The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on August 17, 2011 during the National Environmental Monitoring Conference in Bellevue, Washington. The agenda is attached as Appendix A, the attendees are listed in Appendix B and presented material is listed in Appendix C.

Silky began the meeting by reviewing the changes that have been made to Vol. 1, Modules 2 through 7 of the TNI Standard (see "Summary of Changes" in Appendix C).

1. Data Integrity – it was suggested that the definition needed to include the concept of traceability.
2. Demonstration of Capability – the definition requirements do not specify a time period although annual is inferred. A participant asked if "annual" was defined. The committee responded that continuing demonstrations are meant to be a continuous process rather than a fixed activity. Therefore "annual" did not need a definition, however the definition will be revisited.
3. **Section 1.5 of Modules 2-7:**
   a. A suggestion was made that "non-reference methods" should be used rather than "non-standard methods". The committee responded that the ISO language referred to "standard" and "non-standard methods." The term "reference method" was introduced to eliminate confusion with the publication "Standard Methods", and felt that other terms should comply with ISO terminology whenever possible.
4. **Section 1.6.1 of Modules 2-7:**
   a. "1.6.1 e is duplicated elsewhere: – Response: Intentional to emphasize the frequency.
   b. 1.6.1 f:
      i. Suggestion: Delete 1.6.1 f "All demonstrations shall be documented" infers that all DOCs must have a form. Response: Something (data or report) needs to be generated.
      ii. Suggestion: Change to "all Initial DOCs. . ."
      Suggestion: "documentation" might be an SOP that describes the process
      Suggestion: delete the first sentence
      Response: need to have some record (documentation) for both initial and continuing DOCs.
      iii. Comment: supports clarifications to initial DOC, but does not see the need for any further documentation for continuing.
   c. 1.6.1 e and f: Suggestion: move into section 1.6.2.
   d. 1.6.1 a: Questions: Did we really meant "constant and close"
   Response: Yes
5. V1M3: Suggestion: An asbestos expert should review the language
6. V1M4
   a. 1.4 Paragraph 2:
      i. Comment: "similar reference method" is not auditable; suggest "same technology"
      ii. Question: is the addition of an analyte a modified method?
      Response: change language to "so that the method analyte list has been modified"
   b. 1.5.2.1
      i. Suggestion: Change "component to "analyte" and "test" to "method"
      ii. Suggestion: do not use examples – provide a definitive list of leave out.
      iii. Suggestion: change "not available to "not practicable or impossible".
      iv. Suggestion: put list in a guidance (Florida has a list)
   c. 1.5.2.1 c
      i. Suggest "change in sensitivity (instruments changes all the time).
      ii. Suggest "LOD study" instead of LOD

d. 1.5.2.1 e
    i. Comment: a value above zero does not equal detection; detection does not have a numerical value
    ii. Suggestion: take out parentheses
e. 1.5.2.2 second paragraph
    i. Jerry to send in comment on bullets

7. V1M5
    a. Question: Does “Source water” include aquifers, groundwater and springs?
    Response: Yes – when they are used as a source for drinking water.
    b. 1.5.f: Remove from standard
    c. 1.7.3.1 i: Question: could samples be done at the same time and take the risk of failure?
    Response: Could be done, but good practice to perform before use. Will look into Standard Methods and the Drinking Water cert manual.
    d. 1.7.3.1 ii: Does a single use device need a blank every 10 samples?
    e. 1.7.5 b: What if a client collects samples from multiple sources?
    First-time client require testing each sample. When a history is established, the frequency is reduced to one sample per month per client (not source)
    f. 1.7.5 iii: Add “and”
    g. Question: Should “client” be customer?

There were no comments on radiochemistry or toxicology.

Silky thanked the audience for their input and reminded them that written comments should be submitted before the deadline of September 1, 2011.

Meeting was adjourned at 5:00 PDT.

