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NIST HANDBOOK 150-3 CHECKLIST

BULK ASBESTOS ANALYSIS

Instructions to the Assessor: This checklist addresses the specific accreditation criteria prescribed in NIST Handbook 150-3, Bulk Asbestos Analysis (2006 edition). The numbering of this checklist generally follows the numbering of NIST Handbook 150-3.

- All items on this checklist shall be addressed.
- Place an "X" beside each item that represents a nonconformity (formerly called "deficiency"); or
Place a "C" beside each item on which you are making a comment; or
Place an "OK" beside each item that you observed or verified at the laboratory.
- Record the item number and your nonconformity explanation and/or comments on the comment sheet(s) at the end of this checklist.

1 GENERAL INFORMATION

1.4 References

The laboratory shall have the following documents available:

- _____ 1.4.1 NIST Handbook 150, *NVLAP Procedures and General Requirements*
- _____ 1.4.2 NIST Handbook 150-3, *Bulk Asbestos Analysis*
- _____ 1.4.3 U.S. Environmental Protection Agency (EPA) *Interim Method for the Determination of Asbestos in Bulk Insulation Samples* (EPA 600/M4-82-020) as found in 40 CFR, Part 763, Appendix E to Subpart E, or the current U.S. EPA method for the analysis of asbestos in building material;
- _____ 1.4.4 *Asbestos-Containing Materials in Schools, Final Rule and Notice*, as found in the Federal Register, Volume 52, No. 210, pages 41826 - 41846;
- _____ 1.4.5 U.S. Environmental Protection Agency's *Method for the Determination of Asbestos in Bulk Building Materials* (EPA/600/R-93/116), July 1993, R. L. Perkins and B. W. Harvey;
- _____ 1.4.6 NIST Technical Note 1297, 1994 Edition, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, Barry N, Taylor and Chris E. Kuyatt;
- _____ 1.4.7 reference text(s) on optical mineralogy and crystallography;
- _____ 1.4.8 general reference text(s) on statistics and quality assurance.

Note: The latest versions of NIST Handbooks 150 and 150-3 and their corresponding checklists are available at www.nist.gov/nvlap.

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3 Accreditation process

3.2 Management system review

- _____ 3.2.1 The laboratory shall have a fully implemented management system.
- _____ 3.2.2 Prior to the assessment, the laboratory shall provide a copy of the laboratory's management system and relevant documented procedures to the assessor for review.
- _____ 3.2.3 The laboratory shall provide additional technical documentation and/or records as requested.

3.3 On-site assessment

- _____ 3.3.1 All laboratory equipment shall be available and in good working order.
- _____ 3.3.2 At least one staff member shall be available to answer questions during the assessment.
- _____ 3.3.3 Laboratory personnel shall be prepared to demonstrate selected procedures or tests, as requested.
- _____ 3.3.4 Results of past proficiency tests shall be made available for review during the assessment.

3.4 Proficiency Testing

- _____ 3.4.1 The laboratory shall participate in the NVLAP Proficiency Testing Program (see NIST Handbook 150-3, Section 3.4, Proficiency Testing).
- _____ 3.4.2 Proficiency testing analyses shall not be contracted out to another laboratory.
- _____ 3.4.3 The laboratory shall keep and utilize proficiency testing materials for use as in-house instructional materials.
- _____ 3.4.4 All analysts (*full, part time, and those in sub-facilities*) shall 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*).
- _____ 3.4.5 Each analyst shall separately analyze, record, and report test results.
- _____ 3.4.6 One result shall be reported back to NVLAP by the laboratory unless specified otherwise in the testing instructions.
- _____ 3.4.7 Procedures and calculations (if any) shall be documented as to how the result was determined.

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- _____ 3.4.8 Problems indicated by proficiency testing shall be discussed with appropriate laboratory personnel and documented. (see NIST Handbook 150, Section 4.11, Corrective Action)
 - _____ 3.4.9 Plans for resolving analytical problems shall be developed, implemented and documented.
 - _____ 3.4.10 The proficiency test results shall be used to verify accuracy and precision for each analyst and to judge the analysts' overall performance.
 - _____ 3.4.11 Proficiency test results shall be used for inter-analyst comparisons and entered into the laboratory's management system records.

