



ENVIRONMENTAL LABORATORY SECTOR

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VOLUME 1

MANAGEMENT AND TESTING REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 2: Quality Management System Requirements

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FOREWORD

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body, interested in a subject for which a technical committee has been established, has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. In the field of conformity assessment, ISO and the International Electrotechnical Commission (IEC) develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 supersedes and replaces preceding documents in whole or in part. It conforms to ISO/IEC 17025:2017(E) and includes clauses from that international standard. The ISO/IEC clauses are provided *in italics*. Additional TNI text is provided in a normal font.

This Standard may be used by any organization that wishes to implement a program for the accreditation of environmental laboratories.

Standard Revision History

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Introduction

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

This document requires the laboratory 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 laboratory is responsible for deciding which risks and opportunities need to be addressed.

The use of this document will facilitate cooperation between laboratories 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 laboratories 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, MODULE 2

QUALITY MANAGEMENT SYSTEM REQUIREMENTS

1.0 SCOPE

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

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

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

1.1 Introduction

This Standard includes requirements applicable to environmental laboratories.

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 environmental testing. The *ISO/IEC* clauses are provided in *italics*; added TNI clauses are presented in a non-italicized font.

Each laboratory must have a quality management system. The laboratory's quality management system is the means by which an organization ensures the quality of the products or services it provides and includes a variety of management, technical, and administrative elements. It provides the framework for planning, implementing, assessing, and improving work performed by an organization to provide the client with data of known and documented quality.

This Standard contains the essential elements required to establish a quality management system to support environmental testing activities. It defines the requirements needed to demonstrate a laboratory's technical competence, commitment to producing reliable and trustworthy data, system for ensuring data quality, and processes for constant improvement in laboratory operations. This Standard covers testing activities using reference methods, non-reference methods, reference methods used outside their intended scope, and laboratory developed methods.

Where regulatory or other requirements are applicable, these must be considered, and the most stringent 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.

Some clauses in this Standard contain notes. The notes are used to explain a particular requirement or to provide clarifying examples. The notes do not supersede or modify requirements of the Standard and do not convey any additional requirements.

If a laboratory fails to meet the requirements of this Standard, an accreditation body may choose to deny, suspend, withdraw, or reduce the laboratory's accreditation in full or in part.

2. 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

3. 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: Definitions related to this Standard, which are used differently or do not exist in the above references, are defined below in 3.10 through 3.47. Additional definitions may also be found in the following TNI Volume 1 Modules:

- Volume 1, Module 1: Proficiency Testing Requirements
- Volume 1, Module 3: Asbestos Testing Requirements
- Volume 1, Module 4: Chemical Testing Requirements
- Volume 1, Module 5: Microbiological Testing Requirements
- Volume 1, Module 6: Radiochemical Testing Requirements
- Volume 1, Module 7: Whole Effluent Toxicity Testing Requirement

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).

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 laboratory” 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”.]

¹ Also known as JCGM 200.

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.]

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.

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 Accuracy: The degree of agreement between an observed value and an accepted reference value.

3.11 Analyst: An individual who is authorized to perform a testing method.

3.12 Analyte: A substance, organism, physical parameter, property, or chemical constituent(s) for which an environmental sample is being tested.

3.13 Annual: A period of 12 months, not to exceed 13 months.

3.14 Audit: A systematic and independent examination to determine whether quality and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives.

3.15 Batch: Environmental samples that are prepared and/or analyzed together. A **preparation batch** is composed of environmental samples of the same matrix, prepared by the same process and personnel; using the same lot(s) of reagents; and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various matrices.

3.16 Bias: The systematic error in a measuring system that causes the output results to trend in one direction from the true value (i.e., a skewed dataset distribution). Bias can be either positive or negative.

3.17 Calibration: A process to establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

1) In calibration of support equipment, the values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI).

2) In calibration of analytical equipment, the values realized by standards are typically established through the use of reference materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been verified to meet specifications.

3.18 Calibration Standard: A substance or reference material used for calibration.

3.19 Correction: Action to eliminate a detected nonconformity.

3.20 Corrective Action: An action taken by the laboratory to eliminate or correct the cause(s) of a nonconformity and to prevent recurrence.

3.21 Customer: A person or organization internal or external to the laboratory that requests services from the laboratory.

- 3.22 Data Integrity:** The condition that exists when data are sound, correct, complete and accurately reflect activities and requirements.
- 3.23 Demonstration of Capability:** A record that shows the competency of technical personnel to generate results by a specific method within defined acceptance criteria for precision and accuracy.
- 3.24 Document (n.):** Written component of the laboratory management system (e.g., policy, procedure, instruction, form template, etc.).
- 3.25 Finding:** Conclusions based on evidence collected during an assessment or internal audit against established criteria. Findings can indicate either conformity or nonconformity with criteria or opportunities for improvement.
- 3.26 Holding Time:** The maximum allowed time from when a sample is collected or extracted until it must be extracted or analyzed.
- 3.27 Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample, etc.):** A QC sample of the same matrix as the preparation batch that is free from the analytes of interest and has either been spiked with verified known amounts of analytes or purchased to contain certified amounts of analytes and is taken through all sample preparation and analytical steps of the procedure.
- 3.28 Lot:** A definite amount of material produced during a single manufacturing cycle and intended to have uniform character and quality.
- 3.29 Matrix:** The substrate of a test item. These matrix definitions are used for purposes of batch and quality control requirements:
- **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.
 - **Biological Tissue:** Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples must be grouped according to origin.
 - **Drinking Water:** Any aqueous sample that has been designated as a potable or potential potable water source.
 - **Solids and Chemical Materials**
 - Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.
 - Non-Aqueous Liquid: Any organic liquid with <15% settleable solids.
 - Solids: Includes soils, sediments, sludges and other matrices with >15% settleable solids.
 - **Non-Potable Water**
 - 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.
 - Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other saltwater source such as the Great Salt Lake.
- 3.30 Mobile Facility:** A portable enclosed structure within which testing is performed by analysts. A defined space that is not fixed at one location, operating under the control of a defined quality management system.

NOTE 1: Examples include but are not limited to trailers, vans, and skid-mounted structures configured to house testing equipment and personnel.

NOTE 2: A mobile laboratory is equivalent to a mobile facility.

