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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
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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), 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

1.0 NO CHANGE

2.0 NO CHANGE

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

Analyte: The substance being measured in an analytical procedure**.**

Data Integrity: Data that 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)

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

Reference Method: A reference method is a method issued by an organization generally recognized as competent to do so. (When ISO 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.

4.0 MANAGEMENT REQUIREMENTS

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

4.1.1 to 4.1.6 NO CHANGE

4.1.7 Additional Requirements for Laboratories

4.1.7.1 NO CHANGE
4.1.7.2 The laboratory's technical manager(s), however named, and/or his/her designee(s) shall:

a) Through d) NO CHANGE

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) NO CHANGE

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

4.2.1 through 4.2.7 - NO CHANGE

4.2.8 Additional Management System Requirements

4.2.8.1 though 4.2.8.4 – NO CHANGE

4.2.8.5 Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.

a)through e) – NO CHANGE

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

i. identification of the method;
ii. applicable matrix or matrices;
iii. limits of detection and quantitation;
iv. scope and application, including analytes and parameters to be analyzed;
v. v. through xxii. – NO CHANGE

4.3 NO CHANGE

4.4 NO CHANGE

4.6 NO CHANGE

4.7 NO CHANGE

4.8 NO CHANGE

4.9 NO CHANGE

4.10 NO CHANGE

4.11 NO CHANGE

4.13 NO CHANGE

4.14 NO CHANGE

4.15 NO CHANGE

4.16 NO CHANGE

5.0 TECHNICAL REQUIREMENTS

5.1 NO CHANGE

5.2 NO CHANGE

5.3 NO CHANGE

5.4 Environmental Methods and Method Validation

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

5.4.1 NO CHANGE

5.4.2 NO CHANGE

5.4.3 NO CHANGE

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

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

a) appropriate identification;

b) scope;

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

d) parameters or quantities and ranges to be determined;

e) apparatus and equipment, including technical performance requirements;

f) reference standards and reference materials required;

g) environmental conditions required and any stabilization period needed;

h) description of the procedure, including
- *affixing of identification marks, handling, transporting, storing and preparation of items,*
- *checks to be made before the work is started,*
- *checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,*
- *the method of recording the observations and results,*
- *any safety measures to be observed;*

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

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

k) the uncertainty or the procedure for estimating uncertainty.

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

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

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 See section 1.5. of each of the technical modules (Volume 1 modules 3 through 7) for specific requirements. ~~Except when specified, an initial demonstration of capability (see 1.6 of the technical modules) is adequate to validate reference methods.~~

5.4.6 NO CHANGE

5.5 NO CHANGE

5.6 NO CHANGE

5.7 NO CHANGE

5.8 NO CHANGE

5.9 NO CHANGE

5.10 NO CHANGE