NVLAP®

National
Voluntary
Laboratory
Accreditation
Program

Airborne Asbestos Analysis

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NIST HANDBOOK 150-13

U.S. Department of Commerce
Technology Administration
National Institute of Standards
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- Scientific Computing Environments[2]
- Computer Services
- Computer Systems and Communications[2]
- Information Systems

[1] At Boulder, CO 80303.
[2] Some elements at Boulder, CO 80303.

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U.S. Department of Commerce
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Technology Administration
Mary L. Good, Under Secretary for Technology

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SUMMARY

Any laboratory (including commercial, manufacturer, university, or federal, state, or local government laboratory) that performs the test method that comprises the Airborne Asbestos Analysis Program may apply for NVLAP accreditation. Accreditation will be granted to a laboratory that satisfactorily fulfills the conditions for accreditation defined in NIST Handbook 150, *NVLAP Procedures and General Requirements*, which contain Title 15, Part 285 of the Code of Federal Regulations. These conditions include satisfactory performance in selected proficiency testing as required, and fulfilling the on-site assessment requirements, including resolution of identified deficiencies. The names of NVLAP-accredited laboratories are published in the NVLAP annual directory and other media to which information is regularly provided.

Test method covered: The U.S. Environmental Protection Agency's "Interim Transmission Electron Microscopy Analytical Methods—Mandatory and Nonmandatory—and Mandatory Section to Determine Completion of Response Actions" as found in 40 CFR, Part 763, Subpart E, Appendix A, or the current U.S. Environmental Protection Agency method for the determination of completion of response actions for asbestos.

Period of accreditation: One year, renewable annually.

On-site assessment: Visit by a technical expert to determine compliance with the NVLAP criteria before initial accreditation and every two years thereafter. Additional monitoring visits as required.

Assessors: Technical experts with experience in the appropriate field of testing.

Proficiency testing: Each laboratory is required to test and analyze proficiency testing sample material(s) for specific test methods. The completed test data report is sent to NVLAP, or as directed to the proficiency testing contractor. A summary of results is sent to the participants.

Granting accreditation: Based upon satisfactory on-site assessment and resolution of deficiencies, proficiency testing, and technical evaluation of applicable laboratory information. A Certificate and Scope of Accreditation are issued to the laboratory.

Fees: Payments are required as listed on the NVLAP fee schedule, including the administrative/technical support fee, on-site assessment fee, proficiency testing fee, and test method fee.

Sec. 285.1 Purpose

The purpose of this handbook is to set out procedures and technical requirements for accreditation by NVLAP of laboratories which perform the U.S. Environmental Protection Agency's "Interim Transmission Electron Microscopy Analytical Methods—Mandatory and Nonmandatory—and Mandatory Section to Determine Completion of Response Actions" as found in 40 CFR, Part 763, Subpart E, Appendix A. It complements and supplements the NVLAP programmatic procedures and general requirements found in NIST Handbook 150. The interpretive comments and additional requirements contained in this handbook make the general NVLAP criteria specifically applicable to the Airborne Asbestos Analysis program. The format and subject headings used in this handbook, including the checklists found in Appendices B and C, are consistent with Handbook 150. Specific circumstances under which departures from the NVLAP general procedures are allowable within the scope of the Airborne Asbestos Analysis Program are also addressed in this handbook.

Sec. 285.2 Organization of procedures

(a) The handbook is organized to cross-reference with NIST Handbook 150, *NVLAP Procedures and General Requirements*.

(b) The handbook contains three appendices:

(1) Appendix A provides examples of a Certificate of Accreditation and a Scope of Accreditation for the Airborne Asbestos Analysis program;

(2) Appendix B provides the General Operations Checklist, which NVLAP assessors use during an on-site technical assessment to evaluate a laboratory's ability to conduct testing in general; and

(3) Appendix C provides the Specific Operations Checklist, which NVLAP assessors use during an on-site technical assessment of a laboratory which conducts transmission electron microscopy.

Sec. 285.3 Description of Airborne Asbestos Analysis program

The purpose of the Airborne Asbestos Analysis program is to accredit testing laboratories that have demonstrated their competence in identifying and quantifying asbestos using transmission electron microscopy.

Public Law 99-519, "Asbestos Hazard Emergency Response Act of 1986," referred to as AHERA, requires that the National Institute of Standards and Technology (formerly the National Bureau of Standards) develop an accreditation program for laboratories conducting analyses of air samples for asbestos.

Sec. 285.4 References

References and sources for the Airborne Asbestos Analysis program follow:

(a) NIST Handbook 150, *NVLAP Procedures and General Requirements*; available from:

NIST/NVLAP
Building 411, Room A162
Gaithersburg, MD 20899

Phone: (301) 975-4016
Fax: (301) 926-2884
E-mail: nvlap@enh.nist.gov;

(b) The U.S. Environmental Protection Agency's "Interim Transmission Electron Microscopy Analytical Methods—Mandatory and Nonmandatory—and Mandatory Section to Determine Completion of Response Actions," as found in 40 CFR, Part 763, Subpart E, Appendix A;

(c) "Asbestos-Containing Materials in Schools; Final Rule and Notice," as found in 40 CFR, Part 763, Subpart E;

(d) Steel, E. B. and J. A. Small, "Accuracy of Transmission Electron Microscopy for the Analysis of Asbestos in Ambient Environments," *Analytical Chemistry*, Vol. 57, 1985, pp. 209-213;

(e) Federal Standard 209b (or most recent version), "Federal Standard Clean Room and Work Station Requirements, Controlled Environment," April 24, 1973. Single copies of this standard are available from the General Services Administration, Business Service Centers in Atlanta, Boston, Chicago, Denver, Fort Worth, Kansas City (MO), Los Angeles, New York, San Francisco, and Seattle.

Sec. 285.5 Definitions

Accuracy: The degree of agreement of a measured value with the true or expected value.

AEM: Refers to the analytical electron microscope.

AHERA: Refers to the Asbestos Hazard Emergency Response Act.

Analytical sensitivity: Airborne asbestos concentration represented by each fiber counted under the electron microscope. It is determined by the air volume collected and the proportion of the filter examined.

Asbestos: A commercial term applied to the asbestiform varieties of six different minerals. The asbestos types are chrysotile (asbestiform serpentine), amosite (asbestiform grunerite), crocidolite (asbestiform riebeckite), and asbestiform anthophyllite, asbestiform tremolite, and asbestiform actinolite. The properties of asbestos that caused it to be widely used commercially are: 1) its ability to be separated into long, thin, flexible fibers; 2) high tensile strength; 3) low thermal and electrical conductivity; 4) high mechanical and chemical durability; and 5) high heat resistance.

ASTM: Refers to the American Society for Testing and Materials.

Bias: A systematic error characterized by a consistent (nonrandom) measurement error.

Control chart: A graphical plot of test results with respect to time or sequence of measurement, together with limits within which they are expected to lie when the system is in a state of statistical control.

Detection limit: The smallest concentration/amount of some component of interest that can be measured by a single measurement with a stated, statistical level of confidence.

EDXA: Refers to energy dispersive x-ray analysis.

Field blanks: Filters which are processed by removing the cassette cap for not more than 30 seconds before sampling.

Filter lot blank: An unopened cassette with filter from the filter supplier.

HEPA: Refers to High Efficiency Particulate Air.

Laboratory blank: An unused filter that is exposed in the clean area while a sample set of filters are prepared. The laboratory blanks should be obtained from a lot of filters which has been shown not to be contaminated.

Reference Material (RM): A material or substance, one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. A "certified reference material" means that one or more of the property values of the reference material are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

STEM: Refers to the scanning transmission electron microscope.

Sealed blank: A filter of the same filter lot as those used for sampling. The sealed blank is carried with sample series filters through whole process, but is not opened during sampling operations.

Standard Reference Material (SRM): A reference material certified and distributed by the National Institute of Standards and Technology.

TEM: Refers to the transmission electron microscope.

Sec. 285.6 NVLAP documentation

Checklists contain definitive statements or questions about all aspects of the NVLAP criteria for accreditation. NVLAP programs incorporate two types of checklists:

(a) The NVLAP General Operations Checklist addresses factors applicable to evaluating a laboratory's ability to conduct testing in accordance with the procedures and general requirements for accreditation. The factors include, but are not limited to, the laboratory's organization, management, and quality system in addition to its testing competency.

The General Operations Checklist, presented in Appendix B, is numbered to correspond to the requirements in NIST Handbook 150. The comment sheets are used by the assessor to explain findings and deficiencies noted on the checklist, as well as to make comments on aspects of the laboratory's performance other than deficiencies.

(b) The Specific Operations Checklist contains statements or questions that are specific to the test method(s) in the given program and focus on the testing requirements, including the assessor's observations of test demonstrations.

The Specific Operations Checklist for the Airborne Asbestos Analysis program is presented in Appendix C, along with comment sheets similar to those used with the General Operations Checklist.

Sec. **285.22 Assessing and evaluating a laboratory**

(a) On-Site Assessment

(1) The NVLAP assessor may request manuals and/or documented procedures in advance of the on-site assessment to reduce time at the laboratory. The laboratory should be prepared for conducting test demonstrations, have equipment in good working order, and be ready for examination according to the requirements identified in this handbook, NIST Handbook 150, and the laboratory's quality manual. The assessor will need time and work space to complete assessment documentation during the time at the laboratory.

(2) An assessor performs the following activities during a typical on-site assessment:

(i) Conducts an entry briefing with the laboratory manager to explain the purpose of the on-site visit and to discuss the schedule for the day(s). At the discretion of the laboratory manager, other staff may attend the briefing.

(ii) Reviews laboratory quality manual (if not previously requested and supplied), and records. At least one laboratory staff member must be available to answer questions; however, the assessor may wish to review the documents alone. The assessor does not usually ask to take any laboratory documents with him and documents previously supplied will be returned.

(iii) Physically examines equipment and facilities and observes the demonstration of selected procedures by appropriate personnel assigned to conduct the tests, and interviews personnel. The demonstrations must include sample test material(s), preparation of devices, establishment of test conditions and the setup/use of major equipment. The assessor may provide proficiency test samples and request a specific demonstration.

(iv) Completes an On-Site Assessment Report which contains the minimum requirements prescribed in NIST Handbook 150, Sec. 285.22(b)(2), as well as copies of the completed checklists. At the exit briefing, the report is signed by the assessor and the laboratory's Authorized Representative to acknowledge the discussion, but does not necessarily indicate agreement; challenge(s) may be made through NVLAP. All observations made by the NVLAP assessor are held in the strictest confidence.

(b) Proficiency Testing

(1) The proficiency testing program may be conducted by NVLAP or by a NVLAP-approved contract laboratory. Proficiency testing materials are chosen to test the laboratory's ability to follow the method and to achieve the proper accuracy, precision, and detection limits.

(2) Each laboratory will be sent test materials, data sheets, and instructions for performing the test and reporting the results. The test shall be conducted in accordance with the specific test method using the laboratory's normal operating procedures. Proficiency testing shall not be contracted out to another laboratory. Any special NVLAP instructions shall also be followed. The special instructions are designed to ensure uniformity in procedures among participants. Completed data sheets shall be returned to NVLAP or its designated contractor for analysis by the date specified on the data sheets. Failure to return the proficiency testing data sheets by the deadline date will result in penalties which may include failing that round.

(3) Proficiency testing may involve materials or artifacts that must be returned to NVLAP for use by other participants. These materials shall be protected from damage both in the laboratory and during shipment back to NVLAP, or its designated contractor. Examples of such materials and artifacts are: filters, grids,

photographs and data sheets. These materials may be used to determine testing performance for specific subparts of the test method. Unless otherwise noted, laboratories should keep proficiency testing materials for use as in-house instructional materials.

(4) All analysts (including those in subfacilities) shall participate in proficiency testing. Each analyst shall separately analyze, record, and report test results. A single result is to be reported by the laboratory. The test results are to be used for interanalyst comparisons and entered into the quality system records.

(5) The results of the proficiency testing program will be reported to the participants and in appropriate documents and reports. The identity and performance of individual laboratories will remain confidential. The results of proficiency testing will be made available to on-site assessors for use during laboratory visits. Any problems indicated by proficiency testing will be discussed with appropriate laboratory personnel, who will then be responsible for developing and implementing plans for resolving the problems. Accreditation decisions will be based on satisfactory resolution of proficiency testing deficiencies.

(6) If an accredited laboratory fails a round of proficiency testing, it must do the following in order to maintain its accreditation:

(i) Provide, within 30 days of notification of failure, detailed, written documentation to NVLAP, that includes an analysis of why the laboratory failed each part of the test, and what corrective actions it has taken (analyst training, revised procedures, quality assurance activities, etc.) to resolve its analytical problems so as to avoid similar errors in the future. Documented evidence that the corrective actions have been effectively implemented is required.

