO *shall demonstrate metrological traceability to an appropriate reference, e.g.:*

a. *certified values of certified reference materials provided by a competent producer;*

b. *results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.*

6.6 Externally provided products and services

6.6.1 The FSMO *shall ensure that only suitable externally provided products and services that affect* FSMO *activities are used, when such products and services:*

a. *are intended for incorporation into the* FSMO's *own activities;*

b. *are provided, in part or in full, directly to the customer by the* FSMO*, as received from the external provider;*

c. *are used to support the operation of the* FSMO*.*

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.

NOTE: Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

6.6.2 The FSMO *shall have a procedure and retain records for:*

a. defining, reviewing and approving the FSMO*'s requirements for externally provided products and services;*

b. defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

c. ensuring that externally provided products and services conform to the FSMO*'s established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer; and*

d. taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3 The FSMO shall communicate its requirements to external providers for:

a. the products and services to be provided;

b. the acceptance criteria

c. competence, including any required qualification of personnel;

d. activities that the FSMO, or its customer, intends to perform at the external provider's premises.

7.0 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 The FSMO *shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:*

a. the requirements are adequately defined, documented, and understood;

b. the FSMO *has the capability and resources to meet the requirements;*

c. where external providers are used, the requirements of 6.6 are applied and the FSMO *advises the customer of the specific* FSMO *activities to be performed by the external provider and gains the customer's approval.*

NOTE 1: It is recognized that externally provided FSMO *activities can occur when:*

- *the* FSMO *has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;*
- *the* FSMO *does not have the resources or competence to perform the activities.*

d. the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

NOTE 2: For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

7.1.2 The FSMO shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

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.

NOTE: For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

7.1.4 Any differences between the request or tender and the contract shall be resolved before FSMO *activities commence. Each contract shall be acceptable both to the* FSMO *and the customer. Deviations requested by the customer shall not impact the integrity of the* FSMO *or the validity of the results.*

7.1.5 The customer shall be informed of any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

7.1.7 The FSMO *shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the* FSMO*'s performance in relation to the work performed.*

NOTE: Such cooperation can include:

a. providing reasonable access to relevant areas of the FSMO *to witness customer-specific* FSMO *activities;*

b. preparation, packaging, and dispatch of items needed by the customer for verification purposes.

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.

7.1.8 Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the FSMO *activities.*

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 The FSMO *shall use appropriate methods and procedures for all* FSMO *activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.*

NOTE: "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the FSMO *activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).*

7.2.1.3 The FSMO shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

NOTE: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform FSMO *activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a* FSMO*. It can be necessary to provide additional documentation for optional steps in the method or additional details.*

7.2.1.4 When the customer does not specify the method to be used, the FSMO *shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended.* FSMO*-developed or modified methods can also be used.*

7.2.1.5 The FSMO *shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.*

7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.

7.2.1.7 Deviations from methods for all FSMO *activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.*

NOTE: Customer acceptance of deviations can be agreed in advance in the contract.

7.2.2 Validation of methods

7.2.2.1 The FSMO *shall validate non-standard methods,* FSMO*-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.*

NOTE 1: Validation can include procedures for sampling, handling and transportation of test or calibration items.

NOTE 2: The techniques used for method validation can be one of, or a combination of, the following:

a. calibration or evaluation of bias and precision using reference standards or reference materials;

b. systematic assessment of the factors influencing the result;

c. testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;

d. comparison of results achieved with other validated methods;

*e. inter-*FSMO *comparisons;*

f. evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

NOTE: Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

7.2.2.4 The FSMO *shall retain the following records of validation:*

a. the validation procedure used;

b. specification of the requirements;

c. determination of the performance characteristics of the method;

d. results obtained;

e. a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 The FSMO *shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.*

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.

7.3.2 The sampling method shall describe:

a. the selection of samples or sites;

b. the sampling plan;

c. The preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.

NOTE: When received into the laboratory, further handling can be required as specified in 7.4.

