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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Quality Systems for Toxicity Testing

1.0 TOXICITY TESTING

1.1 through 1.3 NO CHANGE

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.~~Refer to Volume 1 Module 2 Section 5.4.5. No additional requirements for method validation are needed.

1.6 NO CHANGE

1.7 Technical Requirements

1.7.1 Quality Control

The laboratory shall have quality control procedures for monitoring the validity of environmental tests undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in inter-laboratory comparison or proficiency-testing program;

c) replicate tests using the same or different methods;

d) retesting of retained samples; and

e) correlation of results for different characteristics of a sample (for example, total phosphate should be greater than or equal to orthophosphate).

1.7.1.1 through 1.7.1.5 NO CHANGE

1.7.1.6 Constant and Consistent Test Conditions

a) through i) NO CHANGE

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.

k) through y) NO CHANGE

1.7.2 through 1.7.3 NO CHANGE