(ii) Participate successfully in the next round of proficiency testing.

(7) If a laboratory has been NVLAP-accredited and fails any two rounds of proficiency testing within a set of three (3) consecutive rounds, **its accreditation will be immediately suspended**. In order to regain accreditation, the laboratory shall undergo a complete on-site assessment to determine the cause of the deficiencies, and to determine that effective corrective actions have been implemented. The laboratory shall provide NVLAP with documentation within 30 days of the assessment, which adequately demonstrates that the deficiencies noted by the assessor have been satisfactorily resolved. Failure to perform fully satisfactorily in the on-site assessment will result in accreditation remaining suspended.

(8) The full cost of any on-site assessment shall be paid in advance by the laboratory. NVLAP staff will make every effort to expedite these extraordinary assessments to give a laboratory every reasonable opportunity to demonstrate competence to perform the test method and regain accreditation.

(9) Failure to participate in a round of proficiency testing will result in **immediate suspension of accreditation**, and the laboratory shall successfully participate in the next regularly scheduled round in order to have its accreditation reinstated.

Sec. 285.23 Granting and renewing accreditation

Laboratories granted NVLAP accreditation are provided with two documents: a Certificate of Accreditation and a Scope of Accreditation. Samples of these accreditation documents for the Airborne Asbestos Analysis program are shown in Appendix A. Note that the certificate states that the criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987).

Sec. 285.33 Criteria for accreditation

(b) Organization and management

The conditions for continued accreditation of a subfacility in the Airborne Asbestos Analysis Program are contained in this section.

(1) As stated in Sec. 285.5 of NIST Handbook 150, *Definitions*: "NVLAP previously differentiated between *main facilities* and *subfacilities*. This distinction is no longer recognized. (Exception: As long as there is no break in accreditation, any laboratory previously accredited as a subfacility may request to be

'grandfathered' in its accreditation renewal under the former classification as a subfacility, including the unique conditions associated with that classification.)"

(2) Main laboratory facilities and subfacilities are defined as follows:

(i) A *main laboratory facility* permanently maintains staff, equipment, procedures, documentation, and facilities necessary to perform the tests for which it seeks accreditation; implements all quality assurance procedures; and maintains and retains all records, and issues test reports.

(ii) A *subfacility* is physically separate from, but considered an extension of, the main facility. Although it may have all staff, equipment, procedures, and documentation necessary to perform the requisite tests, it receives technical direction and quality management from the main facility. A subfacility shall maintain staff, equipment, procedures, documentation, and facilities necessary to perform the tests for which it seeks accreditation.

(3) To qualify as a subfacility, a laboratory **shall be technically dependent** on the main facility; technical management and supervision shall be provided by the main facility. Quality assurance activities of the subfacility shall be directed by the main facility. The nature, scope, and frequency of on-site quality assurance reviews by the main facility quality manager shall be clearly defined in the quality manual and be appropriate for the nature and scope of work performed by the subfacility. Copies of all permanent quality assurance and personnel records shall be retained at the main facility. Quality assurance data from each subfacility shall be frequently and routinely compared both to the main facility's data and data from other subfacilities. Records of such comparisons shall be retained in quality assurance records along with actions taken to evaluate and resolve differences.

NVLAP accreditation of a laboratory main facility does not extend to accreditation of subfacilities unless the subfacilities have been evaluated separately. These facilities are uniquely identified in the NVLAP accreditation documents. A NVLAP-accredited laboratory shall not represent test data produced at any non-accredited subfacility as having been produced by an accredited facility.

(4) NVLAP will renew the accreditation of a subfacility (in addition to the main facility) if:

(i) the laboratory was accredited as a subfacility prior to October 1, 1993;

(ii) the laboratory main facility meets all NVLAP accreditation criteria;

(iii) the laboratory main facility satisfactorily documents and maintains quality assurance procedures addressing the applicable subfacility;

(iv) the subfacility complies with all applicable NVLAP criteria; and

(v) the main facility is accredited for all test methods for which its subfacilities are accredited.

(5) NVLAP requires that subfacilities undergo on-site assessments and participate in proficiency testing.

(c) **Quality system, audit and review**

(1) The laboratory shall define and document quality objectives for obtaining accurate and precise analytical data. These objectives shall be the benchmark by which the laboratory management assesses overall and individual performance.

(2) Under its quality system, the laboratory shall develop and implement procedures covering all the technical requirements of this handbook. A laboratory analyst shall be able to obtain enough information from the laboratory's quality documentation to perform analyses in the absence of the laboratory manager. Periodic reviews of the quality system shall reflect adherence to NVLAP requirements and the laboratory's quality objectives. These reviews shall also reflect positive aspects of the quality system as well as deficiencies.

(3) The quality manual shall describe the laboratory's staff, facilities and equipment, test procedures, calibration procedures, sample

custody and handling procedures and test report format and procedures. The quality system documentation shall contain specific records (or reference to records) of calibration tests, samples received and their locations, contamination tests and test reports that have been issued. The quality system documentation shall contain schedules for routine quality assurance checks such as calibration, contamination monitoring, and determination of the precision and accuracy of the analysts. The quality system documentation shall also include filled in examples of all standardized forms used in the laboratory. Specific requirements for items discussed above are given in the remainder of this handbook and in Appendix C, Specific Operations Checklist.

(4) The laboratory's quality assurance analyses shall represent at least 10% of the total number of analyses (including non-AHERA analyses). The value of 10% is a minimum value that applies to a laboratory that has: 1) trained analysts, 2) its laboratory calibrations, contamination checks and other quality systems components statistically characterized and in a state-of-control, and 3) a high frequency of analyses. For laboratories not fitting these criteria, the quality assurance analyses must be a higher percentage of the total number of TEM asbestos analyses performed. The quality assurance checks shall be performed routinely, covering all time periods, sample types, instruments, tasks and personnel. The selection of samples for quality assurance checks shall be semirandom and, when possible, the specific checks on personnel performance shall be executed without their prior knowledge. A disproportionate number of analyses shall not be performed prior to internal or external audits. Quality assurance activities shall not be postponed during periods of heavy work loads. The laboratory personnel shall have a positive attitude towards quality assurance activities and the laboratory management shall foster an environment conducive to quality work.

(5) The laboratory maintains and summarizes all of the quality assurance activities each month including 1) contamination checks, problems and corrective measures, 2) accuracy of each analyst and of the laboratory, 3) interlaboratory and intermicroscope analyses, 4) sampling precision determined by filter reanalysis, 5) calibrations, 6) identification of any sample custody errors, such as mixing up samples, losing samples, etc., and 7) deficiency corrections.

(6) The most recent editions of the documents specified in Appendix C, Sec. 2 *Quality system, audit and review*, shall be available as references in maintaining the quality system.

(d) Personnel

(1) Employees shall be aware of the extent of their area of responsibility. This information shall be available in the required job descriptions found in the quality documentation and individual files.

(2) The laboratory shall have a written description of its training program including its criteria for successful completion. The analytical results obtained by new staff members shall be checked by an analyst whose performance has been demonstrated to be acceptable, or by using an independent technique, until the new staff member demonstrates the required level of performance. The laboratory shall establish and document performance criteria to determine when a new analyst is qualified for working independently.

(3) AEM analysts and technical supervisors shall participate in an appropriate form of continuing education, such as formal coursework, in-house education, and scientific or technical meetings, and have access to journals that describe advances in the field of electron microscopy and/or asbestos analysis.

(4) The technical supervisor shall be qualified to conduct AEM studies, apply AEM to crystalline materials and be knowledgeable in the field of asbestos analysis including procedures for sample handling, preparation, analysis, storage, disposal, and contamination monitoring.

(5) The AEM analyst(s) must be capable of following the analysis method, including accurately finding and analyzing fibrous materials, measuring the pertinent physical properties on the AEM, drawing proper conclusions from these data, and knowing when and where to obtain aid in the analysis of the samples as prescribed by the quality manual or other established laboratory procedure. Use of

the transmission electron microscope shall be satisfactorily performed by AEM analysts upon request during an on-site visit by a NVLAP Technical Expert.

(6) Analyst proficiency is important to providing reliable data. All analysts shall be tested routinely to evaluate their performance. Test results shall be recorded in the personnel folder or equivalent of each staff member, and be available during NVLAP on-site assessments. The accuracy of asbestos identification and counting of each analyst shall be evaluated by analyses of reference materials, analyses of NIST proficiency testing materials, verified analyses, and blind testing. Testing shall be frequent enough to ensure quality analyses. Test specimens should include asbestos-containing and look-alike materials routinely examined by the analysts, and those not often encountered. Periodic review and blind testing with infrequently encountered materials will help analysts maintain analytical proficiency. Problems shall be discussed with the analyst, and corrected according to documented procedures. Subsequent quality assurance tests shall determine whether the problem has been corrected. The laboratory shall ensure the quality of analyses while the problem is being corrected. All corrective actions shall be documented in monthly quality assurance summaries, periodic laboratory audits, and individual analyst's files.

(7) Verified asbestos analysis is currently the most definitive way to compare results among analysts and to check for the accuracy of an analyst on an unknown sample (see reference (d) in Sec. 285.4, *References*). Verified asbestos analysis consists of multiple operators independently analyzing a grid square and comparing results. This requires that beam currents be low enough that at least two consecutive analysts can observe electron diffraction patterns from the same fiber. An AEM analyst must attain an average accuracy of $\geq 80\%$ true positives, $\leq 20\%$ false negatives, and $\leq 10\%$ false positives on verified analyses to attain verified status.

(8) Laboratories may find it advantageous to use several operators in a verified analysis of a grid square to characterize initial operator performance if an analyst with verified status is not available. The number of analysts which can analyze a grid square is limited by beam damage to the particles (four operators is typically the maximum number of analysts that can be used). Multiple analysts from different laboratories can be used if the initial orientation of the grid and grid opening is recorded and made known to subsequent laboratories.

(9) One of the most common causes of false negatives in an AEM analysis of asbestos occurs when the operator fails to find or observe a fiber or structure. This is commonly due to the operator missing a whole or partial traverse of the grid square. A source of both false negatives and false positives is the individual operator's interpretation of asbestos structure counting rules as it is applied to complex structures. These types of errors can be uncovered and corrected by the use of verified analyses. As analysts within a laboratory count structures in a more uniform manner, the imprecision (due to the analysts) within the laboratory will decrease.

(10) Verified asbestos analyses shall be performed routinely by the laboratory with sufficient frequency and on sufficient types of samples to determine each operator's initial and continuing performance. Samples having approximately 6-40 structures/grid opening shall be used to achieve statistically significant information on new analysts. During training, all counts used in reports shall be verified until verified status is attained. After initial training, a variety of asbestos loadings, including routine AHERA samples, shall be used to validate analysts' results. At least 20% of verified analyses shall be performed on samples with 6-40 structures/grid opening loadings and at least 5 grid openings with 6-40 structures/grid opening shall be verified annually. Filter blanks, unless known to be contaminated, shall be rarely used for verified counting. After verified status is attained, the frequency of verified analysis shall be at least 1 per 100 grid opening analyses.

(11) The laboratory shall be organized so that staff members are not subjected to undue pressure or inducement that might influence their judgment or results of their work. The laboratory shall be able to demonstrate that the sample work load required for each analyst is consistent with accurate and precise analytical measurement.

(12) The laboratory will be responsible for demonstrating its competence to analyze asbestos samples following the practice outlined in its quality documentation. Any staff member involved in the analysis of samples will be responsible for demonstrating their competence as required during an on-site assessment. In particular, analysts shall be able to demonstrate their ability to use and interpret results from the AEM in imaging, diffraction, and x-ray analysis modes and to identify the various types of asbestos and to differentiate it from nonasbestos fibers.

(e) Accommodation and environment

(1) The laboratory shall have the facilities necessary for the correct analysis of airborne asbestos under safe working conditions. The following facilities shall be available: a) clean room or clean areas for sample preparation and handling separate from bulk asbestos, b) electron microscopy facility, and c) room or area for filter and grid storage separate from bulk asbestos. The clean room or clean area shall have class 100 (or cleaner) HEPA-filtered air under positive pressure and an exhaust hood for safe use of filter dissolution reagents. Safe working conditions shall be maintained including safe handling of asbestos and safe handling and storage of filter-dissolving reagents such as chloroform, dimethyl formamide, acetone, acetic acid, etc.

