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## ENVIRONMENTAL LABORATORY SECTOR

### VOLUME 1

# MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

## Module 2: Quality Systems General Requirements

**Working Draft Standard**  
**July 2011**

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Working Draft Standard

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## PREFACE

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

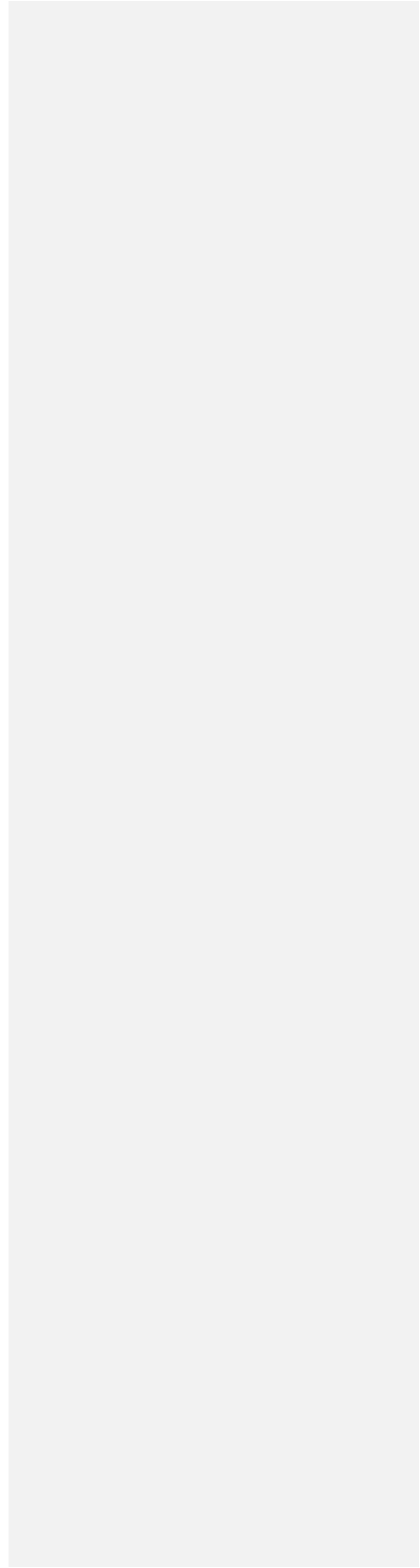
It is conformant with the requirements of ~~ISO/IEC 17025:2005(E)~~ ISO/IEC 17025:2005, and includes applicable clauses from that international standard. The ISO clauses are provided *in italics*. Additional TNI text is provided in a normal font.

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

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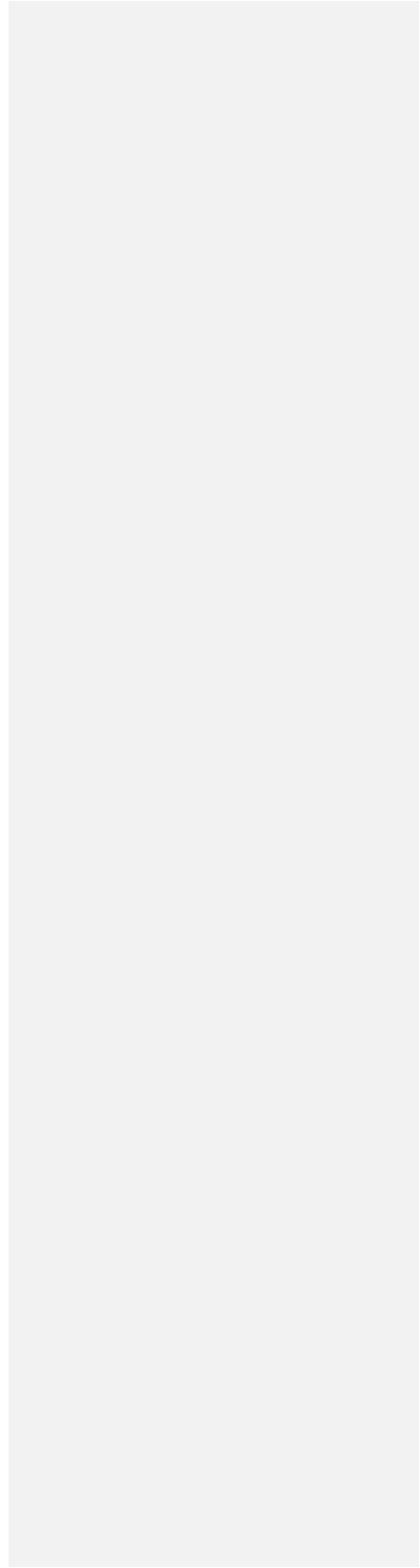
**VOLUME 1, MODULE 2**  
**Quality Systems General Requirements**

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## VOLUME 1, MODULE 2

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### Quality Systems General Requirements

#### 1.0 INTRODUCTION, SCOPE AND APPLICABILITY

##### 1.1 Introduction

Each laboratory shall have a quality system. The laboratory's quality 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 such as:

- a) policies and objectives,
- b) procedures and practices,
- c) organizational authority,
- d) responsibilities, and
- e) performance measures.

The quality system provides the framework for planning, implementing, assessing, and improving work performed by an organization so as to provide the client with data of known and documented quality, sufficient to evaluate the usability of the data to the clients needs. The quality system shall be documented in the laboratory's quality manual and related quality documentation, and shall be referenced in the quality manual.

This Standard contains detailed quality system requirements for consistent and uniform implementation by the laboratories conducting testing and the consistent and uniform evaluation of those laboratories by accreditation bodies. Each laboratory seeking accreditation under this Standard shall ensure that they are implementing their quality system and that all Quality Control procedures specified in this module are being followed. The Quality Assurance policies, which establish quality control procedures, are applicable to environmental laboratories regardless of size and complexity.

This Standard is consistent with ISO/IEC 17025:2005 requirements that are relevant to the scope of environmental testing services.

All items identified in this document shall be available for an on-site assessment.

##### 1.2 Scope

The requirements in this document give the basis for a laboratory's quality system in order to carry out environmental tests. It covers testing performed using reference methods, non-reference methods, and laboratory-developed methods. This document contains the essential elements required to establish a quality system that produces data of known and documented quality, and demonstrates proficiency through the use of proficiency testing and employee training.

The general requirements of this document apply to all organizations performing environmental tests, regardless of the number of personnel or the degree of environmental testing activities. When the use of the data requires compliance with the Standards, these Standards shall be followed.

This document is for use by laboratories, clients, regulatory authorities, and accreditation bodies to ensure the laboratory has appropriate management and technical quality systems to perform environmental testing. This document specifies technical, managerial, and documentation requirements needed for assessment by organizations or accreditation bodies to grant approval. This document provides the requirements needed for laboratory accreditation. If the requirements of this document are met, the laboratory operates a quality system in conformance with the

applicable clauses of ~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005. The ISO/IEC 1725:2005(E)ISO/IEC 17025:2005 language is incorporated verbatim into this standard, and appears as italicized text.

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The notes given provide clarification of the text, examples and/or guidance. They do not contain requirements and do not form an integral part of this Standard

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## 2.0 NORMATIVE REFERENCES (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 2)

*The following referenced documents are indispensable for the application 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 17000, Conformity assessment -- Vocabulary and general principles.*

*VIM, International vocabulary of basic and general terms in metrology, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.*

*NOTE: Further related standards, guides, etc., on subjects included in this International Standard are given in the Bibliography.*

## 3.0 TERMS AND DEFINITIONS

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

### 3.1 Additional Terms and Definitions

**Acceptance Criteria:** Specified limits placed on characteristics of an item, process, or service defined in requirement documents.

**Accreditation:** The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

**Accuracy:** The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.

**Analyst:** The designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

**Analytical Uncertainty:** A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.

Analyte: TheA substance, organism, physical parameter, or chemical constituent that is undergoing analysis, being measured in an analytical procedure.

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**Assessment:** The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of laboratory accreditation).

**Audit:** A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system

1 to determine whether QA/QC and technical activities are being conducted as planned and whether  
2 these activities will effectively achieve quality objectives.

3 **Batch:** Environmental samples that are prepared and/or analyzed together with the same process  
4 and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one (1) to  
5 twenty (20) environmental samples of the same quality systems matrix, meeting the above  
6 mentioned criteria and with a maximum time between the start of processing of the first and last  
7 sample in the batch to be twenty-four (24) hours. An **analytical batch** is composed of prepared  
8 environmental samples (extracts, digestates or concentrates) which are analyzed together as a  
9 group. An analytical batch can include prepared samples originating from various quality system  
10 matrices and can exceed twenty (20) samples.

11 **Bias:** The systematic or persistent distortion of a measurement process, which causes errors in  
12 one direction (i.e., the expected sample measurement is different from the sample's true value).

13 **Blank:** A sample that has not been exposed to the analyzed sample stream in order to monitor  
14 contamination during sampling, transport, storage or analysis. The blank is subjected to the usual  
15 analytical and measurement process to establish a zero baseline or background value and is  
16 sometimes used to adjust or correct routine analytical results. Blanks include:

17 *Method Blank:* A sample of a matrix similar to the batch of associated samples (when available) that is free  
18 from the analytes of interest and is processed simultaneously with and under the same conditions as samples  
19 through all steps of the analytical procedures, and in which no target analytes or interferences are present at  
20 concentrations that impact the analytical results for sample analyses.

21 **Calibration:** A set of operations that establish, under specified conditions, the relationship between  
22 values of quantities indicated by a measuring instrument or measuring system, or values  
23 represented by a material measure or a reference material, and the corresponding values realized  
24 by standards.

- 25 1) In calibration of support equipment the values realized by standards are established through  
26 the use of reference standards that are traceable to the International System of Units (SI).
- 27 2) In calibration according to methods, the values realized by standards are typically established  
28 through the use of Reference Materials that are either purchased by the laboratory with a  
29 certificate of analysis or purity, or prepared by the laboratory using support equipment that  
30 has been calibrated or verified to meet specifications.

31 **Calibration Curve:** The mathematical relationship between the known values, such as  
32 concentrations, of a series of calibration standards and their instrument response.

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

34 **Certified Reference Material (CRM):** Reference material, accompanied by a certificate, having a  
35 value, measurement uncertainty, and stated metrological traceability chain to a national metrology  
36 institute.

37 **Chain of Custody Form:** Record that documents the possession of the samples from the time of  
38 collection to receipt in the laboratory. This record generally includes: the number and types of  
39 containers; the mode of collection; the collector; time of collection; preservation; and requested  
40 analyses. See also Legal Chain of Custody Protocols.

41 **Confirmation:** Verification of the identity of a component through the use of an approach with a  
42 different scientific principle from the original method. These may include, but are not limited to:  
43 Second column confirmation, Alternate wavelength, Derivatization, Mass spectral interpretation,  
44 Alternative detectors, or Additional cleanup procedures.