4 Management requirements for accreditation

4.1 Sub-facilities

- _____ 4.1.1 A sub-facility is technically dependent on the main facility (i.e., technical management and supervision shall be provided by the main facility).
- _____ 4.1.2 Quality assurance activities of the sub-facility shall be directed by the main facility.
- _____ 4.1.3 The nature, scope, and frequency of on-site quality assurance reviews, by the main facility quality manager (or equivalent) shall be:
 - _____ (a) clearly defined in the management system;
 - _____ (b) appropriate for the nature and scope of the work performed by the sub-facility.
- _____ 4.1.4 All permanent quality assurance and personnel records shall be retained at the main facility.
- _____ 4.1.5 Quality assurance data from each sub-facility shall be regularly and routinely compared both to the main facility's data and data from other sub-facilities.
- _____ 4.1.6 Records of such comparisons shall be retained in quality assurance records along with actions taken to evaluate and resolve differences.
- _____ 4.1.7 Analysts at sub-facilities shall participate in NVLAP proficiency testing and records shall be maintained of individual results.

4.2 Management system

(See NIST Handbook 150 checklist)

4.3 Document control

(See NIST Handbook 150 checklist)

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4.4 Review of requests, tenders and contracts

(See NIST Handbook 150 checklist)

4.5 Subcontracting of tests and calibrations

_____ 4.5.1 A laboratory that subcontracts AHERA work shall do so with another NVLAP-accredited laboratory for bulk asbestos analysis.

_____ 4.5.2 A NVLAP-accredited laboratory shall not represent test data produced at a non-accredited sub-facility as having been produced by an accredited laboratory.

4.6 Purchasing services and supplies

(See NIST Handbook 150 checklist)

4.7 Service to the customer

(See NIST Handbook 150 checklist)

4.8 Complaints

(See NIST Handbook 150 checklist)

4.9 Control of nonconforming testing and/or calibration work

(See NIST Handbook 150 checklist)

4.10 Improvement

(See NIST Handbook 150 checklist)

4.11 Corrective action

(See NIST Handbook 150 checklist)

4.12 Preventive action

(See NIST Handbook 150 checklist)

4.13 Control of records

_____ 4.13.1 The period of retention of records shall be three years, unless a longer period is required by the client, regulation, or the laboratory's own procedures.

4.13.2 The records maintained by the laboratory for three years shall include:

_____ a) sample custody records;

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- _____ b) original data collected (including all of the required optical data for each analysis it performs), signed (or initialed), and dated by the analyst;
- _____ c) contamination monitoring data;
- _____ d) calibration and verification data;
- _____ e) data and results of quality control;
- _____ f) equipment and maintenance records;
- _____ g) test reports;
- _____ h) records of proficiency testing results for each analyst.

4.14 Internal audits

_____ 4.14.1 The laboratory shall conduct an annual internal covering compliance with NVLAP requirements, laboratory management system, regulatory, contractual, and testing requirements. The audit results shall be documented in the formal report addressing any corrective and/or preventive actions taken.

_____ 4.14.1 An applicant laboratory shall conduct at least one complete internal audit prior to the first on-site assessment and record of such provided to the assessor before or during the on-site.

_____ 4.14.2 Renewal laboratory internal audit reports conducted since the previous assessment shall be made available for review.

(Internal audits are separate and distinct from management reviews.)

4.15 Management reviews

_____ 4.15.1 Periodic reviews of the management system shall reflect adherence to NVLAP requirements and the laboratory's quality objectives.

_____ 4.15.2 Management reviews shall review all nonconformities and may reflect positive aspects of the management system.

_____ 4.15.3 An applicant laboratory shall perform at least one complete management review prior to the first assessment and record of such provided to the assessor before or during the on-site.

_____ 4.15.4 Renewal laboratory management reviews conducted since the previous assessment shall be made available for review.

(Management reviews are separate and distinct from internal audits.)

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5 Technical requirements for accreditation

5.1 General

(See NIST Handbook 150 checklist)

5.2 Personnel

5.2.1 The laboratory shall maintain documentation for each staff member including:

- _____ a) staff member's title and job position description;
- _____ b) job and quality assurance responsibilities, including assigned laboratory procedures and duties;
- _____ c) résumé;
- _____ d) training;
- _____ e) results of quality assurance activities, including precision and accuracy and the results of NVLAP proficiency testing;
- _____ f) accuracy, precision and error data;
- _____ g) correction of nonconformities.

