



MODULE 2B INDUSTRIAL HYGIENE LABORATORY ACCREDITATION PROGRAM (IHLAP) ADDITIONAL REQUIREMENTS

2B.1 SCOPE

The AIHA - Laboratory Accreditation Programs (AIHA-LAP), LLC's Industrial Hygiene Laboratory Accreditation Program (IHLAP) is intended for accreditation of industrial hygiene laboratories. Laboratory accreditation in this program is based upon a review of the laboratory management systems as defined in Module 2A and this program specific module, and successful participation in AIHA Proficiency Analytical Testing (AIHA PAT) Programs, LLC or an equivalent proficiency testing program approved by AIHA-LAP, LLC, as defined in Module 6.

For purposes of this program, an industrial hygiene laboratory is defined as a laboratory that analyzes samples or materials for the purpose of evaluating occupational exposure or contamination resulting from occupational activities. Available Fields of Testing (FoTs) and corresponding PT requirements for the IHLAP are detailed in the *Scope/PT Table* maintained on the AIHA-LAP, LLC web site (www.aihaaccreditedlabs.org).

2B.2 ANALYTICAL METHODS

A documented process for defining, establishing, verifying, and reporting of minimum reporting limits shall be established and implemented. The following specific requirements for method reporting limits and instrument calibration apply to analytical procedures for industrial hygiene testing, with the exception of gravimetric and asbestos analyses.

- 2B.2.1** Minimum reporting limits shall be established initially by analyzing media spiked samples, prepared at the desired minimum reporting limit concentrations, and taken through the entire analytical process. Acceptance criteria shall be documented.
- 2B.2.2** During the analysis of samples, instrument performance at the minimum reporting limit concentration shall be verified with each analytical batch through the analysis of an analytical standard prepared at or below the analyte's minimum reporting limit concentration. Acceptance criteria shall be documented.
- 2B.2.3** At least annually or when there is a change in methodology or instrumentation minimum reporting limits shall be re-established by a process that requires analysis of a media spiked sample prepared at or below the minimum reporting limit concentration, and taken through the entire analytical process. Acceptance criteria shall be documented.
- 2B.2.4** For industrial hygiene testing, a calibration curve shall be constructed with a minimum of three (3) calibration standards, which bracket the expected sample concentrations and a calibration blank. For those technologies and software packages requiring fewer calibration standards, follow the manufacturer's recommendations (e. g., the instrument operations manual). The calibration curve shall be verified by preparing an independently prepared calibration standard (from neat materials) or with a standard from an independent source. Acceptance criteria for the standard calibration curve and the independent calibration verification standard shall be documented.



- 2B.2.5** For inductively coupled plasma, emission spectroscopy (ICP-AES), an appropriate interference check standard shall be analyzed at the beginning and at the end of each analytical run, applying the same set of standard calibration data. Acceptance criteria shall be documented.
- 2B.2.6** Instrument calibration/standardization shall be verified each 24-hour period of use or at each instrument start-up if the instrument is restarted during the 24-hour period, by analysis of a continuing calibration verification standard. Acceptance criteria shall be documented.
- 2B.2.7** Calibration or working quantification ranges shall encompass the concentrations reported by the laboratory. Continuing calibration verification standards and continuing calibration blanks shall be analyzed in accordance with the specified test methods. Acceptance criteria shall be documented.
- 2B.2.8** Media-based laboratory control spikes (LCS) shall be prepared and analyzed concurrently with each batch of samples. The spike level shall be at a concentration to fall within the calibration curve. Acceptance criteria shall be documented for LCS recoveries.

Precision shall be monitored by the analysis of duplicate portions of client samples where subsampling is performed and where positive test results are expected. Where whole sample analysis is performed and/or where positive test results for client samples are not expected, precision shall be monitored by either the analysis of within-batch laboratory control spike duplicates (LCSD) or by using between-run LCS or reference materials. Acceptance criteria shall be documented for precision.

2B.3 ASBESTOS TESTING

Laboratories seeking accreditation for asbestos testing shall adhere to the management system requirements as defined in Module 2A and this program specific module, Sections 2B.1 through 2B.3 (as applicable), in addition to the following management system requirements:

2B.3.1 Phase Contrast Microscopy (PCM) Analysis

- 2B.3.1.1** U.S. laboratories performing airborne asbestos analysis shall comply with the quality assurance requirements of the Asbestos Standard Appendix A, CFR 1910.1001 and the most current revision of the NIOSH 7400 analytical method. Laboratories outside the United States or its territories have the option of using equivalent methods.