- 3.31 Nonconformity:** An event that demonstrates failure to meet a requirement in a TNI standard, policy, or procedure.
- 3.32 Precision:** A data quality indicator that assesses the degree of variation within a set of observations or measurement of the same property obtained under similar conditions.
- 3.33 Preservation:** Any conditions under which a sample must be kept in order to maintain chemical and/or biological integrity prior to analysis.
- 3.34 Procedure:** Written instructions detailing the performance of a task, process, or other laboratory activity.
- 3.35 Quality Assurance:** An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a product or service is of the type and quality needed and expected by the client.
- 3.36 Quality Control:** The overall system of technical activities that measures the attributes and performance of a product or service against defined standards to verify that they meet the stated requirements.
- 3.37 Quality Control Sample:** A sample used to assess the performance of all or a portion of the method.
- 3.38 Quality Management System:** A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its products, and services. The system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC) activities.
- 3.39 Quarterly:** A period of 3 months, not to exceed 4 months, and occurring 4 times annually.
- 3.40 Raw Data:** The records generated during sampling and analysis. These records include, but are not limited to, field notes, electronic data, magnetic tapes, QC sample results, printouts of chromatograms, instrument outputs, and handwritten records.
- 3.41 Reference Material or Reference Standard:** Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.
- 3.42 Reference Method:** A published method issued by an organization generally recognized as competent to do so. (When the ISO/IEC 17025:2017 language refers to a “standard method”, that term is equivalent to reference method).
- 3.43 Sampling:** Activity related to obtaining a representative test item according to a procedure.
- 3.44 Selectivity:** The ability to analyze, distinguish, and determine a specific analyte.
- 3.45 Technology:** A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.
- 3.46 Test Item (e.g., sample):** The sample received, subsamples, or any derivative sample that is subjected to testing.
- 3.47 Traceability:** The ability to reconstruct the history of a test item by means of records. For calibration, this is metrological traceability.

4 General requirements

4.1 Impartiality

- 4.1.1 *Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.*
- 4.1.2 *The laboratory management shall be committed to impartiality.*
- 4.1.3 *The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.*
- 4.1.4 *The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.*

NOTE A relationship that threatens the impartiality of the laboratory 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 laboratory shall be able to demonstrate how it eliminates or minimizes such risk.*
- 4.1.6 The laboratory must establish and maintain a data integrity system to detect and deter improper, inappropriate, or prohibited actions. The system must address data integrity procedures, data integrity training, periodic in-depth data monitoring, and data integrity investigation.
- 4.1.6.1 The laboratory must not engage in any prohibited actions. See Annex C for information on prohibited actions.
- 4.1.6.2 Data integrity procedures must be approved by management.
- 4.1.6.3 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 including the prohibited actions in Annex C;
 - 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 laboratory and a process whereby laboratory 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.
- 4.1.6.4 Data integrity training must be provided as a formal part of new employee orientation and must also be provided annually for all current employees.

- 4.1.6.5 The laboratory must have records demonstrating when personnel participate in data integrity training and that they understand their obligations related to data integrity.
- 4.1.6.6 Data integrity training must include the following:
- a) organizational mission and its relationship to the critical need for honesty;
 - b) the relationship of laboratory-generated data to public health concerns and the need for known and documented quality;
 - c) data integrity procedures (4.1.6.3);
 - d) how and when to report data integrity issues;
 - e) requirements for keeping accurate analytical records (7.5);
 - f) requirements for reporting qualified data;
 - g) requirements to refrain from improper, inappropriate, and prohibited actions; and
 - h) potential consequences of engaging in improper, inappropriate or prohibited actions:
 - i. Immediate termination
 - ii. Debarment
 - iii. Civil or criminal prosecution
- 4.1.6.7 Periodic In-depth Data Monitoring
- a) In-depth data monitoring must include a review and evaluation of records related to the data generation process, including items such as preparation, equipment, software, calculations, and quality controls. This monitoring must be used to determine if the laboratory uses appropriate data handling activities that align with the laboratory's data integrity procedures.
 - b) The laboratory must define the frequency and a schedule of items to be reviewed for conducting periodic in-depth data monitoring in the data integrity procedures.
 - c) Records of in-depth data monitoring must be maintained to demonstrate compliance with the schedule.
- 4.1.6.8 Data Integrity Investigation
- a) If a data integrity concern is reported, the laboratory management must initiate an investigation and must assign appropriate personnel with technical and quality assurance (QA) expertise to perform the investigation.
 - b) All investigations resulting from data integrity issues should be conducted in a confidential manner until they are completed. These investigations must be recorded, as well as any notifications made to clients receiving any affected data.

4.2 Confidentiality

- 4.2.1 *The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory 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 laboratory 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 laboratory 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 laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.*
- 4.2.4 *Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.*

4.3 Laboratory Responsibilities to the Accreditation Body

- 4.3.1 A laboratory accredited or seeking accreditation to this Standard must commit to meeting the requirements of this Standard, as well as requirements of the accreditation body from whom it seeks accreditation. It must cooperate with the accreditation body to verify its fulfillment of the requirements including providing access to laboratory facilities, personnel, equipment, documents, records, and witnessing of laboratory activities upon request.
- 4.3.1.1 When laboratory activities are performed at a client's site, the laboratory must arrange access for the accreditation body's assessment team for conducting on-site assessment activities.
- 4.3.2 The laboratory must only claim accreditation for the fields of accreditation granted on its approved scope. It must comply with the accreditation body's policy for the use of the accreditation symbol, making accreditation claims, and references to its accreditation status in communication media.
- 4.3.3 The laboratory must inform the accreditation body of significant changes relevant to its accreditation and to assist in the investigation and resolution of any accreditation-related complaints referred to it by the accreditation body.
- 4.3.4 The laboratory must not use its accreditation in such a way that brings the accreditation body into disrepute. The laboratory must not make misleading statements about its accreditation or imply endorsement of individuals, products, or services by the accreditation body.
- 4.3.5 The laboratory must inform affected clients of suspension, reduction or withdrawal of its accreditation within laboratory-defined timelines and must immediately discontinue referencing that accreditation.
- 4.3.6 The laboratory must pay fees as determined by the accreditation body.

4.4 Additional Requirements

- 4.4.1 If more stringent requirements are included in a method, regulation, program, or project, the laboratory must demonstrate conformance with such requirements. If it is not clear which requirements are more stringent, the requirement from the method or regulation is to be followed.
- 4.4.2 The laboratory must comply with requirements outlined in applicable TNI Volume 1 Modules.