_____ 5.2.2 The laboratory shall have a detailed, documented description of its training program for new and current staff members.

5.2.3 The laboratory training shall include:

- _____ a) criteria for successful completion;
- _____ b) training with blanks and blind testing to determine competency;
- _____ c) new analysts' results shall be checked by either an experienced analyst (with an acceptable error rate), or by an independent technique, until the analyst has an acceptable error rate.

_____ 5.2.4 The laboratory shall document performance criteria to determine when a new analyst is qualified to work independently.

_____ 5.2.5 Laboratory analysts shall be able to obtain enough information from the laboratory's quality documentation to perform analyses in the absence of the laboratory manager.

_____ 5.2.6 All staff members shall be trained in their role in the quality assurance system.

_____ 5.2.7 The laboratory shall ensure that staff members are aware of the extent of their area of responsibility.

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- _____ 5.2.8 The laboratory shall ensure that:
- _____ a) analysts and technical supervisors understand polarized light microscopy and its application to crystalline materials sufficiently to conduct analyses. That they understand what the various optical properties are, how they are measured or observed in the microscope, and how the data are used to form a conclusion about the identity of the component, (*e.g., an analyst using central and/or annular focal screening (dispersion staining) to measure refractive index must be able to explain what produces the observed color and how that color is used to determine refractive index*);
 - _____ b) analysts are competent with the polarized light microscope, can properly align the microscope and identify all of the crucial parts;
 - _____ c) technical supervisors have a fundamental knowledge of the method to assure the quality of the laboratory's results.
- _____ 5.2.9 The laboratory shall be organized so that staff members are not subjected to undue pressure or inducement that might influence their judgment or the results of their work.
- _____ 5.2.10 The laboratory shall be able to demonstrate that the sample workload required for each analyst is consistent with accurate and precise analytical measurements.
- _____ 5.2.11 The laboratory shall require and document that analysts and technical supervisors participate in some form of continuing education such as formal course work, in-house education, and scientific/technical meetings. Staff shall also have access to journals that describe advances in the field of microscopy and asbestos analysis.
- 5.3 Accommodation and environmental conditions**
- _____ 5.3.1 The laboratory shall have the proper facilities, including space, lighting, environmental controls, etc., to perform analyses and store asbestos in accordance with federal, state and local laws, and to maintain sample integrity.
- _____ 5.3.2 The laboratory shall have procedures for the use of blanks of asbestos-free material to determine the presence, quantity, and consistency of asbestos contamination in their analytical process and have related procedures to control it.
- _____ 5.3.3 Safe working conditions shall be maintained while handling bulk asbestos samples.

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5.4 Test and calibration methods and method validation

_____ 5.4.1 The laboratory shall use the U.S. Environmental Protection Agency's *Interim Method for the Determination of Asbestos in Bulk Insulation Samples* as found in 40 CFR, Part 763, Subpart E, Appendix E (formerly Subpart F, Appendix A), or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building materials.

Note: On August 1, 1994, the EPA announced in the Federal Register that EPA/600/R-93/116 provides clarification and improvements to the 1982 protocol and recommended that it serve as a preferred substitute method. EPA has determined that it is more capable of producing accurate results than the 1982 method. However, NVLAP must still accredit to the 1982 method; laboratories that use the 1994 method must indicate such on their test reports.

_____ 5.4.2 If departures from the method are made, the laboratory shall have written procedures detailing how the analyses are conducted.

_____ 5.4.3 The laboratory shall have a written procedure for the analysis of samples and methods to ensure the accuracy and precision of analyses. The analytical procedure shall detail the PLM test method, including the measurement of each of the required optical/physical properties, as it is applied in the laboratory (a sample copy of the AHERA test method is not sufficient);

_____ 5.4.3 The laboratory shall have a clear and documented definition of each asbestos type that includes the acceptable optical properties (e.g., such as the range in refractive indices) that the fibers can exhibit and still be identified as the particular asbestos type, and what constitutes asbestiform morphology.

_____ 5.4.4 The laboratory shall determine the identification of fibrous materials by measuring the optical properties (see 4.13.3).

