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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 2: Quality Systems General Requirements

**Voting Draft Standard
December 2011**

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PREFACE

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.

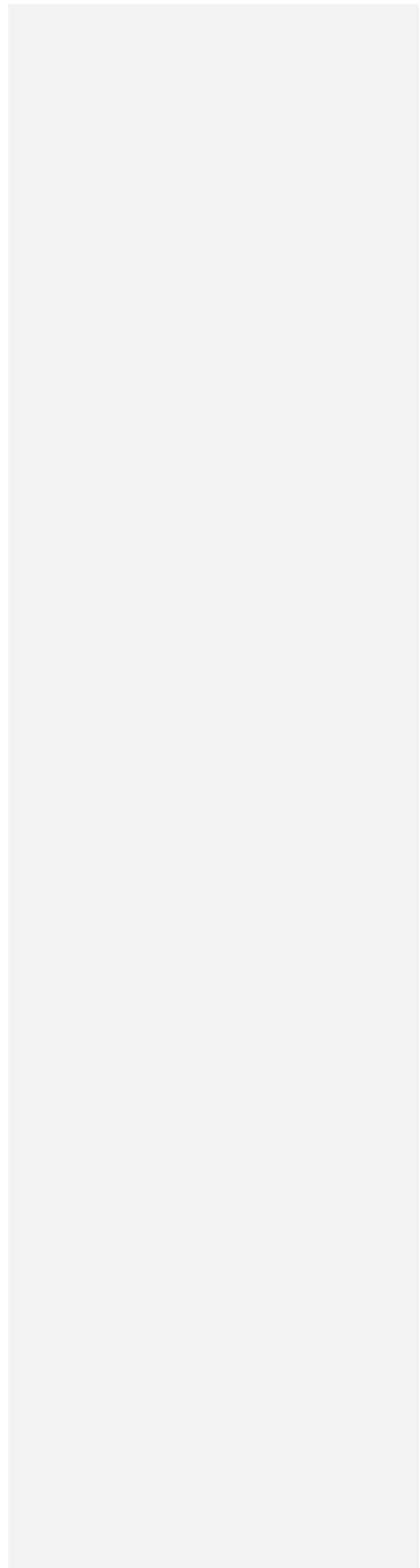
It is conformant with the requirements of ~~ISO/IEC 17025:2005(E)~~ ISO/IEC 17025:2005, and includes applicable clauses from that international standard. The ISO clauses are provided *in italics*. Additional TNI text is provided in a normal font.

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

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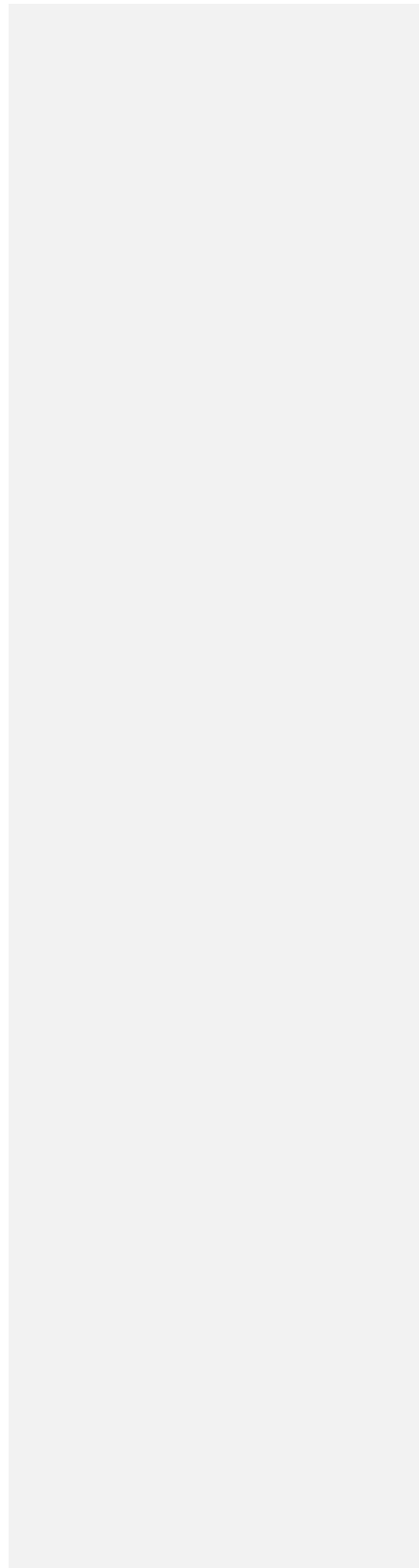