(2) Contamination is a critical factor in the analysis of asbestos. The analysis of asbestos in air typically involves analyzing nano- or picogram quantities of asbestos and, therefore, no statistically significant contamination of areas, personnel, instrumentation, or materials used for preparation or analysis of air filter samples can be tolerated. There shall be written procedures for the prevention, monitoring, and control of contamination of filters and grids. There shall be a procedure (or flow chart) for the systematic checking for possible sources of contamination if contamination is detected. This shall include checking all areas, instrumentation, and materials used in the preparation and analysis of air filter samples.

(3) All personnel shall be instructed in contamination prevention. A major potential source of contamination is from areas, personnel, instrumentation and material used for the preparation and analysis of bulk materials that contain asbestos. The probability of cross-contamination requires that these areas, personnel, instrumentation and materials be kept completely separate from those used for preparation and analysis of bulk samples. Personnel who have worked with bulk samples shall not subsequently be allowed to work with air filter samples on the same day. It is acceptable, however, for personnel to work on bulk samples after having worked with air samples. All reagents shall be checked for asbestos contamination prior to use for sample preparation.

(4) The quality system shall outline the frequency and timing of checks for contamination of blank materials by asbestos. Blank materials most commonly consist of filters that have not been used for sampling but can also include carbon film grids or other items useful for detection of contamination. Filter blanks include filter lot blanks, sealed blanks, field blanks and laboratory blanks (for definitions of these blanks see section 285.5). Laboratory blanks shall be analyzed routinely and with increased frequency after actual contamination is discovered and corrected. At a minimum, one laboratory blank shall be prepared for every sample set from a site or for 10% of the samples (whichever is greater). A laboratory blank shall be analyzed after analysis of 25 samples and when the average count for a full set of filters is found to be above 70 structures/mm^2. A laboratory blank shall also be prepared and analyzed after cleaning or servicing the clean room or clean area. Field and sealed blanks shall be prepared with each set of samples and shall be analyzed when the full indoor/outdoor analysis is performed. The frequency of blank analyses shall be sufficient to show the validity of any analysis found to be statistically above the laboratory blank level.

(5) When contamination above acceptable levels is found, analyses for AHERA clearance shall be discontinued until the cause of contamination has been found or until data shows that the contamination problem no longer exists.

(f) Equipment and reference materials

(1) The laboratory shall have the following sample preparation equipment or equivalent available in the clean room or area:

(i) filter preparation equipment, including a condensation washer and/or Jaffe wick or with appropriate reagents and supplies;

(ii) filter handling materials (e.g., scalpels, forceps, probe needles, microscope slides, indexed TEM grids, etc.);

(iii) carbon evaporator; and

(iv) low temperature plasma asher.

The low temperature plasma asher shall be supplied with oxygen, allow for control of the speed of evacuation and venting to atmospheric pressure to minimize disturbance of particles on the filter surface and shall not be used for bulk samples (asbestos or other). The laboratory shall have a carbon evaporator that attains a vacuum of 13 Pa (10^{-4} torr) or lower and has controlled venting to atmospheric pressure. The laboratory shall have spectrochemically pure carbon rods, a carbon rod sharpener, and gold or aluminum wire for evaporation (or have a sputter coater with a gold target).

(2) The laboratory shall have an electron microscope, which has the following under routine asbestos analysis conditions:

(i) capability of operation at a voltage between 80 keV-120 keV;

(ii) capability of producing an electron diffraction pattern of single fibers of chrysotile that are $\geq$ 0.5 μm in length;

(iii) capability of displaying and resolving the hollow tube of chrysotile;

(iv) capability of precise fiber length (at 0.5 μm and 5.0 μm) and diffraction pattern measurement, regardless of image (fiber or pattern orientation);

(v) mechanical stage with linear, reproducible movements along two perpendicular directions;

(vi) capability of producing a spot at crossover that is $\leq$ 250 nm during EDXA analysis; and

(vii) an imaging system for recording brightfield images and electron diffraction patterns on film or on other suitable media.

It is strongly recommended that the laboratory possess a holder capable of obtaining zone axis diffraction patterns (either a double-tilt or rotation-tilt holder).

(3) The laboratory shall be able to record and produce hard copies of images (on film or other media) to document:

(i) visibility of chrysotile hollow tubes and beam damage;

(ii) visibility and measurement of electron diffraction patterns, in particular chrysotile (002), (004), (110), (020), (130), and (200) reflections;

(iii) complex arrangement of fibers;

(iv) a range of magnifications from 1000$\times$ to 100 000$\times$ in brightfield imaging mode; and

(v) a range of diffraction camera lengths that enable accurate diffraction pattern measurement (approximately 20 cm to 80 cm).

(4) An EDXA system shall be interfaced to all electron microscopes used for asbestos analysis. The EDXA system (detector and multichannel analyzer) shall, under routine analysis conditions, have: 1) a resolution of 175 eV or better at the Mn Kα peak, 2) proven detection of Na peak in standard crocidolite or equivalent, 3) capability of obtaining significant Mg and Si peaks from a single fibril of chrysotile, and 4) consistent relative sensitivity factors over large areas of the specimen grid. A low background holder may be necessary to meet these requirements.

(5) The multichannel analyzer shall have software capable of obtaining background corrected peak intensities or integrals for Na, Mg, Al, Si, Ca, Fe and other elements as needed. The multichannel analyzer system shall have the capability of accumulation and display of an x-ray spectrum (minimum 0.7 keV-

10 keV) and the capability of making a hard copy of an x-ray spectrum.

(6) The laboratory shall have reference materials and any associated certificates for evaluation of personnel and calibration of equipment. The laboratory shall have materials with a certified value for the loading of asbestos on filters such as NIST SRM 1876b and optionally NIST RM 8410 and RM 8411. SRM 1876 and SRM 1876a are not acceptable as they were certified using sets of counting rules that are no longer in use. The laboratory shall have characterized materials such as NIST SRM 1866 and SRM 1867 for training and for evaluation of analysts' ability to identify asbestos. These SRMs contain bulk asbestos and, therefore, precautions need to be taken against contaminating the filter preparation area and AEM with these specimens. The laboratory shall have calibration materials for the x-ray system including SRM 2063. The laboratory shall have a standard optical grating replica for magnification calibration and gold or aluminum film material for electron diffraction calibration.

(7) The laboratory shall develop its own internal standards to supplement existing NIST standards or where NIST standards are not available. The internal standards must be well-characterized (for instance by use of interlaboratory tests).

(g) Measurement traceability and calibration

(1) Calibration of equipment and personnel is important in demonstrating the validity of data collected during the analysis of asbestos. Calibration data on known reference samples give a database from which unknown samples can be analyzed, interoperator and interlaboratory results can be compared, and analytical error can be estimated.

(2) All calibrations shall be performed with the instrument, stage, sample, x-ray detector and other parameters at routine asbestos analysis conditions (e.g., tilt, apertures, location, specimen height, accelerating voltage, etc.) and with the microscope aligned. Tilting the viewing screen and specimen grid during fiber measurement, or the viewing screen during diffraction measurement is not recommended. Laboratories using tilts must demonstrate the required measurement accuracy and precision for all fiber and diffraction maxima orientations.

(3) Control charts shall be a principal means for summarizing calibration data. The laboratory shall have specific procedures in its quality system documentation for the development and use of control charts. Control charts shall be constructed to show calibration values vs. time, the magnitude of their variation, and the allowable limits of variation. The magnitude of variation specified for many calibrations in this program is defined as 2 s (where s is the estimated standard deviation of a set of measurements). Initially, many (15-30) calibrations shall be performed in less than 1 year's time to establish the variation of the measurement. If the variation is within specified limits and the accuracy is acceptable, the frequency of the calibration can be reduced. Calibrations shall be performed on a frequent enough basis to ensure accurate results. In general, the majority of calibrations shall have been performed within 3 months prior to analyses for clients.

(4) Parameters of the electron microscope that are required to be calibrated include the magnification, electron diffraction camera constant, beam dose and analytical spot size for well-resolved x-ray microanalysis (see Appendix C, Section 6 *Measurement traceability and calibration* for more specific information on these calibrations).

(5) Parameters of the EDXA system shall be calibrated including the resolution, eV/channel, and the relative sensitivity factors relative to Si for elements found in regulated asbestos minerals (see Appendix C, Section 6 *Measurement traceability and calibration* for more specific information). The proper analytical conditions for x-ray analysis on the AEM shall be determined including: specimen tilt angle, holder type, lens and aperture conditions, and regions of TEM specimen holders for which absorption will affect the quality of EDXA spectra.

[NOTE: An x-ray detector's performance on an AEM can change dramatically as a function of time, often due to damage to the silicon detector or from oil and/or ice contamination of the detector and/or detector window. These problems can cause peak broadening across the

spectrum and reduced sensitivity at lower x-ray energies. Since these changes in sensitivity are a function of x-ray energy, they can affect the identification criteria for asbestos. The best way to calibrate the detector and check for these effects is with a reference material of known thickness and composition that yields low, medium, and high energy x-rays, such as SRM 2063.]

(7) Calibrations of the low temperature asher, the quality of sample preparations, and the grid opening measurement system shall be performed. Performance of the AEM analysts on verified counts, analyses of SRM 1876b, and identification of bundles and single fibers of asbestos structures $\geq$ 1 μm in length shall be summarized using control charts.

(8) Interlaboratory analyses shall be performed to detect laboratory bias. If more than one AEM is used for asbestos analysis, intermicroscope analysis shall be performed to detect instrument bias. The precision of analyses of samples shall be determined by repeat preparation and analysis of the same filter by the same and different analysts.

(h) Calibration and test methods

(1) The laboratory shall use the test method contained in the U.S. EPA "Interim Transmission Electron Microscopy Analytical Methods—Mandatory and Nonmandatory—and Mandatory Section to Determine Completion of Response Actions" and any NIST or U.S. Environmental Protection Agency clarifications, modifications, or updates to the TEM method for the analysis of asbestos. The laboratory must have written procedures that describe how the method is implemented in the laboratory. The laboratory shall conform in all respects with the test method except when a departure becomes necessary for technical reasons. Laboratories utilizing departures from a test method shall have written procedures detailing how the analysis is conducted. These procedures shall include criteria to determine when such departures are warranted.

(2) Quality documentation shall detail the procedures used to conduct the AEM test method as it is applied in the laboratory. (A simple copy of the published method is not sufficient to meet this requirement.) The laboratory must have detailed instructions for sample handling, analysis, and reporting as performed in their laboratory. Summaries of changes and problems are entered into the quality assurance records on the test method.

(3) The laboratory shall have written procedures for the preparation of filters, determination of number of grid squares to be analyzed, evaluation of the quality of prepared grids, determination of the area of grid squares, operation of the AEM for asbestos analysis, for examining a grid square and for verifying report calculations (see Appendix C, Section 7 *Test methods and calibrations* for more details). The laboratory shall adhere to its written procedures. The laboratory shall prepare at least three grids per filter and perform the necessary analyses on two of the grid squares. The AEM analysts shall record sufficient information for each analysis so that a verified analysis can subsequently be performed. AEM analysts shall record an electron diffraction pattern of an asbestos structure from every five samples that contain asbestos.

(i) Handling of calibration and test items

(1) The laboratory shall have written procedures covering all aspects of receipt, handling and storage of filter materials and prepared grids. The log-in system shall include documentation of the date of receipt, identity of the client, unique identification for the sample, air volume pulled through sample, filter pore size, condition of the samples, and the acceptance or rejection of the samples. The laboratory shall have written criteria for acceptance or rejection of filter cassettes.

(2) The laboratory shall have a chain-of-custody system that documents the following information:

(i) location of the sample;

(ii) personnel who have handled or worked with the sample; and

(iii) what has been done to the sample.

The system for identifying samples to be tested must remain in force from the date of receipt of the item to the date of its disposal, either through documents or through marking, to

ensure that there is no confusion regarding the identity of the samples and the results of the measurements.

(3) The laboratory shall have a system for storing the unused portions of filters and their cassettes for at least 30 days and for the storage of all prepared grids (even if not analyzed) for at least three years. The stored filters and grids must be archived so that a specified sample can be retrieved within one work day.

(4) The laboratory sample coordinator (see Section (d) *Personnel*) shall be responsible for ensuring that all procedures related to sample custody and handling are followed.

(j) Records (see Specific Operations Checklist)

Records may be kept in hard copy or computer form (with an adequate back-up system), but they shall be readily accessible and secure. The period of retention shall be 3 years, unless a longer period is required by the client, regulation, or the laboratory's own procedures. The records shall be stored in a logical fashion allowing retrieval within one working day. The records to be maintained include:

(1) personnel records including operator characterization;

(2) sample custody records;

(3) original data collected by analyst;

(4) contamination monitoring data;

(5) calibration and verification data;

(6) data and results of quality control;

(7) facility and equipment and maintenance records; and

(8) test reports.