45 **Data Integrity:** Data A process that produces data that The condition that exists when data are  
46 sound, correct, and complete and accurately reflects activities and requirements. It is achieved by  
47 preventing accidental or deliberate but unauthorized insertion, modification or destruction of data.  
48 (TNI)

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- 1 | **Data Reduction:** The process of transforming the number of data items by arithmetic or statistical  
2 calculation, standard curves, and concentration factors, and collating them into a more useful form.
- 3 **Demonstration of Capability:** A procedure to establish the ability of the analyst to generate  
4 analytical results of acceptable accuracy and precision.
- 5 **Field of Accreditation:** Those matrix, technology/method, and analyte combinations for which the  
6 accreditation body offers accreditation.
- 7 **Finding:** An assessment conclusion referenced to a laboratory accreditation standard and  
8 supported by objective evidence that identifies a deviation from a laboratory accreditation standard  
9 requirement.
- 10 **Holding Times:** The maximum time that can elapse between two (2) specified activities.
- 11 **Internal Standard:** A known amount of standard added to a test portion of a sample as a reference  
12 for evaluating and controlling the precision and bias of the applied analytical method.
- 13 **Laboratory Control Sample (however named, such as laboratory fortified blank, spiked  
14 blank, or QC check sample):** A sample matrix, free from the analytes of interest, spiked with  
15 verified known amounts of analytes or a material containing known and verified amounts of  
16 analytes and taken through all sample preparation and analytical steps of the procedure unless  
17 otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst  
18 specific precision and bias or to assess the performance of all or a portion of the measurement  
19 system.
- 20 **Legal Chain of Custody Protocols:** Procedures employed to record the possession of samples  
21 from the time of sampling through the retention time specified by the client or program. These  
22 procedures are performed at the special request of the client and include the use of a Chain of  
23 Custody Form that documents the collection, transport, and receipt of compliance samples by the  
24 laboratory. In addition, these protocols document all handling of the samples within the laboratory.
- 25 **Limit(s) of Detection (LOD):** A laboratory's estimate of the minimum amount of an analyte in a  
26 given matrix that an analytical process can reliably detect in their facility.
- 27 **Limit(s) of Quantitation (LOQ):** The minimum levels, concentrations, or quantities of a target  
28 variable (e.g., target analyte) that can be reported with a specified degree of confidence.
- 29 **Matrix:** The substrate of a test sample.
- 30 **Matrix Duplicate:** A replicate matrix prepared in the laboratory and analyzed to obtain a measure  
31 of precision.
- 32 **Matrix Spike (spiked sample or fortified sample):** A sample prepared, taken through all sample  
33 preparation and analytical steps of the procedure unless otherwise noted in a referenced method,  
34 by adding a known amount of target analyte to a specified amount of sample for which an  
35 independent test result of target analyte concentration is available. Matrix spikes are used, for  
36 example, to determine the effect of the matrix on a method's recovery efficiency.
- 37 **Matrix Spike Duplicate (spiked sample or fortified sample duplicate):** A replicate matrix spike  
38 prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for  
39 each analyte.
- 40 **Measurement System:** A method, as implemented at a particular laboratory, and which includes  
41 the equipment used to perform the test and the operator(s).
- 42 **Method:** A body of procedures and techniques for performing an activity (e.g., sampling, chemical  
43 analysis, quantification), systematically presented in the order in which they are to be executed.
- 44 **Mobile Laboratory:** A portable enclosed structure with necessary and appropriate accommodation  
45 and environmental conditions for a laboratory, within which testing is performed by analysts.  
46 Examples include but are not limited to trailers, vans, and skid-mounted structures configured to  
47 house testing equipment and personnel.

1 **National Institute of Standards and Technology (NIST):** A federal agency of the US Department  
2 of Commerce's Technology Administration that is designed as the United States national metrology  
3 institute (NMI).

4 **Parameter:** a measurable quantity, e.g. temperature, that determines the result of a scientific  
5 experiment and can be altered to vary the result

6 **Physical Parameter:** a measurement of a physical characteristic or property of a sample as  
7 distinguished from the concentrations of chemical or biological components.

8 **Precision:** The degree to which a set of observations or measurements of the same property,  
9 obtained under similar conditions, conform to themselves; a data quality indicator. Precision is  
10 usually expressed as standard deviation, variance or range, in either absolute or relative terms.

11 **Preservation:** Any conditions under which a sample must be kept in order to maintain chemical  
12 and/or biological integrity prior to analysis.

13 **Procedure:** A specified way to carry out an activity or process. Procedures can be documented or  
14 not.

15 **Proficiency Testing:** A means of evaluating a laboratory's performance under controlled  
16 conditions relative to a given set of criteria through analysis of unknown samples provided by an  
17 external source.

18 **Proficiency Testing Program:** The aggregate of providing rigorously controlled and standardized  
19 environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the  
20 results and the collective demographics and results summary of all participating laboratories.

21 **Proficiency Test Sample (PT):** A sample, the composition of which is unknown to the laboratory  
22 and is provided to test whether the laboratory can produce analytical results within the specified  
23 acceptance criteria.

24 **Protocol:** A detailed written procedure for field and/or laboratory operation (e.g., sampling,  
25 analysis) which must be strictly followed.

26 **Quality Assurance:** An integrated system of management activities involving planning,  
27 implementation, assessment, reporting, and quality improvement to ensure that a process, item, or  
28 service is of the type and quality needed and expected by the client.

29 **Quality Control:** The overall system of technical activities that measures the attributes and  
30 performance of a process, item, or service against defined standards to verify that they meet the  
31 stated requirements established by the customer; operational techniques and activities that are  
32 used to fulfill requirements for quality; also the system of activities and checks used to ensure that  
33 measurement systems are maintained within prescribed limits, providing protection against "out of  
34 control" conditions and ensuring that the results are of acceptable quality.

35 **Quality Control Sample:** A sample used to assess the performance of all or a portion of the  
36 measurement system. One of any number of samples, such as Certified Reference Materials, a  
37 quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to  
38 demonstrate that a measurement system or activity is in control.

39 **Quality Manual:** A document stating the management policies, objectives, principles,  
40 organizational structure and authority, responsibilities, accountability, and implementation of an  
41 agency, organization, or laboratory, to ensure the quality of its product and the utility of its product  
42 to its users.

43 **Quality System:** A structured and documented management system describing the policies,  
44 objectives, principles, organizational authority, responsibilities, accountability, and implementation  
45 plan of an organization for ensuring quality in its work processes, products (items), and services.  
46 The quality system provides the framework for planning, implementing, and assessing work

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performed by the organization and for carrying out required quality assurance (QA) and quality control (QC) activities.

**Quality System Matrix:** These matrix definitions are to be 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.

*Aqueous:* Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, ground water effluents, and TCLP or other extracts.

*Biological Tissue:* Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

*Chemical Waste:* A product or by-product of an industrial process that results in a matrix not previously defined.

*Drinking Water:* Any aqueous sample that has been designated a potable or potential potable water source.

*Non-Aqueous Liquid:* Any organic liquid with <15% settleable solids.

*Saline/Estuarine:* Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

*Solids:* Includes soils, sediments, sludges and other matrices with >15% settleable solids.

**Raw Data:** The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records.

**Reference Material:** Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

**Reference Method:** A reference method is a validated published method issued by an organization generally recognized as competent to do so. (When the ISO language refers to a "standard method", that term is equivalent to reference method). When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology. Reference Methods do not require validation as outlined in 5.4.5 of this standard, but must follow the applicable technical requirements found in Section 1.5. of Modules 3-7.

**Reference Standard:** Standard used for the calibration of working measurement standards in a given organization or at a given location.

**Sampling:** Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

**Selectivity:** The ability to analyze, distinguish, and determine a specific analyte or parameter from another component that may be a potential interferent or that may behave similarly to the target analyte or parameter within the measurement system.

**Sensitivity:** The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.

**Standard:** The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies.

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1 **Standard Operating Procedures (SOPs):** A written document that details the method for an  
2 operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially  
3 approved as the methods for performing certain routine or repetitive tasks.

4 **Technology:** A specific arrangement of analytical instruments, detection systems, and/or  
5 preparation techniques.

6 **Traceability:** The ability to trace the history, application, or location of an entity by means of  
7 recorded identifications. In a calibration sense, traceability relates measuring equipment to national  
8 or international standards, primary standards, basic physical constants or properties, or reference  
9 materials. In a data collection sense, it relates calculations and data generated throughout the  
10 project back to the requirements for the quality of the project.

11 **Verification:** Confirmation by examination and objective evidence that specified requirements have  
12 been met.

13 **NOTE:** In connection with the management of measuring equipment, verification provides a means  
14 for checking that the deviations between values indicated by a measuring instrument and  
15 corresponding known values of a measured quantity are consistently smaller than the  
16 maximum allowable error defined in a standard, regulation or specification peculiar to the  
17 management of the measuring equipment.

18 The result of verification leads to a decision either to restore in service, to perform  
19 adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a  
20 written trace of the verification performed shall be kept on the measuring instrument's  
21 individual record.

### 22 3.2 Sources

23 40CFR Part 136 Guidelines Establishing Test Procedures for the Analysis of Pollutants

24 American Society for Quality Control (ASQC), Definitions of Environmental Quality Assurance  
25 Terms, 1996

26 American National Standards Institute (ANSI), Style Manual for Preparation of Proposed American  
27 National Standards, Eighth Edition, March 1991

28 ANSI N42.23-1995, Measurement and Associated Instrument Quality Assurance for Radiobioassay  
29 Laboratories

30 International Vocabulary of Basic and General Terms in Metrology (VIM): 1984. Issued by Bureau  
31 International des Poids et Mesures (BIPM), International Electrotechnical Commission (IEC),  
32 International Organization for Standardization (ISO)/IEC and International Organization of Legal  
33 Metrology (OIML)

34 National Institute of Standards and Technology (NIST)

35 National Environmental Laboratory Accreditation Conference (NELAC), July 2003 Standards

36 Random House College Dictionary

37 United States Environmental Protection Agency (US EPA) Quality Assurance Management Section  
38 (QAMS), Glossary of Terms of Quality Assurance Terms, 8/31/92 and 12/6/95

39 Webster's New World Dictionary of the American Language

40 Uniform Federal Policy for Quality Assurance Project Plans (UFP QAPP) March 2005

41 VIM – Draft edition October 2005

42 TNI Technical Modules, as follows:

43 Volume 1, Module 3 Quality Systems for Asbestos Testing

44 Volume 1, Module 4 Quality Systems for Chemical Testing

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1 Volume 1, Module 5 Quality Systems for Microbiological Testing

2 Volume 1, Module 6 Quality Systems for Radiochemical Testing

3 Volume 1, Module 7 Quality Systems for Toxicity Testing

4  
5 **3.3 Exclusions and Exceptions**

6  
7 **Reserved**

8  
9 **4.0 MANAGEMENT REQUIREMENTS**

10  
11 **4.1 Organization (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.1)**

12  
13 4.1.1 *The laboratory or the organization of which it is part shall be an entity that can be held legally*  
14 *responsible.*

15  
16 4.1.2 *It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to*  
17 *meet the requirements of this International Standard and to satisfy the needs of the customer, the*  
18 *regulatory authorities or organizations providing recognition.*

19  
20 4.1.3 *The management system shall cover work carried out in the laboratory's permanent facilities, at sites*  
21 *away from its permanent facilities, or in associated temporary or mobile facilities.*

22  
23 4.1.4 *If the laboratory is part of an organization performing activities other than testing and/or calibration,*  
24 *the responsibilities of key personnel in the organization that have an involvement or influence on the*  
25 *testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts*  
26 *of interest.*

27  
28 *NOTE 1: Where a laboratory is part of a larger organization, the organizational arrangements should be*  
29 *such that departments having conflicting interests, such as production, commercial marketing*  
30 *or financing do not adversely influence the laboratory's compliance with the requirements of this*  
31 *International Standard.*

32  
33 *NOTE 2: If the laboratory wishes to be recognized as a third-party laboratory, it should be able to*  
34 *demonstrate that it is impartial and that it and its personnel are free from any undue*  
35 *commercial, financial and other pressures which might influence their technical judgment.*  
36 *The third-party testing or calibration laboratory should not engage in any activities that may*  
37 *endanger the trust in its independence of judgment and integrity in relation to its testing or*  
38 *calibration activities.*

