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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 6: Quality Systems for Radiochemical Testing

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.

This Standard supplements Module 2, Quality Systems General Requirements, and may be used by any organization that wishes to implement a program for the accreditation of environmental laboratories.

Section 1.7.1 c) of this document has been processed in accordance with the TNI requirement for a Tentative Interim Amendment. The same or similar amendment will undergo the consensus standards development process within the time-frame specified in SOP 2-100.

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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 1.5.12.1 and 1.61.5.3. 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.

1.5.2 Detectable Activity

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All procedures used shall be documented. The procedure a laboratory uses to determine minimum detectable activity (MDA) shall be documented in writing. The quality system matrix used in the initial method validation shall be identified, and all supporting documentation for the initial study must be retained. Thus does not preclude performing and reporting sample-specific MDAs. The procedure a laboratory uses to determine MDAs must also comply with the specific requirements of Sections 1.5.2.1 and 1.5.2.2. Documentation shall include the quality system matrix type. All supporting data shall be retained.

1.5.2.1 Minimum Detectable Activity (MDA)

The laboratory shall utilize a method that provides an MDA that is appropriate and relevant for the intended use of the data. MDAs shall be determined by the protocol in the mandated method. If the protocol for determining the MDA is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the method.

a) The laboratory shall determine the MDA for the method for each target analyte of concern in the quality system sample matrices. All sample processing steps of the analytical method shall be included in the determination of the MDA.

aa) The MDA shall be initially determined for the analytes of interest in each method in a quality system matrix in which there are no target analytes and no interferences at levels that would impact the results.

c) The MDA shall be determined 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 analytical detection capability.

dc) At a minimum, The the MDA is must be an estimate of the smallest true activity (or activity concentration) of analyte in a sample that ensures a 95% probability of detection, given a detection criterion that ensures only a 5% probability of detection in analyte-free samples.

1.6 Demonstration of Capability (DOC)

1.6.1 General

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

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.

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.

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

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

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

1.6.3 Ongoing DOC

1.6.3.1 The laboratory shall have a documented procedure describing ongoing DOC that includes how the laboratory intends to identify data associated with ongoing DOCs.. 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 reviewing QC samples performed by an analyst or groups of analysts relative to the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. This review can be used to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary.~~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.

1.7.1 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.~~

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

~~1.7.2.6 Selectivity~~

~~The laboratory shall evaluate selectivity by following the checks established within the method.~~

1.7.2.~~7~~6 Constant and Consistent Test Conditions

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