NOTE 2: Refer to Annex C.4 for considerations in describing the sampling method.

7.3.3 The FSMO *shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:*

a. reference to the sampling method used;

b. date and time of sampling;

c. data to identify and describe the sample (e.g. number, amount, name);

d. identification of the personnel performing sampling;

e. identification of the equipment used;

f. environmental or transport conditions;

g. diagrams or other equivalent means to identify the sampling location, when appropriate;

h. deviations, additions to or exclusions from the sampling method and sampling plan.

7.4 Handling of Test or Calibration Items

7.4.1 The FSMO *shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the* FSMO *and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.*

7.4.2 The FSMO *shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the* FSMO*. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.*

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the FSMO *shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the* FSMO *shall include a disclaimer in the report indicating which results may be affected by the deviation.*

NOTE: Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations, or sampling.

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

NOTE: For FSMOs, the requirements for “test and calibration items” apply to “field samples”. That is, these requirements apply to both FSMO “field samples” and “test and calibration items” as applicable.

7.5 Technical records

7.5.1 The FSMO *shall ensure that technical records for each* FSMO *activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the* FSMO *activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each* FSMO *activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.*

7.5.1.1 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 All records, except those which are generated and retained by automated data collection systems or equipment, must be recorded directly and promptly, and include the identity of the person performing the activity. 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.

7.5.2 The FSMO *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 retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.6 Evaluation of measurement uncertainty

7.6.1 FSMO*s shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.*

7.6.2 A FSMO *performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.*

7.6.3 A FSMO *performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.*

NOTE 1: In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the FSMO *is considered to have satisfied 7.6.3 by following the test method and reporting instructions.*

NOTE 2: For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the FSMO *can demonstrate that the identified critical influencing factors are under control.*

NOTE 3: For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.

7.7 Ensuring the validity of results

7.7.1 The FSMO *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:*

a. use of reference materials or quality control materials;

b. use of alternative instrumentation that has been calibrated to provide traceable results;

c. functional check(s) of measuring and testing equipment;

d. use of check or working standards with control charts, where applicable;

e. intermediate checks on measuring equipment;

f. replicate tests or calibrations using the same or different methods;

g. retesting or recalibration of retained items;

h. correlation of results for different characteristics of an item;

i. review of reported results;

j. intralaboratory comparisons; and

k. testing of blind sample(s).

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.

7.7.2 The FSMO *shall monitor its performance by comparison with results of other* FSMO*s, 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:*

a. participation in proficiency testing;

NOTE: ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b. participation in interlaboratory comparisons other than proficiency testing.

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.

7.7.3 Data from monitoring activities shall be analysed, used to control and, if applicable, improve the FSMO*'s activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.*

7.8 Reporting of results

7.8.1 General

7.8.1.1 The results shall be reviewed and authorized prior to release.

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

NOTE 1: For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.

NOTE 2: Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 Each report shall include at least the following information, unless the FSMO *has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:*

a. a title (e.g. "Test Report," "Calibration Certificate" or "Report of Sampling");

b. the name and address of the FSMO*;*

c. the location of performance of the FSMO *activities, including when performed at a customer facility or at sites away from the* FSMO*'s permanent facilities, or in associated temporary or mobile facilities;*

d. unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;

e. the name and contact information of the customer;

f. identification of the method used;

g. a description, unambiguous identification, and, when necessary, the condition of the item;

h. the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;

i. the date(s) of performance of the FSMO *activity;*

j. the date of issue of the report;

k. reference to the sampling plan and sampling method used by the FSMO *or other bodies where these are relevant to the validity or application of the results;*

l. a statement to the effect that the results relate only to the items tested, calibrated or sampled;

m. the results with, where appropriate, the units of measurement;

n. additions to, deviations, or exclusions from the method;

o. identification of the person(s) authorizing the report;

p. clear identification when results are from external providers.

q. Any deviation or addition to the sampling plan must be documented in detail and included in the final report. These

changes should be linked to the final results of the planned target analytes.