_____ 5.4.5 The laboratory shall have a written procedure for dealing with samples in which the fibers are heavily coated with binder that hinders analysis.

_____ 5.4.6 The laboratory shall maintain a list of non-asbestos fibers that can be confused with asbestos and the specific optical properties for each that can be used to distinguish between asbestos and non-asbestos.

_____ 5.4.7 The laboratory shall measure and record at least one optical property for non-asbestos fibers that serves to distinguish them from asbestos.

_____ 5.4.8 The laboratory shall have specific sample preparation techniques for dealing with samples that are semi- or non-friable;

_____ 5.4.9 The laboratory shall use the point-count technique or a technique that it has demonstrated, and documented, to be equivalent for quantitative analysis. (See 5.6.7)

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_____ 5.4.10 The laboratory shall homogenize the sample in some way or analyze a sufficient number of sub-samples to obtain a representative analysis (at least three sub-samples for negative samples, as per EPA/600/R-93/116).

_____ 5.4.11 The laboratory shall have a working definition of trace and be able to distinguish between trace concentrations of asbestos and concentrations near 1 %.

Note: It is important to differentiate the following two cases for a very practical reason: whether additional analysis by a different method is warranted to ascertain the asbestos concentration reported by the PLM analyst.

a) When reporting the asbestos content as “trace”, the analyst ascertains that although there are asbestos fibers in the sample, its concentration is so low that it is far from the level of 1 % by calibrated visual estimation (CVE) or point counting. In this case, the analyst is confident that it is not necessary to make a recommendation to the client that the sample should be analyzed by a more accurate and precise method to verify results.

b) When reporting the asbestos content as near, but less than 1 %, the analyst ascertains that the asbestos concentration is definitely not equal or higher than 1 % by CVE or point counting. Due to the inherited uncertainty of the quantification technique(s) employed during analysis, the analyst should recommend to the client that verification of the results is necessary by a more accurate and precise method, such as the bulk TEM method.

5.5 Equipment

_____ 5.5.1 The laboratory shall have documentation for equipment maintenance and calibration.

5.5.2 The laboratory shall have the following equipment and materials:

_____ a) HEPA-filtered, Class I biohazard hood, or a glove box with continuous airflow (negative pressure);

_____ b) sampling utensils, (scalpels, forceps, probes, needles, tweezers, razors, etc.);

_____ c) microscope slides and cover slips;

_____ d) refractive index liquids, 1.490 - 1.720 in increments of less than or equal to 0.005 (high dispersion liquids are optional);

_____ e) stereomicroscope or low power binocular microscope, approximately 10 X - 45 X, with light source;

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- _____ f) mortar and pestle;
- _____ g) sample containers (ceramic bowls, glass plates, petri dishes, glassine paper, etc.);
- _____ h) thermometer that will allow the laboratory to meet NVLAP requirements (a laboratory thermometer from a reputable scientific supply company is acceptable).

5.5.3 The laboratory shall have a polarized light microscope (PLM) with:

- _____ a) binocular or monocular with cross hair reticule (or functional equivalent) that locks into position or is marked, and that does not rotate during normal operation of the microscope;
- _____ b) low ($\geq 5 X$ and $\leq 15 X$), medium ($> 15 X$ and $< 40 X$), and high ($\geq 40 X$) objectives;
- _____ c) light source;
- _____ d) 360° rotating stage;
- _____ e) substage condenser with iris diaphragm;
- _____ f) polarizer and analyzer that can be placed at 90° to each other;
- _____ g) accessory slot at 45° to polarizers for compensators;
- _____ h) first-order red (or λ) compensator (530-550 nm retardation);
- _____ i) dispersion staining objective complete with accessories (optional);
- _____ h) test slide made of orthorhombic fibers, such as anthophyllite from SRM 1867, or other straight fibers of parallel extinction, such as polypropylene, polyethylene, etc., for aligning cross hairs with the privileged directions of the polarizer and analyzer.

5.5.4 The laboratory shall ensure that each microscope is in proper working condition. The optical system, including objectives, condensers, polarizers, etc., shall not be damaged or modified in any way that would affect microscope resolution or depolarize the light, (i.e., the lens is relatively free of scratches, nicks, corrosion, signs of impact, etc., and there is no stop in the back focal plane other than for dispersion staining objectives).