5 Structural requirements

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

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

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

- 5.3 *The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.*
- 5.4 *Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory 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 laboratory shall:*
- a) *define the organization and management structure of the laboratory, 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 laboratory activities;*
 - c) *document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.*
- 5.5.1 The laboratory must have a procedure for how roles and responsibilities are filled when personnel responsible for the laboratory, the review and release of analytical data, or the quality management system, are unable to fulfill their responsibilities. The procedure must define:
- 5.5.1.1 the work that must be halted when those personnel are unable to fulfil responsibilities,
 - 5.5.1.2 the processes that may continue, and for how long, when those personnel are unable to fulfill responsibilities,
 - 5.5.1.3 the duration for which designated alternates may perform tasks, and
 - 5.5.1.4 any relevant qualifications for designated alternates.
- 5.6 *The laboratory 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 laboratory activities;*
 - c) *initiation of actions to prevent or minimize such deviations;*
 - d) *reporting to laboratory management on the performance of the management system and any need for improvement;*
 - e) *ensuring the effectiveness of laboratory activities.*
- 5.6.1 The laboratory must have a Quality Specialist(s) (however named) who:
- 5.6.1.1 functions independently from laboratory activities for which they have quality assurance oversight;
 - 5.6.1.2 has training and/or experience in the laboratory's quality management system;
 - 5.6.1.3 has a general knowledge of the analytical methods for which data review is performed;
 - 5.6.1.4 has the authority to manage nonconforming work and initiate the actions specified in 7.10.1b); and

- 5.6.1.5 is responsible for:
- a) coordinating quality activities;
 - b) evaluating data objectively and performing assessments without undue outside or managerial influence;
 - c) maintaining the quality manual;
 - d) arranging for or conducting internal audits as per Section 8.8;
 - e) initiating the actions specified in 7.10.1 b);
 - f) notifying laboratory management of deficiencies in the quality management system; and
 - g) monitoring nonconforming work and corrective actions.
- 5.6.3 The laboratory must have a Technical Specialist(s) (however named) to provide technical guidance to laboratory personnel for all work associated with the laboratory's scope of accreditation. The laboratory must clearly define its technical structure and how Technical Specialist responsibilities align with the laboratory's scope. A laboratory may have one or more Technical Specialists that may also hold additional primary job responsibilities. Annex C provides examples of how a laboratory may define this structure.
- 5.6.3.1 Technical Specialist(s) must:
- a) ensure laboratory activities related to the generation of analytical data and test results, including but not limited to method development and validation, procedure development, sample preparation, instrument calibration, sample analysis, quality control, and data reduction, comply with the laboratory's quality management system and with relevant regulatory requirements for which the data will be used and
 - b) have the authority to halt work, repeat work, withhold reports, and resume work as part of the management of nonconforming work, as defined in 7.10.
- 5.6.4 A Technical Specialist may be appointed across multiple laboratories, subject to approval by the primary accreditation body. Requests for approval must include a plan outlining how the Technical Specialist will meet the requirements in section 5.6.3 across multiple locations. Records of the accreditation body's approval, including the approved plan, must be retained.
- 5.6.5 If a Technical Specialist is unable to fulfill the duties in sections 5.6.3 a) and b) for fifteen consecutive calendar days:
- 5.6.5.1 a designated alternate must be appointed per the procedure in 5.5.1 and assume the responsibilities of the Technical Specialist or
 - 5.6.5.2 work in that area of responsibility must be halted or subcontracted to another qualified laboratory.
- 5.6.6 The designated alternate is not required to meet the same qualification requirements of a Technical Specialist but must meet the requirements the laboratory defines in the procedure described in 5.5.1.
- 5.6.7 When a designated alternate assumes the responsibilities of a Technical Specialist, the laboratory must notify the primary accreditation body within sixty days if a qualified Technical Specialist does not resume the responsibilities. The notification must be in writing for accreditation body approval and must include a plan with a timeline for appointing a qualified Technical Specialist.

NOTE: If approval is not granted the laboratory accreditation may be suspended.

5.6.8 The laboratory must define how the responsibilities of the Technical Specialist and the Quality Specialist are segregated when they are filled by the same person.

5.7 *Laboratory 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; and*
- c) *the importance of statutory and regulatory requirements is communicated.*

6 Resource requirements

6.1 General

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

6.2 Personnel

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

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

6.2.2.1 Technical Specialist (however named) Qualifications

The laboratory must retain a record showing that each Technical Specialist meets the requirements of 6.2.2.2 or exceptions of 6.2.2.3. Where coursework is required, the laboratory must retain records that show courses were successfully completed (e.g., certificate, letter, transcript).

6.2.2.2 A Technical Specialist must meet one of the combinations of education and experience qualifications listed below. Experience must be in the area of responsibility for the Technical Specialist. If the Technical Specialist is responsible for Microbiology (TNI Volume 1 Module 5) or Radiochemistry (TNI Volume 1 Module 6), completion of a relevant technical course is required, which may or may not be part of the educational qualifications listed below. Further information and examples regarding appropriate courses and experience can be found in Annex C.

- a) a master's or doctoral degree in a STEM (science, technology, engineering, or mathematics) field and one year of experience,
- b) a bachelor's degree in a STEM field and two years of experience,
- c) an associate's degree in a STEM field and three years of experience, or
- d) four college level STEM courses and four years of experience. A TNI credential applicable to the areas of the Technical Specialist responsibilities can be substituted for the college level STEM courses. Vendor courses with certificates and a minimum of 3 CEUs may be considered equivalent to a college level STEM course.

6.2.2.3 Technical Specialist Qualification Options for Exempting Education and Experience Requirements

- a) Any person who was formerly recognized as a Technical Specialist based on requirements or exceptions in previous revisions of this Standard qualifies as a Technical Specialist for the

same areas of responsibility at any accredited laboratory. Appropriate records must be available to show previous recognition as a Technical Specialist.

- b) A water or wastewater operator trained in laboratory procedures as part of their certification and who has completed two years of laboratory experience qualifies as a Technical Specialist at that facility (or another facility of equivalent or smaller size and scope) for the testing required for the facility by their state regulator or Control Authority.
- c) An accreditation body may provide an exemption other than those listed in a) and b). The laboratory must receive the exemption from each of its accreditation bodies. The laboratory must retain the record of the exemption for the same duration required for the retention of the data generated during the employment of that Technical Specialist.