Conference Call Agenda:

The NELAC Institute Quality Systems Expert Committee

August 17, 2011 1:00 pm PDT
Conference Call

Meeting in Bellevue, Washington During the National Environmental Monitoring Conference

Agenda		
Roll Call Introduction Summary of Changes Comments on global changes	Quality Systems Committee	30 minutes
Comments on V1M2, Sections 1.0 - 5.4	All	30 minutes
Comments on V1M2 Sections 5.4 – 5.10		30 minutes
Break		30 minutes
Comments on V1M3 Asbestos		10 minutes
Comments on V1M4 Chemistry		20 minutes
Comments on V1M5 Microbiology		10 minutes
Comments on V1M6 Radiochemistry		10 minutes
Comments on V1M7 Toxicity		10 minutes
Parking lot items Next Steps		20 minutes

Appendix B - Participants

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Appendix C
Material Presented During Quality Systems Meeting

Summary of Changes to V1 M2 – M7
Items underlined and in italics are those that were modified/revised from the previous version.

Global Changes:
Change "parameter" or "compound:"to "analyte"
Converted "notes" added by TNI to requirements (if applicable)

V1M2
Change ISO citation from ISO/IEC 17025:2005(E) to ISO/IEC 17025:2005
Add language specifically excluding all notes as requirements
Definitions
Analyte (revised)
Data Integrity (revised)
Parameter (deleted)
Physical parameter (added)
Reference Method (revised)
5.4.4 Non Standard Methods – added ISO Text
5.4.5 Validation of Methods – added ISO Text
5.4.5.4 *(TNI additional requirements) – revised for clarity)*

V1M3
1.4 Method Selection – deleted majority of text and referred to Module 2
1.5 Method Validation – deleted majority of text and referred to Module 2
Specified requirements for non-standard and reference methods as separate items.
1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.
1.6.3 Revised for clarity – *on-going DOC are meant to be continuous rather than singular events.*

V1M4
Removed proposed definition for Physical Parameter and placed it Module 2
1.4 Method Selection – deleted majority of text and referred to Module 2
1.5 Method Validation – deleted majority of text and referred to Module 2
Validation for non-standard and reference methods revised for clarity. Separate items outline requirements for each.
1.5.2.1 LOD
Removed "etc." as suggested.
a) through e) reordered for clarity
1.5.2.2 LOQ
Substituted the word "determine(d)" for "establish(ed)" to clarify how LOQs are ascertained.
Removed "etc." as suggested.
Clarified that LOQs are verified on each instrument used for a specific test.
Reordered b) through d) for clarity
1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.
1.6.3.1 Revised for clarity – *on-going DOC are meant to be continuous rather than singular events.*

V1M5
Added Definition for "**Source Water**"
1.4 Method Selection – deleted majority of text and referred to Module 2
1.5 Method Validation – deleted majority of text and referred to Module 2
Validation for non-standard and reference methods revised for clarity. Separate items outline requirements for each.
1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.
1.6.2.2 a) "*sterile" added to further characterize and quality system matrix.*
1.7.3.1 b) *Sterility Checks reordered for clarity*
1.7.5 b) Removed multiple uses of "source" in the paragraph

The use of sterile buffered water or peptone was modified with the statement "When required by method, the diluents". Removed the perceived inconsistency between a quality system matrix and the use of sterile diluents.
1.6.3.1 Revised for clarity – *on-going DOC are meant to be continuous rather than singular events.*

V1M6
1.4 Method Selection – deleted majority of text and referred to Module 2
1.5 Method Validation – deleted majority of text and referred to Module 2
Validation for non-standard and reference methods revised for clarity. Separate items outline requirements for each.
1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.
1.6.3.1 Revised for clarity – *on-going DOC are meant to be continuous rather than singular events.*
1.7.1 c)
Added language to distinguish background measurements from short-term contamination checks.
c) iii) *Changed "weekly" to "quarterly" for consistency with the ASTM standard.*

V1M 7
1.4 Method Selection – deleted majority of text and referred to Module 2
1.5 Method Validation – deleted majority of text and referred to Module 2
Specific requirements for reference and non-standard methods are stated.
1.6.1 Added clarifying language to indicate that DOC's are related to individual competency.
1.6.3 Revised for clarity – *on-going DOC are meant to be continuous rather than singular events.*

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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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VOLUME 1, MODULE 2

Quality Systems General Requirements

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

1.1 Introduction

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

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~~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 date 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~~

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: 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

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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.~~

Selectivity: The ability to analyze, distinguish, and determine a specific analyte ~~or parameter f~~rom 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.

~~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.

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

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:

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

h) monitor corrective actions.