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.

NOTE: Including a statement specifying that the report shall not be reproduced except in full without approval of the FSMO *can provide assurance that parts of a report are not taken out of context.*

7.8.2.2 The FSMO *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* FSMO *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.*

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a. information on specific test conditions, such as environmental conditions;

b. where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

c. where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:

- *it is relevant to the validity or application of the test results;*
- *a customer's instruction so requires, or*
- *the measurement uncertainty affects conformity to a specification limit;*

d. where appropriate, opinions and interpretations (see 7.8.7);

e. additional information that may be required by specific methods, authorities, customers or groups of customers.

f. information required by the sampling method or plan.

7.8.3.2 Where the FSMO *is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.*

7.8.4 Specific requirements for calibration certificates

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:

a. the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

NOTE: According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

b. the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

c. a statement identifying how the measurements are metrologically traceable (see Annex A);

d. the results before and after any adjustment or repair, if available;

e. where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

f. where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2 Where the FSMO *is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.*

7.8.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

7.8.5 Reporting sampling – specific requirements

Where the FSMO *is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:*

a. the date of sampling;

b. unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);

c. the location of sampling, including any diagrams, sketches or photographs;

d. a reference to the sampling plan and sampling method;

e. details of any environmental conditions during sampling that affect the interpretation of the results;

f. information required to evaluate measurement uncertainty for subsequent testing or calibration.

g. information required by the sampling method or plan.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the FSMO *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.*

NOTE: Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 The FSMO *shall report on the statement of conformity, such that the statement clearly identifies:*

a. to which results the statement of conformity applies;

b. which specifications, standards or parts thereof are met or not met;

c. the decision rule applied (unless it is inherent in the requested specification or standard).

NOTE: For further information, see ISO/IEC Guide 98-4.

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the FSMO *shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The* FSMO *shall document the basis upon which the opinions and interpretations have been made.*

NOTE: It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.

7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

7.8.8 Amendments to reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording.

Such amendments shall meet all the requirements of this document.

7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

7.9 Complaints

7.9.1 The FSMO *shall have a documented process to receive, evaluate and make decisions on complaints.*

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 FSMO *shall confirm whether the complaint relates to* FSMO *activities that it is responsible for and, if so, shall deal with it. The* FSMO *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;

b. tracking and recording complaints, including actions undertaken to resolve them;

c. ensuring that any appropriate action is taken.

7.9.4 The FSMO *receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.*

7.9.5 Whenever possible, the FSMO *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 FSMO *activities in question.*

NOTE: This can be performed by external personnel.

7.9.7 Whenever possible, the FSMO *shall give formal notice of the end of the complaint handling to the complainant.*

7.10 Nonconforming work

7.10.1 The FSMO *shall have a procedure that shall be implemented when any aspect of its* FSMO *activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:*

a. the responsibilities and authorities for the management of nonconforming work are defined;

b. actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the FSMO*;*

c. an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

d. a decision is taken on the acceptability of the nonconforming work;

e. where necessary, the customer is notified and work is recalled;

f. the responsibility for authorizing the resumption of work is defined.

7.10.2 The FSMO *shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).*

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the FSMO*'s operations with its own management system, the* FSMO *shall implement corrective action.*

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.

7.11 Control of data and information management

7.11.1 The FSMO *shall have access to the data and information needed to perform* FSMO *activities.*

7.11.2 The FSMO *information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the* FSMO *information management system(s) by the* FSMO *before introduction. Whenever there are any changes, including* FSMO *software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.*

*NOTE 1: In this document "*FSMO *information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.*

NOTE 2: Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

7.11.3 The FSMO *information management system(s) shall:*

a. be protected from unauthorized access;

b. be safeguarded against tampering and loss;

c. be operated in an environment that complies with provider or FSMO *specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;*

d. be maintained in a manner that ensures the integrity of the data and information;

e. include recording system failures and the appropriate immediate and corrective actions.