6.2.3 *The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.*

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

6.2.5 *The laboratory 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.*

6.2.6 *The laboratory shall authorize personnel to perform specific laboratory 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 laboratory 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 laboratory activities shall be documented.*

6.3.3 *The laboratory 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 laboratory activities;*
 - b) *prevention of contamination, interference or adverse influences on laboratory activities; and*
 - c) *effective separation between areas with incompatible laboratory activities.*
- 6.3.5 *When the laboratory performs laboratory 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.*

6.4 Equipment

- 6.4.1 *The laboratory 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 laboratory 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.

- 6.4.1.1 *Analytical equipment is equipment that produces an output that contributes directly to a reportable result. Support equipment does not directly produce a reportable result but rather supports laboratory operations. Depending on the intended use of the data, equipment may be considered support equipment in some instances, and analytical equipment in others. Additional requirements for support equipment are listed in 6.4.6.1 – 6.4.6.5.*
- 6.4.1.2 *Calibration and/or verification requirements for support equipment are included in this Section while requirements for analytical equipment calibration are included in TNI Volume 1 Modules 3-7 (Asbestos, Chemistry, Microbiology, Radiochemistry and Whole Effluent Toxicity).*
- 6.4.1.3 *Independent verification, as described in section 6.4.6.2, is not required for support equipment incorporated into analytical equipment.*
- 6.4.2 *When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.*
- 6.4.3 *The laboratory 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.*
- 6.4.4 *The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.*
- 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.*
- 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;*

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

- 6.4.6.1 Support equipment may include, but is not limited to: balances, weights, ovens, refrigerators, freezers, incubators, water baths, temperature measuring equipment (including thermometers and thermistors), thermal/pressure sample preparation equipment, and mechanical volumetric dispensing equipment (such as pipettes, burettes, dilutors and dispensers).
- 6.4.6.2 All support equipment must be calibrated or verified, using a recognized National Metrology Institute, such as the National Institute of Standards and Technology, traceable reference when available. A table of the verification and calibration frequency requirements is in 6.4.6.5.
- 6.4.6.3 On each day ovens, refrigerators, freezers, incubators and water baths are used, the temperature must be recorded. The acceptability for use or continued use must be according to the needs of the analysis or application for which the equipment is being used.
- 6.4.6.4 Verification is required when quantitative results are dependent on accuracy. The laboratory must ensure verification is completed as listed in Table 1. A certificate that demonstrates verification was completed in compliance with Table 1 may be used.

6.4.6.5 **Table 1 - Support Equipment – Verification and Calibration Requirements and Frequencies**

Equipment	Activity	Frequency
Table 1 – 1 of 2		
a) Balances	Verify the range of use.	Daily before use
b) Balances	Calibration	Annually
c) Gastight syringes and Class A glassware Note: plastic labware identified as Class A does not meet Class A glassware specifications.	Exempt from verification requirements beyond what is stated in Sections 6.6.1 and 6.6.2.	Not applicable

	Equipment	Activity	Frequency
	Table 1 - 2 of 2		
d)	Mechanical Volumetric Dispensing Equipment	<p>If used at one volume, verify the volume of use.</p> <p>If used at more than one volume, verify at volumes bracketing the range of use and at the mid-point.</p>	Prior to first use and quarterly
e)	Single-use, non-Class A volumetric equipment	<p>If used at one volume, verify the volume of use.</p> <p>If used at more than one volume, verify at volumes bracketing the range of use.</p> <p>Verification may be performed by comparison to a certificate that verifies the volume of use or the volumes bracketing the range of use, as applicable.</p>	Once per lot prior to or in conjunction with its first use
f)	All other volumetric support equipment	<p>If used at one volume, verify the volume of use.</p> <p>If used at more than one volume, verify at volumes bracketing the range of use.</p> <p>Verification may be performed by comparison to a certificate that verifies the volume of use or the volumes bracketing the range of use, as applicable.</p>	Prior to or in conjunction with its first use
g)	Temperature Measuring Equipment – Working	<p>Verification or Calibration</p> <p>If used $\leq 10^{\circ}\text{C}$ range, single-point within range of use.</p> <p>If used $> 10^{\circ}\text{C}$ range, bracket range of use.</p>	Annually
h)	Weights - Working	Verification or Calibration	Annually

	Equipment	Activity	Frequency
i)	Monitoring of other equipment requiring temperature checks	Evaluate against reference method or laboratory requirements, whichever is more stringent.	Each day before use, or as required by reference method, whichever is more frequent.
j)	All other support equipment	Verification or Calibration If used at one measurement, use a single-point. If used at more than one measurement, bracket the range of use.	Annually

6.4.7 *The laboratory 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 laboratory shall establish a procedure for maintaining the calibration program, addressing at least the following:

- a) specification for acceptability, including the use of any necessary correction factors,
- b) calibration frequency of reference standards of measurement in accordance with the metrological traceability requirements described in 6.5.2, and
- c) use of reference standards exclusively for verification of working standards.

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 laboratory 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 laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.*

6.4.12 *The laboratory 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 laboratory 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; and*
- h) *details of any damage, malfunction, modification to, or repair of, the equipment.*

6.5 Metrological traceability

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

- a) *calibration provided by a competent laboratory; or*

NOTE 1 Laboratories 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 laboratory 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 laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:*

- a) *are intended for incorporation into the laboratory's own activities;*
- b) *are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;*
- c) *are used to support the operation of the laboratory.*

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 laboratory shall have a procedure and retain records for:*

- a) *defining, reviewing and approving the laboratory'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;*
 - i) *When the laboratory subcontracts work that requires TNI accreditation, this work must be placed with a laboratory accredited to this Standard for the tests to be performed.*
 - ii) *Where the laboratory arranges for an external sampling organization to be used, the laboratory must have procedures to ensure that the experience and technical competence of the samplers are sufficient for sampling activities and that they comply with the relevant clauses of this document and other sampling documents as required (i.e., sampling plans, sampling methods, regulatory documents, etc.). Use of a National Environmental Field Activities Program (NEFAP) accredited Field Sampling Measurement Organization (FSMO) meets the requirements of this Standard.*
- c) *ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;*
- d) *taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.*

6.6.3 *The laboratory shall communicate its requirements to external providers for:*

- a) *the products and services to be provided;*
- b) *the acceptance criteria;*
- c) *competence, including any required qualification of personnel;*
- d) *activities that the laboratory, or its customer, intends to perform at the external provider's premises.*

6.6.4 Additional Requirements for Reference Materials and Reagents (including Media)

6.6.4.1 The laboratory shall have a procedure for the purchase, receipt and storage of reference materials and reagents (including media) used for laboratory activities.