(k) Certificates and reports

(1) In addition to the test report requirements found in Sec. 285.33(k) of NIST Handbook 150, the following information shall be reported for each sample:

(i) area of filter analyzed;

(ii) volume of air sampled (with reference to sampling data sheet);

(iii) analytical sensitivity for the analysis;

(iv) number of total asbestos structures and number of structures by asbestos type;

(v) concentration of asbestos structures per square millimeter of filter and asbestos structures per cubic centimeter of air for total asbestos structures and with data broken down by size (≥ 5 μm and ≥ 0.5 μm to < 5 μm) and by asbestos type (chrysotile and/or type of amphibole);

(vi) statement of analytical uncertainty, including laboratory-analyst accuracy/precision and sample variability; and

(vii) micrograph number of any recorded diffraction patterns;

(viii) a copy of AEM analysis data record with analyst's signature or initials; and

(ix) descriptions of any departures from the test method.

(2) The following information shall also be supplied if asbestos abatement clearance is determined by the laboratory:

(i) calculation formulas;

(ii) all calculation variables and constants; and

(iii) all calculation results.

(3) A laboratory which subcontracts its asbestos analysis work, must ensure that the subcontracted laboratory meets all the requirements of this handbook and Sec. 285.33(l) of NIST Handbook 150.

APPENDIX A

SAMPLE ACCREDITATION DOCUMENTS

United States Department of Commerce
National Institute of Standards and Technology

NVLAP®

ISO/IEC GUIDE 25:1990
ISO/IEC GUIDE 58:1993
ISO 9002:1994

Certificate of Accreditation

DEPARTMENT OF COMMERCE ★ UNITED STATES OF AMERICA ★

LABORATORY, INC.
ANYTOWN, MD

is recognized under the National Voluntary Laboratory Accreditation Program for satisfactory compliance with criteria established in Title 15, Part 285 Code of Federal Regulations. These criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987) as suppliers of calibration or test results. Accreditation is awarded for specific services, listed on the Scope of Accreditation for:

AIRBORNE ASBESTOS FIBER ANALYSIS

January 1, 19xx
Effective until

For the National Institute of Standards and Technology

NVLAP LAB CODE: 0000

National Institute of Standards and Technology

NVLAP®

National Voluntary Laboratory Accreditation Program

ISO/IEC GUIDE 25:1990
ISO/IEC GUIDE 58:1993
ISO 9002:1994

Scope of Accreditation

AIRBORNE ASBESTOS FIBER ANALYSIS **NVLAP LAB CODE 0000**

Laboratory, Inc.
1 Main Street
Anytown, MD 00000
John Doe Phone: 301-555-1212

NVLAP Code	*Designation*
18/A02	40 Code of Federal Regulations Chapter I (1-1-87 edition) Part 763, Subpart E, Appendix A or the current U. S. Environmental Protection Agency TEM method for the determination of completion of response actions for asbestos.

January 1, 19xx

Effective until

For the National Institute of Standards and Technology

APPENDIX B

GENERAL OPERATIONS CHECKLIST

NVLAP LAB CODE: [ ]

GENERAL OPERATIONS CHECKLIST

Instructions to the Assessor: This checklist addresses general accreditation criteria prescribed in applicable sections of NIST Handbook 150, *NVLAP Procedures and General Requirements*.

This checklist follows and is numbered to correspond to the *NVLAP Procedures and General Requirements*, Subsection 285.33. The numbers in square brackets identify related checklist items. A small black triangle appears in the left-hand margin of selected lines of text throughout this checklist; the marked text applies only to the Calibration Laboratory Accreditation Program (LAP).

Place an "X" beside each checklist item which represents a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments in this list or on the attached comment sheets. Place a check beside all other items you observed or verified at the laboratory.

SEC. 285.33 CRITERIA FOR ACCREDITATION

(b) ***Organization and management***

(1) The laboratory shall be:

_____ (i) legally identifiable;

Legal name of laboratory ownership: _____

(ii) organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the NVLAP requirements [see also (b)(2)(i), (c)(2)(ii)];

_____ (iii) properly identified on the NVLAP Application.

(2) The laboratory shall:

_____ (i) have managerial staff with the authority and resources needed to discharge their duties [see also (b)(1)(ii), (c)(2)(ii)];

_____ (ii) have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

_____ (iii) be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

_____ (iv) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

_____ (v) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test, and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

_____ (vi) have a technical manager (however named) who has overall responsibility for the technical operations;

Name of person: _____

_____ (vii) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

Name of person: _____

_____ (viii) nominate deputy(ies) in case of absence of the technical or quality manager;

Name(s): _____

_____ (ix) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights [see also (c)(2)(xviii)];

_____ (x) where appropriate, participate in interlaboratory comparisons and proficiency testing programs [see also (c)(2)(xiv), (c)(6)(ii), (g)(3)];

_____ (xi) have documented policy and procedures to ensure that its clients are served with impartiality and integrity.

(c) ***Quality system, audit and review***

(1) The laboratory shall:

_____ (i) have an established and maintained quality system appropriate to the type, range and volume of calibration and testing activities it undertakes;

_____ (ii) have the elements of the quality system documented;

_____ (iii) ensure that the quality documentation is available for use by the laboratory personnel;

_____ (iv) define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services;

_____ (v) have the laboratory management which ensures that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned;

_____ (vi) ensure that the quality manual is maintained current under the responsibility of the quality manager [see also (c)(2)(iv)].

Date of quality manual: _____

Date of latest update: _____

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the NVLAP requirements. The quality manual and related quality documentation shall contain:

_____ (i) a quality policy statement, including objectives and commitments, by top management;

_____ (ii) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

_____ (iii) the relations between management, technical operations, support services and the quality system;

_____ (iv) procedures for control and maintenance of documentation [see also (c)(1)(vi), (j)(1)];

_____ (v) job descriptions of key staff and reference to the job descriptions of other staff;

_____ (vi) identification of the laboratory's approved signatories (list here or in the comments section): _____

_____

_____ (vii) the laboratory's procedures for achieving traceability of measurements;

_____ (viii) the laboratory's scope of calibrations and/or tests;

_____ (ix) written procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

_____ (x) reference to the calibration, verification and/or test procedures used;

_____ (xi) procedures for handling calibration and test items;

_____ (xii) reference to the major equipment and reference measurement standards used;

_____ (xiii) reference to procedures for calibration, verification and maintenance of equipment;

_____ (xiv) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes [see also (b)(2)(x), (c)(6)(ii), (g)(3)];

(xv) procedures to be followed for feedback and corrective action whenever:

_____ a) testing discrepancies are detected, or

_____ b) departures from documented policies and procedures occur;

_____ (xvi) the laboratory management policies for departures from documented policies and procedures or from standard specifications;

_____ (xvii) procedures for dealing with complaints [see also (n)];

_____ (xviii) procedures for protecting confidentiality and proprietary rights [see also (b)(2)(ix)];

_____ (xix) procedures for audit and review;

_____ (xx) a description of the laboratory's policy regarding the use of the NVLAP logo;

▸ _____ (xxi) a statement of the laboratory's policy for establishing and changing
▸ calibration intervals for equipment it controls; and

_____ (xxii) a statement of the laboratory's policy concerning the technique(s) to be used for determining measurement uncertainty and calibration/verification adequacy.

_____ (3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

The audits shall be objective and be conducted internally or on contract. The audits shall include both general criteria (documents, records and policies) and technical compliance (test methods and practices and calibration procedures).

_____ (4) The quality system adopted to satisfy the NVLAP requirements shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

_____ (5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

_____ (i) internal quality control plans, such as control charts and other available statistical techniques;

NOTE: Measurement assurance techniques are acceptable means to control the measurement process and consistently produce the highest quality measurements.

_____ (ii) participation in proficiency testing or other interlaboratory comparisons [see also (b)(2)(x), (c)(2)(xiv), (g)(3)];

_____ (iii) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

_____ (iv) replicate testings using the same or different methods;

_____ (v) retesting of retained items;

_____ (vi) correlation of results for different characteristics of an item.

(d) ***Personnel*** [see also (c)(2)(v)]

_____ (1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

_____ (2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

_____ (3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) ***Accommodation (facilities) and environment*** [see also (i)(3)]

_____ (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

NOTE: Laboratory design will be, to the maximum extent practical, in accordance with the guidelines found in the NCSL Recommended Practice #7, *Laboratory Design*, July 25, 1993.

_____ (2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

NOTE: It is expected that environments which do not meet generally accepted norms, such as those found in NCSL Recommended Practice #7, yet which exhibit the stability required to apply necessary correction factors, will be specified by the laboratory for the purpose of assessment of compliance with its own procedures to achieve its stated uncertainties.

_____ (3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

_____ (4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

_____ (5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

_____ (6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

NOTE: While it is the laboratory's responsibility to comply with relevant health and safety requirements, this is outside the scope of this assessment.

(f) ***Equipment and reference materials***

(1) The laboratory shall:

_____ (i) be furnished with all items of equipment (including hardware, software, and reference materials) required for the correct performance of calibrations and tests;

_____ (ii) in those cases where the laboratory needs to use equipment outside its permanent control, including rented, leased and client-owned equipment, ensure that the relevant NVLAP requirements are met.

_____ (2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

_____ (3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

_____ (4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

_____ (i) the name of the item of equipment, software or reference material;

_____ (ii) the manufacturer's name, type identification, and serial number or other unique identification;

_____ (iii) date received and date placed in service;

NOTE: For initial accreditation, the date received and the date placed in service are not considered mandatory requirements for inclusion in laboratory records, although this is encouraged as good laboratory practice.

_____ (iv) current location, where appropriate;

_____ (v) condition when received (e.g., new, used, reconditioned);

_____ (vi) copy of the manufacturer's instructions, where available;

_____ (vii) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

_____ (viii) details of maintenance carried out to date and planned for the future;

_____ (ix) history of any damage, malfunction, modification or repair;

▸ _____ (x) measured value observed for each parameter found to be out of tolerance
▸ during calibration/verification.

(g) ***Measurement traceability and calibration***

_____ (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. The program will ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable.

_____ (2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall, wherever applicable, indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

NOTE: Traceability to national standards includes traceability to standards maintained or defined at national laboratories in foreign countries where applicable. In these cases, traceability is achieved via international standards. This includes intrinsic standards of measurement where available.

Where applicable, the methodology of the *Guide to the expression of uncertainty in measurement*: 1993, shall be used as the basis for expression of uncertainty of the measurement. NIST Technical Note 1297; January 1993, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, is a practical application document written around the *Guide to the expression of uncertainty in measurement.* Where detailed procedures are not used to quantify and combine uncertainties (i.e., use of test accuracy ratio concepts), the sources of uncertainty shall be tabulated and demonstrated to be acceptable for the measurement undertaken.

NOTE: A significant number of intrinsic standards, such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard, have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials, and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, interlaboratory comparisons, or other suitable means, that its intrinsic standard measurement results are correlated with those of national or international standards.

_____ (3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing [see also (b)(2)(x), (c)(2)(xiv), (c)(6)(ii)].

NOTE: Traceability requirements may also be satisfied by:

(i) internationally accepted standards in the field concerned;

(ii) suitable reference materials;

(iii) ratio or reciprocity measurements; or

(iv) mutual consent standards which are clearly specified and mutually agreed upon by all parties concerned.

_____ (4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

_____ (5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

_____ (6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

_____ (7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

(h) ***Calibration and test methods***

_____ (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

_____ (2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

NOTES:

(i) Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.

(ii) The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well-defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

_____ (3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

_____ (4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports [see also (k)(2)(x)].

_____ (5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples [see also (k)(2)(ix)].

_____ (6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall have written procedures which ensure that:

_____ (i) the NVLAP requirements are complied with;

_____ (ii) computer software, computers or automated equipment is documented and adequate for use;

_____ (iii) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

_____ (iv) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data [see also (f)(1)];

_____ (v) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

_____ (8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory [see also (m)(2)].

(i) ***Handling of calibration and test items***

_____ (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time [see also (k)(2)(v)].

_____ (2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

_____ (3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned [see also (e)].

_____ (4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

_____ (5) Tamper-resistant seals shall be affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.

NOTE: Tamper-resistant seals are sometimes affixed to equipment to prevent unauthorized access to areas where adjustments or critical components are located.

(j) ***Records***

_____ (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing [see also (c)(2)(iv)].

▸ **EXCEPTION:** The retention of all original observations, calculations, and
▸ derived data in the calibration record system is not a mandatory requirement
▸ for calibration laboratories, although it is encouraged as good laboratory
▸ practice.

_____ (2) All records (including those listed in (f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client [see also (b)(2)(ix), (c)(2)(xviii)].