39  
40 4.1.5 *The laboratory shall:*

41  
42 a) *have managerial and technical personnel who, irrespective of other responsibilities, have the*  
43 *authority and resources needed to carry out their duties, including the implementation,*  
44 *maintenance and improvement of the management system, and to identify the occurrence of*  
45 *departures from the management system or from the procedures for performing tests and/or*  
46 *calibrations, and to initiate actions to prevent or minimize such departures (see also Section 5.2);*

47  
48 b) *have arrangements to ensure that its management and personnel are free from any undue*  
49 *internal and external commercial, financial and other pressures and influences that may adversely*  
50 *affect the quality of their work;*

51  
52 c) *have policies and procedures to ensure the protection of its customers' confidential information*  
53 *and proprietary rights, including procedures for protecting the electronic storage and transmission*  
54 *of results;*



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- d) *have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;*
  - e) *define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;*
  - f) *specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;*
  - g) *provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;*
  - h) *have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;*
  - i) *appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;*
  - j) *appoint deputies for key managerial personnel (see Note);*
  - k) *ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.*

*NOTE: Individuals may have more than one function and it may be impractical to appoint deputies for every function.*

4.1.6 *Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.*

4.1.7 Additional Requirements for Laboratories

4.1.7.1 Quality Manager - Where staffing is limited, the quality manager may also be the technical manager. The laboratory's quality manager and/or his/her designee(s) shall:

- a) serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;
- b) have functions independent from laboratory operations for which they have quality assurance oversight;
- c) be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;
- d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system;
- e) have a general knowledge of the analytical methods for which data review is performed;
- f) arrange for or conduct internal audits as per Section 4.14 annually;
- g) notify laboratory management of deficiencies in the quality system; and

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h) monitor corrective actions.

~~NOTE: ii Where staffing is limited, the quality manager may also be the technical manager.~~

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4.1.7.2 The laboratory's technical manager(s), however named, and/or his/her designee(s) shall:

- a) be a member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results; \_\_\_\_\_
- b) be experienced in the fields of accreditation for which the laboratory is seeking accreditation;
- c) have duties that include:
  - i. monitoring standards of performance in quality control and quality assurance, and
  - ii. monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.
- d) not be the technical manager(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body. Circumstances to be considered in the decision to grant such authorization shall include:
  - i. the extent to which operating hours of the laboratories to be directed overlap,
  - ii. adequacy of supervision in each laboratory, and
  - iii. the availability of environmental laboratory services in the area served.
- e) if absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical manager(s) to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing; and
- f) meet qualification requirements as specified in Section 5.2.6.1.

**4.2 Management (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.2)**

42.1 *The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.*

4.2.2 *The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:*

- a) *the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;*
- b) *the management's statement of the laboratory's standard of service;*
- c) *the purpose of the management system related to quality;*

1  
2 d) *a requirement that all personnel concerned with testing and calibration activities within the*  
3 *laboratory familiarize themselves with the quality documentation and implement the policies and*  
4 *procedures in their work; and*  
5

6 e) *the laboratory management's commitment to comply with this International Standard and to*  
7 *continually improve the effectiveness of the management system.*  
8

9 *NOTE: The quality policy statement should be concise and may include the requirement that tests*  
10 *and/or calibrations shall always be carried out in accordance with stated methods and customers'*  
11 *requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy*  
12 *elements may be in other documents.*  
13

14 4.2.3 *Top management shall provide evidence of commitment to the development and implementation of the*  
15 *management system and to continually improving its effectiveness.*  
16

17 4.2.4 *Top management shall communicate to the organization the importance of meeting customer*  
18 *requirements as well as statutory and regulatory requirements.*  
19

20 4.2.5 *The quality manual shall include or make reference to the supporting procedures including technical*  
21 *procedures. It shall outline the structure of the documentation used in the management system.*  
22

23 4.2.6 *The roles and responsibilities of technical management and the quality manager, including their*  
24 *responsibility for ensuring compliance with this International Standard, shall be defined in the quality*  
25 *manual.*  
26

27 4.2.7 *Top management shall ensure that the integrity of the management system is maintained when*  
28 *changes to the management system are planned and implemented.*  
29

30 4.2.8 Additional Management System Requirements  
31

32 4.2.8.1 The laboratory shall establish and maintain a documented data integrity system. There are four (4)  
33 required elements within a data integrity system. These are 1) data integrity training, 2) signed data  
34 integrity documentation for all laboratory employees, 3) in-depth, periodic monitoring of data  
35 integrity, and 4) data integrity procedure documentation. The data integrity procedures shall be  
36 signed and dated by top management. The requirements for data integrity investigation are listed in  
37 Section 4.16. The requirements for data integrity training and documentation are listed in Section  
38 5.2.7. Management shall annually review data integrity procedures and update as needed.  
39

40 a) Laboratory management shall provide a procedure for confidential reporting of data integrity  
41 issues in their laboratory. A primary element of the procedure is to assure confidentiality and  
42 a receptive environment in which all employees may privately discuss ethical issues or report  
43 items of ethical concern.  
44

45 b) In instances of ethical concern, the procedure shall include a process whereby laboratory  
46 management is to be informed of the need for any further detailed investigation.  
47

48 4.2.8.2 The quality manager shall be responsible for maintaining the currency of the quality manual.  
49

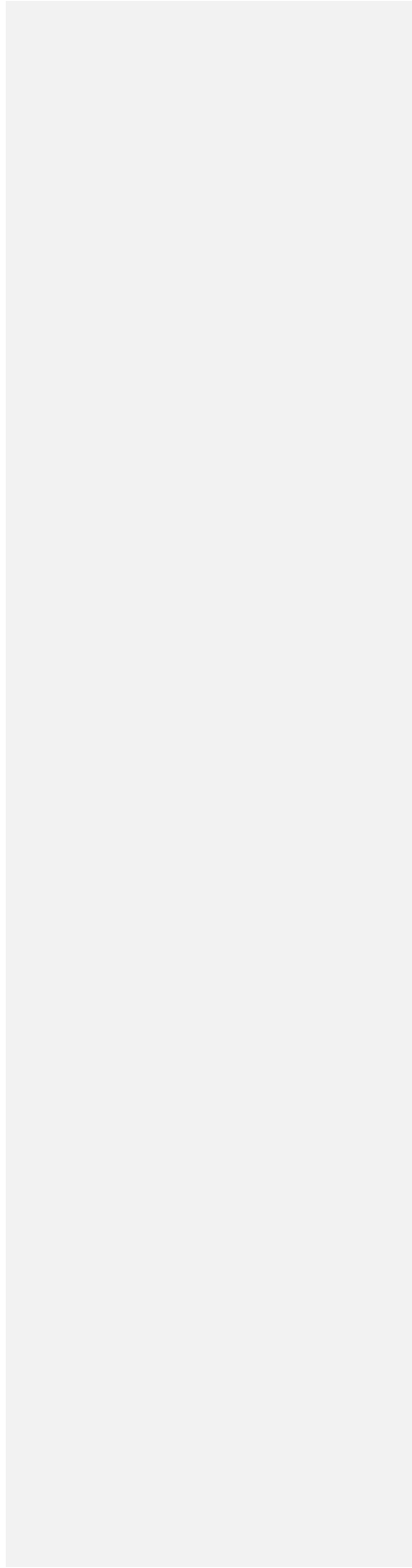
50 4.2.8.3 The quality manual shall contain:  
51

52 a) document title;  
53

54 b) laboratory's full name and address;  
55

- 1 c) name, address (if different from above), and telephone number of individual(s) responsible for  
2 the laboratory;
- 3
- 4 d) identification of all major organizational units which are to be covered by this quality manual  
5 and the effective date of the version;
- 6
- 7 e) identification of the laboratory's approved signatories;
- 8
- 9 f) the signed and dated concurrence (with appropriate names and titles), of all responsible  
10 parties including the quality manager(s), technical manager(s), and the agent who is in  
11 charge of all laboratory activities, such as the laboratory director or laboratory manager;
- 12
- 13 g) the objectives of the quality system and contain or reference the laboratory's policies and  
14 procedures;
- 15
- 16

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1 h) the laboratory's official quality policy statement, which shall include quality system objectives  
2 and management's commitment to ethical laboratory practices and to upholding the  
3 requirements of this Standard; and

4  
5 i) a table of contents, and applicable lists of references, glossaries and appendices.  
6

7 4.2.8.4 The quality manual shall contain or reference:  
8

9 a) all maintenance, calibration and verification procedures used by the laboratory in conducting  
10 tests;

11  
12 b) major equipment and reference measurement standards used as well as the facilities and  
13 services used by the laboratory in conducting tests;

14  
15 c) verification practices, which may include inter-laboratory comparisons, proficiency testing  
16 programs, use of reference materials and internal quality control schemes;

17  
18 d) procedures for reporting analytical results;

19  
20 e) the organization and management structure of the laboratory, its place in any parent  
21 organization, and relevant organizational charts;

22  
23 f) procedures to ensure that all records required under this Standard are retained, as well as  
24 procedures for control and maintenance of documentation through a document control  
25 system that ensures that all standard operating procedures (SOPs), manuals, or documents  
26 clearly indicate the time period during which the procedure or document was in force;

27  
28 g) job descriptions of key staff and reference to the job descriptions of other laboratory staff;

29  
30 h) procedures for achieving traceability of measurements;

31  
32 i) a list of all methods under which the laboratory performs its accredited testing;

33  
34 j) procedures for ensuring that the laboratory reviews all new work to ensure that it has the  
35 appropriate facilities and resources before commencing such work;

36  
37 k) procedures for handling samples;

38  
39 l) procedures to be followed for feedback and corrective action whenever testing discrepancies  
40 are detected, or departures from documented policies and procedures occur;

41  
42 m) policy for permitting departures from documented policies and procedures or from standard  
43 specifications;

44  
45 n) procedures for dealing with complaints;

46  
47 o) procedures for protecting confidentiality (including national security concerns), and  
48 proprietary rights;

49  
50 p) procedures for audits and data review;

51  
52 q) procedures for establishing that personnel are adequately experienced in the duties they are  
53 expected to carry out and are receiving any needed training; and

54  
55 r) policy addressing the use of unique electronic signatures, where applicable.  
56

- 1 4.2.8.5 Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities,  
2 such as assessing data integrity, corrective actions, handling customer complaints, and all  
3 methods.  
4  
5 a) These documents, for example, may be equipment manuals provided by the manufacturer, or  
6 internally written documents with adequate detail to allow someone similarly qualified, other  
7 than the analyst, to reproduce the procedures used to generate the test result.  
8  
9 b) The relevant SOPs shall be readily accessible to all personnel.  
10  
11 c) Each SOP shall clearly indicate the effective date of the document, the revision number, and  
12 the signature(s) of the approving authority.  
13  
14 d) Documents that contain sufficient information to perform the tests, do not need to be  
15 supplemented or rewritten as internal procedures if the documents are written in a way that  
16 they can be used as written. Any changes, including the use of a selected option, shall be  
17 documented and included in the laboratory's method records.  
18  
19 e) The laboratory shall have and maintain an SOP for each accredited analyte or method.  
20  
21 f) The SOP may be a copy of a published or referenced method or may be written by the  
22 laboratory. In cases where modifications to the published method have been made by the  
23 laboratory or where the referenced method is ambiguous or provides insufficient detail,  
24 these changes or clarifications shall be clearly described. Each method shall include or  
25 reference the following topics where applicable:  
26  
27 i. identification of the method;  
28 ii. applicable matrix or matrices;  
29 iii. limits of detection and quantitation;  
30 iv. scope and application, including **analytes parameters** to be analyzed;  
31 v. summary of the method;  
32 vi. definitions;  
33 vii. interferences;  
34 viii. safety;  
35 ix. equipment and supplies;  
36 x. reagents and standards;  
37 xi. sample collection, preservation, shipment and storage;  
38 xii. quality control;  
39 xiii. calibration and standardization;  
40 xiv. procedure;  
41 xv. data analysis and calculations;  
42 xvi. method performance;  
43 xvii. pollution prevention;  
44 xviii. data assessment and acceptance criteria for quality control measures;  
45 xix. corrective actions for out-of-control data;  
46 xx. contingencies for handling out-of-control or unacceptable data;  
47 xxi. waste management;  
48 xxii. references; and  
49 xxiii. any tables, diagrams, flowcharts and validation data.