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

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)*

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

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

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

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

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

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

4.9 **Control of Nonconforming Environmental Testing Work *(~~ISO/IEC 17025:2005(E)~~ISO/IEC***

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

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

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

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

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

5.0 TECHNICAL REQUIREMENTS

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

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.

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

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

5.4 **Environmental Methods and Method Validation**

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

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

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

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

5.4.4 Non-Standard Methods *(~~ISO/IEC 17025:2005(E)~~ISO/IEC 17025:2005, 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.*

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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)~~ISO/IEC 17025:2005, 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 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.~~

5.5 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.~~

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

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

5.8.5 Additional Requirements – Documentation

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

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

5.8.7 Additional Requirements – Sample Receipt Protocols

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

a) This sample receipt log shall record the following:

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

b) During the login process, the following information shall be unequivocally linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, the records shall be part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample.

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

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

5.10 Reporting the Results

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

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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 3 : Quality Systems for Asbestos Testing

Working Draft Standard
July 2011

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VOLUME 1, MODULE 3

Quality Systems for Asbestos Testing

1.0 ASBESTOS TESTING

1.4 Method Selection

~~a.~~ Refer to Volume 1 Module 2, Sections 5.4.2, 5.4.3 and 5.4.4.~~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 a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method. If there is not a regulatory requirement for the parameter/method combination, the parameter/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology.~~

The inclusion of the ~~parameter~~analyte in the method shall meet all required calibration requirements of the method and the quality control requirements of the method to which the ~~parameter~~analyte is being added. If no QC exists in the method, the laboratory shall adhere to the requirements outlined in ~~the~~ a similar reference method (when available). A method that meets these ~~above~~ requirements shall be identified in such a way so that there is no confusion that the method has been modified.

~~(1) When it is necessary to use methods not covered by reference methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test. The method developed shall have been validated appropriately before use.~~

1.5 Method Validation

Prior to acceptance and institution of any method for which data will be reported, all methods shall be validated.

~~Refer to Volume 1 Module 2, Section 5.4.5.~~~~Validation is the confirmation, by examination and objective evidence, that the particular requirements for a specific intended use are fulfilled. The laboratory shall validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference 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.~~

For ~~all methods (e.g. reference)~~both reference and non-standard methods, ~~Laboratories~~ laboratories shall participate in proficiency testing programs. The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.

None standard methods must comply with ~~There are no specific requirements for validating non-standard methods except those provided in~~ the requirements in Volume 1 Module 2, Section 5.4.5.

1.6 Demonstration of Capability (DOC)

1.6.1 General

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a) An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision until a satisfactory initial DOC is required (see Section 1.6.2). ~~Prior to acceptance and institution of any method for data reporting, satisfactory initial DOC is required (see Section 1.6.2).~~

b) Thereafter, ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) is required.

c) In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, ~~In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel~~ or method, the on-going DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.

d) For the initial DOC, appropriate records as discussed in Section 1.6.2 shall be completed.

e) An initial DOC shall be completed each time there is a change in instrument type, personnel, or method.

f) All demonstrations shall be documented. All data applicable to the demonstration shall be retained and readily available at the laboratory.

1.6.2 Initial DOC

An individual must successfully perform an initial DOC prior to using any method (see 1.6.1 a) above), and at any time there is a change in instrument type, or method or any time that a method has not been performed by the analyst in a twelve (12) month period.

~~An initial DOC shall be conducted prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period.~~

1.6.3 On-Going DOC

1.6.3.1 The laboratory shall have a documented procedure describing ongoing demonstration of capability. The analyst(s) shall demonstrate on-going capability by routinely meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. If the method has not been performed by the analyst in a twelve (12) month period, an Initial DOC (1.6.2) shall be performed. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.

1.6.3.2 For asbestos, this ongoing DOC may be one of the following:

a) acceptable performance of a blind sample (single blind to the analyst) (Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the tests);

NOTE: ~~Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the tests~~.

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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 4: Quality Systems for Chemical Testing

Working Draft Standard
July 2011

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VOLUME 1, MODULE 4

Quality Systems for Chemical Testing

1.0 CHEMICAL TESTING

1.3 Terms and Definitions

1.3.1 Additional Terms and Definitions

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

1.4 Method Selection

Refer to Volume 1 Module 2 Sections 5.4.2, 5.4.3 and 5.4.4.