NOTE: The period of retention shall be specified in the quality manual.

Record retention time specified: _____

(k) ***Certificates and reports***

_____ (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used [see also (k)(4)(i)].

NOTE: It is recognized that the results of each calibration do not always result in the production of a calibration certificate or report. Whenever a certificate or report is produced, the above requirements shall be met.

(2) Each certificate or report shall include at least the following information:

_____ (i) a title, e.g., "Calibration Certificate," "Test Report" or "Test Certificate";

_____ (ii) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

_____ (iii) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

_____ (iv) name and address of client, where appropriate;

_____ (v) description and unambiguous identification of the item calibrated or tested [see also (i)(1)];

_____ (vi) characterization and condition of the calibration or test item;

_____ (vii) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

EXCEPTION: Although it is encouraged as good laboratory practice, the requirement for inclusion of the date received is not mandatory for calibration laboratories.

_____ (viii) identification of the calibration or test method used, or unambiguous description of any non-standard method used;

_____ (ix) reference to sampling procedure, where relevant [see also (h)(5)];

_____ (x) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions [see also (c)(2)(xv), (h)(4)];

_____ (xi) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

_____ (xii) a statement of the estimated uncertainty of the calibration or test result, where relevant;

_____ (xiii) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue [see also (c)(2)(vi)];

_____ (xiv) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

_____ (xv) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

_____ (xvi) a statement that the report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government;

_____ (xvii) the signature of an approved signatory for all test and calibration reports endorsed with the NVLAP logo;

▸ _____ (xviii) special limitations of use; and

▸ _____ (xix) traceability statement.

_____ (3) Where the certificate or report contains results of calibrations or tests performed by subcontractors, these results shall be clearly identified [see also (l)].

_____ (4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible [see also (k)(1)].

_____ (5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate (or Test Report or Test Certificate), serial number ... (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the relevant requirements of item (j).

_____ (6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report, or test certificate or amendment to a report or certificate.

NOTE: Such notification shall quantify the magnitude of error created in the calibration results. The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out of tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.

_____ (7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the NVLAP requirements are met and that confidentiality is preserved.

_____ (8) Whenever a laboratory accredited by NVLAP issues a calibration or test report which contains data covered by the accreditation and also data not covered by the accreditation, it must clearly identify in its records, and in the report to the client, specifically which calibration or test method(s), or portion of a calibration or test method(s), was not covered by the accreditation. The laboratory must also inform the client, before the fact, when calibrations or tests requested are not covered by the accreditation.

NVLAP policy regarding calibration and test reports issued by an accredited laboratory, which reference the laboratory's accredited status, requires that any calibration or test report containing data from calibrations or tests which are not covered by the accreditation include:

_____ (i) a statement at the beginning of the report prominently indicating, "This report contains data which are not covered by the NVLAP accreditation"; and

_____ (ii) a clear indication of which data are not covered by the accreditation.

The laboratory must not misrepresent its accreditation. When a client requires or requests accredited services and any of the requested services are not covered by the accreditation, the client must be so advised.

(l) ***Subcontracting of calibration or testing*** [see also (k)(3)]

_____ (1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

_____ (2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

_____ (3) A NVLAP-accredited laboratory intending to subcontract testing or calibration work that will be performed and reported as meeting NVLAP procedures and criteria must:

_____ (i) have in its quality manual a subcontracting policy compatible with the NVLAP policy, with a description of the procedures for administering and implementing those actions to demonstrate the conformance and consistency of the subcontracted laboratory to perform according to NVLAP procedures;

_____ (ii) place the subcontracted work with a laboratory that maintains accreditation established by NVLAP shown by a current NVLAP Lab Code, or provide and maintain current records that demonstrate that the subcontracted laboratory is competent to perform the test(s) or calibration(s) and that it operates in a manner consistent with and in conformance to NVLAP criteria for accreditation;

_____ (iii) clearly identify in its records, and in the report to the client, exactly which data were obtained by the NVLAP-accredited laboratory and which data were obtained by the subcontractor, NVLAP-accredited or not;

_____ (iv) inform its client, before the fact, that it intends to subcontract for completion of all or a portion of the client's work; and

_____ (v) include at the beginning of the report the name, address, and contact person of the subcontracted laboratory(ies), and one of the following statements, as appropriate:

if NVLAP-accredited

"This report contains data which were produced by a subcontracted laboratory **ACCREDITED (NVLAP LAB CODE)** for the calibration or test methods performed"

if not NVLAP-accredited

"This report contains data which were produced by a subcontracted laboratory **NOT ACCREDITED** for the calibration or test methods performed."

The requirements of this section do not supersede any regulation, law, contract specification, or other related conditions which require NVLAP accreditation.

(m) ***Outside support services and supplies***

_____ (1) Where the laboratory procures outside services and supplies in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

_____ (2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned [see also (h)(8)].

_____ (3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) ***Complaints*** [see also (c)(2)(xvii)]

_____ (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

_____ (2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the NVLAP requirements or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with item (c)(3).

(o) ***Measuring and test equipment (M & TE)***

NOTE: This section applies to the control of measuring and test equipment (M & TE) used to assure that supplies and services comply with prescribed customer requirements. It is based in large part on the requirements found in government audit standards such as MIL-STD 45662A, and is found in Part II of the ANSI/NCSL Z540-1-1994 (Draft) standard.

(1) General requirements for M & TE

_____ (i) The supplier shall establish and document a system to control the calibration/verification of M & TE.

_____ (ii) M & TE used to determine compliance with customer technical specifications shall be calibrated or verified in accordance with sections 285.33(b) through (n).

_____ (iii) The supplier shall have a program to recall for calibration or verification, or remove from service, M & TE that has exceeded its calibration interval, has broken calibration seals, or is suspected to be malfunctioning because of mishandling, misuse, or unusual results.

_____ (iv) All operations performed by the supplier in compliance with these requirements shall be subject to customer verification at unscheduled intervals.

_____ (v) The supplier shall carry out, or arrange to have carried out, periodic quality auditing of the calibration and verification system in order to ensure its continuing effective implementation and compliance with these requirements.

- Based on the results of the audits and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.

- Plans and procedures for the audits shall be documented. The conduct of the audit and any subsequent corrective action shall also be documented.

(2) Detailed requirements for M & TE

_____ (i) Calibration system description: The supplier shall provide and maintain a written description of the calibration/verification system covering M & TE and measurement standards. The description shall be sufficient to satisfy each requirement of section 285.33(o) and any deviations shall be submitted with supporting documentation to the customer for approval.

_____ (ii) Adequacy of measurement standards: Measurement standards used by the supplier for calibrating M & TE and other measurement standards shall comply with the requirements of items (f)(1), (g)(1), and (h)(2).

_____ (iii) Environmental conditions: M & TE shall be used in an environment controlled to the extent necessary to ensure valid results. Due consideration shall be given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

_____ (iv) Intervals of calibration and verification: M & TE requiring calibration shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that M & TE will remain in-tolerance throughout the interval. Intervals shall be established for all M & TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration or verification. All exemptions from periodic calibration or verification shall be documented. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of the customer's requirements.

_____ (v) Calibration procedures: Procedures used to calibrate/verify the supplier's M & TE shall comply with the requirements of items (h)(1) and (h)(2).

_____ (vi) Out-of-tolerance conditions: If any M & TE is found to be significantly out of tolerance during the calibration/verification process, the supplier's system shall provide for notification to the user and to the supplier's quality element, if appropriate, of the out-of-tolerance condition with the associated measurement data so that appropriate action can be taken.

_____ (vii) Adequacy of calibration system: The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with these requirements.

_____ (viii) Calibration sources: M & TE requiring calibration shall be calibrated or verified by laboratories that comply with sections 285.33(b) through (n).

_____ (ix) Records: These requirements shall be supported by records documenting that established schedules and procedures are followed to maintain the adequacy of all M & TE. The records for M & TE requiring calibration shall include an individual record of calibration or verification, or other means of control, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration results (data and/or condition status) and calibration action taken (adjusted, repaired, new value assigned, derated, etc.).

_____ (x) Calibration status: M & TE shall be labeled to indicate calibration or verification status. The label shall identify specific date calibrated (day, month, year, Julian date, or equivalent) and the specific calibration due date or usage equivalent. Items not calibrated to their full capability or which have other limitations of use, shall be labeled or otherwise identified as to the limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status. Tamper-resistant seals are affixed to operator accessible controls or adjustments which if moved will invalidate the calibration. The quality system shall provide instructions for the disposition of equipment with broken tamper-resistant seals.

_____ (xi) Control of subcontractor calibration: The supplier is responsible for assuring that the subcontractor's calibration system conforms to section 285.33 (l) to the degree necessary to assure compliance with contractual requirements. NVLAP accreditation of the subcontractor's laboratory can serve as the basis for compliance with this requirement.

_____ (xii) Storage and handling: M & TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment.

NVLAP LAB CODE: _____

GENERAL OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

NVLAP LAB CODE:

GENERAL OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

APPENDIX C

SPECIFIC OPERATIONS CHECKLIST

NVLAP LAB CODE: _____

AIRBORNE ASBESTOS SPECIFIC OPERATIONS CHECKLIST

Instructions to the Assessor: This checklist addresses specific accreditation criteria prescribed in applicable sections of NIST Handbook 150-13.

Place an "X" beside any of the checklist items which represent a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments on this list or on the comment sheet(s). Place a check beside all other items you observed or verified at the laboratory.

1 Organization and management

1.1 See General Operations Checklist

2 Quality system, audit and review

2.1 The quality system documentation contains the following:

_____ a. a summary outline or Table of Contents that refers to the major portions of the quality manual. If parts of the quality system documentation are kept in different places, then this summary should include the location of the procedures, instructions, records, etc.;

_____ b. descriptions (or reference to descriptions) of the laboratory staff positions, facilities and equipment, calibration procedures, sample handling and custody procedures, contamination control and test report format and procedures;

_____ c. specific records (or reference to records) of calibration tests, samples received and their locations, contamination tests and test reports that have been issued by the laboratory; and

_____ d. schedules (for routine timing and frequency) planned for calibration, contamination monitoring and determination of the precision and accuracy of the analysts.

_____ 2.2 The laboratory's quality assurance analyses (including non-AHERA analyses) represent at least 10% of the total number of TEM asbestos analyses performed.

NOTE: *The value of 10% is a minimum value that applies to a laboratory that has: 1) trained analysts, 2) its laboratory calibrations, contamination checks and other quality systems components statistically characterized and in a state-of-control and 3) a high frequency of analyses. For laboratories not fitting these criteria, the quality assurance analyses must be a higher percentage of the total number of TEM asbestos analyses performed.*

_____ 2.3 Quality assurance analyses are performed regularly covering all time periods, sample types, instruments, tasks, and personnel. The selection of samples is semirandom and, when possible, the checks on personnel performance are executed without their prior knowledge. A disproportionate number of analyses are not performed prior to internal or external audits. Quality assurance analyses are not postponed during periods of heavy work loads.

2.4 The laboratory summarizes all of the quality assurance activities each month including:

_____ a. contamination checks, problems and corrective measures;
_____ b. accuracy of each analyst and of the laboratory;
_____ c. interlaboratory and intermicroscope analyses;
_____ d. sampling precision determined by filter reanalysis;
_____ e. calibrations;
_____ f. identification of any sample custody errors, such as mixing up samples, losing samples, etc.; and
_____ g. deficiency corrections.

2.5 The laboratory has the following documents available for reference:

_____ a. NIST Handbook 150, *NVLAP Procedures and General Requirements;*
_____ b. NIST Handbook 150-13, *NVLAP Airborne Asbestos Analysis;*
_____ c. the Environmental Protection Agency's, *Interim Transmission Electron Microscopy Analytical Methods—Mandatory and Nonmandatory—and Mandatory Section to Determine Completion of Response Actions*, Appendix A to Subpart E, 40 CFR part 763, October 30, 1987, or the current U.S. Environmental Protection Agency AEM method for the determination of completion of response actions;
_____ d. *Asbestos-Containing Materials in Schools; Final Rule and Notice*, 40 CFR, Part 763, Subpart E;
_____ e. general references on analytical electron microscopy, transmission electron microscopy, asbestos analysis, and crystallography;
_____ f. AEM manufacturer's operation manual; and
_____ g. multichannel analyzer manufacturer's operation manual.