Note: PCM objectives are generally not suitable for PLM work.

5.5.5 The laboratory shall have written procedures for aligning the polarized light microscope daily (or prior to use) in such a way that:

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- _____ a) the privileged directions of the sub-stage polarizer and the analyzer shall be oriented at 90° to one another. The orientations of the privileged direction of the polarizers shall be known. The accessory slot shall be at 45° to these privileged directions;
- _____ b) the ocular cross hairs coincide with the privileged directions of the polarizer and the analyzer and this condition shall be verified with a test slide (or similar standard);
- _____ c) the objectives and/or stage shall be centered to prevent and grains from leaving the fields of view during stage rotation;
- _____ d) the sub-stage condenser, which is visualized through the image of the (close down) field diaphragm, shall be centered on the optic axis;
- _____ e) the daily alignment check shall be recorded in a logbook.

_____ 5.5.6 The laboratory shall have calibrated refractive index solids, or a refractometer (or access to one), for calibrating refractive index liquids.

_____ 5.5.7 The laboratory shall have written procedures for calibrating refractive index liquids, including the lot number for each of the measured oils, to determine whether their actual or calibrated RI value at 589 nm and 25 °C, are within ± 0.004 of their nominal values. The procedures shall include:

- _____ a) if the calibrated RI value at 589 nm and 25 °C deviates more than ± 0.004 from the nominal value, the liquid shall not be used;
- _____ b) the temperature at the workstation at the time of calibration shall be recorded and, if not 25 °C, used to perform temperature correction of the calibrated RI value.

_____ 5.5.8 The laboratory shall maintain the necessary equipment for any optional procedure(s) it performs.

5.6 Measurement traceability

_____ 5.6.1 The laboratory shall have reference materials and if available, Standard Reference Materials (SRMs) with certificates for chrysotile, amosite, crocidolite, tremolite, actinolite, anthophyllite and glass fiber traceable to NIST (SRM 1866 and SRM 1867);

Note: The SRMs, if available, may be purchased from the NIST Standard Reference Materials Program (SRMP), 100 Bureau Drive, Stop 2322, Gaithersburg, MD 20899-2322; phone (301) 975-8776.

_____ 5.6.2 The laboratory shall have a qualitative error rate of less than 1 %, which is calculated by dividing the number of qualitative errors (false negatives, false positives, and asbestos types) by the total number of QA samples.

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- _____ 5.6.3 The laboratory shall identify problem samples, such as floor tiles, that are difficult to analyze qualitatively and shall have specific written procedures to deal with problem samples to reduce the errors to less than 1 %.
- _____ 5.6.4 The laboratory shall have written procedures describing how reference standards are used to verify the accuracy of an analyst's ability to correctly determine the optical properties of asbestos.
- _____ 5.6.5 The laboratory shall determine precision on the qualitative and quantitative analyses of samples by:
- _____ a) repeatability - repeat analyses by the same analyst;
- _____ b) comparison of results from multiple slide mounts of the same material;
- _____ c) reproducibility - analysis of samples by multiple analysts if possible (single analyst laboratories require more interlaboratory data);
- _____ d) interlaboratory analysis - analysis of samples by other laboratories.
- _____ 5.6.6 The laboratory shall determine the accuracy of the qualitative and quantitative analyses of samples by:
- _____ a) analysis of proficiency testing materials;
- _____ b) analysis of standards either prepared in-house or purchased;
- _____ c) analysis of samples using independent methods (e.g., XRD, gravimetry, etc.).
- _____ 5.6.7 If an estimation technique that is equivalent to point counting is used, the laboratory shall use one or more of the following for calibration and have data to show equivalency:
- _____ a) bulk standards; (Percent asbestos in these standards must have been determined by non-visual estimation method(s). This could include repeat analysis by point counting, by quantitative XRD, or by gravimetric measurement of asbestos during sample formulation.)
- _____ b) prepared (permanent) slides that have been point-counted;
- _____ c) photomicrographs of grain mounts that have been calibrated for relative area;
- _____ d) other appropriate standards.

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5.7 Sampling

_____ Specific sampling procedures shall be documented where appropriate (especially for samples containing multiple layers).