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VOLUME 1, MODULE 2
Quality Systems General Requirements

1.0 INTRODUCTION, SCOPE AND APPLICABILITY
1.2 Scope

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.

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

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

3.0 TERMS AND DEFINITIONS

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

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

Demonstration of Capability: A procedure to establish the ability of the analyst to generate perform analyses with analytical results of acceptable accuracy and precision.

In-depth Data Monitoring: When used in the context of data integrity activities, a review and evaluation of documentation related to all aspects of the data generation process that includes items such as preparation, equipment, software, calculations and quality controls. Such monitoring shall determine if the laboratory uses appropriate data handling, data use and data reduction activities to support the laboratory's data integrity policies and procedures.

Limit(s) of Detection (LOD): A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility. The minimum result which can be reliably discriminated from a blank with a predetermined confidence level.

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

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

Reference Method: To be used to determine the extent of method validation in Modules 3-7. 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

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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.~~

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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.

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

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

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

4.0 MANAGEMENT REQUIREMENTS

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

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:

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h) monitor corrective actions.

~~NOTE: j) 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:

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

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

4.2.8 Additional Management System Requirements

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

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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) Documents that contain sufficient information to perform the tests, do not need to be
6 supplemented or rewritten as internal procedures if the documents are written in a way that
7 they can be used as written. Any changes, including the use of a selected option, shall be
8 documented and included in the laboratory's ~~test~~ records.

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10 f) The SOP may be a copy of a published or referenced method or may be written by the
11 laboratory. In cases where modifications to the published method have been made by the
12 laboratory or where the referenced method is ambiguous or provides insufficient detail,
13 these changes or clarifications shall be clearly described. Each method shall include or
14 reference the following topics where applicable:

15
16 i. scope and application, including analytes parameters to be analyzed;

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18 4.3 Document Control (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.3)

19
20 4.4 Review of Requests, Tenders and Contracts (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005,
21 Clause 4.4)

22
23 4.5 Subcontracting of Environmental Tests (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause
24 4.5)

25
26 4.6 Purchasing Services and Supplies (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.6)

27
28 4.7 Service to the Client (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.7)

29
30 4.8 Complaints (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.8)

31
32 4.9 Control of Nonconforming Environmental Testing Work (~~ISO/IEC 17025:2005(E)~~ISO/IEC
33 17025:2005, Clause 4.9)

34
35 4.10 Improvement (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.10)

36
37 4.11 Corrective Action (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.11)

38
39 4.12 Preventive Action (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.12)

40
41 4.13 Control of Records (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.13)

42
43 4.14 Internal Audits (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.14)

44
45 4.15 Management Reviews (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 4.15)

46 47 5.0 TECHNICAL REQUIREMENTS

48
49 5.1 General (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.1)

50
51 5.2 Personnel (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.2)

52 ~~Note: All references to Calibration Certificates in ISO/IEC 17025:2005(E)ISO/IEC 17025:2005~~

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

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

3 | **5.4 Environmental Methods and Method Validation**

4 | **NOTE** All references to Calibration Laboratories and Calibration Methods in ~~ISO/IEC~~
5 | ~~17025:2005(E)~~ISO/IEC 17025:2005 in these Clauses are not applicable to environmental
6 | testing.