~~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 a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method.~~

~~If there is not a regulatory requirement for the parameter/method combination, the parameter/ method combination need not be validated under 1.5.1b) as a non-reference method if it can be analyzed by another similar reference method of the same matrix and technology.~~ The inclusion of the ~~parameter~~analyte in the method shall meet all required calibration requirements and the quality control requirements of the method to which the ~~parameter~~analyte is being added. If no QC exists in the method, the laboratory shall adhere to the requirements outlined in ~~the~~ a similar reference method (when available). For example, when adding acetone to Method 624, the calibration and QC requirements shall follow Method 624. A method that meets these ~~above~~ requirements shall be identified in such a way so that there is no confusion that the method has been modified.

~~When it is necessary to use methods not covered by reference methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test. The method developed shall have been validated appropriately before use.~~

1.5 Method Validation

1.5.1 Validation of Methods

Prior to acceptance and institution of any method for which data will be reported, all methods shall be validated.

~~a) The laboratory shall validate reference methods via the procedures specified in Sections 1.5.12 and 1.5.3Refer to Volume 1 Module 2, Section 5.4.5.~~

a) The laboratory shall validate reference methods via the procedures specified in Sections 1.5.2 and 1.5.3. For reference methods, the procedures outlined in 1.6 can satisfy the requirements of 1.5.23.

b) For all methods, except reference methods, the validation must comply with Volume 1, Module 2, Sections 5.4.5.1, 5.4.5.2, and 5.4.5.3. This validation must include the minimum requirements outlined in Sections 1.5.2, 1.5.3 and 1.5.4. of this module.

~~The laboratory shall validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods to confirm that the methods are fit for the intended use. The validation~~

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~~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. In the absence of other specifications, the minimum requirements for method validation are given in Sections 1.5.2, 1.5.3 and 1.5.4.~~

1.5.2 Limit of Detection and Limit of Quantitation (However Named)

Procedures used for determining limits of detection and quantitation shall be documented. Documentation shall include the quality system matrix type. All supporting data shall be retained.

1.5.2.1 Limit of Detection (LOD)

If the laboratory is not reporting a value below the Limit of Quantitation, a Limit of Detection study is not required, unless specified by the method.

An LOD study is not required for physical parameters, for any component for which spiking solutions are not available or for any test that does not use a calibration curve (e.g., residues, specific conductance, chlorophyll, or titrimetric determinations~~,etc~~.).

The laboratory shall utilize a method that provides an LOD that is appropriate and relevant for the intended use of the data. If a mandated method or regulation includes ~~protocols~~ procedures for determining detection limits, these shall be followed. The laboratory shall document how LODs were derived from the determinations. If the protocol for determining the LOD is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the method.

All sample-processing and analysis steps of the analytical method shall be included in the determination or validation of the LOD.

a) When required, the laboratory shall determine or verify the LOD for the method for each target analyte of concern in the quality system matrices.

b) The LOD shall be initially determined for the analytes of interest in each method in a quality system matrix in which there are neither target analytes nor interferences at a concentration that would impact the results or the LOD shall be performed in the quality system matrix of interest.

c) An LOD shall be performed each time there is a change in the method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.

d) The LOD, if required, shall be verified annually for each quality system matrix, technology, and analyte.

e) The validity of the LOD shall be verified by detection (a value above zero) of the analyte(s) in a QC sample in each quality system matrix. This QC sample shall contain the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests. This verification shall be performed on every instrument that is to be used for analysis of samples and reporting of data. The validity of the LOD shall be verified as part of the LOD determination process. This verification shall be done prior to the use of the LOD for the sample analysis.

~~e) An LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature.~~

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~~d~~c) ~~The LOD shall be initially determined for the compound~~analytes ~~of interest in each method in a quality system matrix in which there are neither target analytes nor interferences at a concentration that would impact the results or the LOD shall be performed in the quality system matrix of interest.~~

~~e~~d) ~~An LOD shall be performed each time there is a change in the method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.~~

~~f~~e) ~~The LOD, if required, shall be verified annually for each quality system matrix, technology, and analyte.~~

1.5.2.2 Limit of Quantitation (LOQ)

The LOQ must be established for each analyte in a reported test. A determination of an LOQ is not required for physical parameters, for any ~~component~~ analyte for which spiking solutions are not available or for any test that does not use a calibration curve (e.g., ~~residues,~~ specific conductance, chlorophyll, or titrimetric determinations~~, etc.~~). While an LOQ determination may not be required, some methods or regulations require reporting to a specific level or restrict reporting values below a certain level (e.g., BOD and residues).