5.8 Handling of test and calibration methods;

5.8.1 The laboratory shall have written procedures and/or instructions describing the following:

- _____ a) sample custody and handling procedures, i.e., sample receipt, log-in, storage and disposal;
- _____ b) disposal/return of bulk samples (including retaining the documentation with all other data and information regarding the sample);
- _____ c) proper storage of materials to prevent damage or cross contamination;
- _____ d) sample retention (hold samples for a minimum of 30 days after analysis unless earlier return is requested by the client or prevented by law or regulation);
- _____ e) safe disposal of bulk samples and in accordance with any and all federal, state and local regulations.

5.8.2 The laboratory shall have a sample log system used to uniquely identify the test item and document the action. The log shall include:

- _____ a) the date of receipt of the test item;
- _____ b) the condition of the test item;
- _____ c) documentation of acceptance or rejection of test item, reasons for rejection (e.g., air samples mixed with the bulk samples);
- _____ d) a unique laboratory identification number for each test sample;
- _____ e) the client identification number, which is the number that the client (or sample taker) assigns to the test item;
- _____ f) the initials of the person making the above entries in the sample log book.

5.9 Assuring the quality of test and calibration methods

_____ 5.9.1 The laboratory shall ensure that the quality assurance analyses represent at least 10 % of the total number of analyses performed.

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- _____ 5.9.2 Quality assurance analyses shall be performed regularly covering all time periods, sample types, instruments, tasks, and personnel.
- _____ 5.9.3 The selection of samples shall be semi-random, focusing more on positive samples and difficult samples, and, when possible, the checks on personnel performance executed without their prior knowledge.
- _____ 5.9.4 QC samples shall be analyzed routinely with actual workload, and in an on-going manner.
- _____ 5.9.5 The laboratory shall maintain and summarize all of the quality assurance activities at least monthly to include:
- _____ a) contamination checks using asbestos-free material, non-fibrous material, such as corn starch or fine table salt;
- _____ b) internal and NIST proficiency testing for each analyst;
- _____ c) interlaboratory analyses;
- _____ d) overall accuracy and precision for each microscopist for qualitative and quantitative analyses as defined in its management system documentation;
- _____ e) control charts for accuracy and precision;
- _____ f) identification of any sample custody errors, such as mixing up samples, losing samples, etc.;
- _____ g) comparison of results of independent techniques with PLM results, if appropriate;
- _____ h) deficiency corrections;
- _____ i) the total qualitative error rate of the laboratory.
- _____ 5.9.6 The laboratory shall have a documented procedure for constructing control charts, including the algorithms for calculating warning and control limits.
- 5.10 Reporting the results**
- _____ 5.10.1 The laboratory shall record the following stereomicroscopic data for bulk examination to include:
- _____ a) homogeneity;
- _____ b) texture;
- _____ c) color;
- _____ d) estimated concentration of asbestos.

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5.10.2 The laboratory shall record the following data for the asbestos type(s) identified by PLM examination:

- _____ a) morphology;
- _____ b) color and pleochroism;
- _____ c) indices of refraction (nD) parallel and perpendicular for each asbestiform;
- _____ d) birefringence;
- _____ e) extinction characteristics including measurement of extinction angles if observed;
- _____ f) sign of elongation;
- _____ g) estimated concentration of asbestos;
- _____ h) temperature at the workstation at the time of analysis;
- _____ i) result of the analysis.

5.10.3 Each test report shall include the following information:

- _____ a) color (and any other information that serves to macroscopically identify and describe the sample);
- _____ b) presence or absence of asbestos;
- _____ c) type or types of asbestos present;
- _____ d) estimate of the area percent for each type of asbestos present;
- _____ e) identity of other fibrous materials (if known);
- _____ f) estimate of the area percent for other fibrous materials present;
- _____ g) identity of matrix materials if known;
- _____ h) a statement shall be made to indicate if the sample is inhomogeneous and if sub-samples of the components were analyzed separately;
- _____ i) a description of any problems encountered in the analysis;
- _____ j) departures from the test method;
- _____ k) an approved signatory's signature.

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- _____ 5.10.4 The laboratory shall report the results of samples containing one or more layers consistent with the most current EPA guidelines.

 - _____ 5.10.5 The laboratory shall ensure that the client receives a copy of the test report, either paper or electronic. Electronic copies must be in a tamper-resistant format.

