



## **ENVIRONMENTAL LABORATORY SECTOR**

### **VOLUME 1**

# **MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS**

## **Module 5: Quality Systems for Microbiological Testing**

**Voting Draft Standard**  
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**P.O. Box 2439  
Weatherford, TX 76086  
817-598-1624  
[www.nelac-institute.org](http://www.nelac-institute.org)**

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## PREFACE

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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 5**  
**Quality Systems for Microbiological Testing**

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## VOLUME 1, MODULE 5

### Quality Systems for Microbiological Testing

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1.0 NO CHANGE

1.1 NO CHANGE

1.2 NO CHANGE

1.3 Terms and Definitions

The relevant definitions from TNI, Volume 1, Module 2, Section 3.0 apply. Definitions related to this document, which are used differently or do not exist in the above references are defined below.

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)

1.3.2 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 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. Refer to Volume 1, Module 2 section 5.4.5.
- b. The laboratory shall validate reference methods via the procedures outlined in 1.6.
- c. For all other methods, except reference methods, the validation must 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.
- d. 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.
- e. 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 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.~~

1.5.1 through 1.5.3 NO CHANGE

## 1.6 Demonstration of Capability (DOC)

1.6.1 NO CHANGE

1.6.2 Initial DOC

An initial DOC shall be made 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.

1.6.2.1 NO CHANGE.

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 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 ~~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.

b) through f) NO CHANGE

g) Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all ~~compounds~~ organisms of interest beginning with b).

1.6.3 NO CHANGE

## 1.7 Technical Requirements

1.7.1 NO CHANGE

1.7.2 NO CHANGE



## 1.7.3 Quality Control

## 1.7.3.1 Sterility Checks and Method Blanks

- a) NO CHANGE
- b) Sterility Checks
  - i) Through v) NO CHANGE

vi) Any other materials or supplies (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.

1.7.3.2 through 1.7.3.7 NO CHANGE

1.7.4 NO CHANGE

## 1.7.5 Sample Handling

- a) NO CHANGE
- 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) through iv) NO CHANGE