The PCM Quality Assurance program shall address and maintain records of:

- a) Microscope adjustment and alignment for each day of use, including phase ring alignment
- b) Frequency of verification of Walton-Beckett Gaticule diameter using a NIST - traceable, or equivalent, stage micrometer
- c) Frequency and results of HSE/NPL test slide checks performed with either a red or green HSE/NPL Mark III test slide, or equivalent (e.g. a Mark II test slide), used in accordance with its Test Certificate's stated performance criteria (yellow HSE/NPL test slides are not acceptable for checking phase shift of microscopes used for PCM analysis).
- d) Analysis and evaluation of reference slides by each analyst, each day of analysis, with



- acceptance criteria stated
- e) Calculation of intra- and inter-analyst precision (Sr) for each fiber density range specified in NIOSH 7400, using the reference slide and/or blind recount data.
 - f) Calculation of intra-laboratory (Sr) values
 - g) 10% blind recount analyses and evaluation using the intra-counter Sr for the appropriate fiber loading
 - h) Participation in a proficiency testing program in compliance with or equivalent to AIHA-PAT, LLC's program.

2B.3.1.2 Final PCM reports shall include:

- a) Both fiber density and fibers/cc (or total fibers per sample)
- b) Applicable intra-laboratory Sr value(s)

2B.3.1.3 In the United States, a fiber counting microscopist is required to have completed a NIOSH 582 course or an equivalent course. AIHA-LAP, LLC recognition of NIOSH 582 equivalent courses is based on course information supplied by the course provider. A certificate of completion from such a course is acceptable to AIHA-LAP, LLC as evidence of 582 equivalent training. Applicants submitting a certificate of completion for a 582 equivalent training course, not on the list of AIHA-LAP, LLC recognized courses, shall be required to submit a description of the course as evidence of equivalent training. The description shall include dates of training, course outline, contact hours, and record of examination.

2B.3.1.4 In addition to the requirements noted above, all laboratories providing data to be used with OSHA requirements are required to participate in round robin program and post the results.

2B.3.2 Polarized Light Microscopy (PLM) Analysis

2B.3.2.1 U.S. laboratories performing bulk asbestos analysis under the Asbestos Hazard Emergency Response Act (AHERA) shall utilize U.S. EPA's "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" as found in 40 CFR, Part 763, Appendix E to Subpart E, the current EPA method for the analysis of asbestos in building material, or a method meeting the requirements of Module 2A, Section 2A.7.2.

2B.3.2.2 A bulk asbestos microscopist is required to have completed a course on the theory and use of polarized light microscopy pertinent to asbestos fiber identification and quantification.

2B.3.2.3 The laboratory shall have a stereo microscope (~ 7-40x mag.) and HEPA- filtered hood with appropriate flow documented for sample preparation.

2B.3.2.4 The laboratory shall have sample preparation tools, including a mortar and pestle or other grinding equipment.

2B.3.2.5 The laboratory shall have the appropriate refractive index liquids in the range of 1.490 to 1.570 and 1.590 to 1.720. The refractive indices of the liquids shall be calibrated.



- 2B.3.2.6** The laboratory shall have a PLM microscope with the following:
- a) Crosshair reticule or equivalent, capable of being aligned with the polarizer and analyzer
 - b) Range of objectives giving a total magnification of ~ 50 to 400X, with each objective capable of being centered with respect to stage rotation
 - c) Light source
 - d) 360 degree rotating stage
 - e) Substage condenser with iris diaphragm
 - f) Polarizer and analyzer at 90 degrees
 - g) 45 degree accessory slot with 530-550 nm (Red 1) compensator

2B.3.2.7 The laboratory shall have standards – NIST 1866 and 1867 (six regulated asbestos types and fibrous glass) or equivalent.

2B.3.2.8 The laboratory shall document, for each asbestos fiber type, morphology, color, pleochroism, indices of refraction, birefringence, extinction and sign of elongation. The laboratory shall document, for each non asbestos type, at least one of the above which distinguishes it from asbestos.

- 2B.3.2.9** The Quality Assurance program shall address:
- a) Reanalysis by same and different analyst, including frequency and acceptance criteria
 - b) Verification of the refractive indices of the refractive index liquids
 - c) Recording temperature during analysis and refractive index liquid calibration
 - d) Microscope alignment for each day of use
 - e) Analysis of reference samples of known asbestos content to calibrate/evaluate analysts' fiber identification and quantitation ability
 - f) Proficiency testing

2B.3.3 Transmission Electron Microscopy (TEM) Analysis

2B.3.3.1 Analysts performing TEM shall be trained in use, calibration, alignment, EDXA use, collection and interpretation of spectra. Interpretation of spectra training should include, but is not limited to, recognition of artifacts, electron diffraction interpretation, determination of d-spacings, Miller indices and zone axes, asbestos counting methods, asbestos identification, and recognition of acceptable sample preparation.

2B.3.3.2 The laboratory shall have a clean bench or clean room (Class 100).