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7 | 5.4.1 General (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.1)

8 | 5.4.2 Selection of Methods (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.2)

9 | 5.4.3 Laboratory-Developed Methods (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.3)

10 | 5.4.4 Non-Standard Methods (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.4) ~~is not~~
11 | ~~applicable in this module and is addressed in specific technical modules based on technology.~~
12 | ~~When it is necessary to use methods not covered by standard methods, these shall be subject to~~
13 | ~~agreement with the customer and shall include a clear specification of the customer's requirements~~
14 | ~~and the purpose of the test and/or calibration. The method developed shall have been validated~~
15 | ~~appropriately before use.~~

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

18 | a) appropriate identification;

19 | b) scope;

20 | c) description of the type of item to be tested or calibrated;

21 | d) parameters or quantities and ranges to be determined;

22 | e) apparatus and equipment, including technical performance requirements;

23 | f) reference standards and reference materials required;

24 | g) environmental conditions required and any stabilization period needed;

25 | h) description of the procedure, including

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

27 | – checks to be made before the work is started,

28 | – checks that the equipment is working properly and, where required, calibration and adjustment of the
29 | equipment before each use,

30 | – the method of recording the observations and results,

31 | – any safety measures to be observed;

32 | i) criteria and/or requirements for approval/rejection;

33 | j) data to be recorded and method of analysis and presentation;

34 | k) the uncertainty or the procedure for estimating uncertainty.

35 | 5.4.5 Validation of Methods (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.4.5) ~~is not applicable~~
36 | ~~in this module and is addressed in specific technical modules based on technology.~~

37 | 5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that
38 | the particular requirements for a specific intended use are fulfilled.

39 |

5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- interlaboratory comparisons;
- systematic assessment of the factors influencing the result;
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

5.4.5.4 All methods used by the laboratory, whether non standard method or standard (reference) methods shall be validated before use to ensure that the laboratory has the capability of using the method for its intended use. See section 1.5. of each of the technical modules (Volume 1 modules 3 through 7) for specific validation requirements. Non-standard methods must comply with 5.4.5.1 – 5.4.5.3 above in addition to specific requirements in Section 1.5 of the technical modules. Except when specified, an initial demonstration of capability (see 1.6 of the technical modules) is adequate to validate reference methods.

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

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.

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

5.6 Measurement Traceability

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1 | 5.6.1 General (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.6.1) is not applicable to
2 | environmental testing.

4 | 5.6.2 Specific Requirements (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.6.2) is not
5 | applicable to environmental testing.

7 | 5.6.3 Reference Standards and Reference Materials (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005,
8 | Clause 5.6.3)

10 | **5.7 Collection of Samples** (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.7)

12 | **5.8 Handling Samples and Test Items** (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.8)

14 | 5.8.5 Additional Requirements – Documentation

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

- 18 | a) The laboratory shall have a documented system for uniquely identifying the ~~sample~~
19 | ~~containers that hold~~ samples to be tested, to ensure that there can be no confusion regarding
20 | the identity of such samples at any time. This system shall include identification for all
21 | samples, sub-samples, preservations, sample containers, tests, and subsequent extracts
22 | and/or digestates.

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24 | 5.8.7.3 The laboratory shall utilize a permanent chronological record such as a logbook or electronic
25 | database to document receipt of all sample containers.

- 27 | a) This sample receipt log shall record the following:

- 29 | i) client/project name,
30 | ii) date and time of laboratory receipt,
31 | iii) unique laboratory ID code (~~see Section 5.12.1 b)~~5.8.5 a), and
32 | iv) signature or initials of the person making the entries.

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35 | ~~NOTE: The placement of the laboratory ID number on the sample container is not
36 | considered a permanent record.~~

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38 | **5.9 Quality Assurance for Environmental Testing** (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005,
39 | Clause 5.9)

41 | **5.10 Reporting the Results**

43 | ~~NOTE: All references to Calibration Certificates in ISO/IEC 17025:2005 are not applicable to
44 | environmental testing.~~

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46 | 5.10.1 General (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.10.1)

48 | 5.10.2 Test Reports and Calibration Certificates (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause
49 | 5.10.2)

51 | 5.10.3 Test Reports (~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, Clause 5.10.3)

53 | 5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation
54 | of the test results, include the following:

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

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- 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.
- 5.10.10 Exceptions
- Some regulatory reporting requirements or formats, such as monthly operating reports, may not require all items listed known 5.10.2 and 5.10.3 above; however, the laboratory shall provide all the required information to their client for use in preparing such regulatory reports.

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