- 6.6.4.2 The laboratory must retain records for purchased reference materials and reagents (including media) that include, where available, the manufacturer/vendor, the manufacturer's Certificate of Analysis, the lot number, the expiration date, the date of receipt, and the manufacturer's recommended storage conditions.
- If an expiration date is provided by the manufacturer or vendor, it must be recorded on the original container.
 - If an expiration date is not provided by the manufacturer or vendor, then one is not required.
- 6.6.4.3 The laboratory must have procedures and retain records for the preparation and storage of standards and reagents (including media).
- The laboratory must maintain records for these preparations that include an unequivocal link to the equipment used, products used, mass, volumes, and/or quantities used, date of preparation, expiration date, and preparer's initials.
 - All containers of these preparations must bear an expiration date and identifier with an unequivocal link to the preparation records.
- 6.6.4.4 Purchased or prepared reference materials, standards, and reagents (including media) must not be used beyond their expiration dates unless verified for acceptable use by the laboratory. The laboratory must have a procedure for and maintain records of the verification. TNI Volume 1 Modules 3-7 may have different or additional requirements for the use of reference materials and reagents (including media) beyond their expiration date.

7 Process requirements

7.1 Review of requests, tenders and contracts

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

- the requirements are adequately defined, documented and understood;*
- the laboratory has the capability and resources to meet the requirements;*
- where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;*
 - The laboratory must maintain a record of the customer's approval.

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

- the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;*
 - the laboratory does not have the resources or competence to perform the activities.*
- 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 laboratory 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 laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory 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 laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.*

NOTE Such cooperation can include:

- a) *providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;*
- b) *preparation, packaging, and dispatch of items needed by the customer for verification purposes.*

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 laboratory activities.*

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 *The laboratory shall use appropriate methods and procedures for all laboratory 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 laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).*

7.2.1.3 *The laboratory 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 laboratory 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 laboratory. 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 laboratory 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. Laboratory-developed or modified methods can also be used.*
- 7.2.1.5 *The laboratory 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 laboratory 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 laboratory shall validate non-standard methods, laboratory-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.*

- a) *The laboratory must use one or more of the techniques listed in Note 2.*

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) *interlaboratory 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 laboratory 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 laboratory 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.*

7.3.2 *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.

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

- 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.*

7.3.3.1 *The sample description must include the matrix.*

7.3.3.2 *Where sampling is not performed by the laboratory, sampling records provided must be retained.*

7.3.4 *Use of NEFAP accredited FSMO meets these requirements.*

7.4 Handling of test or calibration items

7.4.1 *The laboratory 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 laboratory 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.*

7.4.1.1 The procedure must address the following:

- a) sample receipt acceptance criteria, including sampling record requirements in 7.3.3
- b) proper sample labeling to include indelible unambiguous identification;
- c) use of appropriate test item containers;
- d) verification of preservation;
- e) adherence to specified holding times;
- f) verification of sufficient quantity;
- g) actions to be taken when test items show signs of damage, contamination, or inadequate collection or preservation;
- h) the identification of any test item(s) that do not meet the above requirements; and
- i) the disposal of test items.

7.4.1.2 If a customer requires legal chain of custody procedures and the laboratory accepts the samples, the laboratory must have a legal chain of custody procedure describing how it will ensure chronological traceability of custody of a test item from collection to disposal. The procedure must describe how the custody of test items is recorded during possession and handling within the laboratory to ensure the location and possession of the test item can be historically reconstructed.

Samples are considered to be under custody when they are:

- a) In the physical possession of laboratory staff;
- b) Within view of laboratory staff, after being in their physical possession; or
- c) Stored in a secured, restricted, and defined storage location within the laboratory. Note: A general description of "laboratory" is not a defined storage location.

7.4.2 *The laboratory 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 laboratory. 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.*

7.4.2.1 The laboratory must assign each test item an unambiguous identifier that is linked to the following:

- a) date and time of collection,
- b) date and time of laboratory receipt,
- c) client/project name,
- d) field identifier,

- e) requested analyses, and
- f) identification of the person receiving the test item

NOTE: The placement of the unambiguous identifier on the test item container is not considered a permanent record.

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 laboratory 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 laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.*

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

7.4.4.1 Test items must be stored in a manner that prevents cross contamination. Test items must be stored away from all standards, reagents, and food.

7.5 **Technical records**

7.5.1 *The laboratory shall ensure that technical records for each laboratory 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 laboratory 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 laboratory 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.*

NOTE: The phrase “enable the repetition” is equivalent to “enabling historical reconstruction” of the laboratory activity.

7.5.1.1 Technical records must also include any of the following that are applicable:

- a) records associated with samples received;
- b) raw data for calibrations, samples and quality control measurements, including analyst worksheets and data output records;
- c) a written description or reference to the specific method used, which includes a description of the specific computational steps used to obtain the reported analytical value;
- d) unambiguous test item identifier;
- e) date of analysis;
- f) time of analysis is required if the holding time is seventy-two (72) hours or less;
- g) instrumentation identification and instrument operating conditions/parameters (or reference to such data);
- h) manual calculations;
- i) sample preparation, including cleanup, separation procedures, incubation periods, unambiguous identifier, volumes, weights, instrument reports, meter readings, calculations, reagents;
- j) test results;

- k) standard and reagent origin, receipt, preparation, and use;
 - l) calibration criteria, frequency and acceptance criteria;
 - m) data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
 - n) quality control evaluation against acceptance criteria;
 - o) electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;
 - p) proficiency test results;
 - q) demonstration of capability for each analyst; and
 - r) names, initials, and signatures for all individuals who sign or initial any laboratory record.
- 7.5.1.2 All records must be legible and indelible.
- 7.5.1.3 The laboratory must have a procedure to ensure that customer records are maintained or transferred according to contractual, regulatory, and state legal requirements in the event that the laboratory is no longer obligated to maintain customer records (i.e., transfer of ownership, loss of business, etc.).
- 7.5.2 *The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.*
- 7.5.2.1 Amendments due to reasons other than transcription errors must specify the reason for the amendment.
- 7.5.2.2 Requirements for amendments to technical records also apply to changes to the original output of the software such as manual integrations and elimination of “false positives” performed by laboratory personnel. These changes to the original output of the software must be reviewed by technically qualified personnel. Records of this review must be maintained.

