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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

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.

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VOLUME 1, MODULE 7

Quality Systems for Toxicity Testing

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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 completed (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.

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

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

d. 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

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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.

e. 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 that includes how the laboratory intends to identify data associated with ongoing DOCs.. 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 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. ~~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.~~

1.7 Technical Requirements

1.7.1 Quality Control
1.7.1.6 Constant and Consistent Test Conditions

e) Equipment used for routine support measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, ammonia and weight shall be calibrated, and/or standardized per manufacturer's instructions.

i. All chemical measurements used in the course of monitoring toxicity shall meet the requirements of V1M4, sections 1.4, 1.5, 1.7 and 1.7.
ii. All measurements and calibrations shall be documented.

j) A subset of organisms used in bioaccumulation tests shall be analyzed at the start of the test (baseline) for the target ~~compound~~analytes to be measured in the bioaccumulation tests.

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