2.6 The laboratory has references available and shall be knowledgeable on the following topics; however, the exact reference is not required:

_____ a. **for verified asbestos analysis**, see:
- E. B. Steel and J. A. Small, *Accuracy of Transmission Electron Microscopy for the Analysis of Asbestos in Ambient Environments*, Analytical Chemistry, Vol. 57, 1985, pp. 209-213;
- S. Turner and E. B. Steel, *Analysis of Transmission Electron Microscopy Analysis of Asbestos on Filters: Interlaboratory Study*, Analytical Chemistry, Vol. 63, 1991, pp. 868-872; and
- S. Turner and E. B. Steel, NISTIR 5351, *Airborne Asbestos Method: Standard Test Method for Verified Analysis of Asbestos by Transmission Electron Microscopy - Version 2.0*, 1994;

_____ b. **for spot size measurement**, see:

- D. B. Williams, *Practical Analytical Electron Microscopy in Materials Science*, Philips Electronics Instruments, Inc., Mahwah, New Jersey, 1984, pp. 34-35 (for TEM or STEM mode);
- D. B. Williams, *Standardized Definitions of X-ray Analysis Performance Criteria in the AEM*, in A. D. Romig Jr. and W. F. Chambers, (ed.), *Microbeam Analysis 1986*, San Francisco Press, San Francisco, 1986, pp. 443-448 (for TEM mode); and
- J. I. Goldstein, et al., *Scanning Electron Microscopy and X-ray Microanalysis*, Plenum Press, New York, 1981, p. 48 (for STEM mode);

_____ c. **for k-factor measurement**, see:
- D. C. Joy, A. D. Romig, J. I. Goldstein, *Introduction to Analytical Electron Microscopy*, Plenum Press, New York, 1986; or
- D. B. Williams, *Practical Analytical Electron Microscopy in Materials Science*, Philips Electronics Instruments, Inc., Mahwah, New Jersey, 1984;

_____ d. **for quality assurance**, see J. K. Taylor, *Quality Assurance of Chemical Measurements*, Lewis Publishers, Chelsea, Michigan, 1987;

_____ e. **for statistical analysis**, see M. G. Natrella, *Experimental Statistics*, John Wiley & Sons, New York, 1966;

_____ f. **for control charts**, see *Manual on Presentation of Data and Control Chart Analysis*, ASTM, Philadelphia, 1991; and

_____ g. reference data on the crystallography and chemical composition of minerals that analytically interfere with the regulated asbestos minerals.

3 Personnel

_____ 3.1 Staff members are aware of both the extent and limitation of their area of responsibility.

_____ 3.2 The laboratory has a written description of its training program which includes training with standards and blind testing to determine competency and criteria for successful completion.

_____ 3.3 Analysts and technical supervisors participate in an appropriate form of continuing education, such as formal coursework, in-house education, and scientific or technical meetings, and have access to journals that describe advances in the field of electron microscopy and/or asbestos analysis.

_____ 3.4 The technical supervisor(s) shall be qualified to conduct AEM studies, apply AEM to crystalline materials and is knowledgeable in the field of asbestos analysis including procedures for sample handling, preparation, analysis, storage, disposal, and contamination monitoring.

3.5 AEM analysts are trained and are proficient in:

_____ a. AEM use, calibration, alignment, electron micrography (or functional equivalent);

_____ b. EDXA, x-ray collection and interpretation including recognition of artifacts and abnormal features in spectra resulting from detector problems, contamination or detector-sample geometry;

_____ c. electron diffraction measurement and interpretation including the determination of d-spacings, Miller indices, zone axes;

_____ d. asbestos counting methods including:

- _____ counting rules for simple and complex structures;
- _____ grid and grid square selection (nonadjacent, random);
- _____ x-y stage translation and parallel traverses;
- _____ stage positioning and repositioning;

_____ e. asbestos identification including:

- _____ morphology criteria;
- _____ crystallographic criteria through electron diffraction analysis;
- _____ chemical composition criteria through EDXA;

_____ f. differentiation between regulated asbestos minerals and other minerals that resemble the regulated asbestos minerals;

_____ g. determination of the concentration of fibers on a filter sample;

_____ h. verified asbestos analysis;

_____ i. recognition of acceptable and unacceptable sample preparations; and

_____ j. recognition of sample and instrumental artifacts.

3.6 The accuracy of asbestos identification and counting of each AEM analyst is evaluated by:

_____ a. analyses of reference materials prepared in-house and purchased;

_____ b. analyses of NIST proficiency testing samples; and

_____ c. verified analyses.

NOTE: *Additional quality assurance information may be gained by determining the precision of AEM analysts by repeat analysis of grid squares.*

3.7 Verified asbestos analyses are performed routinely by the laboratory with sufficient frequency and on sufficient types of samples to determine each operator's initial and continuing performance that the following conditions are satisfied:

_____ a. samples having approximately 6-40 structures/grid opening are used to achieve statistically significant information on new analysts;

_____ b. after initial training, a variety of asbestos loadings, including routine AHERA samples, are used to validate analysts' results. Samples include loadings seen in typical AHERA samples up to 6-40 structures/grid opening. At least 20% of verified analyses are performed on samples with 6-40 structures/grid opening loadings and at least 5 grid openings with 6-40 structures/grid opening are counted annually;

_____ c. filter blanks, unless known to be contaminated, are not used for verified counting;

_____ d. during training, all counts used in reports are verified until verified status is attained; and

_____ e. after verified status is attained, the frequency of verified analysis is at least 1 per 100 grid opening analyses.

NOTE: *Labs may find it advantageous to use up to 4 operators on one analysis to characterize initial operator performance, if an analyst with verified status is not available. An analyst that obtains verified status has an average accuracy ≥80% of true positives, ≤20% false negatives, and ≤10% false positives on both standard and field samples.*

_____ 3.8 The laboratory has a person responsible for tracking and storing samples (a laboratory sample coordinator).

_____ 3.9 The laboratory is organized so that staff members are not subject to undue pressure or inducement that might influence their judgment or results of their work. The laboratory is able to demonstrate that the sample work load required for each analyst is consistent with accurate and precise analytical measurement.

4 Accommodation (facilities) and environment

4.1 The following facilities are available:

_____ a. clean room or clean areas for sample preparation and handling separate from bulk asbestos;
_____ b. electron microscopy facility; and
_____ c. room or area for filter and grid storage separate from bulk asbestos.

4.2 The following are available in the clean room or clean area:

_____ a. class 100 (or cleaner) HEPA-filtered air under positive pressure; and
_____ b. exhaust hood for safe use of filter dissolution reagents.

4.3 Safe working conditions are maintained, including:

_____ a. safe handling of asbestos; and
_____ b. safe handling and storage of filter-dissolving reagents such as chloroform, dimethyl formamide, acetone, acetic acid, etc.

4.4 Quality system documentation contains:

_____ a. procedures for the prevention, monitoring, and control of contamination of filters and grids; and
_____ b. procedure (or flow chart) for the systematic checking for possible sources of contamination if contamination is detected. This includes checking all areas, instrumentation and materials used in the preparation and analysis of air filter samples.

4.5 To minimize the possibility of contamination of samples, the following is performed:

_____ a. all personnel are instructed in contamination prevention;
_____ b. personnel, instrumentation and materials used for the preparation of bulk materials that potentially contain asbestos are kept separate from areas used for air filter preparation, handling or analysis; and

_____ c. all reagents are checked for asbestos contamination prior to use in sample preparation.

NOTE: *Personnel who have worked with bulk samples should not subsequently be allowed to work with air filter samples on the same day. It is acceptable, however, for personnel to work on bulk samples after having worked with air samples.*

NOTE: *The next four items concern the use of blank materials for contamination monitoring. Definitions of filter lot, sealed, field and laboratory blanks are given in Section 285.5 of NIST Handbook 150-13. Other blanks should be used as needed to determine and correct sources of contamination, including blanks for AEM specimen holders, evaporators, Jaffe wick, low temperature asher, laboratory air samples, etc.*

_____ 4.6 A laboratory blank filter is present in the clean room or clean area during sample preparation and after cleaning or servicing of the clean room or clean area. The laboratory blanks are obtained from a filter lot that has been shown not to be contaminated.

4.7 The maximum allowed contamination levels for filter lot, sealed, field and laboratory blanks are:

_____ a. a cumulative average level of 18 structures per mm^2; and

_____ b. a single preparation level of 53 structures per mm^2.

4.8 Preparation of nominally blank filters is done:

_____ a. on a minimum of one laboratory blank per sample set or 10% of samples (whichever is greater);

_____ b. of a laboratory blank after cleaning or servicing the clean room or clean area; and

_____ c. on all field and sealed blanks with each series of samples (if these blanks are not identified and known to laboratory, all filter samples are prepared with the series).

NOTE: *The laboratory must properly record and archive prepared grids (even if not analyzed).*

4.9 Analysis of nominally blank filters is done:

_____ a. on a minimum of one laboratory blank per 25 filter analyses;

_____ b. of the laboratory blank when the average count for the full set of filters exceeds 70 structures/mm^2; and

_____ c. on the field and sealed blank when the full indoor/outdoor analysis is performed.

NOTE: *If the Z-test is performed by the laboratory, then the field and sealed blanks must be known to the laboratory. The laboratory is responsible for the analysis of the filter lot blanks only when contracted to analyze them by the sampling organization.*

The laboratory blank analyses can be counted towards the required 10% quality assurance analyses. The field and sealed blank analyses, however, cannot be counted towards this requirement.

_____ 4.10 When contamination above acceptable levels is found, analyses for AHERA clearance are discontinued until the cause is found and corrected or until data shows that the contamination problem no longer exists.

5 Equipment and reference materials

5.1 The following sample preparation equipment or equivalent is available in the clean room or area:

_____ a. condensation washer and/or Jaffe wick with the appropriate reagents and supplies;

_____ b. filter preparation materials (e.g., scalpel, microscope slides, tweezers, etc.);

_____ c. indexed 200-mesh TEM grids—also referred to as finder grids (only grids with uniquely identifiable grid openings may be used; grids with only a symmetrical central marking do ***not*** qualify as finder grids); and

_____ d. other materials as needed.

5.2 The laboratory has a low temperature plasma asher which:

_____ a. is supplied with oxygen;

_____ b. allows for control of speed of evacuation and venting to minimize disturbance of particles on filter surface; and

_____ c. is not used for bulk samples (asbestos or other).

5.3 The laboratory has:

_____ a. a carbon evaporator which attains a vacuum of 13 Pa (10^{-4} torr) or lower and has controlled venting to atmospheric pressure;

_____ b. spectrochemically pure carbon rods;

_____ c. a carbon rod sharpener; and

_____ d. gold or aluminum wire for evaporation (or have sputter coater with gold target).

5.4 The laboratory has an electron microscope, which has the following under routine asbestos analysis conditions:

_____ a. capability of operation at a voltage between 80 keV-120 keV;

_____ b. capability of producing an electron diffraction pattern of a single fibril of chrysotile;

_____ c. capability of displaying and resolving hollow tube of chrysotile;

_____ d. capability of precise fiber length (at 0.5 μm and 5.0 μm) and diffraction pattern measurement, regardless of image (fiber or pattern) orientation (often fulfilled through use of a fluorescent screen with calibrated gradations in the form of circles or at least two perpendicular lines);

_____ e. mechanical stage with linear, reproducible movements along two perpendicular directions;

_____ f. capability of producing a spot at crossover that is ≤ 250 nm during EDXA analysis; and

_____ g. an imaging system for recording brightfield images and electron diffraction patterns on electron micrographs or on other suitable media.

NOTE: *It is strongly recommended that the laboratory possess a holder capable of obtaining zone axis diffraction patterns (either a double-tilt or rotation-tilt holder).*

5.5 The laboratory is able to record and produce hard copies of images (on electron micrographs or other media) to document:

_____ a. visibility of chrysotile hollow tubes and beam damage;

_____ b. visibility and measurement of electron diffraction patterns, in particular chrysotile (002), (004), (110), (020), (130), and (200) reflections;

_____ c. complex arrangement of fibers;

_____ d. a range of magnifications from 1000× to 100 000× in brightfield imaging mode; and

_____ e. a range of diffraction camera lengths that enable accurate diffraction pattern measurement (approximately 20 cm to 80 cm).