7.11.4 When a FSMO *information management system is managed and maintained off-site or through an external provider, the* FSMO *shall ensure that the provider or operator of the system complies with all applicable requirements of this document.*

7.11.5 The FSMO *shall ensure that instructions, manuals and reference data relevant to the* FSMO *information management system(s) are made readily available to personnel.*

7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

8.0 Management system requirements

8.1 Options

8.1.1 General

The FSMO *shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the* FSMO *results. In addition to meeting the requirements of Clauses 4 to 7, the* FSMO *shall implement a management system in accordance with Option A or Option B.*

NOTE: See Annex B for more information.

8.1.2 Option A

As a minimum, the management system of the FSMO *shall address the following:*

— *management system documentation (see 8.2);*

— *control of management system documents (see 8.3);*

— *control of records (see 8.4);*

— *actions to address risks and opportunities (see 8.5);*

— *improvement (see 8.6);*

— *corrective actions (see 8.7);*

— *internal audits (see 8.8);*

— *management reviews (see 8.9).*

8.1.3 Option B

A FSMO *that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.*

8.2 Management system documentation (Option A)

8.2.1 FSMO *management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the* FSMO *organization.*

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the FSMO*.*

8.2.3 FSMO *management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.*

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

8.2.5 All personnel involved in FSMO *activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.*

8.3 Control of management system documents (Option A)

8.3.1 The FSMO *shall control the documents (internal and external) that relate to the fulfilment of this document.*

NOTE: In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, textbooks, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

8.3.2 The FSMO *shall ensure that:*

a. documents are approved for adequacy prior to issue by authorized personnel;

b. documents are periodically reviewed, and updated as necessary;

c. changes and the current revision status of documents are identified;

d. relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e. documents are uniquely identified;

f. the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

8.4 Control of records (Option A)

8.4.1 The FSMO *shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.*

8.4.2 The FSMO *shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The* FSMO *shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.*

NOTE: Additional requirements regarding technical records are given in 7.5.

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.

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The FSMO *shall consider the risks and opportunities associated with the* FSMO *activities in order to:*

a. give assurance that the management system achieves its intended results;

b. enhance opportunities to achieve the purpose and objectives of the FSMO*;*

c. prevent, or reduce, undesired impacts and potential failures in the FSMO *activities;*

d. achieve improvement.

8.5.2 The FSMO *shall plan:*

a. actions to address these risks and opportunities.

b. how to:

— integrate and implement these actions into its management system;

— evaluate the effectiveness of these actions.

NOTE: Although this document specifies that the FSMO *plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process.* FSMO*s can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.*

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of FSMO *results.*

NOTE 1: Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2: Opportunities can lead to expanding the scope of the FSMO *activities, addressing new customers, using new technology and other possibilities to address customer needs.*

8.6 Improvement (Option A)

8.6.1 The FSMO *shall identify and select opportunities for improvement and implement any necessary actions.*

NOTE: Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

8.6.2 The FSMO *shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system,* FSMO *activities and customer service.*

NOTE: Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

8.7 Corrective actions (Option A)

8.7.1 When a nonconformity occurs, the FSMO *shall:*

a. react to the nonconformity and, as applicable:

— take action to control and correct it;

— address the consequences;

b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

- *reviewing and analysing the nonconformity;*
- *determining the causes of the nonconformity;*
- *determining if similar nonconformities exist, or could potentially occur;*

c. implement any action needed;

d. review the effectiveness of any corrective action taken;

e. update risks and opportunities determined during planning, if necessary;

f. make changes to the management system, if necessary.

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The FSMO *shall retain records as evidence of:*

a. the nature of the nonconformities, cause(s) and any subsequent actions taken;

b. the results of any corrective action.

8.8 Internal audits (Option A)

8.8.1 The FSMO *shall conduct internal audits at planned intervals to provide information on whether the management system:*

a. conforms to:

- *the* FSMO*'s own requirements for its management system, including the* FSMO *activities;*
- *the requirements of this document;*

b. is effectively implemented and maintained.

c. The FSMO must, at least annually and in accordance with documented procedure(s), conduct internal audits of its activities.