7.6 Evaluation of measurement uncertainty

- 7.6.1 *Laboratories 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 laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.*
- 7.6.3 *A laboratory 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 laboratory 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 laboratory 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 laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:*

- 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;*
- k) testing of blind sample(s).*

7.7.2 *The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:*

- 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.*

7.7.3 *Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory'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.*

7.7.3.1 *The laboratory must have procedures for the development of acceptance/rejection criteria where no pre-defined method or regulatory criteria exist.*

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 laboratory 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 laboratory;*
- c) *the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory'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 laboratory activity;*
- j) *the date of issue of the report;*
- k) *reference to the sampling plan and sampling method used by the laboratory 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.*

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

q) data associated with nonconforming work, if reported, must be appropriately identified.

7.8.2.2 *The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.*

7.8.3 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) *time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to seventy-two (72) hours;*
- g) *clear indication of the basis on which results are reported, such as dry weight or wet weight, if samples are not reported on an as-received basis;*
- h) *clear identification of the status of accreditation for results, when claims of accreditation to this Standard are made.*

7.8.3.2 *Where the laboratory 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 laboratory 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 laboratory 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.*

7.8.6 Reporting statements of conformity

7.8.6.1 *When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.*

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 laboratory 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 laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory 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 laboratory 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 laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.*

7.9.3 *The process for handling complaints shall include at least the following elements and methods:*

- a) *description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;*
- b) *tracking and recording complaints, including actions undertaken to resolve them;*
- c) *ensuring that any appropriate action is taken.*

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

7.9.5 *Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.*

7.9.6 *The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.*

NOTE This can be performed by external personnel.

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

7.10 Nonconforming work

7.10.1 *The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory 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 laboratory;*

NOTE: Withholding reports includes withholding test values however presented or transmitted.

- 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 laboratory 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 laboratory's operations with its own management system, the laboratory shall implement corrective action.*

7.11 Control of data and information management

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

7.11.2 *The laboratory 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 laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.*

NOTE 1 *In this document "laboratory 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 laboratory 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 laboratory 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 laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.*

7.11.5 *The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory 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 Management system requirements

8.1 Options

8.1.1 General

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

NOTE See **Annex B** for more information.

8.1.1.1 *Option B is not allowed for environmental laboratories.*

8.1.2 Option A

As a minimum, the management system of the laboratory 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 laboratory 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 *Laboratory 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 laboratory organization.*

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

8.2.3 *Laboratory 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 laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.*
- 8.2.5.1 The laboratory must have a quality manual. The quality manual must contain:
- a) document title;
 - b) laboratory's full name and address;
 - c) name, title, location (if different from the address in 8.2.5.1 b)), and contact information for the individual(s) responsible for the laboratory; and
 - d) identification of all major organizational units which are to be covered by this quality manual and the effective date of the revision; and
- 8.2.5.2 The quality manual must include or make reference to the following at a minimum:
- a) procedure(s) for addressing impartiality and confidentiality requirements defined in 4.1 and 4.2;
 - b) the identity of management that has overall responsibility for the laboratory, as per 5.2,
 - c) the range of laboratory activities for which it conforms with this document as per 5.3 and 5.4, including the identification of any activities not performed at its permanent facilities;
 - d) the organization and management structural requirements, including its place in any parent organization, as per 5.5 a) and include relevant organization chart(s);
 - e) how the laboratory management communicates management system effectiveness as per 5.7 a);
 - e) how the laboratory management ensures the integrity of the management system when changes are made as per 5.7 b);
 - f) roles and authorities for personnel performing laboratory activities per 5.5, 5.6, and 6.2;
 - g) procedure(s) for personnel requirements as per 6.2.5;
 - h) the measures used to control facilities and environmental conditions per 6.3;
 - i) procedures for meeting the equipment requirements of 6.4;
 - j) procedures for meeting metrological traceability requirements of 6.5;
 - k) procedures for meeting the externally provided products and services requirements of 6.6;
 - l) procedures for the review of requests, tenders and contracts as per 7.1;
 - m) procedures for the selection, verification, and validation of methods as per 7.2;
 - n) when the laboratory is responsible for sampling, procedures for meeting requirements as per 7.3;
 - o) procedures for handling the test or calibration items, and for subsampling when not defined by the reference test method, as per 7.4;
 - p) procedures for technical records as per 7.5;

- q) procedures for evaluating measurement uncertainty as per 7.6;
- r) procedures for ensuring the validity of results as per 7.7, including defining which strategies are used by the laboratory and frequency of monitoring activities;
- s) procedures for reporting results to clients and, where appropriate, internal calibration reports, that meet the requirements of 7.8;
- t) procedures for handling and resolving complaints as per 7.9 and addressing nonconforming work as per 7.10;
- u) procedures for the control of data and information management system as per 7.11;
- v) how the laboratory meets the management system requirements of 8.1.2;
- w) the objectives of the quality management system as per 8.2.1; and
- x) procedures for document control (8.3), non-technical record control (8.4), risk management (8.5), improvement (8.6), corrective action (8.7), internal auditing (8.8), and management review (8.9).

8.3 Control of management system documents (Option A)

8.3.1 *The laboratory 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, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

NOTE 2: Form templates used to record details of laboratory activities are documents. Once the form has been filled, it is a record.

8.3.2 *The laboratory 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.*
- g) *there is an indication that the document is complete (e.g., page numbers, total number of pages, electronic document management system); and*
- h) *it has authorized editions of external documents that provide instruction to the analyst. Authorized editions of the TNI standard revision and reference methods to which the laboratory is accredited must be available within the laboratory's controlled document system.*

8.3.3 The laboratory must maintain documents that accurately reflect all current laboratory activities.

8.3.3.1 Collectively, these documents must provide instruction for implementing management system requirements and test method requirements.

NOTE: These documents may be from external sources or internally prepared. For example, they may be equipment manuals provided by the manufacturer, published reference methods, or internally generated procedures. External documents that contain sufficient information to perform the activity do not need to be supplemented or rewritten as internal procedures.