_____ 5.6 An EDXA system is interfaced to all electron microscopes used for asbestos analysis.

5.7 The EDXA system (detector and multichannel analyzer), under routine analysis conditions, meets the following specifications:

_____ a. 175 eV or better resolution at Mn Kα peak;

_____ b. proven detection of Na peak in standard crocidolite or equivalent;

_____ c. capable of obtaining statistically significant Mg and Si peaks from a single fibril of chrysotile; and

_____ d. consistent relative sensitivity factors over large areas of the specimen grid.

NOTE: *(1) A low background holder may be necessary to meet these requirements, (2) for item 5.7b, the Na K-lines and Cu L-lines (potentially from the Cu TEM grid) have significant overlap and care must be taken to show that Na is measured above the Cu L-line background.*

5.8 The multichannel analyzer has the following:

_____ a. software capable of obtaining background corrected peak intensities or integrals for Na, Mg, Al, Si, Ca, Fe and other elements as needed;

_____ b. capability of accumulation and display of an x-ray spectrum (minimum 0.7 keV-10 keV); and

_____ c. capability of making a hard copy of an x-ray spectrum.

5.9 The following standards and any associated certificates are available:

_____ a. materials with a certified value for the loading of asbestos on filters
  _____ NIST SRM 1876b
  _____ optional - NIST RM 8410 and RM 8411

_____ b. materials that are characterized as asbestos for training and analyst evaluation;
  _____ NIST SRMs 1866 and 1867 or NIST-traceable standard

_____ c. calibration material(s) for the x-ray system
  _____ SRM 2063 or NIST-traceable standard;

_____ d. standard optical grating replica for magnification calibration; and

_____ e. gold or aluminum film material for electron diffraction calibration.

NOTE: *(1) The laboratory must use SRM 1876b for calibration and not SRMs 1876 or 1876a. SRM 1876 and 1876a were certified using sets of counting rules that are no longer in use. (2) SRMs 1866 and 1867 contain bulk asbestos and, therefore, precautions need to be taken against contaminating the filter preparation area and AEM with these specimens. (3) The laboratory has the primary responsibility for developing or obtaining a set of standards useful for checking the identification, analysis and concentration of asbestos on filters. For example, internal standards can be drawn from samples received by the laboratory or developed by the laboratory through water filtration of asbestos mixtures or by other methods. The samples then must be well-characterized by the laboratory for use as standards. NVLAP proficiency testing samples do not qualify as NIST-traceable standards.*

6 Measurement traceability and calibration

NOTE: *Control charts should be constructed to show calibrated values vs. time, the magnitude of their variation, and the allowable limits of variation. The magnitude of variation specified for many calibrations in this program is defined as 2 s (s is the estimated standard deviation of a set of measurements). Initially, many (15-30) calibrations should be performed in a few month's time to establish a baseline for variation in the measurement. If the variation is within specified limits and the accuracy is acceptable, the frequency of the calibration can be reduced. In general, the majority of calibrations should have been done within 3 months prior to analyses performed for clients.*

All calibrations should be performed with the instrument, stage, sample, x-ray detector and other parameters at routine asbestos analysis conditions (e.g., tilt, apertures, location, specimen height, accelerating voltage, etc.) and with the microscope aligned. Tilting the viewing screen and specimen grid during fiber measurement, or the viewing screen during diffraction measurement is not recommended. Laboratories using tilts must demonstrate the required measurement accuracy and precision for all fiber and diffraction maxima orientations.

_____ 6.1 The laboratory has specific procedures in its quality system documentation for the development and use of control charts.

_____ 6.2 The laboratory uses control charts to summarize calibration data.

6.3 The magnification of the electron microscope is calibrated:

_____ a. using an optical diffraction grating replica (the variation in the calibration measurements (2 *s*) is <5% of the mean calibration value);

_____ b. for magnifications commonly used for asbestos analysis and for any other magnification used for measurement (e.g., the magnification used to measure grid square size); and

_____ c. on all measurement systems applied in the laboratory for asbestos analysis such as the phosphor viewing screen, film, monitor and/or image analysis system.

6.4 The accuracy and precision of measurements at 0.5 μm are determined by:

_____ a. calibration of the measuring system(s) (on screen, film, monitor, and/or image analysis system) at 0.5 μm; and

_____ b. repeat analysis by the same and different analysts of asbestos fibers approximately 0.5 μm in length. (This data may be derived in part from verified analysis data for fibers close to 0.5 micrometers in length.)

6.5 The diffraction camera constant is calibrated:

_____ a. using an evaporated gold or aluminum film (the variation in the calibration measurements (2 *s*) is <5% of the mean calibration value);

_____ b. for the camera lengths commonly used for asbestos analysis;

_____ c. under the conditions used for asbestos analysis; and

_____ d. on all measurement systems including the TEM screen, film, monitor, image analysis system and/or any other system as applied in the laboratory for asbestos analysis.

NOTE: *A minimum of three measurements at 45-degree angles are required on the innermost ring. These measurements will allow detection of deviations of a ring from a circle. Measurements of at least two of the outer rings must be made to monitor for radial distortions and to ensure that an error in measurement of the inner ring did not occur. If significant distortion is found, more measurements are needed for better characterization.*

_____ 6.6 The beam dose is calibrated so that beam damage to chrysotile is minimized—specifically so that an electron diffraction pattern from a single fibril ≥ 1 μm in length from a NIST SRM chrysotile sample is stable in the electron beam for at least 15 seconds.

_____ 6.7 The laboratory has recorded the setting of the electron microscope (condenser aperture, spot size, etc.) that allows for the stability of chrysotile specified in item 6.6 above. This setting is used as the standard operation procedure for routine analyses of possible chrysotile structures.

6.8 The spot size of the electron beam used for well resolved x-ray microanalysis is determined and the:

_____ a. the average spot size for a properly stigmated beam is ≤ 250 nm; and

_____ b. the variation in diameter measurements (2 *s*) is < 25% of the mean value.

6.9 The EDXA system is shown through calibration data to have:

_____ a. a resolution (full-width, half-maximum) for Mn Kα that is < 175 eV; and

_____ b. a value for the sum of the resolution and the variation (2 s) that is < 180 eV.

_____ 6.10 The x-ray energy vs. channel number for the EDXA system is calibrated to within 20 eV for at least two peaks between 0.7 keV and 10 keV. One peak should be from the low end (0.7 keV to 2 keV) and the other peak from the high end (7 keV to 10 keV) of this range. The calibration of the x-ray energy is checked prior to each analysis of samples and recalibrated if out of the specified range.

6.11 The relative sensitivity (k-factors) factors relative to Si for elements found in asbestos (Na, Mg, Al, Si, Ca, Fe) are determined so that:

_____ a. the k-factors are determined to a precision (2 *s*) within 10% relative to the mean value obtained for Mg, Al, Si, Fe, and within 20% relative to the mean value obtained for Na;

_____ b. the k-factor relative to Si for Na is between 1.0 and 4.0, for Mg and Fe is between 1.0 and 2.0, and for Al and Ca is between 1.0 and 1.75; and

_____ c. the k-factor for Mg relative to Fe on SRM 2063(a) or other standard traceable to NIST is 1.5 or less.

NOTE: *SRM 2063 or SRM 2063a can be used for the determination of k-factors for Mg, Si, Ca and Fe. The laboratory must obtain its own chemically characterized materials for determining the Na and Al k-factors. Examples include albite for Na k-factor determination and biotite or albite for Al k-factor determination. Na k-factors are sensitive to electron beam dose (current and time). It is suggested that small particles (≤ 0.1 μm in size) be used for Na k-factor determination to minimize the effect of Na migration.*

_____ 6.12 The portions of a grid in a specimen holder for which abnormal x-ray spectra are generated under routine asbestos analysis conditions are determined and these areas are avoided in asbestos analysis.

NOTE: *X-rays can be absorbed due to the relative position of the area of interest, the grid bars, specimen holder and x-ray detector and give an abnormal spectra (for an example of an abnormal spectra see S. Turner, E. B. Steel, S. S. Doorn, and S. B. Burris, "Proficiency Tests for the NIST Airborne Asbestos Program - 1991," NISTIR 5432). The laboratory should use a standard material (SRM 2063 is recommended) to map out the spectra obtained over the grid area and to thereby determine the regions that should be avoided in routine analysis.*

_____ 6.13 The low temperature asher is calibrated by determining a calibration curve for the weight vs. ashing time of collapsed mixed-cellulose-ester (mce) filters.

NOTE: *The AHERA method specifies that a mixed-cellulose-ester filter is to be ashed by 10%. However, if ashing by this amount generates a texture in the replica that affects structure counting, it is permissible to etch by less than this amount.*

_____ 6.14 The determination of the quality of sample preparations is calibrated or the laboratory has the following documentation available:

_____ a. images and samples showing good preparations and examples of the types of problems that occur in poor preparations (readily available to analysts); and

_____ b. a record of repeat evaluations of images and samples by the same and different analysts. (This data may be derived in part from sample preparation evaluations done in the course of verified analysis.)

_____ 6.15 The magnification of the grid opening measurement system is calibrated using an appropriate standard. The variation in the calibration measurements (2 *s*) is $<5\%$ of the mean calibration value.

_____ 6.16 Trained AEM analysts have an average accuracy $\geq 80\%$ of true positives, $\leq 20\%$ false negatives, and $\leq 10\%$ false positives (these data are reported on a structures per grid square basis).

_____ 6.17 The laboratory and AEM analysts obtain mean analytical results on SRM 1876b so that trimmed mean values fall within 80% of the lower limit and 110% of the upper limit of the 95% confidence limits as published on the certificate (these limits are derived from the allowable false positives and false negatives given in the previous item). The SRM is analyzed a minimum of once a year by each AEM analyst.

_____ 6.18 The laboratory has documentation demonstrating that AEM analysts correctly classify at least 90% of both bundles and single fibrils of asbestos structures ≥ 1 μm in length in known standard materials traceable to NIST (such as the bulk asbestos SRM 1866).

_____ 6.19 Interlaboratory analyses are performed to detect laboratory bias. The frequency of interlaboratory verified analyses corresponds to a minimum of 1 of 200 grid square analyses for clients.

_____ 6.20 If more than one AEM is used for asbestos analysis, intermicroscope analyses are performed to detect instrument bias.

_____ 6.21 The sampling precision is determined by repeat preparation and analysis of the same filter by the same and different analysts.

_____ 6.22 Required calibrations are performed correctly and on a frequent enough basis to ensure accurate results.

7 Test methods and calibration

_____ 7.1 The laboratory uses Environmental Protection Agency, "Interim Transmission Electron Microscopy Analytical Methods—Mandatory and Nonmandatory—and Mandatory Section to Determine Completion of Response Actions," Appendix A to Subpart E, 40 CFR part 763, October 30, 1987, and any NIST or U.S. Environmental Protection Agency clarifications, modifications, or updates to the TEM method for the analysis of asbestos.

_____ 7.2 Quality system documentation details the AEM method as it is applied in the laboratory. (A simple copy of the AHERA method is not sufficient). If departures are made from the method, the laboratory has written procedures detailing how the analyses are conducted.

7.3 The laboratory has written procedures for:

_____ a. preparation of mixed-cellulose-ester filters, including techniques for collapsing, etching, carbon coating and dissolution of filters;

_____ b. preparation of polycarbonate filters, including techniques for carbon coating and dissolution of filters; and

_____ c. determination of the number of grid squares and grid area to be analyzed per sample.

7.4 Laboratory personnel:

_____ a. prepare at least three grids per filter; and

_____ b. analyze approximately half of the predetermined sample area to be analyzed on one grid and the remaining half on a second grid preparation.

7.5 The laboratory has written procedures for the evaluation of the quality of prepared grids. The criteria for acceptance include:

_____ a. the percentage of grid openings covered by the replica section (coherent or noncoherent) is greater than approximately 50%;

_____ b. the percentage of grid openings covered by the replica section that:

_____ are intact is greater than approximately 50%;

_____ have undissolved filter is less than approximately 50%; and

_____ have overlapping or folded replica is less than approximately 50%.

_____ c. at least 20 grid squares have no overlapping or folded replica, < 5% holes and < 5% opaque area due to incomplete filter dissolution. "Opaque area" means that the sample preparation artifact is sufficiently opaque to the electron beam that recognition and analysis of fibers will be difficult or impossible.

NOTE: *NIST Interagency Reports, in preparation, will give a description of sample preparation features and a procedure for choosing grid squares for analysis.*

_____ 7.6 The laboratory has written procedures for the determination of the area of grid squares.

NOTE: *The AHERA method requires that either 1) the area of the grid square analyzed be determined, or 2) the average area of grid squares in a grid lot of 1000 be determined by measurement of 20 grid squares on each of 20 grids. If premeasured grids are purchased, the laboratory should confirm the measurements as a quality assurance procedure. Initially, many grid squares should be remeasured. If the values are in agreement with those given with the grids, then the number of remeasurements can be reduced to approximately 5% of those required by the AHERA method. Premeasured grids must have a report of analysis which gives the mean grid opening area, the number of grids and openings measured, the standard deviation of the opening area, and the method of analysis.*

7.7 The laboratory has written procedures for operation of the AEM for asbestos analysis including:

_____ a. method for alignment of the electron microscope so that the electron beam travels down the optic center of the column. This includes alignment of the electron gun, apertures, and tilt as described in the manufacturer's and laboratory's operating manual; and

_____ b. standard operating conditions of the AEM

_____ voltage (between 80 keV-120 keV)

_____ microscope magnification (15 000× - 20 000× for analysis).

_____ 7.8 There is documentation to show that the quality of alignment of the electron microscope is checked daily or prior to each use for analyses and calibrations. The alignment is checked by, at minimum, changing the magnification, spot size, and image focus and by checking the stigmation of the electron beam. The AEM analyst aligns the electron microscope if the instrument does not meet the laboratory's alignment criteria as stated in the quality manual. (Note: Alternatively, the AEM can be aligned daily or prior to each use).

