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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P.O. Box 2439
Weatherford, TX 76086
817-598-1624
www.nelac-institute.org

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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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Quality Systems for Radiochemical Testing

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VOLUME 1, MODULE 6

Quality Systems for Radiochemical Testing

1.0 RADIOCHEMICAL TESTING

1.1 NO CHANGE

1.2 NO CHANGE

1.3 NO CHANGE

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

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 include ~~types (e.g., non-reference methods, laboratory-developed)~~ the minimum requirements for method validation are 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 through 1.5.5 **NO CHANGE**

1.6 NO CHANGE

1.7 Technical Requirements

1.7.1 Instrument Calibration

a) Through b) NO CHANGE

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 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 weekly basis.~~each day of use.~~

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

d) Instrument Contamination Monitoring

The laboratory shall have a written procedure for monitoring radiation measurement instrumentation for radioactive contamination. The procedure shall indicate the frequency of the monitoring and shall indicate criteria, which initiates corrective action.

1.7.2 through 1.7.4 NO CHANGE