- 8.3.4 The laboratory's test method documents must include instructions for all fields of accreditation.
- 8.3.4.1 In cases where modifications to published reference methods have been made by the laboratory, these modifications must be clearly identified and described in the test method instructions.
- 8.3.4.2 In cases where the published reference method provides options, is ambiguous, or provides insufficient detail, the choices and/or clarifications made by the laboratory must be clearly identified and described in the test method instructions.
- 8.3.4.3 These instructions must include or reference the following topics where applicable:
- a) These topics must be included in the instructions:
 - i. identification of the method,
 - ii. applicable matrix or matrices,
 - iii. scope and application, including analytes to be analyzed,
 - iv. summary of the method,
 - v. interferences,
 - vi. safety measures for hazards specific to the test method,
 - vii. equipment and supplies,
 - viii. reagents and standards and their quality,
 - ix. sample collection, preservation, shipment and storage,
 - x. complete list of quality control samples to be analyzed and preparation instructions for those quality control samples,
 - xi. calibration of analytical instrumentation,
 - xii. procedure,
 - xiii. data analysis and calculations, and
 - xiii. references.
 - b) These topics must be addressed but may be included by reference to other documents or records:
 - i. definitions,
 - ii. limits of detection and quantitation,
 - iii. demonstration of capability,
 - iv. analytical instrumentation calibration evaluation and acceptance criteria,
 - v. data assessment and acceptance criteria for quality control samples,

- vi. actions for handling out-of-control or unacceptable data, and
- vii. pollution prevention and waste management.

8.4 Control of records (Option A)

- 8.4.1 *The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.*
- 8.4.2 *The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory 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.

- 8.4.2.1 *The laboratory must retain all records for a minimum of five years from generation of the last entry in the records.*
- 8.4.2.2 *Records that are stored only on electronic media must be supported by the hardware and software necessary for their retrieval for the entirety of the electronic record retention duration.*
- 8.4.2.3 *Access to archived information must be recorded.*

8.5 Actions to address risks and opportunities (Option A)

- 8.5.1 *The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:*
- a) *give assurance that the management system achieves its intended results;*
 - b) *enhance opportunities to achieve the purpose and objectives of the laboratory;*
 - c) *prevent, or reduce, undesired impacts and potential failures in the laboratory activities;*
 - d) *achieve improvement.*
- 8.5.2 *The laboratory shall plan:*
- a) *actions to address these risks and opportunities;*
 - b) *how to:*
 - *integrate and implement these actions into its management system;*
 - *evaluate the effectiveness of these actions.*

NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories 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 laboratory 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 laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

8.5.4 Records of the identification and mitigation of risk must be maintained.

8.5.5 Identified risks and any mitigation plans must be reviewed annually and updated as applicable.

8.6 Improvement (Option A)

8.6.1 *The laboratory 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 laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory 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 laboratory 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 laboratory 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 laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:*

- a) *conforms to:*
 - *the laboratory's own requirements for its management system, including the laboratory activities;*
 - *the requirements of this document;*
- b) *is effectively implemented and maintained.*

8.8.2 *The laboratory 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 laboratory activities concerned, changes affecting the laboratory, 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.*

8.8.3 In addition to the requirements listed in 8.8.1 and 8.8.2, the internal audit program must:

- 8.8.3.1 include a review of all requirements of TNI Volume 1 Modules 1 and 2 annually, and
- 8.8.3.2 include a review of all elements of TNI Volume 1 Modules 3-7 over a 3-year period as applicable to the laboratory's scope, that
 - a) includes a representative selection of analytes, matrices, and technologies annually, and
 - b) covers all methods under which the laboratory performs its accredited testing, with at least one-third of the methods being reviewed annually.

8.9 Management reviews (Option A)

8.9.1 *The laboratory 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.*

8.9.1.1 Management review must be completed on an annual basis.

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 laboratory;*
- 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 laboratory activities;*
- i) *customer and personnel feedback;*
- j) *complaints;*
- 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*
- o) *other relevant factors, such as monitoring activities and training.*

8.9.2.1 The management review must also include the following:

- a) results of interlaboratory comparisons and/or proficiency tests, and
- b) a review of the effectiveness of the data integrity system.

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 laboratory activities related to the fulfilment of the requirements of this document;*
- c) *provision of required resources;*
- d) *any need for change.*

8.9.4 When any changes are identified, management must have a plan for implementation.

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 laboratories 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 laboratory. 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 laboratory 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 *Laboratories are responsible for establishing metrological traceability in accordance with this document. Calibration results from laboratories 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 Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability. Scopes of accredited laboratories 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.

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Annex B (informative)

Management system options

B.1 Growth in the use of management systems generally has increased the need to ensure that laboratories 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 laboratory. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of laboratory activities that are covered by the management system. Laboratories 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 laboratories 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. Laboratories that implement Option B of Clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the management system within which the laboratory operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the laboratory 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 laboratory 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 laboratory, as described in Clause 7.