7.9 The laboratory has written procedures for examining a grid square and for counting and analyzing particles (a detailed description is necessary—a copy of the EPA method is not sufficient) including:

_____ a. method for recording grid orientation in the microscope;

_____ b. particle loading acceptance criteria (>10% by area particulate loading or uneven particle loading is rejected);

_____ c. unique grid and grid square labelling system (indexed grids);

_____ d. grid square traversing method, including the use of orthogonal scans;

NOTE: *The intent is to completely cover the grid square without having structures missed or counted twice. To do this, parallel, overlapping traverses are made across a grid square. Care is taken to move only one translator during a traverse. If an asbestos structure is encountered and the other translator is moved for analysis, then the stage is returned to the original traverse position before continuation of the traverse.*

_____ e. recording rules;
_____ f. structure counting rules; and
_____ g. determination of whether a sample set passes or fails AHERA clearance if required by the client.

7.10 The laboratory has quality system documentation which contains criteria for:
_____ a. identification of electron diffraction patterns of regulated asbestos minerals and of nonasbestos minerals, including those that closely resemble regulated asbestos minerals;
_____ b. identification of EDXA spectra of regulated asbestos minerals and of nonasbestos patterns, including those that closely resemble regulated asbestos minerals; and
_____ c. differentiating asbestos minerals from at least the following phases: the pyroxenes, hornblende, wollastonite, halloysite, palygorskite, sepiolite, antigorite, lizardite, talc, and vermiculite. The minimum criteria for differentiation must be presented.

_____ 7.11 AEM analysts record sufficient information for each analysis so that a verified analysis can subsequently be performed.

NOTE: *Information sufficient for performing a verified analysis includes the orientation of the grid at the analysis magnification, a sketch (or image) for each structure and the size of each structure (the recording of the location of the structure is also of use). Recording this information will allow for random quality assurance checks of any analysis and removes the bias that can occur when verification is done with the analysts' foreknowledge. The laboratory may want to refer to E. S. Windsor, S. Turner and E. B. Steel, NISTIR 5358, in which a recording form suitable for verification is described.*

_____ 7.12 AEM analysts record an electron diffraction pattern of one asbestos structure from every five samples that contain asbestos. The identification of diffraction patterns is verified by a qualified individual. It is shown that the AEM analyst is correct 80% of the time in identification of recorded diffraction patterns.

_____ 7.13 The laboratory has written procedures for verifying report calculations.

8 Handling of calibration and test items

8.1 The log-in system includes documentation of:
_____ a. the date of receipt;
_____ b. identity of the client;
_____ c. unique identification for sample;
_____ d. air volume pulled through sample;
_____ e. filter pore size;
_____ f. condition of the samples; and
_____ g. acceptance or rejection of the samples.

_____ 8.2 The laboratory has written criteria for acceptance or rejection of filter cassettes.

NOTE: *Examples of rejection criteria include: insufficient sampling documentation, bulk samples included with air filter samples, filter cassettes open, filters overloaded with particulate, uneven particle loading, sampling parameters not meeting AHERA sampling criteria, filters not uniquely identified, filters of incorrect pore size, tampering with cassettes evident, sample that laboratory is not capable of preparing properly, etc.*

8.3 The laboratory has a documented chain-of-custody system by which the following is recorded:

_____ a. location of sample;
_____ b. a listing of personnel that have handled or worked with the sample; and
_____ c. a listing of what has been done to the sample.

8.4 The laboratory:

_____ a. stores the unused portions of filters in their cassettes for at least 30 days;
_____ b. stores all prepared grids (even if not analyzed) for at least three years; and
_____ c. stores the filters and grids in a logical fashion so that specified samples can be retrieved within one working day.

9 Records

_____ 9.1 All records are retained for a minimum of three years and are stored in a logical fashion allowing retrieval within one working day.

_____ 9.2 The laboratory has documentation, either electronic backup or "paper" hard copy, to ensure survival of original data if computers are used for data retention.

9.3 The quality system documentation contains standardized methods (forms) for recording the following:

_____ a. log-in of samples;
_____ b. criteria for acceptance or rejection;
_____ c. evaluation of quality of prepared grids; and
_____ d. AEM sample analysis data.

9.4 The laboratory has records relating to:

_____ a. sample custody; and
_____ b. contamination monitoring.

9.5 Records related to contamination include results and timing of all checks of the following:

_____ a. filter lot blanks;
_____ b. field blanks;
_____ c. laboratory blanks;

_____ d. all other areas and samples, as needed, to track contamination;
_____ e. summary of contamination problems and resolution; and
_____ f. a summary of blank results in control chart or similar format.

9.6 All records related to quality assurance testing of staff and laboratory are retained including results of:

_____ a. analyses of reference materials;
_____ b. analysis of NIST proficiency testing materials;
_____ c. verified analyses;
_____ d. interlaboratory analyses;
_____ e. intermicroscope analyses (if the laboratory uses more than one AEM for asbestos analysis);
_____ f. repeat preparation and analysis of same filter by same analyst and by different analysts;
_____ g. identification of mineral types; and
_____ h. evaluation of filter preparations.

9.7 Records related to the AEM analysis of a filter include:

_____ a. general information:
  _____ operator (analyst must sign and date analysis sheet),
  _____ sample identification,
  _____ client identification,
  _____ date;
_____ b. instrument used (if more than one available);
_____ c. operating parameters of the instrument used including:
  _____ magnification,
  _____ accelerating voltage,
  _____ other, as needed to ensure alignment and calibration compliance;
_____ d. filter and grid related information:
  _____ filter sampling data sheet as received with sample,
  _____ filter type,
  _____ area of grid squares analyzed,
  _____ number of grids prepared and their location,
  _____ evaluation of prepared grids,
  _____ orientation of grid in AEM,
  _____ grids and grid squares analyzed;
_____ e. original data records include (for AHERA analysis):
  _____ structure type (fiber, bundle, cluster, matrix),
  _____ the number of fibers that are $\geq$ 0.5 micrometers and $<$ 5 micrometers,
  _____ the number of fibers that are $\geq$ 5 micrometers,
  _____ classification of structures as chrysotile, amphibole (as grunerite (Amosite), riebeckite (crocidolite), anthophyllite, actinolite, or tremolite), or nonasbestos,
  _____ at a minimum, measurement results of both EDXA and electron diffraction for each structure (usually the first 4) identified as amphibole that caused the concentration of

regulated asbestos minerals on the filter to reach or exceed 70 structures/mm^2,

_____ at a minimum, measurement results of electron diffraction for each structure (usually the first four) identified as chrysotile, that caused the concentration of regulated asbestos minerals on the filter to reach or exceed 70 structures/mm^2,

_____ documentation of positive electron diffraction ***or*** EDXA for each chrysotile asbestos structure subsequent to the asbestos structure that caused the concentration on the filter to reach or exceed 70 structures/mm^2, and documentation of positive EDXA or measured zone axis diffraction pattern, for each amphibole structure subsequent to the asbestos structure that caused the concentration of asbestos on the filter to reach or exceed 70 structures/mm^2,

_____ at a minimum, documentation or measurement of results of EDXA and/or measurement of a zone axis electron diffraction pattern for each structure in the nonasbestos class that corresponds to a concentration of over 70 structures/mm^2,

_____ micrograph numbers or appropriate identification for the required one electron diffraction pattern for every five samples that contain asbestos and for any other patterns taken,

_____ criteria used to classify particles as nonasbestos, that is the property or properties that differentiate it from regulated asbestos minerals;

NOTE: *For structures whose qualitative chemical composition is distinct from regulated asbestos minerals, e.g., gypsum, only documentation of the qualitative chemical composition is necessary. For structures that have similar qualitative composition, semiquantitative measurement of composition by EDXA and/or measurement of the distinguishing features of the diffraction pattern is required.*

Measurement results include sufficient quantitative data (e.g., x-ray intensities or diffraction maxima d-spacing) to identify regulated asbestos minerals positively, as defined by laboratory identification criteria. Documentation of positive diffraction or EDXA means that the analyst records (e.g., checks off) that these properties visually and/or qualitatively match the lab's identification criteria.

_____ f. information related to report to client:

_____ concentration of asbestos in structures/mm^2 on filter and structures/cm^3 in sampled air,

_____ number of asbestos structures counted,

_____ types of asbestos,

_____ area analyzed,

_____ volume of air sampled; and

_____ 9.8 A cumulative record of results from precision and accuracy testing is maintained and summarized at least monthly.

10 Certificates and reports

10.1 Test reports include the following information for each sample set:

_____ a. area of filter analyzed;
_____ b. volume of air sampled (with reference to sampling data sheet);
_____ c. analytical sensitivity used for the analysis;
_____ d. number of total asbestos structures and number of structures by asbestos type (chrysotile, grunerite, riebeckite, anthophyllite, tremolite, or actinolite);
_____ e. concentration in asbestos structures/mm^2 of filter and asbestos structures/cm^3 of air for total asbestos structures, and with data broken down by size ($\geq$ 5 μm and $\geq$ 0.5 μm to $<$ 5 μm), and by asbestos type;
_____ f. statement of analytical uncertainty, including 95% confidence limits on the reported concentration and laboratory and analyst accuracy and precision;

NOTE: *A NISTIR containing a procedure for determining the uncertainty of measurements due to sampling is in preparation. Upon notification, the laboratories should report this uncertainty for their measured values. Subsequently, additional information will be issued regarding reporting uncertainty of the measurement.*

_____ g. micrograph number of any recorded diffraction patterns;
_____ h. copy of AEM analysis data record with analyst's signature or initials; and
_____ i. descriptions of any departures from the test method.

10.2 The following additional information shall be supplied if asbestos abatement clearance is determined to be necessary:

_____ a. calculation formulas;
_____ b. all calculation variables and constants; and
_____ c. all calculation results.

11 Subcontracting of calibration or testing

See General Operations Checklist

12 Outside support services and supplies

See General Operations Checklist

13 Complaints

See General Operations Checklist

14 Proficiency testing

14.1 The laboratory participates in mandatory airborne asbestos proficiency testing, which includes (but is not limited to) the following:

_____ a. the laboratory has written procedures for handling, analysis, and use of NIST proficiency testing materials;

_____ b. analyses are not contracted out to another laboratory;

_____ c. the laboratory keeps and uses proficiency testing materials as in-house instructional materials, unless otherwise directed;

_____ d. all analysts (full and part time) participate in all proficiency testing rounds (all analysts need not participate in proficiency testing prior to returning the results to NVLAP, but all analysts shall participate without prior knowledge of the testing results at a later date);

_____ e. each analyst separately analyzes, records and reports test results;

_____ f. a single result is reported back to NVLAP by the laboratory unless otherwise specified in the testing instructions;

_____ g. procedures and calculations (if any) are documented as to how a single result is determined;

_____ h. test results are used for interanalyst comparisons;

_____ i. corrective actions are taken and documented for problems indicated by proficiency testing;

_____ j. plans are developed and implemented for resolving problems and are documented; and

_____ k. test results, when applicable, are used in determining accuracy and precision for each analyst.

15 Subfacilities

_____ 15.1 A subfacility **is technically dependent** on the main facility (i.e., technical management and supervision are provided by the main facility).

_____ 15.2 Quality assurance activities of the subfacility are directed by the main facility.

15.3 The nature, scope, and frequency of on-site quality assurance reviews by the main facility quality manager (or equivalent) are:

_____ a. clearly defined in the quality manual; and

_____ b. appropriate for the nature and scope of work performed by the subfacility.

_____ 15.4 All permanent quality assurance and personnel records are retained at the main facility.

_____ 15.5 Quality assurance data from each subfacility are compared each month to both the main facility's data and to data from other subfacilities. Records of such comparisons are retained in quality assurance records, along with actions taken to evaluate and resolve differences.

_____ 15.6 Analysts at subfacilities participate in NVLAP proficiency testing and records are maintained of individual results.

NVLAP LAB CODE: _____

SPECIFIC OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

NVLAP LAB CODE: [ ]

SPECIFIC OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

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Item No.	*Comments and/or Deficiencies*

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