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51 | **4.3 Document Control (ISO/IEC 17025:2005(E)ISO/IEC 17025:2005, Clause 4.3)**

52  
53 | 4.3.1 *General*

54  
55 *The laboratory shall establish and maintain procedures to control all documents that form part of its*  
56 *management system (internally generated or from external sources), such as regulations, standards,*

1 other normative documents, test and/or calibration methods, as well as drawings, software,  
2 specifications, instructions and manuals.

3  
4 NOTE 1: In this context "document" could be policy statements, procedures, specifications, calibration  
5 tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may  
6 be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or  
7 written.

8  
9 NOTE 2: The control of data related to testing and calibration is covered in 5.4.7. The control of records  
10 is covered in 4.13.

#### 11 4.3.2 Document Approval and Issue

12  
13 4.3.2.1 All documents issued to personnel in the laboratory as part of the management system shall be  
14 reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent  
15 document control procedure identifying the current revision status and distribution of documents in the  
16 management system shall be established and shall be readily available to preclude the use of invalid  
17 and/or obsolete documents.

18  
19 4.3.2.2 The procedure(s) adopted shall ensure that:

- 20  
21 a) authorized editions of appropriate documents are available at all locations where operations  
22 essential to the effective functioning of the laboratory are performed;  
23  
24 b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability  
25 and compliance with applicable requirements;  
26  
27 c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured  
28 against unintended use;  
29  
30 d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

31  
32 4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified. Such  
33 identification shall include the date of issue and/or revision identification, page numbering, and the  
34 total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

#### 35 4.3.3 Document Changes

36  
37 4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original  
38 review unless specifically designated otherwise. The designated personnel shall have access to  
39 pertinent background information upon which to base their review and approval.

40  
41 4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

42  
43 4.3.3.3 If the laboratory's document control system allows for the amendment of documents by hand pending  
44 the re-issue of the documents, the procedures and authorities for such amendments shall be defined.  
45 Amendments shall be clearly marked, initialled and dated. A revised document shall be formally re-issued as  
46 soon as practicable.

47  
48 4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized  
49 systems are made and controlled.

#### 50 4.4 Review of Requests, Tenders and Contracts (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, 51 Clause 4.4) 52 53 54 55

1 4.4.1 *The laboratory shall establish and maintain procedures for the review of requests, tenders and*  
2 *contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration*  
3 *shall ensure that:*

- 4  
5 a) *the requirements, including the methods to be used, are adequately defined, documented and*  
6 *understood (see 5.4.2);*  
7  
8 b) *the laboratory has the capability and resources to meet the requirements;*  
9  
10 c) *the appropriate test and/or calibration method is selected and is capable of meeting the*  
11 *customers' requirements (see 5.4.2).*

12  
13 *Any differences between the request or tender and the contract shall be resolved before any work*  
14 *commences. Each contract shall be acceptable both to the laboratory and the customer.*

15  
16 *NOTE 1: The request, tender and contract review should be conducted in a practical and efficient*  
17 *manner, and the effect of financial, legal and time schedule aspects should be taken into*  
18 *account. For internal customers, reviews of requests, tenders and contracts can be performed*  
19 *in a simplified way.*

20  
21 *NOTE 2: The review of capability should establish that the laboratory possesses the necessary*  
22 *physical, personnel and information resources, and that the laboratory's personnel have the*  
23 *skills and expertise necessary for the performance of the tests and/or calibrations in*  
24 *question. The review may also encompass results of earlier participation in interlaboratory*  
25 *comparisons or proficiency testing and/or the running of trial test or calibration programmes*  
26 *using samples or items of known value in order to determine uncertainties of measurement,*  
27 *limits of detection, confidence limits, etc.*

28  
29 *NOTE 3: A contract may be any written or oral agreement to provide a customer with testing and/or*  
30 *calibration services.*

31  
32 4.4.2 *Records of reviews, including any significant changes, shall be maintained. Records shall also be*  
33 *maintained of pertinent discussions with a customer relating to the customer's requirements or the results of*  
34 *the work during the period of execution of the contract.*

35  
36 *NOTE: For review of routine and other simple tasks, the date and the identification (e.g. the*  
37 *initials) of the person in the laboratory responsible for carrying out the contracted work*  
38 *are considered adequate. For repetitive routine tasks, the review need be made only at*  
39 *the initial enquiry stage or on granting of the contract for on-going routine work performed*  
40 *under a general agreement with the customer, provided that the customer's requirements*  
41 *remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more*  
42 *comprehensive record should be maintained.*

43  
44 4.4.3 *The review shall also cover any work that is subcontracted by the laboratory.*

45  
46 4.4.4 *The customer shall be informed of any deviation from the contract.*

47  
48 4.4.5 *If a contract needs to be amended after work has commenced, the same contract review process*  
49 *shall be repeated and any amendments shall be communicated to all affected personnel.*

50  
51 | **4.5 Subcontracting of Environmental Tests (ISO/IEC 17025:2005(E)ISO/IEC 17025:2005, Clause**  
52 **4.5)**

53  
54 4.5.1 *When a laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for*  
55 *further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting,*  
56 *agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent*



subcontractor is one that, for example, complies with this International Standard for the work in question.

4.5.2 The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

4.5.3 The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.

4.5.5 When a laboratory subcontracts work, this work shall be placed with a laboratory accredited to this Standard for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed. The laboratory performing the subcontracted work shall be indicated in the final report. The laboratory shall make a copy of the subcontractor's report available to the client when requested.

#### 4.6 Purchasing Services and Supplies (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.6)

4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

NOTE: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.

4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

#### 4.7 Service to the Client (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.7)

4.7.1 The laboratory shall be willing to 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, provided that the laboratory ensures confidentiality to other customers.

NOTE 1: Such cooperation may include:

- a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer;
- b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

1 NOTE 2: Customers value the maintenance of good communication, advice and guidance in  
2 technical matters, and opinions and interpretations based on results. Communication with  
3 the customer, especially in large assignments, should be maintained throughout the  
4 work. The laboratory should inform the customer of any delays or major deviations in the  
5 performance of the tests and/or calibrations.  
6

7 4.7.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback  
8 shall be used and analysed to improve the management system, testing and calibration activities  
9 and customer service.  
10

11 NOTE: Examples of the types of feedback include customer satisfaction surveys and review of  
12 test or calibration reports with customers.  
13

14 | **4.8 Complaints (ISO/IEC 17025:2005(E)ISO/IEC 17025:2005, Clause 4.8)**  
15

16 The laboratory shall have a policy and procedure for the resolution of complaints received from  
17 customers or other parties. Records shall be maintained of all complaints and of the investigations and  
18 corrective actions taken by the laboratory (see also 4.11).  
19

20 | **4.9 Control of Nonconforming Environmental Testing Work (ISO/IEC 17025:2005(E)ISO/IEC  
21 17025:2005, Clause 4.9)**  
22

23 4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing  
24 and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed  
25 requirements of the customer. The policy and procedures shall ensure that:  
26

- 27 a) the responsibilities and authorities for the management of nonconforming work are designated  
28 and actions (including halting of work and withholding of test reports and calibration certificates, as  
29 necessary) are defined and taken when nonconforming work is identified;  
30  
31 b) an evaluation of the significance of the nonconforming work is made;  
32  
33 c) correction is taken immediately, together with any decision about the acceptability of the  
34 nonconforming work;  
35  
36 d) where necessary, the customer is notified and work is recalled;  
37  
38 e) the responsibility for authorizing the resumption of work is defined.  
39

40 NOTE: Identification of nonconforming work or problems with the management system or with testing  
41 and/or calibration activities can occur at various places within the management system and  
42 technical operations. Examples are customer complaints, quality control, instrument calibration,  
43 checking of consumable materials, staff observations or supervision, test report and calibration certificate  
44 checking, management reviews and internal or external audits.  
45

46 4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about  
47 the compliance of the laboratory's operations with its own policies and procedures, the corrective action  
48 procedures given in 4.11 shall be promptly followed.  
49

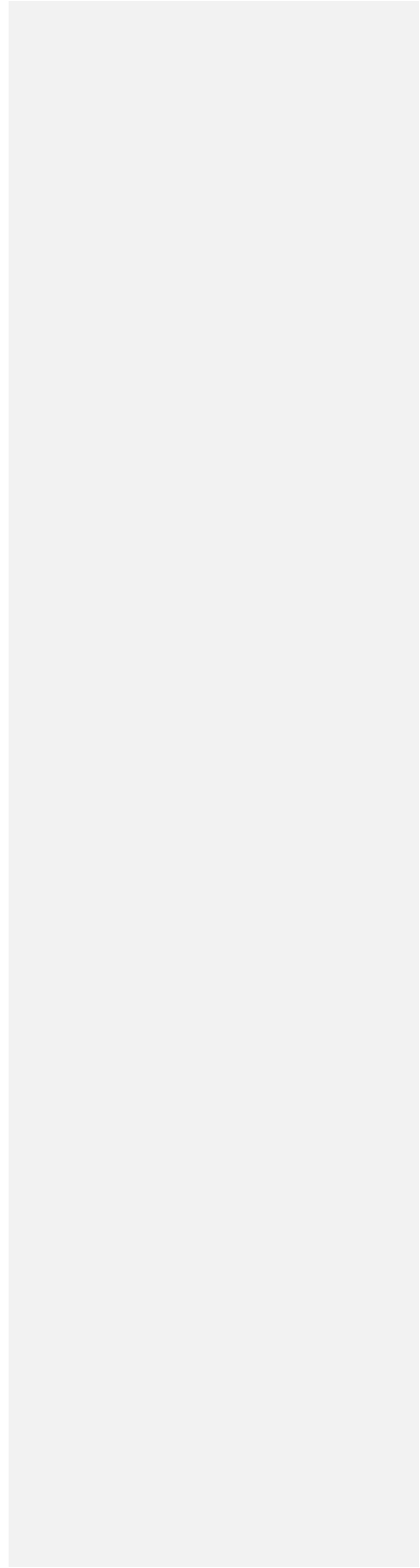
50 | **4.10 Improvement (ISO/IEC 17025:2005(E)ISO/IEC 17025:2005, Clause 4.10)**  
51

52 The laboratory shall continually improve the effectiveness of its management system through the use of  
53 the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and  
54 management review.  
55

56 | **4.11 Corrective Action (ISO/IEC 17025:2005(E)ISO/IEC 17025:2005, Clause 4.11)**

1  
2

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## 4.11.1 General

The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

NOTE: A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, and feedback from customers and from staff observations.

## 4.11.2 Cause Analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE: Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

## 4.11.3 Selection and Implementation of Corrective Actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The laboratory shall document and implement any required changes resulting from corrective action investigations.