~~When required, t~~The laboratory shall establish the LOQ by:

- using test conditions or instrument restrictions (e.g., sample volume, accuracy of balance, method QC requirements) or
- by a study using spiked samples (when required)~~. If spiking samples is not an option, or the laboratory shall determine an appropriate LOQ~~ or as the basis

a) All sample-processing and analysis steps of the analytical method shall be included in the determination of the LOQ.

~~b) The LOQ study is not required for any component or property for which spiking solutions or quality control samples are not available or otherwise inappropriate (e.g., pH).~~

~~c~~b) The LOQ shall be verified annually for each quality system matrix, technology, and analyte. Such verification shall be performed on every instrument that is to be used for analysis of samples and reporting of data unless~~However, the annual LOQ verification is not required~~ if the LOD was determined or verified annually on that instrument.

c) The validity of the LOQ shall be verified by successful analysis of a QC sample containing the analytes of concern in each quality system matrix at 1 to 2 times the claimed LOQ. A successful analysis is one where the recovery of each analyte is within the laboratory-established method acceptance criteria or client data quality objectives for accuracy.

d~~e~~) When an LOD is determined or verified by the laboratory, the LOQ shall be above the LOD.

~~e) The LOQ shall be verified annually for each quality system matrix, technology, and analyte. However, the annual LOQ verification is not required if the LOD was determined or verified annually on that instrument.~~

1.6 Demonstration of Capability (DOC)

1.6.1 General

a) ~~Prior to~~ An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision until ~~acceptance and institution of any method for which data will be reported,~~ a satisfactory initial DOC is required (see Section 1.6.2).

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b) Thereafter, ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples) is required.

c) In cases where ~~a laboratory analyzes~~an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type~~, personnel~~ or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.

d) For the initial DOC, appropriate records as discussed in Section 1.6.2 shall be completed.

e) An initial DOC shall be completed each time there is a change in instrument type, personnel, or method.

f) All demonstrations shall be documented. All data applicable to the demonstration shall be retained and readily available at the laboratory.

1.6.2 Initial DOC

An individual must successfully perform ~~A~~an initial DOC ~~shall be conducted~~ prior to using any method (see 1.6.1 a) above), and at any time there is a change in instrument type, ~~personnel~~ or method or any time that a method has not been performed by the ~~laboratory or~~ analyst in a twelve (12) month period.

1.6.3 Ongoing DOC

1.6.3.1 The laboratory shall have a documented procedure describing ongoing DOC. The analyst(s) shall demonstrate on-going capability by routinely meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. If the method has not been performed by the analyst in a twelve (12) month period, an Initial DOC (1.6.2) shall be performed. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.

1.6.3.2 This on-going demonstration may be one of the following:

a) acceptable performance of a blind sample (single blind to the analyst) (A Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the tests.);

~~Note: Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the tests.~~

b) another initial DOC;

c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCSs for each method for each analyst each year;

d) a documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary;

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e) if a) through d) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) shall be performed.

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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 5: Quality Systems for Microbiological Testing

Working Draft Standard
July 2011

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VOLUME 1, MODULE 5

Quality Systems for Microbiological Testing

1.0 MICROBIOLOGICAL TESTING

1.3 Terms and Definitions

1.3.1 Additional Terms and Definitions

~~Reserved~~**Source Water** – Untreated water from streams, rivers, lakes, or underground aquifers, which is used to supply private and public drinking water supplies. (EPA)

1.4 Method Selection

Refer to Volume 1, Module 2 Sections 5.4.2, 5.4.3 and 5.4.4.~~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 a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method. If there is not a regulatory requirement for the parameter/method combination, the parameter/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology.~~

~~When it is necessary to use methods not covered by reference methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test. The method developed shall have been validated appropriately before use.~~

1.5 Method Validation

a) Prior to acceptance and institution of any method for which data will be reported, all methods shall be validated.