8.8.2 The FSMO shall:

a. plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the FSMO activities concerned, changes affecting the FSMO, and the results of previous audits;

b. define the audit criteria and scope for each audit;

c. ensure that the results of the audits are reported to relevant management;

d. implement appropriate correction and corrective actions without undue delay;

e. retain records as evidence of the implementation of the audit programme and the audit results.

NOTE: ISO 19011 provides guidance for internal audits.

8.9 Management Reviews (Option A)

8.9.1 The FSMO *management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.*

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a. changes in internal and external issues that are relevant to the FSMO*;*

b. fulfilment of objectives;

c. suitability of policies and procedures;

d. status of actions from previous management reviews;

e. outcome of recent internal audits;

f. corrective actions;

g. assessments by external bodies;

h. changes in the volume and type of the work or in the range of FSMO *activities;*

i. customer and personnel feedback;

j. complaint;

k. effectiveness of any implemented improvements;

l. adequacy of resources;

m. results of risk identification;

n. outcomes of the assurance of the validity of results; and

NOTE: This includes the items identified in Section 7.7.

o. other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review shall record all decisions and actions related to at least:

a. the effectiveness of the management system and its processes;

b. improvement of the FSMO *activities related to the fulfilment of the requirements of this document;*

c. provision of required resources;

d. any need for change.

Annex A
(informative)

Metrological Traceability

A.1 General

This annex provides additional information on metrological traceability, which is an important concept to ensure comparability of measurement results both nationally and internationally.

A.2 Establishing metrological traceability

A.2.1 *Metrological traceability is established by considering, and then ensuring, the following:*

a) the specification of the measurand (quantity to be measured);

b) a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards);

c) that measurement uncertainty for each step in the traceability chain is evaluated according to agreed methods;

d) that each step of the chain is performed in accordance with appropriate methods, with the measurement results and with associated, recorded measurement uncertainties;

e) that the FSMO*s performing one or more steps in the chain supply evidence for their technical competence.*

A.2.2 *The systematic measurement error (sometimes called "bias") of the calibrated equipment is taken into account to disseminate metrological traceability to measurement results in the* FSMO*. There are several mechanisms available to take into account the systematic measurement errors in the dissemination of measurement metrological traceability.*

A.2.3 *Measurement standards that have reported information from a competent* FSMO *that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:*

— *the use of an appropriate decision rule to establish conformity;*

— *the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.*

The technical basis for this approach is that the declared conformance to a specification defines a range of measurement values, within which the true value is expected to lie, at a specified level of confidence, which considers both any bias from the true value, as well as the measurement uncertainty.

EXAMPLE: The use of OIML R 111 class weights to calibrate a balance.

A.3 Demonstrating Metrological Traceability

A.3.1 FSMO*s are responsible for establishing metrological traceability in accordance with this document. Calibration results from* FSMO*s conforming to this document provide metrological traceability. Certified values of certified reference materials from reference material producers conforming to ISO 17034 provide metrological traceability. There are various ways to demonstrate conformity with this document: third party recognition (such as an accreditation body), external assessment by customers or self-assessment. Internationally accepted paths include, but are not limited to, the following.*

a) Calibration and measurement capabilities provided by national metrology institutes and designated institutes that have been subject to suitable peer-review processes. Such peer-review is conducted under the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service.

b) Calibration and measurement capabilities that have been accredited by an accreditation body subject to the ILAC (International FSMO *Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability. Scopes of accredited* FSMO*s are publicly available from their respective accreditation bodies.*

A.3.2 *The Joint BIPM, OIML (International Organization of Legal Metrology), ILAC and ISO Declaration on Metrological Traceability provides specific guidance when there is a need to demonstrate international acceptability of the metrological traceability chain.*

Annex B
(informative)