2B.3.3.3 The laboratory shall have appropriate equipment for sample preparation which may include:

- a) Exhaust hood for solvent use
- b) Low-temperature oxygen plasma asher with controlled venting
- c) Carbon evaporator, which can obtain better than 10^{-4} torr

2B.3.3.4 The electron microscope (80-120 keV) used for analysis shall be capable of:

- a) producing a diffraction pattern from a single fibril of chrysotile;
- b) resolving the hollow tube in chrysotile;
- c) fiber measurement at the length(s) of interest for the method used;
- d) producing a diffraction pattern in a form that is capable of being indexed;
- e) producing a spot at crossover less than or equal to 250 nm; and



f) recording images.

2B.3.3.5 The EDXA system shall be capable of producing resolution equal to or less than 175 eV at Mn K-alpha, statistically significant Na peak in crocidolite, statistically significant Mg and Si peaks from a single fibril of chrysotile, and have software for calculating background corrected net intensities.

2B.3.3.6 The laboratory shall have 6 asbestos types (NIST SRM 1866 & 1867), NIST SRM 2063 or equivalent for calculating k-factors, optical grating for magnification calibration, and Au diffraction standard or equivalent.

2B.3.3.7 The Quality Assurance program shall address:

- a) 10% QA analysis
- b) TEM alignment for each day of use
- c) Grid opening size calibration (each lot) and measuring system calibration
- d) EDXA energy calibration for each day of use
- e) EDXA k-factor measurement for Mg, Si, Ca, Fe using SRM 2063 or equivalent; Mg:Fe sensitivity shall be ≤ 1.5
- f) EDXA resolution
- g) TEM magnification
- h) TEM minimum beam size
- i) Plasma asher calibration
- j) Recounts
- k) Verification of training
- l) External proficiency samples
- m) Internal proficiency samples using reference unknowns

2B.4 COMPRESSED/BREATHING AIR TESTING

Accreditation for compressed/breathing air testing in the IHLAP is intended for all laboratories, company, government, trade and independent, performing air tests on samples of compressed and/or breathing air. Typically, these samples come from compressed air sources, but may be from ambient air as well. Fire departments, divers, hospitals and commercial industry use breathing air from compressed gas sources. OSHA, National Fire Protection Association (NFPA), Compressed Gas Association (CGA), Professional Association of Diving Instructors (PADI) plus many others have specifications for the requirements of compressed/breathing air.

Laboratories seeking accreditation for compressed/breathing air testing shall adhere to the management system and quality system requirements as defined in Module 2A, this program specific Module 2B, Sections 2B.1 through 2B.4 (as applicable), and Module 6, with the following exceptions:

2B.4.1 The laboratory shall use methods that are recognized nationally and internationally, including, but not limited to, the following sources: CGA, NFPA, and U.S. Pharmacopoeia (USP). Proprietary methods may also be used when appropriate.

2B.4.2 A calibration curve shall be constructed with a minimum of three (3) calibration standards which bracket the expected sample concentrations. If a full calibration curve is not run each 24- hour period, then a single point calibration in the range of the three (3) point calibration curve can be used. Validity of this one (1) point calibration shall be checked at least once for each 24-hour



period with an additional calibration standard that falls within the three (3) point range. Acceptance criteria for the standard calibration curve shall be documented. These requirements supersede the requirements of this module, Section 2B.3.4.

2B.5 BERYLLIUM TESTING

Accreditation for beryllium testing is intended for all laboratories that perform beryllium analysis related to industrial hygiene monitoring. Laboratories seeking accreditation for beryllium testing shall adhere to the management system requirements as defined in Module 2A and this program specific module, Sections 2B.1 through 2B.2 (as applicable).

2B.6 PHARMACEUTICAL TESTING

Accreditation for pharmaceutical testing is intended for industrial hygiene laboratories that develop methods and analyze samples for the purpose of evaluating potential occupational exposure to pharmaceutical compounds in the workplace. Laboratories seeking accreditation for pharmaceutical testing shall adhere to the management system and quality system requirements as defined in Module 2A, this program specific module, Sections 2B.1 through 2B.6 (as applicable) maintained on the AIHA-LAP, LLC web site.

Successful participation in the Pharmaceutical Round Robin Proficiency Testing Program, or other equivalent program approved by AIHA-LAP, is required in accordance with the requirements defined in Module 6. The Pharmaceutical Round Robin Proficiency Testing Program is designed to share samples among participating laboratories to document that accurate analytical results can be generated by independent analysts following documented procedures. As a round robin program, each laboratory takes turns being the lead laboratory and coordinating the testing round.

2B.6.1 Sample Handling and Preparation

Due to the increasing potency of pharmaceutical industrial hygiene samples and the unique hazards this poses, the following procedures shall apply to both proficiency samples and customer samples.

- a) Sample handling procedures shall ensure the safety of all employees handling pharmaceutical industrial hygiene samples.
- b) Sample handling procedures shall minimize cross contamination.
- c) Samples shall be extracted using in-situ extraction procedures.
- d) Effective decontamination and cleanup procedures shall be followed.