~~b) Refer to Volume 1, Module 2 section 5.4.5.~~

c) Reference methods shall be validated The laboratory shall validate reference methods via the procedures outlined in 1.6.

~~d)~~ For all ~~other~~ methods, except reference methods, the validation must comply with Volume 1, Module 2, Sections 5.4.5.1, 5.4.5.2, and 5.4.5.3. This validation must include the minimum requirements outlined in Sections 1.5.2, 1.5.3 and 1.5.4. of this module.~~include, the refer to Volume 1 Module 2, Section 5.4.5. In addition, minimum requirements for method validation are given in Sections 1.5.1, 1.5.2 and 1.5.3.~~

e) Laboratories shall participate in a proficiency test program when available. The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.

f) The laboratory shall maintain documentation of the validation procedure for as long as the method is in use and for at least five (5) years past the date of last use.

~~The laboratory shall validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference 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~~

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~~whether the method is fit for the intended use. The minimum requirements for method validation are given in Sections 1.5.1, 1.5.2 and 1.5.3.~~

~~The laboratory shall maintain documentation of the validation procedure for as long as the method is in use and for at least five (5) years past the date of last use.~~

~~Laboratories shall participate in a proficiency test program when available. The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.~~

~~The following assessment shall be performed. If no reference method exists, or if the data quality objectives are different from the reference method, then the laboratory shall demonstrate that the method meets the quality objectives for the intended use.~~

1.6 Demonstration of Capability (DOC)

1.6.1 General

a) An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision until a satisfactory initial DOC is required (see Section 1.6.2). ~~Prior to acceptance and institution of any method for data reporting, satisfactory initial DOC is required (see Section 1.6.2).~~

b) Thereafter, ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.3, is required.

c) In cases where an individual has prepared and/or analyzed ~~In cases where a laboratory analyzes samples~~ using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, ~~personnel~~ or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.

d) For the initial DOC, appropriate records as discussed in Section 1.6.2 shall be completed.

e) An initial DOC shall be completed each time there is a change in instrument type, personnel, or method.

f) All demonstrations shall be documented. All data applicable to the demonstration shall be retained and readily available at the laboratory.

1.6.2 Initial DOC

1.6.2.2 If the method or regulation does not specify an initial DOC, the following procedure is acceptable. It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate.

a) The target organism(s) shall be diluted in a volume of sterile, ~~clean~~ quality system matrix (a sample in which no target organisms or interferences are present at concentrations that will impact the results of a specific method). ~~This~~ When required by method, the diluent ~~matrix~~ shall be sterile ~~phosphate or sterile peptone solution~~buffered water and/or sterile peptone water unless specified by the manufacturer. Prepare at least four (4) aliquots at the concentration specified, or if unspecified, to the countable range for plate methods or working range for most probable number (MPN) type methods.

1.6.3 Ongoing DOC

1.6.3.1 The laboratory shall have a documented procedure describing ongoing DOC. The analyst(s) shall demonstrate ongoing capability by routinely meeting the quality control requirements of the method,

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laboratory SOP, client specifications, and/or this Standard. If the method has not been performed by the analyst in a twelve (12) month period, an Initial DOC (1.6.2) shall be performed. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.

1.6.3.2 This ongoing demonstration may include one of the following or by performing another initial DOC.

a) Analysis of one sample or clean matrix that is fortified with a known quantity of the target organism, with results meeting the laboratory acceptance criteria for accuracy and, where applicable to the testing technique, also meeting the observational details expected for the presumptive, confirmed and completed phases defined in the method.

b) Analysis of one sample in duplicate for each target organism and test, with results meeting the laboratory acceptance criterion for precision.

c) Acceptable results for one-single-blind proficiency test sample for target organisms in each field of accreditation.

d) Performance of an alternate adequate procedure for the field of accreditation, the procedure and acceptance criteria being documented in the laboratory's quality system.

e) A documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary; or

f) if a) through e) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) shall be performed.