## 4.11.4 Monitoring of Corrective Actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

## 4.11.5 Additional Audits

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

NOTE: Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

## 4.11.6 The laboratory shall have documented procedure(s) to address Sections 4.11.1 and 4.11.3 through 4.11.5. These procedure(s) shall also include:

- a) which individual(s) or positions are responsible for assessing each QC data type; and
- b) which individual(s) or positions are responsible for initiating and/or recommending corrective actions.

## 4.11.7 Cause analysis described in Section 4.11.2 applies to failures that indicate a systematic error.

**4.12 Preventive Action (ISO/IEC 17025:2005(E)/ISO/IEC 17025:2005, Clause 4.12)**

4.12.1 *Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.*

4.12.2 *Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.*

NOTE 1: *Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.*

NOTE 2: *Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.*

**4.13 Control of Records (ISO/IEC 17025:2005(E)/ISO/IEC 17025:2005, Clause 4.13)****4.13.1 General**

4.13.1.1 *The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.*

4.13.1.2 *All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.*

NOTE: *Records may be in any media, such as hard copy or electronic media.*

4.13.1.3 *All records shall be held secure and in confidence.*

4.13.1.4 *The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.*

**4.13.2 Technical Records**

4.13.2.1 *The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.*

NOTE 1: *In certain fields it may be impossible or impractical to retain records of all original observations.*

NOTE 2: *Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.*

4.13.2.2 *Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.*

1  
2 4.13.2.3 *When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted,*  
3 *and the correct value entered alongside. All such alterations to records shall be signed or initialled by the*  
4 *person making the correction. In the case of records stored electronically, equivalent measures shall be*  
5 *taken to avoid loss or change of original data.*

6  
7 4.13.3 Additional Requirements

- 8  
9 a) The laboratory shall establish a record keeping system that allows the history of the sample  
10 and associated data to be readily understood through the documentation. This system shall  
11 produce unequivocal, accurate records that document all laboratory activities such as  
12 laboratory facilities, equipment, analytical methods, and related laboratory activities, such as  
13 sample receipt, sample preparation, or data verification, and inter-laboratory transfers of  
14 samples and/or extracts.  
15  
16 b) The laboratory shall retain all records for a minimum of five (5) years from generation of the  
17 last entry in the records.  
18  
19 c) Records shall be available to the accreditation body.  
20  
21 d) Records that are stored only on electronic media shall be supported by the hardware and  
22 software necessary for their retrieval.  
23  
24 e) Access to archived information shall be documented with an access log.  
25  
26 f) All information necessary for the historical reconstruction of data shall be maintained by the  
27 laboratory.  
28  
29 i) all raw data, whether hard copy or electronic, for calibrations, samples and quality  
30 control measures, including analysts' worksheets and data output records  
31 (chromatograms, strip charts, and other instrument response readout records);  
32  
33 ii) a written description or reference to the specific method used, which includes a  
34 description of the specific computational steps used to translate parametric  
35 observations into a reportable analytical value;  
36  
37 iii) laboratory sample ID code;  
38  
39 iv) date of analysis;  
40  
41 v) time of analysis is required if the holding time is seventy-two (72) hours or less, or  
42 when time critical steps are included in the analysis (e.g., extractions and incubations);  
43  
44 vi) instrumentation identification and instrument operating conditions/parameters (or  
45 reference to such data);  
46  
47 vii) all manual calculations;  
48  
49 viii) analyst's or operator's initials/signature or electronic identification;  
50  
51 ix) sample preparation, including cleanup, separation protocols, incubation periods or  
52 subculture, ID codes, volumes, weights, instrument printouts, meter readings,  
53 calculations, reagents;  
54  
55 x) test results;  
56

- 1 xi) standard and reagent origin, receipt, preparation, and use;  
2  
3 xii) calibration criteria, frequency and acceptance criteria;  
4  
5 xiii) data and statistical calculations, review, confirmation, interpretation, assessment and  
6 reporting conventions;  
7  
8 xiv) quality control protocols and assessment;  
9  
10 xv) electronic data security, software documentation and verification, software and  
11 hardware audits, backups, and records of any changes to automated data entries;  
12  
13 xvi) method performance criteria including expected quality control requirements;  
14  
15 xvii) proficiency test results;  
16  
17 xviii) records of demonstration of capability for each analyst; and  
18  
19 xix) a record of names, initials, and signatures for all individuals who are responsible for  
20 signing or initialing any laboratory record.  
21  
22 g) All generated data, except those that are generated by automated data collection systems,  
23 shall be recorded legibly in permanent ink.  
24  
25 i) An individual making corrections to records shall date and initial the correction.  
26  
27 ii) Corrections due to reasons other than transcription errors shall specify the reason for  
28 the correction.  
29  
30 h) The laboratory shall have a plan to ensure that the records are maintained or transferred  
31 according to the clients' instructions in the event that a laboratory transfers ownership or goes  
32 out of business. In addition, appropriate regulatory and state legal requirements concerning  
33 laboratory records shall be followed.  
34

#### 35 4.14 Internal Audits (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.14)

36  
37 4.14.1 *The laboratory shall periodically, and in accordance with a predetermined schedule and procedure,*  
38 *conduct internal audits of its activities to verify that its operations continue to comply with the*  
39 *requirements of the management system and this International Standard. The internal audit programme*  
40 *shall address all elements of the management system, including the testing and/or calibration activities.*  
41 *It is the responsibility of the quality manager to plan and organize audits as required by the schedule*  
42 *and requested by management. Such audits shall be carried out by trained and qualified personnel who*  
43 *are, wherever resources permit, independent of the activity to be audited.*

44  
45 *NOTE: The cycle for internal auditing should normally be completed in one year.*

46  
47 4.14.2 *When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of*  
48 *the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify*  
49 *customers in writing if investigations show that the laboratory results may have been affected.*

50  
51 4.14.3 *The area of activity audited, the audit findings and corrective actions that arise from them shall be*  
52 *recorded.*

53  
54 4.14.4 *Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective*  
55 *action taken.*  
56

## 4.14.5 Additional Items

- a) The laboratory shall have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results.
- b) The laboratory management shall ensure that these actions are discharged within the agreed time frame.
- c) The Internal audit schedule shall be completed annually,

**4.15 Management Reviews (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.15)**

4.15.1 *In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:*

- *the suitability of policies and procedures;*
- *reports from managerial and supervisory personnel;*
- *the outcome of recent internal audits;*
- *corrective and preventive actions;*
- *assessments by external bodies;*
- *the results of interlaboratory comparisons or proficiency tests;*
- *changes in the volume and type of the work;*
- *customer feedback;*
- *complaints;*
- *recommendations for improvement;*
- *other relevant factors, such as quality control activities, resources, and staff training.*

*NOTE 1: A typical period for conducting a management review is once every 12 months.*

*NOTE 2: Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.*

*NOTE 3: A management review includes consideration of related subjects at regular management meetings.*

4.15.2 *Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.*

4.15.3 Management review shall be completed on an annual basis.

**4.16 Data Integrity Investigations**

All investigations resulting from data integrity issues should be conducted in a confidential manner until they are completed. These investigations shall be documented, as well as any notifications made to clients receiving any affected data.

**5.0 TECHNICAL REQUIREMENTS**



**5.1 General (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.1)**

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- human factors (5.2);
- accommodation and environmental conditions (5.3);
- test and calibration methods and method validation (5.4);
- equipment (5.5);
- measurement traceability (5.6);
- sampling (5.7);
- the handling of test and calibration items (5.8).

5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

**5.2 Personnel (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.2)**

~~Note: All references to Calibration Certificates in ISO/IEC 17025:2005(E)ISO/IEC 17025:2005 are not applicable to environmental testing.~~

5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

NOTE 1: In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer.

NOTE 2: The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

- relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;
- knowledge of the general requirements expressed in the legislation and standards; and
- an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.

5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.

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1 5.2.3 *The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where*  
2 *contracted and additional technical and key support personnel are used, the laboratory shall ensure that*  
3 *such personnel are supervised and competent and that they work in accordance with the laboratory's*  
4 *management system.*

5  
6 5.2.4 *The laboratory shall maintain current job descriptions for managerial, technical and key support*  
7 *personnel involved in tests and/or calibrations.*

8  
9 *NOTE: Job descriptions can be defined in many ways. As a minimum, the following should be defined:*

- 10 — *the responsibilities with respect to performing tests and/or calibrations;*
- 11 — *the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;*
- 12 — *the responsibilities for reporting opinions and interpretations;*
- 13 — *the responsibilities with respect to method modification and development and validation of new*  
14 *methods;*
- 15 — *expertise and experience required;*
- 16 — *qualifications and training programmes;*
- 17 — *managerial duties.*

18  
19  
20 5.2.5 *The management shall authorize specific personnel to perform particular types of sampling, test*  
21 *and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to*  
22 *operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s),*  
23 *competence, educational and professional qualifications, training, skills and experience of all technical*  
24 *personnel, including contracted personnel. This information shall be readily available and shall include the*  
25 *date on which authorization and/or competence is confirmed.*

26  
27 *NOTE: All references to Calibration Certificates in ISO/IEC 17025:2005(E) ISO/IEC 17025:2005 are*  
28 *not applicable to environmental testing.*

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29  
30 5.2.6 Additional Personnel Requirements

31  
32 5.2.6.1 Technical Manager Qualifications

33  
34 The applicable requirements for technical managers are given below.

- 35  
36 a) Any technical manager of an accredited environmental laboratory engaged in chemical  
37 analysis shall be a person with a bachelor's degree in the chemical, environmental, biological  
38 sciences, physical sciences or engineering, with at least twenty-four (24) college semester  
39 credit hours in chemistry and at least two (2) years of experience in the environmental  
40 analysis of representative inorganic and organic analytes for which the laboratory seeks or  
41 maintains accreditation. A master's or doctoral degree in one of the above disciplines may be  
42 substituted for one (1) year of experience.
- 43  
44 b) Any technical manager of an accredited environmental laboratory limited to inorganic  
45 chemical analysis, other than metals analysis, shall be a person with at least an earned  
46 associate's degree in the chemical, physical or environmental sciences, or two (2) years of  
47 equivalent and successful college education, with a minimum of sixteen (16) college  
48 semester credit hours in chemistry. In addition, such a person shall have at least two (2)  
49 years of experience performing such analysis.
- 50  
51 c) Any technical manager of an accredited environmental laboratory engaged in microbiological  
52 or biological analysis shall be a person with a bachelor's degree in microbiology, biology,  
53 chemistry, environmental sciences, physical sciences or engineering with a minimum of  
54 sixteen (16) college semester credit hours in general microbiology and biology and at least

two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology may be the technical manager(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one (1) year of experience in microbiological analyses.

- d) Any technical manager of an accredited environmental laboratory engaged in radiological analysis shall be a person with a bachelor's degree in chemistry, environmental, biological sciences, physical sciences or engineering with twenty-four (24) college semester credit hours of chemistry with two (2) or more years of experience in the radiological analysis of environmental samples. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.
- e) The technical manager(s) of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:
  - i. For procedures requiring the use of a transmission electron microscope, a bachelor's degree, successful completion of courses in the use of the instrument, and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.
  - ii. For procedures requiring the use of a polarized light microscope, an associate's degree or two (2) years of college study, successful completion of formal coursework in polarized light microscopy, and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.
  - iii. For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, an associate's degree or two (2) years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one (1) year of experience, under supervision, in the use of the instrument.
- f) Any technical manager of an accredited environmental laboratory engaged in the examination of radon in air shall have at least an associate's degree or two (2) years of college and one (1) year of experience in radiation measurements, including at least one (1) year of experience in the measurement of radon and/or radon progeny.