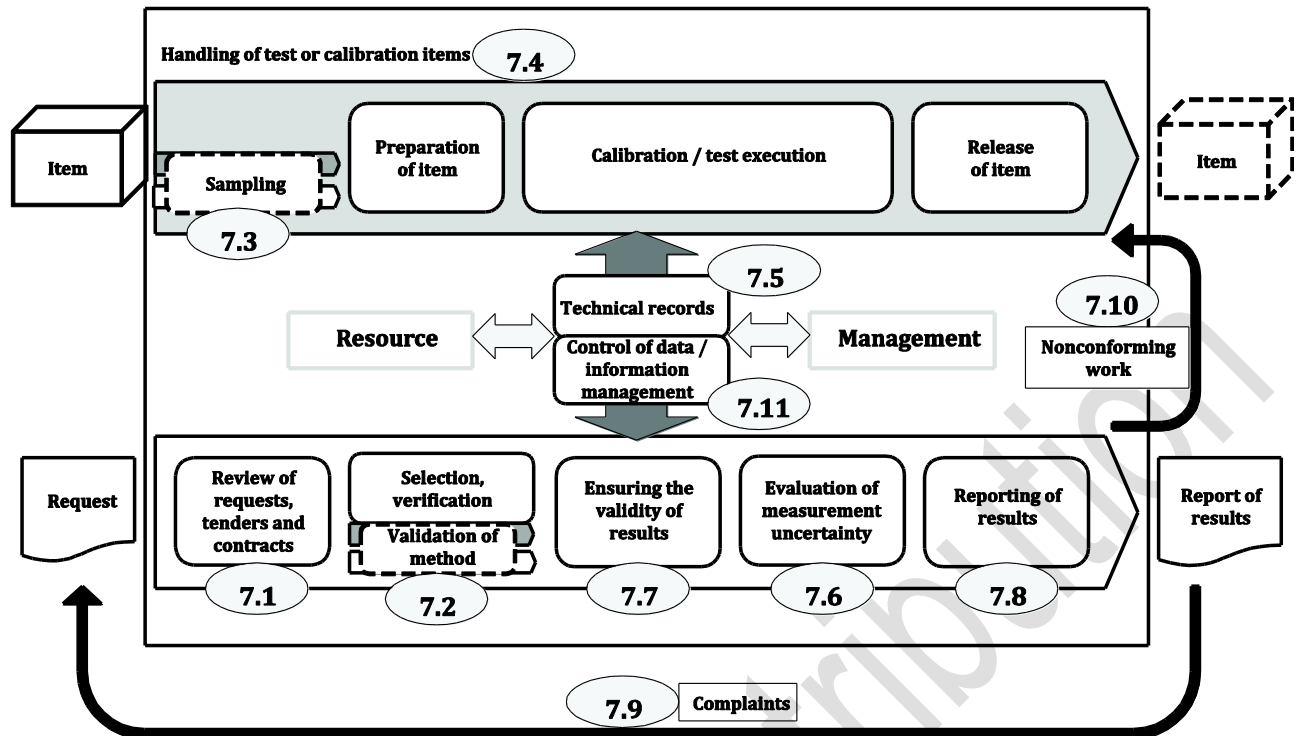


Figure B.1 — Possible schematic representation of the operational processes of a laboratory

Annex C (informative)

Implementation Examples

C.1 General

This annex provides additional non-mandatory information to help a laboratory implement the TNI EL Volume 1 Standard. The examples in this Annex are not prescriptive and do not represent the only options.

C.2 Data Integrity – Prohibited Actions

The laboratory should not engage in any prohibited actions. The following are examples of such actions:

The following actions are prohibited and may be included in Data Integrity procedures and in Data Integrity training, as needed:

- a) fabricating, falsifying, or misrepresenting data, including creating data for an analysis that was not performed or for a sample that was not collected (dry lab);
- b) using external analysts, equipment, and/or laboratories 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, 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 (e.g., chromatographic or spectrophotometric baselines);
- f) turning off, or otherwise disabling, electronic instrument audit/tracking functions;
- g) misrepresenting or misreporting QC samples, including representing spiked samples as being digested or extracted when a digestion or extraction was not performed;
- 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 laboratory 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 analytical or sample problem;
- n) removing failed QC analyses from the record of an analytical 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 laboratory 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.3 Technical Specialist

C.3.1 Examples of Technical Specialist Responsibility Assignments

C.3.1.1 The following examples illustrate possible approaches to assigning Technical Specialist responsibilities in laboratories with different scopes and operational models. Laboratories may implement alternative arrangements provided that Technical Specialist responsibilities are clearly defined and effectively implemented in accordance with the requirements of the TNI EL Volume 1 Standard.

Example 1 – Laboratory A with One Technical Specialist

- One Technical Specialist responsible for the laboratory's entire accredited scope

Example 2 – Laboratory B with Two Technical Specialists

- One Technical Specialist responsible for Inorganic Chemistry and Microbiology
- One Technical Specialist responsible for Organic Chemistry

Example 3 – Laboratory C with Multiple Technical Specialists

- One Technical Specialist responsible for Drinking Water
- One Technical Specialist responsible for PFAS
- One Technical Specialist responsible for Solids and Chemical Wastes

Example 4 – Laboratory D with Multiple Technical Specialists

- One Technical Specialist responsible for Inorganic Chemistry – Manual Methods
- One Technical Specialist responsible for Inorganic Chemistry – Instrumental Methods
- One Technical Specialist responsible for Metals
- One Technical Specialist responsible for Organic Chemistry
- One Technical Specialist responsible for Radiochemistry – Sample Preparation
- One Technical Specialist responsible for Radiochemistry – Counting
- One Technical Specialist responsible for Microbiology

Example 5 – Laboratory E with Technical Specialists Responsible for Each Volume 1 Modules 3-7

- One Technical Specialist responsible for Module 3 - Asbestos
- One Technical Specialist responsible for Module 4 - Chemistry
- One Technical Specialist responsible for Module 5 - Microbiology
- One Technical Specialist responsible for Module 6 - Radiochemistry
- One Technical Specialist responsible for Module 7 - Whole Effluent Toxicity

Example 6 – Laboratory F with Multiple Technical Specialists

- One Technical Specialist responsible for Air Testing
- One Technical Specialist responsible for Microbiology
- One Technical Specialist responsible for all other testing

C.3.2 Examples of relevant technical education and training for Technical Specialists may include coursework or formal training in:

C.3.2.1 Microbiology

This course can be in-person, online or virtual reality.

Training course examples include but are not limited to:

- TNI online Microbiology courses (set of 5) with a subsequent laboratory course
- TNI online Microbiology courses (set of 5) with 3 years of relevant laboratory experience

College-level course examples with a laboratory component include but are not limited to:

- General/Advanced/Introduction to Microbiology, not limited to Medical, Clinical, Research, Pathogenic, Environmental and/or Food
- Cell biology
- Genetics
- Immunology
- Virology
- Food microbiology
- Mycology

C.3.2.2 Radiochemistry

Examples include but are not limited to:

- TNI online Radiochemistry technical course series (Set of 5)
- APHL/CDC Radiochemistry Graduate Certificate Program <https://chem.uiowa.edu/graduate/radiochemistry-certificate>
- APHL Peer-to-Peer Program <https://www.aphl.org/aboutAPHL/publications/Documents/QSA-Peer-to-Peer-Learninig-Program.pdf>
- Mirion Technologies, Inc. Connects Annual User Conference (instrument specific) and general training classes <https://www.mirion.com/discover/training>
- Ortec Training <https://www.ortec-online.com/service-and-support/training>
- Eastern Regional Radon Training Center at Rutgers: <https://cpe.rutgers.edu/radon>
- Provides radon measurement certification classes: <https://cpe.rutgers.edu/radon/radon-measurement-online>
- Eichrom on-site trainings and workshops <https://www.eichrom.com/>

C.3.3 Experience Considerations

C.3.3.1 Examples of acceptable experience that support Technical Specialist competency may include:

- Hands-on analytical work;
- Technical data validation and review;
- Quality assurance oversight activities;
- Hands-on technical training of laboratory personnel; or

- Relevant technical experience obtained in another industry with comparable analytical practices.
- C.3.3.2 Experience does not require that a Technical Specialist:
- Perform a Demonstration of Capability (DOC) for every method within the assigned scope;
 - Personally run every method within the assigned scope; or
 - Perform exclusively bench-level analytical work.
- C.3.3.3 Experience that is not considered suitable
- Academic education is already considered through allowable reductions in required experience as education increases and is not a substitute for meeting technical experience requirements.
 - Administrative management of personnel.

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