1.7 Technical Requirements

1.7.3 Quality Control

1.7.3.1 Sterility Checks and Method Blanks

b) Sterility Checks

All materials or supplies that are needed to process the sample and ~~which~~ are required to be sterile prior to use (whether sterilized in the lab or purchased as sterilized) ~~which are required to be sterile prior to use in testing~~ must be checked once per purchased or prepared lot using a nonselective growth media. These checks shall include but are not limited to:

i. A sterility check shall be analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory. This shall be done prior to first use of the medium.

ii. For pre-sterilized single use funnels, a sterility check shall be performed on one funnel per lot. For laboratory-sterilized funnels, a sterility check shall be performed on one funnel per sterilization batch.

iii. Sterility checks on sample containers shall be performed on at least one (1) container for each lot of purchased, pre-sterilized containers. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one (1) container per sterilized batch with nonselective growth media. These sterility checks may be performed by a contracted laboratory if the laboratory does not have the requisite equipment to perform them. All correspondence and results from a contracted laboratory shall be retained for a period of five (5) years after the completion of the test(s).

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iv. A sterility check shall be performed on each batch of dilution water prepared in the laboratory and on each lot of pre-prepared, ready-to-use dilution water with non-selective growth media.

v. At least one (1) filter from each new lot of membrane filters shall be checked for sterility with nonselective growth media.

~~vi) All materials or supplies that are needed to process the sample and which are required to be sterile prior to use (whether sterilized in the lab or purchased as sterilized) which are required to be sterile prior to use in testing must be checked once per purchased or prepared lot using a nonselective growth media. These checks shall include but are not limited to:~~

1.7.5 Sample Handling

b) Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where chlorine usage is suspected (such a new client or a new source) and all potable water ~~sources~~ supplies (including source water) shall be checked for absence of chlorine residual. Laboratories that receive samples from potable water ~~sources~~ supplies (including source water) that have a demonstrated history of acceptable preservation may check a sample from each ~~source~~ client at a frequency of once per month if:

i) the laboratory can show that the received sample containers are from their laboratory;

ii) sufficient sodium thiosulfate was in each container before sample collection to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples;

iii) one container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/l chlorine or 15 mg/l chlorine as appropriate and the check is documented;

iv) chlorine residual is checked in the field and actual concentration is documented with sample submission.

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THE NELAC INSTITUTE

ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 6: Quality Systems for Radiochemical Testing

Working Draft Standard
July 2011

P.O. Box 2439
Weatherford, TX 76086
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VOLUME 1, MODULE 6

Quality Systems for Radiochemical Testing

1.0 RADIOCHEMICAL TESTING

1.4 Method Selection

Refer to Volume 1 Module 2 sections 5.4.2, 5.4.3 and 5.4.4. ~~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 a parameter by a specific method due to a regulatory requirement, the parameter/method combination is recognized as a reference method. If there is not a regulatory requirement for the parameter/method combination, the parameter/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology, and the inclusion of the parameter in the method meets all required calibration requirements of the method and the quality control requirements of the method to which the parameter is being added. If no QC exists in the method, the laboratory shall adhere to the requirements outlined in the similar method.~~

~~When it is necessary to use methods not covered by reference methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test. The method developed shall have been validated appropriately before use.~~

1.5 Method Validation

1.5.1 Validation of Methods

Prior to acceptance and institution of any method for which data will be reported, all methods shall be validated.

a) ~~Refer to Volume 1, Module 2 section 5.4.5. Validation is the confirmation by examination and the objective evidence that the particular requirements for a specific intended use are fulfilled.~~

b) The laboratory shall validate reference methods via the procedures specified in Sections 1.5.~~1~~2.1 and ~~1.6~~1.5.3. For reference methods, the procedures outlined in 1.6 can satisfy the requirements of 1.5.2. ~~For reference methods, the minimum detectable activity (Section 1.5.2.1) applies. Evaluating precision and bias is covered in Section 1.5.3.~~

c) For all ~~other~~ methods, except reference methods, the validation must comply with Volume 1, Module 2, Sections 5.4.5.1, 5.4.5.2, and 5.4.5.3. This validation must include ~~types (e.g., non-reference methods, laboratory-developed)~~ the minimum requirements for method validation ~~are~~ outlined ~~given~~ in Sections ~~1.5.1,~~ 1.5.2, 1.5.3 ~~and~~ 1.5.4 and 1.5.5. ~~The laboratory shall validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference 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. The minimum requirements for method validation are given in Sections 1.5.2 – 1.5.5.~~

1.6 Demonstration of Capability (DOC)

1.6.3 Ongoing DOC

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1.6.3.1 The laboratory shall have a documented procedure describing ongoing DOC. The analyst(s) shall demonstrate ongoing capability by routinely meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. If the method has not been performed by the analyst in a twelve (12) month period, an Initial DOC (1.6.2) shall be performed. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.