#### 5.2.6.2 Technical Manager Qualification Exceptions

- a) Notwithstanding any other provision of this Section, a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational requirements as the technical manager. A technical manager shall have two (2) year testing experience devoted exclusively to the testing of environmental samples specified in the scope of the facility's regulatory permit. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit.
- b) A full-time employee of an industrial waste treatment facility with a minimum of two (2) years of experience under supervision in testing of environmental samples taken within such facility

1 for the scope of that facility's regulatory permit shall be deemed to meet the requirements for  
2 serving as the technical manager of an accredited laboratory. Such accreditation for an  
3 industrial waste treatment facility shall be limited to the scope of that facility's regulatory  
4 permit.

5  
6 c) Persons who do not meet the education credential requirements but possess the requisite  
7 experience of Section 5.2.6.1 shall qualify as technical manager(s) subject to the following  
8 conditions.

9  
10 i) The person shall be a technical manager of the laboratory on the date the laboratory  
11 applies for accreditation and/or becomes subject to accreditation under this Standard,  
12 and shall have been a technical manager in that laboratory continuously for the  
13 previous twelve (12) months or more.

14  
15 ii) The person will be approved as a technical manager for only those fields of  
16 accreditation for which he/she has been technical manager in that laboratory for the  
17 previous twelve (12) months or more.

18  
19 iii) A person who is admitted as a technical manager under these conditions, and leaves  
20 the laboratory, will be eligible for hire as a technical manager for the same fields of  
21 accreditation in another accredited laboratory.

#### 22 23 5.2.7 Data Integrity Training

24  
25 Data integrity training shall be provided as a formal part of new employee orientation and shall also  
26 be provided on an annual basis for all current employees. Employees are required to understand  
27 that any infractions of the laboratory data integrity procedures shall result in a detailed investigation  
28 that could lead to very serious consequences including immediate termination, debarment or  
29 civil/criminal prosecution. The initial data integrity training and the annual refresher training shall  
30 have a signature attendance sheet or other form of documentation that demonstrates all staff have  
31 participated and understand their obligations related to data integrity.

32  
33 Data integrity training requires emphasis on the importance of proper written narration on the part of  
34 the analyst with respect to those cases where analytical data may be useful, but are in one sense  
35 or another partially deficient. The topics covered in such training shall be documented in writing  
36 (such as an agenda) and provided to all trainees. At a minimum, the following topics and activities  
37 shall be included:

- 38  
39 a) organizational mission and its relationship to the critical need for honesty and full disclosure  
40 in all analytical reporting, how and when to report data integrity issues, and record keeping;  
41  
42 b) training, including discussion regarding all data integrity procedures;  
43  
44 c) data integrity training documentation;  
45  
46 d) in-depth data monitoring and data integrity procedure documentation; and  
47  
48 e) specific examples of breaches of ethical behavior such as improper data manipulations,  
49 adjustments of instrument time clocks, and inappropriate changes in concentrations of  
50 standards.

51  
52 The data integrity procedures may also include written ethics agreements, examples of improper  
53 practices, examples of improper chromatographic manipulations, requirements for external ethics  
54 program training, and any external resources available to employees.  
55

1 **5.3 Accommodation and Environmental Conditions (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005,**  
2 **Clause 5.3)**

3  
4 5.3.1 *Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting*  
5 *and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.*  
6 *The laboratory shall ensure that the environmental conditions do not invalidate the results or*  
7 *adversely affect the required quality of any measurement. Particular care shall be taken when*  
8 *sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory*  
9 *facility. The technical requirements for accommodation and environmental conditions that can affect*  
10 *the results of tests and calibrations shall be documented.*

11  
12 5.3.2 *The laboratory shall monitor, control and record environmental conditions as required by the relevant*  
13 *specifications, methods and procedures or where they influence the quality of the results. Due attention shall*  
14 *be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical*  
15 *supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.*  
16 *Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests*  
17 *and/or calibrations.*

18  
19 5.3.3 *There shall be effective separation between neighbouring areas in which there are incompatible activities.*  
20 *Measures shall be taken to prevent cross-contamination.*

21  
22 5.3.4 *Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The*  
23 *laboratory shall determine the extent of control based on its particular circumstances.*

24  
25 5.3.5 *Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be*  
26 *prepared where necessary.*

27  
28 **5.4 Environmental Methods and Method Validation**

29  
30 **NOTE** All references to Calibration Laboratories and Calibration Methods in ~~ISO/IEC~~  
31 ~~17025:2005(E)~~ISO/IEC 17025:2005 in these Clauses are not applicable to environmental  
32 testing.

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33  
34 5.4.1 **General (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.1)**

35  
36 *The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within*  
37 *its scope. These include sampling, handling, transport, storage and preparation of items to be*  
38 *tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as*  
39 *well as statistical techniques for analysis of test and/or calibration data.*

40  
41 *The laboratory shall have instructions on the use and operation of all relevant equipment, and on the*  
42 *handling and preparation of items for testing and/or calibration, or both, where the absence of such*  
43 *instructions could jeopardize the results of tests and/or calibrations. All instructions, standards,*  
44 *manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall*  
45 *be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall*  
46 *occur only if the deviation has been documented, technically justified, authorized, and accepted by the*  
47 *customer.*

48  
49 **NOTE:** *International, regional or national standards or other recognized specifications that contain*  
50 *sufficient and concise information on how to perform the tests and/or calibrations do not need to be*  
51 *supplemented or rewritten as internal procedures if these standards are written in a way that they can be*  
52 *used as published by the operating staff in a laboratory. It may be necessary to provide additional*  
53 *documentation for optional steps in the method or additional details.*

54  
55 5.4.2 **Selection of Methods (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.2)**

56

1 The laboratory shall use test and/or calibration methods, including methods for sampling, which meet  
2 the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes.  
3 Methods published in international, regional or national standards shall preferably be used. The  
4 laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or  
5 possible to do so. When necessary, the standard shall be supplemented with additional details to ensure  
6 consistent application.  
7

8 When the customer does not specify the method to be used, the laboratory shall select appropriate  
9 methods that have been published either in international, regional or national standards, or by  
10 reputable technical organizations, or in relevant scientific texts or journals, or as specified by the  
11 manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory  
12 may also be used if they are appropriate for the intended use and if they are validated. The customer  
13 shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate  
14 standard methods before introducing the tests or calibrations. If the standard method changes, the  
15 confirmation shall be repeated.  
16

17 The laboratory shall inform the customer when the method proposed by the customer is considered to  
18 be inappropriate or out of date.  
19

20 | 5.4.3 Laboratory-Developed Methods (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.3)  
21

22 The introduction of test and calibration methods developed by the laboratory for its own use shall  
23 be a planned activity and shall be assigned to qualified personnel equipped with adequate  
24 resources.  
25

26 Plans shall be updated as development proceeds and effective communication amongst all  
27 personnel involved shall be ensured.  
28

29 | 5.4.4 Non-Standard Methods (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.4) ~~is not~~  
30 ~~applicable in this module and is addressed in specific technical modules based on technology.~~  
31 ~~When it is necessary to use methods not covered by standard methods, these shall be subject to~~  
32 ~~agreement with the customer and shall include a clear specification of the customer's requirements~~  
33 ~~and the purpose of the test and/or calibration. The method developed shall have been validated~~  
34 ~~appropriately before use.~~  
35

36 NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or  
37 calibrations being performed and should contain at least the following information:  
38

39 a) appropriate identification;  
40

41 b) scope;  
42

43 c) description of the type of item to be tested or calibrated;  
44

45 d) parameters or quantities and ranges to be determined;  
46

47 e) apparatus and equipment, including technical performance requirements;  
48

49 f) reference standards and reference materials required;  
50

51 g) environmental conditions required and any stabilization period needed;  
52

53 h) description of the procedure, including  
54

55 – affixing of identification marks, handling, transporting, storing and preparation of items,

56 – checks to be made before the work is started,

57 – checks that the equipment is working properly and, where required, calibration and adjustment of the  
58 equipment before each use,

– the method of recording the observations and results.

1                    – any safety measures to be observed;  
 2  
 3                    i) criteria and/or requirements for approval/rejection;  
 4  
 5                    j) data to be recorded and method of analysis and presentation;  
 6  
 7                    k) the uncertainty or the procedure for estimating uncertainty.  
 8  
 9   5.4.5   Validation of Methods (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.5) ~~is not applicable~~  
 10            ~~in this module and is addressed in specific technical modules based on technology.~~  
 11  
 12            5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that  
 13            the particular requirements for a specific intended use are fulfilled.  
 14  
 15            5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed  
 16            methods, standard methods used outside their intended scope, and amplifications and  
 17            modifications of standard methods to confirm that the methods are fit for the intended use. The  
 18            validation shall be as extensive as is necessary to meet the needs of the given application or field  
 19            of application. The laboratory shall record the results obtained, the procedure used for the  
 20            validation, and a statement as to whether the method is fit for the intended use.  
 21  
 22            NOTE 1 Validation may include procedures for sampling, handling and transportation.  
 23  
 24            NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a  
 25            combination of, the following:  
 26            – calibration using reference standards or reference materials;  
 27            – comparison of results achieved with other methods;  
 28            – interlaboratory comparisons;  
 29            – systematic assessment of the factors influencing the result;  
 30            – assessment of the uncertainty of the results based on scientific understanding of the theoretical  
 31            principles of the method and practical experience.  
 32  
 33            NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes  
 34            should be documented and, if appropriate, a new validation should be carried out.  
 35  
 36            5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the  
 37            uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability  
 38            and/or reproducibility, robustness against external influences and/or cross-sensitivity against  
 39            interference from the matrix of the sample/test object), as assessed for the intended use, shall be  
 40            relevant to the customers' needs.  
 41  
 42            NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the  
 43            methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.  
 44  
 45            NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the  
 46            customer are still being fulfilled. Any change in requirements requiring modifications to the development plan  
 47            should be approved and authorized.  
 48  
 49            NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases  
 50            in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity,  
 51            repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack  
 52            of information.  
 53  
 54   5.4.5.4   All methods used by the laboratory, whether non standard method or standard (reference) methods  
 55            shall be validated before use to ensure that the laboratory has the capability of using the method for  
 56            its intended use. See section 1.5, of each of the technical modules (Volume 1 modules 3 through  
 57            7) for specific validation requirements. Non-standard methods must comply with 5.4.5.1 – 5.4.5.3  
 58            above in addition to specific requirements in Section 1.5 of the technical modules. Except when

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~~specified, an initial demonstration of capability (see 1.6 of the technical modules) is adequate to validate reference methods.~~

#### 5.4.6 Estimation of Analytical Uncertainty

Clause 5.4.6 of the *ISO/IEC/IEC 17025:2005(E)* concerning calibration testing does not apply. The following requirement replaces the *ISO/IEC Clause*. Environmental testing laboratories shall have a procedure(s) for estimating analytical uncertainty. Quality control measurement data may be used to determine analytical uncertainty.

#### 5.4.7 Control of Data (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.7)

##### 5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

##### 5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

- a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
- b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

NOTE: Commercial off-the-shelf software (e.g. word processing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2 a).

#### 5.5 Calibration Requirements (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.5)

~~ISO/IEC Clauses 5.5.1 to 5.5.12 apply with respect to equipment in environmental testing laboratories.~~

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.

5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.



