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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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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 5

Quality Systems for Microbiological Testing

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VOLUME 1, MODULE 5

Quality Systems for Microbiological Testing

1.0 MICROBIOLOGICAL TESTING

1.3.1 Additional Terms and Definitions

~~Reserved~~**Source Water** – ~~When sampled for drinking water compliance~~, untreated water from streams, rivers, lakes, or underground aquifers, which is used to supply private and public drinking water supplies. (EPA)

1.3.2 Exclusions and Exceptions

Reserved

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) Prior to acceptance and institution of any method for which data will be reported, all methods shall be validated.

~~Refer to Volume 1, Module 2 section 5.4.5~~

b) Reference methods shall be validated The laboratory shall validate reference methods via the procedures outlined in 1.6.

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 the minimum requirements outlined in Sections 1.5.1, 1.5.2, and 1.5.3 of this module ~~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~~

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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.

1.6 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 1.7.3, is required.

c) In cases where an individual has prepared and/or analyzed 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 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.

d) 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

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 sterile 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 When required by method, the diluent matrix shall be sterile phosphate or sterile peptone solutionbuffered 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.

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

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organisms of interest beginning with b).

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 ongoing demonstration may include one of the following or by performing another initial DOC.

e) 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~~; or

1.7.3 Quality Control

1.7.3.1 Sterility Checks and Method Blanks

b) Sterility Checks

All materials or supplies that are needed to process the sample and ~~which~~ are required to be sterile prior to use (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. These checks shall include but are not limited to:

i. A sterility check shall be analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory. This shall be done prior to first use of the medium.

ii. For pre-sterilized single use funnels, a sterility check shall be performed on one funnel per lot. For laboratory-sterilized funnels, a sterility check shall be performed on one funnel per sterilization batch.

iii. Sterility checks on sample containers shall be performed on at least one (1) container for each lot of purchased, pre-sterilized containers. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one (1) container per sterilized batch with nonselective growth media. These sterility checks may be performed by a contracted laboratory if the laboratory does not have the requisite equipment to perform them. All correspondence and results from a contracted laboratory shall be retained for a period of five (5) years after the completion of the test(s).

iv. A sterility check shall be performed on each batch of dilution water prepared in the laboratory and on each lot of pre-prepared, ready-to-use dilution water with non-selective growth media.

v. At least one (1) filter from each new lot of membrane filters shall be checked for sterility with nonselective growth media.

~~vi) All materials or supplies that are needed to process the sample and which are required to be sterile prior to use (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~~

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~~purchased or prepared lot using a nonselective growth media. These checks shall include but are not limited to:~~

1.7.3.5 Quality of Standards, Reagents and Media

The laboratory shall ensure that the quality of the reagents and media used is appropriate for the test concerned.

a) Media – Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use.

i) Laboratory-prepared media

1. Media prepared by the laboratory from basic ingredients and/or commercial dehydrated powder shall be tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, and growth inhibition). These tests shall be performed at a minimum with ~~prior to~~ first use.

ii) Ready-to-use media

1. See 1.7.3.5 a) i) 1.

2. Ready-to-use media shall be used within the manufacturer's expiration date. If the manufacturer's expiration date is greater than those noted in Section 1.7.3.5 a) i) 2. above, the laboratory shall request, and have available documentation from the manufacturer demonstrating media quality for the extended time period.

c) Reagent Water

ii) The quality of the water shall be monitored for chlorine residual, specific conductance, total organic carbon, ammonia/organic nitrogen and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month. The monthly ammonia/organic nitrogen test is not required if the laboratory annually performs a full bacteriological water quality test (flasks A-E) that meets the requirements of Standard Method 9020

1.7.3.6 Selectivity

b) To ensure that analysis results are accurate, target organism identity shall be verified as specified in the method ~~(e.g., by use of the completed test, or by use of secondary verification tests such as a catalase test or by the use of a completed test such as brilliant green (BG) or E. coli (EC) broth~~.

c) In order to ensure identity and traceability, reference cultures used for positive and negative

1.7.5 Sample Handling

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.

~~When a demonstrated history of acceptable preservation has been established, l~~Laboratories ~~laboratories that~~ receiv~~e~~ing samples from potable water ~~sources~~ supplies (including source water) or known chlorinated sources (such as wastewater effluent) may reduce the chlorine checks to one sample per month per client if: ~~that have a demonstrated history of~~

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~~acceptable preservation, may check a sample from each source at a frequency of once per month if:~~

i) the laboratory can show that the received sample containers are from their laboratory;

ii) sufficient sodium thiosulfate was in each container before sample collection to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples;

iii) one container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/l chlorine or 15 mg/l chlorine as appropriate and the check is documented; and

iv) chlorine residual is checked in the field and actual concentration is documented with sample submission.

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