1.6.3.2 This on-going demonstration may include one of the following:

a) acceptable performance of a blind sample (single blind to the analyst);

Note: Successful analysis of a blind performance sample on a similar method using the same technology.

b) another initial DOC;

c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCS for each method for each analyst each year;

d) a documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary;

e) if a) through d) are not technically feasible, then analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) shall be performed.

1.7 Technical Requirements

1.7.1 Instrument Calibration

c) Background Measurement

Background measurements shall be made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required measurement quality objectives. (This background measurement is not the short term check for contamination that is addressed in 1.7.1 d). These values are long term counts to ~~must~~ be subtracted from the total measured activity in the determination of the sample activity.

i) For gamma-ray spectroscopy systems, background measurements shall be performed on at least a monthly basis.

ii) For alpha-particle spectroscopy systems, background measurements shall be performed on at least a monthly basis.

iii) For gas-proportional counters background measurements shall be performed on at least a quarterly ~~weekly~~ basis.~~each day of use.~~

iv) For scintillation counters, background measurements shall be performed each day of use.

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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 7: Quality Systems for Toxicity Testing

Working Draft Standard
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VOLUME 1, MODULE 7

Quality Systems for Toxicity Testing

1.0 TOXICITY TESTING

1.4 Method Selection

~~When it is necessary to use testing methods not covered by an approved method, these shall be subject to agreement with the data user and shall include a clear specification of the data user's requirements and the purpose of the environmental test. The method developed shall have been validated appropriately before use.~~ Refer to Volume 1, Module 2 Sections 5.4.2, 5.4.3 and 5.4.**4.**

The characteristics of validated methods (e.g., the uncertainty of the results, 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 users' needs.

1.5 Method Validation

~~Validation is the confirmation by examination and the objective evidence that the particular requirements for a specific intended use are fulfilled.~~ Reference methods require no validation.

The validation of non standard methods must comply with Volume 1, Module 2, Sections 5.4.5.1, 5.4.5.2, and 5.4.5.3. ~~Refer to Volume 1 Module 2 Section 5.4.5.~~ No additional technical requirements for method validation are needed.

1.6 Demonstration of Capability (DOC)

1.6.1 General

a. An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision until a satisfactory initial DOC is required (see Section 1.6.2). ~~Prior to acceptance and institution of any method for data reporting, satisfactory initial DOC is required (see Section 1.6.2).~~

b. Thereafter, ongoing DOC (Section 1.6.3), as per the quality control requirements in Section 1.7.1.2 is required.

c. In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type. ~~In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in personnel~~ or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.

d. For the initial DOC, appropriate records as discussed in Section 1.6.2.1 shall be completed.

e. An initial DOC shall be completed each time there is a change in personnel, or method.

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f. In general, this demonstration does not test the performance of the method in real world samples. However, before any results are reported, the initial DOC shall be performed. An initial DOC may be completed by a group of analysts and is for situations in which several individuals perform part of a set of activities that would produce a testing result.

g. All demonstrations shall be documented. All data applicable to the demonstration shall be retained and readily available at the laboratory.

1.6.2 Initial DOC

An individual must successfully perform an ~~An~~ initial DOC ~~shall be made~~ prior to using any method, (see 1.6.1 a) above), and at any time there is a significant change in ~~personnel~~ or method or any time that a method has not been performed by the ~~laboratory or~~ analyst in a twelve (12) month period.

1.6.3 Ongoing DOC

The laboratory shall have a documented procedure describing ongoing DOC. The analyst(s) shall demonstrate on-going capability by routinely meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. If the method has not been performed by the analyst in a twelve (12) month period, an Initial DOC (1.6.2) shall be performed. It is the responsibility of the laboratory to document that other approaches to on-going demonstration of capability are adequate. This on-going demonstration may include performing another initial demonstration of capability as per 1.6.2 or a documented process of analyst review using QC samples can serve as the annual on-going demonstration of capability. QC samples shall be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary.

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