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- 5.5.5 *Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:*
- a) *the identity of the item of equipment and its software;*
  - b) *the manufacturer's name, type identification, and serial number or other unique identification;*
  - c) *checks that equipment complies with the specification (see 5.5.2);*
  - d) *the current location, where appropriate;*
  - e) *the manufacturer's instructions, if available, or reference to their location;*
  - f) *dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;*
  - g) *the maintenance plan, where appropriate, and maintenance carried out to date; h) any damage, malfunction, modification or repair to the equipment.*
- 5.5.6 *The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.*
- NOTE: Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.*
- 5.5.7 *Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, 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 repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).*
- 5.5.8 *Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.*
- 5.5.9 *When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.*
- 5.5.10 *When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.*
- 5.5.11 *Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.*
- 5.5.12 *Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.*
- NOTE: ISO/IEC Clauses 5.5.1 to 5.5.12 apply with respect to equipment in environmental testing laboratories. Why did we need this???*
- 5.5.13 *Additional Requirements and Clarifications*

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1 Calibration requirements for analytical support equipment are included in this Section while  
2 requirements for instrument (testing) calibration are included in technical modules (i.e., Asbestos,  
3 Chemistry, Microbiology, Radiochemistry and Toxicology).

#### 4 5 5.5.13.1 Support Equipment

6  
7 This Standard applies to all devices that may not be the actual test instrument, but are necessary to  
8 support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators,  
9 freezers, incubators, water baths, temperature measuring devices (including thermometers and  
10 thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such  
11 as Eppendorf® or automatic dilutor/dispensing devices), if quantitative results are dependent on  
12 their accuracy, as in standard preparation and dispensing or dilution into a specified volume.

- 13  
14 a) All support equipment shall be maintained in proper working order. The records of all repair  
15 and maintenance activities, including service calls, shall be kept.
- 16  
17 b) All support equipment shall be calibrated or verified at least annually, using a recognized  
18 National Metrology Institute, such as NIST, traceable references when available, bracketing  
19 the range of use. The results of such calibration or verification shall be within the  
20 specifications required of the application for which this equipment is used or:
- 21  
22 i) the equipment shall be removed from service until repaired; or  
23  
24 ii) the laboratory shall maintain records of established correction factors to correct all  
25 measurements.
- 26  
27 c) Raw data records shall be retained to document equipment performance.
- 28  
29 d) On each day the equipment is used, balances, ovens, refrigerators, freezers and water baths  
30 shall be checked and documented. The acceptability for use or continued use shall be  
31 according to the needs of the analysis or application for which the equipment is being used.
- 32  
33 e) Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall  
34 be checked for accuracy on a quarterly basis.

## 35 36 5.6 Measurement Traceability

37  
38 5.6.1 General (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.6.1) is not applicable to  
39 environmental testing.

40  
41 5.6.2 Specific Requirements (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.6.2) is not  
42 applicable to environmental testing.

43  
44 5.6.3 Reference Standards and Reference Materials (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005,  
45 Clause 5.6.3)

### 46 47 5.6.3.1 Reference Standards

48  
49 *The laboratory shall have a programme and procedure for the calibration of its reference standards.  
50 Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.  
51 Such reference standards of measurement held by the laboratory shall be used for calibration only and  
52 for no other purpose, unless it can be shown that their performance as reference standards would not  
53 be invalidated. Reference standards shall be calibrated before and after any adjustment.*

### 54 55 5.6.3.2 Reference Materials

56

1            *Reference materials shall, where possible, be traceable to SI units of measurement, or to certified*  
2            *reference materials. Internal reference materials shall be checked as far as is technically and*  
3            *economically practicable.*

4  
5    5.6.3.3    *Intermediate Checks*

6  
7            *Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working*  
8            *standards and reference materials shall be carried out according to defined procedures and schedules.*

9  
10   5.6.3.4    *Transport and Storage*

11            *The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and*  
12            *reference materials in order to prevent contamination or deterioration and in order to protect their integrity.*

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

15  
16  
17  
18   5.6.4       Additional Requirements and Clarifications

19  
20   5.6.4.1     Reference Standards and Reference Materials

21            The laboratory shall provide satisfactory evidence of correlation of results, for example, by  
22            participation in a suitable program of inter-laboratory comparisons, proficiency testing, or  
23            independent analysis.

24  
25  
26       a)       Reference Standards

27            Where commercially available, this traceability shall be to a national standard of  
28            measurement.

29  
30  
31       b)       Reference Materials

32            Where possible, traceability shall be to national or international standards of measurement or  
33            to national or international standard reference materials. Internal reference materials shall be  
34            checked as far as is technically and economically practicable.

35  
36  
37   5.6.4.2     Documentation and Labeling of Standards, Reagents, and Reference Materials

38            Documented procedures shall exist for the purchase, receipt and storage of consumable materials  
39            used for the technical operations of the laboratory.

40  
41  
42       a)       The laboratory shall retain records for all standards, reagents, reference materials, and  
43            media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity  
44            (if available), the date of receipt, and recommended storage conditions.

45  
46       b)       For original containers, if an expiration date is provided by the manufacturer or vendor it shall  
47            be recorded on the container. If an expiration date is not provided by the manufacturer or  
48            vendor it is not required.

49  
50       c)       Records shall be maintained on standard, reference material, and reagent preparation. These  
51            records shall indicate traceability to purchased stocks or neat compounds, reference to the  
52            method of preparation, date of preparation, expiration date and preparer's initials.

53  
54       d)       All containers of prepared standards, reference materials, and reagents shall bear a unique  
55            identifier and expiration date.  
56

- 1 e) Procedures shall be in place to ensure prepared reagents meet the requirements of the  
2 method.  
3  
4 f) Standards, reference materials, and reagents shall not be used after their expiration dates  
5 unless their reliability is verified by the laboratory.  
6

7 | **5.7 Collection of Samples (ISO/IEC 17025:2005(E)|ISO/IEC 17025:2005, Clause 5.7)**  
8

9 5.7.1 *The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of*  
10 *substances, materials or products for subsequent testing or calibration. The sampling plan as well as the*  
11 *sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall,*  
12 *whenever reasonable, be based on appropriate statistical methods. The sampling process shall address*  
13 *the factors to be controlled to ensure the validity of the test and calibration results.*  
14

15 NOTE 1: *Sampling is a defined procedure whereby a part of a substance, material or product is taken*  
16 *to provide for testing or calibration of a representative sample of the whole. Sampling may also be*  
17 *required by the appropriate specification for which the substance, material or product is to be*  
18 *tested or calibrated. In certain cases (e.g. forensic analysis), the sample may not be representative*  
19 *but is determined by availability.*  
20

21 NOTE 2: *Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of*  
22 *a sample or samples from a substance, material or product to yield the required information.*  
23

24 5.7.2 *Where the customer requires deviations, additions or exclusions from the documented sampling*  
25 *procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in*  
26 *all documents containing test and/or calibration results, and shall be communicated to the appropriate*  
27 *personnel.*  
28

29 5.7.3 *The laboratory shall have procedures for recording relevant data and operations relating to sampling that*  
30 *forms part of the testing or calibration that is undertaken. These records shall include the sampling*  
31 *procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or*  
32 *other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics*  
33 *the sampling procedures are based upon.*  
34

35 5.7.4 Additional Requirements  
36

- 37 a) Documentation shall include the date and time of sampling.  
38  
39 b) Any deviations from sampling procedures shall be documented.  
40

41 | **5.8 Handling Samples and Test Items (ISO/IEC 17025:2005(E)|ISO/IEC 17025:2005, Clause 5.8)**  
42

43 5.8.1 *The laboratory shall have procedures for the transportation, receipt, handling, protection, storage,*  
44 *retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the*  
45 *integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.*  
46

47 5.8.2 *The laboratory shall have a system for identifying test and/or calibration items. The identification shall be*  
48 *retained throughout the life of the item in the laboratory. The system shall be designed and operated so*  
49 *as to ensure that items cannot be confused physically or when referred to in records or other documents.*  
50 *The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items*  
51 *within and from the laboratory.*  
52

53 5.8.3 *Upon receipt of the test or calibration item, abnormalities or departures from normal or specified*  
54 *conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to*  
55 *the suitability of an item for test or calibration, or when an item does not conform to the description*  
56 *provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult*

1            *the customer for further instructions before proceeding and shall record the discussion.*

2  
3 5.8.4    *The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or*  
4 *damage to the test or calibration item during storage, handling and preparation. Handling instructions*  
5 *provided with the item shall be followed. When items have to be stored or conditioned under specified*  
6 *environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or*  
7 *calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for*  
8 *storage and security that protect the condition and integrity of the secured items or portions concerned.*  
9

10        *NOTE 1: Where test items are to be returned into service after testing, special care is required to ensure*  
11 *that they are not damaged or injured during the handling, testing or storing/waiting processes.*

12  
13        *NOTE 2: A sampling procedure and information on storage and transport of samples, including information*  
14 *on sampling factors influencing the test or calibration result, should be provided to those responsible*  
15 *for taking and transporting the samples.*

16  
17        *NOTE 3: Reasons for keeping a test or calibration item secure can be for reasons of record, safety or*  
18 *value, or to enable complementary tests and/or calibrations to be performed later.*

19  
20 5.8.5    Additional Requirements – Documentation

21        The following are essential to ensure the validity of the laboratory's data.

- 22  
23  
24 a)    The laboratory shall have a documented system for uniquely identifying the samples to be  
25 tested, to ensure that there can be no confusion regarding the identity of such samples at any  
26 time. This system shall include identification for all samples, sub-samples, preservations,  
27 sample containers, tests, and subsequent extracts and/or digestates.  
28  
29 b)    This laboratory code shall maintain an unequivocal link with the unique field ID code assigned  
30 to each sample.  
31  
32 c)    The laboratory ID code shall be placed as a durable mark on the sample container.  
33  
34 d)    The laboratory ID code shall be entered into the laboratory records and shall be the link that  
35 associates the sample with related laboratory activities such as sample preparation.  
36  
37 e)    In cases where the sample collector and analyst are the same individual, or the laboratory  
38 pre-assigns numbers to sample containers, the laboratory ID code may be the same as the  
39 field ID code.  
40

41 5.8.6    Additional Requirements – Sample Acceptance Policy

42        The laboratory shall have a written sample acceptance policy that includes the following:

- 43  
44 a)    proper, full, and complete documentation, which shall include sample identification, the  
45 location, date and time of collection, collector's name, preservation type, sample type and any  
46 special remarks concerning the sample;  
47  
48 b)    proper sample labeling to include unique identification and a labeling system for the samples  
49 with requirements concerning the durability of the labels (water resistant) and the use of  
50 indelible ink;  
51  
52 c)    use of appropriate sample containers;  
53  
54 d)    adherence to specified holding times;  
55  
56

