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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 3 : Quality Systems for Asbestos 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 3

Quality Systems for Asbestos Testing

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VOLUME 1, MODULE 3

Quality Systems for Asbestos Testing

1.0 ASBESTOS TESTING

1.4 Method Selection

~~a)~~ 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.~~

The inclusion of the ~~parameter~~analyte in the method shall meet all required calibration requirements of the method and the quality control requirements of the method to which the ~~parameter~~analyte is being added. If no QC exists in the method, the laboratory shall adhere to the requirements outlined in ~~the~~ a similar reference method (when available). A method that meets these ~~above~~ requirements shall be identified in such a way so that there is no confusion that the method has been modified.

~~(1) 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

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.~~~~Validation is the confirmation, by examination and objective evidence, that the particular requirements for a specific intended use are fulfilled. 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.~~

For ~~all methods (e.g. reference)~~both reference and non-standard methods, ~~Laboratories~~ laboratories shall participate in proficiency testing programs. The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.

None standard methods must comply with ~~There are no specific requirements for validating non-standard methods except those provided in~~ the requirements in Volume 1 Module 2, Section 5.4.5.

1.6 Demonstration of Capability (DOC)

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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 required (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 (such as laboratory control samples) 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 instrument type, personnel~~ or method, the on-going 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

An individual must successfully perform an initial DOC prior to using any method (see 1.6.1 a) above), and at any time there is a change in instrument type, or method or any time that a method has not been performed by the analyst in a twelve (12) month period.

~~An initial DOC shall be conducted 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 The laboratory shall document each initial DOC in a manner such that the following information is readily available for each affected employee:

a) analyst(s) involved in preparation and/or analysis;

b) matrix;

c) analyte(s), class of analyte(s)~~, or measured parameter(s)~~

d) identification of method(s) performed;

e) identification of laboratory-specific SOP used for analysis, including revision number;

f) date(s) of analysis; and

g) summary of analyses, including information outlined in Section 1.6.2.2.c.

1.6.2.2

d) Compare the information from (c) above to the corresponding acceptance criteria for precision and accuracy in the method (if applicable) or in laboratory-generated acceptance

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criteria (if there are not established mandatory criteria). If all ~~parameter~~analytes meet the acceptance criteria, the analysis of actual samples may begin. If any one of the ~~parameter~~analytes does not meet the acceptance criteria, the performance is unacceptable for that ~~parameter~~analyte.

e) When one or more of the tested ~~parameter~~analytes fail at least one of the acceptance criteria, the analyst shall proceed according to i) or ii) below.

i. Locate and correct the source of the problem and repeat the test for all ~~parameter~~analytes of interest beginning with c) above.

ii. Beginning with c) above, repeat the test for all ~~parameter~~analytes that failed to meet criteria.

f) 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 ~~compound~~analytes of interest beginning with b).

1.6.3 On-Going DOC

1.6.3.1 The laboratory shall have a documented procedure describing ongoing demonstration of capability 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 ongoing DOC are adequate.

1.6.3.2 For asbestos, this ongoing DOC may be one of the following:

a) acceptable performance of a blind sample (single blind to the analyst);

~~NOTE: S~~or successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260); ~~would only require documentation for one of the test.~~

b) another initial DOC;

c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing laboratory control samples (LCS) for each method for each analyst each year;

d) 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 quality control (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

e) if a) through d) are not technically feasible, then analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) shall be performed.

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1.7 Technical Requirements

1.7.7.1 Transmission Electron Microscopy

1.7.7.1.1 Water and Wastewater

a) The concentration of asbestos in a given sample shall be calculated in accordance with EPA/600/R-94/134, Method 100.2, Section 12.1.

b) Measurement Uncertainties. The laboratory shall calculate and report the upper and lower 95% confidence limits on the mean concentration of asbestos fibers found in the sample.

1.7.7.1.2 Air

a) The concentration of asbestos in a given sample shall be calculated in accordance with the method utilized.

b) Measurement Uncertainties. The laboratory shall calculate and report the upper and lower 95% confidence limits on the mean concentration of asbestos fibers found in the sample.

1.7.7.1.3 Bulk Samples

a) The concentration of asbestos in a given sample shall be calculated in accordance with the method utilized (e.g., ~~EPA/600/R-93/116, July 1993~~ EPA 600/M4-82-020(1982)).

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b) Measurement Uncertainties. Proficiency testing for floor tiles analyzed by TEM following careful gravimetric reduction has revealed an inter-laboratory standard deviation of approximately 20% for residues containing 70% or more asbestos. Standard deviations range from 20% to 60% for residues with lower asbestos content.

1.7.7.2 Phase Contrast Microscopy

1.7.7.2.1 Airborne fiber concentration in a given sample shall be calculated in accordance with NIOSH 7400, Issue 2, 15 August 1994, Sections 20 and 21.

1.7.7.2.2 Measurement Uncertainties. The laboratory shall calculate and report the intra-laboratory and inter-laboratory relative standard deviation with each set of results (NIOSH 7400, Issue 2, 15 August 1994).

1.7.7.2.3 Fiber counts above 1300 fibers/mm^2 and fiber counts from samples with >50% of the filter area covered with particulate shall be reported as “uncountable” or “probably biased”. Other fiber counts outside the 100-1300 fibers/mm^2 range shall be reported as having “greater than optimal variability” and as being “probably biased”.

1.7.7.3 Polarized Light Microscopy

1.7.7.3.1 The concentration of asbestos in a given sample shall be calculated in accordance with the method utilized (e.g., ~~EPA/600/R-93/116, July 1993~~ EPA 600/M4-82-020(1982)).

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1.7.7.3.2 Method Uncertainties. Precision and accuracy shall be determined by the individual laboratory for the percent range involved. If point counting and/or visual estimates are

used, a table of reasonable expanded errors shall be generated for different concentrations of asbestos.

1.7.8 Constant and Consistent Test Conditions Sample and Sampling Requirements

1.7.8.1 Samples shall be transported to the laboratory as soon as possible after collection. Date and time of sampling shall be noted on submittal forms. The names of the collectors with their signatures and the site shall be included on the chain-of-custody forms. No preservatives are required during sampling.

1.7.8.2 The laboratory shall establish and adhere to written procedures to minimize the possibility of cross contamination between samples.

1.7.8.3 Refer to the specific method of analysis for additional requirements.