Management Systems Options

B.1 *Growth in the use of management systems generally has increased the need to ensure that* FSMO*s can operate a management system that is seen as conforming to ISO 9001, as well as to this document. As a result, this document provides two options for the requirements related to the implementation of a management system.*

B.2 *Option A (see 8.1.2) lists the minimum requirements for implementation of a management system in a* FSMO*. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of* FSMO *activities that are covered by the management system.* FSMO*s that comply with Clauses 4 to 7 and implement Option A of Clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.*

B.3 *Option B (see 8.1.3) allows* FSMO*s to establish and maintain a management system in accordance with the requirements of ISO 9001, in a manner that supports and demonstrates the consistent fulfilment of Clauses 4 to 7.* FSMO*s that implement Option B of Clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the management system within which the* FSMO *operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the* FSMO *to produce technically valid data and results. This is accomplished through compliance with Clauses 4 to 7.*

B.4 *Both options are intended to achieve the same result in the performance of the management system and compliance with Clauses 4 to 7.*

NOTE: Documents, data and records are components of documented information as used in ISO 9001 and other management system standards. Control of documents is covered in 8.3. The control of records is covered in 8.4 and 7.5. The control of data related to the FSMO *activities is covered in 7.11.*

B.5 *Figure B.1 illustrates an example of a possible schematic representation of the operational processes of a* FSMO*, as described in Clause 7.*

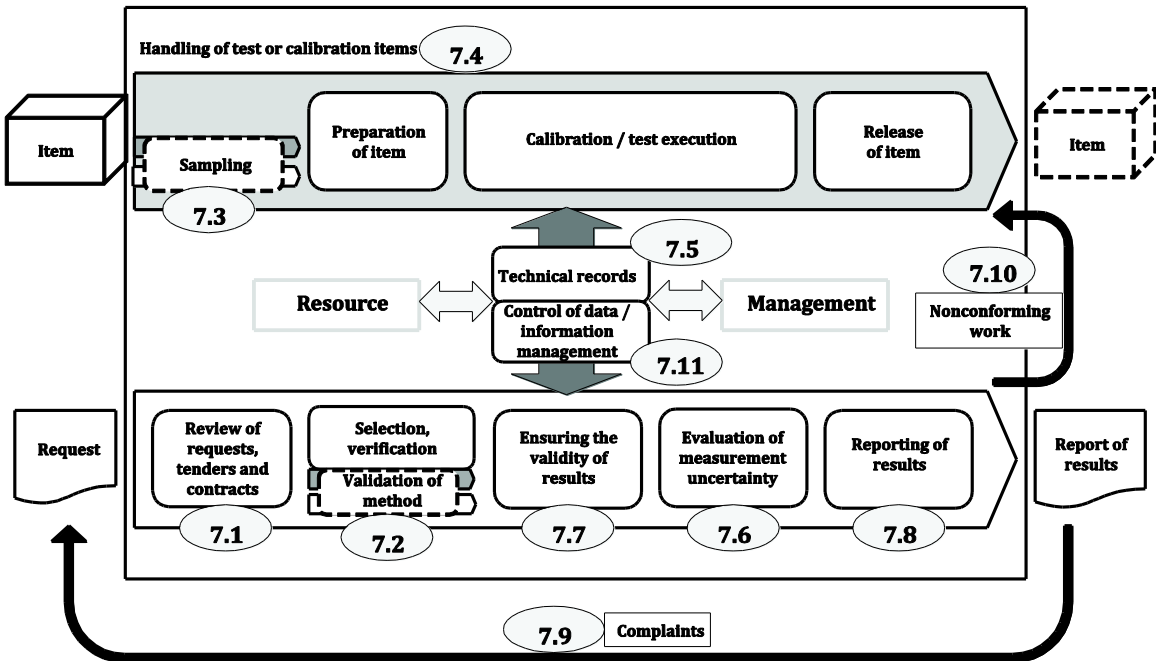

Figure B.1 — Possible schematic representation of the operational processes of a FSMO

Annex C
(informative)

Implementation Examples

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.

i. 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 landmarks.

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