- 1 e) sufficient sample volume to perform the necessary tests;
- 2
- 3 f) procedures to be used when samples show signs of damage, contamination or inadequate
- 4 preservation; and
- 5
- 6 g) qualification of any data that do not meet the above requirements.
- 7
- 8 5.8.7 Additional Requirements – Sample Receipt Protocols
- 9
- 10 5.8.7.1 The laboratory shall implement procedures for verifying and documenting preservation.
- 11
- 12 5.8.7.2 If the sample does not meet the sample receipt acceptance criteria listed in this Standard, the
- 13 laboratory shall either:
- 14
- 15 a) retain correspondence and/or records of conversations concerning the final disposition of
- 16 rejected samples; or
- 17
- 18 b) fully document any decision to proceed with the analysis of samples not meeting acceptance
- 19 criteria.
- 20
- 21 i) The condition of these samples shall be noted on the chain of custody or transmittal
- 22 form and laboratory receipt documents.
- 23
- 24 ii) The analysis data shall be appropriately qualified on the final report.
- 25
- 26 5.8.7.3 The laboratory shall utilize a permanent chronological record such as a logbook or electronic
- 27 database to document receipt of all sample containers.
- 28
- 29 a) This sample receipt log shall record the following:
- 30
- 31 i) client/project name,
- 32 ii) date and time of laboratory receipt,
- 33 iii) unique laboratory ID code (see Section 5.12.4 b), 5.8.5 a), and
- 34 iv) signature or initials of the person making the entries.
- 35
- 36 b) During the login process, the following information shall be unequivocally linked to the log
- 37 record or included as a part of the log. If such information is recorded/documentated
- 38 elsewhere, the records shall be part of the laboratory's permanent records, easily retrievable
- 39 upon request and readily available to individuals who will process the sample.
- 40
- 41 ~~NOTE: The placement of the laboratory ID number on the sample container is not~~
- 42 ~~considered a permanent record.~~
- 43
- 44 i) The field ID code, which identifies each sample, shall be linked to the laboratory ID
- 45 code in the sample receipt log.
- 46
- 47 ii) The date and time of sample collection shall be linked to the sample and to the date
- 48 and time of receipt in the laboratory.
- 49
- 50 iii) The requested analyses (including applicable approved method numbers) shall be
- 51 linked to the laboratory ID code.
- 52
- 53 iv) Any comments resulting from inspection for sample rejection shall be linked to the
- 54 laboratory ID code.
- 55
- 56

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- 1 5.8.7.4 All documentation, such as memos, chain of custody, or transmittal forms that are transmitted to the  
2 laboratory by the sample transmitter, shall be retained.  
3
- 4 5.8.7.5 A complete chain of custody record form, if utilized, shall be maintained.  
5
- 6 5.8.8 Additional Requirements – Legal Chain of Custody Protocols  
7  
8 Legal chain of custody procedures are used for evidentiary or legal purposes. If a client specifies  
9 that a sample is to be used for evidentiary purposes, then a laboratory shall have a written SOP for  
10 how that laboratory will carry out legal chain of custody.  
11
- 12 5.8.9 Additional Requirements – Sample Storage and Disposal  
13  
14 a) Samples shall be stored according to the conditions specified by preservation protocols.  
15  
16 i) Samples that require thermal preservation shall be stored under refrigeration that is +/-  
17 2°C of the specified preservation temperature unless regulatory or method specific  
18 criteria exist. For samples with a specified storage temperature of 4°C, storage at a  
19 temperature above the freezing point of water to 6°C shall be acceptable.  
20  
21 ii) Samples shall be stored away from all standards, reagents, and food. Samples shall be  
22 stored in such a manner to prevent cross contamination.  
23
- 24 b) Sample fractions, extracts, leachates and other sample preparation products shall be stored  
25 according to Section 5.8.9 a) above or according to specifications in the method.  
26
- 27 c) The laboratory shall have SOPs for the disposal of samples, digestates, leachates and  
28 extracts or other sample preparation products.  
29
- 30 **5.9 Quality Assurance for Environmental Testing (ISO/IEC 17025:2005(E)/ISO/IEC 17025:2005,  
31 Clause 5.9)**  
32
- 33 5.9.1 *The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations  
34 undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where  
35 practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be  
36 planned and reviewed and may include, but not be limited to, the following:*  
37
- 38 a) *regular use of certified reference materials and/or internal quality control using secondary  
39 reference materials;*  
40
- 41 b) *participation in interlaboratory comparison or proficiency-testing programmes;*  
42
- 43 c) *replicate tests or calibrations using the same or different methods;*  
44
- 45 d) *retesting or recalibration of retained items;*  
46
- 47 e) *correlation of results for different characteristics of an item.*  
48
- 49 *NOTE: The selected methods should be appropriate for the type and volume of the work undertaken.*  
50
- 51 5.9.2 *Quality control data shall be analysed and, where they are found to be outside pre-defined criteria,  
52 planned action shall be taken to correct the problem and to prevent incorrect results from being  
53 reported.*  
54
- 55 5.9.3 Essential Quality Control Procedures  
56

1 These general quality control principles shall apply, where applicable, to all testing laboratories. The  
2 manner in which they are implemented is dependent on the types of tests performed by the  
3 laboratory (i.e., asbestos, chemical, microbiological, radiological, toxicity) and are further described  
4 in Technical Modules. The standards for any given test type shall assure that the applicable  
5 principles are addressed:  
6

- 7 a) All laboratories shall have detailed written protocols in place to monitor the following quality  
8 controls:  
9
- 10 i) positive and negative controls (see technical modules), chemical or microbiological as  
11 applicable to the test type, to monitor tests such as blanks, matrix spikes, reference  
12 toxicants;
  - 13 ii) tests to define the variability and/or repeatability of the laboratory results such as  
14 replicates;
  - 15 iii) measures to assure the accuracy of the method including calibration and/or continuing  
16 calibrations, use of certified reference materials, proficiency test samples, or other  
17 measures;
  - 18 iv) measures to evaluate method capability, such as limit of detection and limit of  
19 quantitation or range of applicability such as linearity;
  - 20 v) selection of appropriate formulae to reduce raw data to final results such as regression  
21 analysis, comparison to internal/external standard calculations, and statistical analyses;
  - 22 vi) selection and use of reagents and standards of appropriate quality;
  - 23 vii) measures to assure the selectivity of the test for its intended purpose; and  
24
  - 25 viii) measures to assure constant and consistent test conditions (both instrumental and  
26 environmental) where required by the method such as temperature, humidity, light or  
27 specific instrument conditions.
- 28 b) All quality control measures shall be assessed and evaluated on an on-going basis and  
29 quality control acceptance criteria shall be used.  
30
- 31 c) The laboratory shall have procedures for the development of acceptance/rejection criteria  
32 where no method or regulatory criteria exist.  
33

34 The quality control protocols specified by the laboratory's SOP shall be followed (see Section  
35 4.2.8.5 in this Standard). The laboratory shall ensure that the essential standards outlined in  
36 Technical Modules or mandated methods or regulations (whichever are more stringent) are  
37 incorporated into their method manuals. When it is not apparent which is more stringent, the  
38 QC in the mandated method or regulations is to be followed.  
39

## 40 5.10 Reporting the Results

41 **NOTE**—All references to Calibration Certificates in *ISO/IEC 17025:2005* are not applicable to  
42 environmental testing.

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### 43 5.10.1 General (~~ISO/IEC 17025:2005(E)~~ *ISO/IEC 17025:2005*, Clause 5.10.1)

44 *The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall*  
45 *be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific*  
46 *instructions in the test or calibration methods.*  
47  
48  
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The results shall be reported, usually in a test report or a calibration certificate (see Note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

NOTE 1: Test reports and calibration certificates are sometimes called test certificates and calibration reports respectively.

NOTE 2: The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.

5.10.2 Test Reports and Calibration Certificates (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.10.2)

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

- a) a title (e.g. "Test Report" or "Calibration Certificate");
- b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;
- c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;
- d) the name and address of the customer;
- e) identification of the method used;
- f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;
- g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;
- h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- i) the test or calibration results with, where appropriate, the units of measurement;
- j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;
- k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

NOTE 1: Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

NOTE 2: *It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.*

5.10.3 Test Reports (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.10.3)

5.10.3.1 *In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:*

- a) *deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;*
- b) *where relevant, a statement of compliance/non-compliance with requirements and/or specifications;*
- c) *where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;*
- d) *where appropriate and needed, opinions and interpretations (see 5.10.5);*

~~e) additional information which may be required by specific methods, customers or groups of customers.~~

5.10.3.2 *In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:*

- a) *the date of sampling;*
- ~~b) additional information which may be required by specific methods, customers or groups of customers.~~
- ~~b)c) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);~~
- ~~e)d) the location of sampling, including any diagrams, sketches or photographs;~~
- ~~e)e) a reference to the sampling plan and procedures used;~~
- ~~e)f) details of any environmental conditions during sampling that may affect the interpretation of the test results;~~
- ~~f)g) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.~~

5.10.4 Calibration Certificates (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.10.4) does not apply to environmental testing activities.

5.10.5 *Opinions and interpretations*

*When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.*

NOTE 1: *Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.*

1 NOTE 2: *Opinions and interpretations included in a test report may comprise, but not be limited to, the*  
2 *following:*

- 3
- 4 • *an opinion on the statement of compliance/noncompliance of the results with*
- 5 *requirements;*
- 6 • *fulfilment of contractual requirements;*
- 7 • *recommendations on how to use the results;*
- 8 • *guidance to be used for improvements.*
- 9

10 NOTE 3: *In many cases it might be appropriate to communicate the opinions and interpretations by*  
11 *direct dialogue with the customer. Such dialogue should be written down.*

12

13 5.10.6 *Testing and calibration results obtained from subcontractors*

14

15 *When the test report contains results of tests performed by subcontractors, these results shall be*  
16 *clearly identified. The subcontractor shall report the results in writing or electronically. When a*  
17 *calibration has been subcontracted, the laboratory performing the work shall issue the calibration*  
18 *certificate to the contracting laboratory.*

19

20 5.10.7 *Electronic transmission of results*

21

22 *In the case of transmission of test or calibration results by telephone, telex, facsimile or other*  
23 *electronic or electromagnetic means, the requirements of this International Standard shall be met*  
24 *(see also 5.4.7).*

25

26 5.10.8 *Format of reports and certificates*

27

28 *The format shall be designed to accommodate each type of test or calibration carried out and to*  
29 *minimize the possibility of misunderstanding or misuse.*

30

31 NOTE 1: *Attention should be given to the lay-out of the test report or calibration certificate, especially*  
32 *with regard to the presentation of the test or calibration data and ease of assimilation by the*  
33 *reader.*

34

35 NOTE 2: *The headings should be standardized as far as possible.*

36

37 5.10.9 *Amendments to test reports and calibration certificates*

38

39 *Material amendments to a test report or calibration certificate after issue shall be made only in the*  
40 *form of a further document, or data transfer, which includes the statement: "Supplement to Test*  
41 *Report [or Calibration Certificate], serial number... [or as otherwise identified]", or an equivalent*  
42 *form of wording. Such amendments shall meet all the requirements of this International Standard.*  
43 *When it is necessary to issue a complete new test report or calibration certificate, this shall be*  
44 *uniquely identified and shall contain a reference to the original that it replaces.*

45

46 5.10.10 *Exceptions*

47

48 *Some regulatory reporting requirements or formats, such as monthly operating reports, may not*  
49 *require all items listed below; however, the laboratory shall provide all the required information to*  
50 *their client for use in preparing such regulatory reports.*

51

52 *Laboratories operated solely to provide data for compliance purposes (in-house or captive*  
53 *laboratories) shall have all applicable information specified in Section 5.10 readily available for*  
54 *review by the accreditation body. However, formal reports detailing the information are not required*  
55 *if:*

56

- 1 a) the in-house laboratory is itself responsible for preparing the regulatory reports; or
- 2
- 3 b) the laboratory provides information to another individual within the organization for
- 4 preparation of regulatory reports. The facility management shall ensure that the appropriate
- 5 report items are in the report to the regulatory authority, if such information is required; or
- 6
- 7 c) see Section 5.10.1, paragraph 3.
- 8
- 9 5.10.11 Additional Requirements
- 10
- 11 a) Time of sample preparation and/or analysis if the required holding time for either activity is
- 12 less than or equal to seventy-two (72) hours.
- 13
- 14 b) Results that are reported on a basis other than as received (e. g., dry weight).
- 15
- 16 c) Any non-accredited tests shall be clearly identified as such to the client when claims of
- 17 accreditation to this Standard are made in the analytical report or in the supporting electronic
- 18 or hardcopy deliverables.
- 19
- 20 d) Clear identification of numerical results with values outside the calibration range.
- 21

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Working Draft Standard