



## MODULE 2B

### INDUSTRIAL HYGIENE LABORATORY ACCREDITATION PROGRAM (IHLAP) SPECIFIC ADDITIONAL REQUIREMENTS

#### 2B.1 SCOPE

The American Industrial Hygiene Association 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.

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 *IHLAP Scope /PT Table* maintained on the AIHA-LAP, LLC web site ([www.aihaaccreditedlabs.org](http://www.aihaaccreditedlabs.org)).

#### 2B.2 FACILITIES

Mobile and field operations laboratories shall maintain records of the locations where analyses are performed.

#### 2B.3 PERSONNEL

The following sections define the qualifications for the titled positions.

##### 2B.3.1 Technical Manager

Qualifications of the TM in addition to those in 2A are a minimum of three (3) years relevant nonacademic analytical experience. A minimum of two (2) years experience shall be in industrial hygiene analyses within the scope of accreditation. The remaining one (1) year may be from other laboratory analytical procedures. Relevant academic experience may be substituted for the remaining one (1) year work experience. A relevant post-graduate degree (MS or Ph.D.) shall also be considered equivalent to one (1) year of work experience. Academic experience and post-graduate degrees may not be substituted for the two (2) years industrial hygiene experience. (Environmental, forensic, or similar microanalytical experience shall be reviewed to determine if the specific experience is a reasonable substitute.)

##### 2B.3.2 Laboratory Analytical Staff

The industrial hygiene program distinguishes two titles for those conducting analytical procedures within the laboratory. An analyst is one who has a bachelor's degree in chemistry or a related science. A technician is one who does not have a degree in chemistry or a related science.

**2B.3.2.1** All analysts and technicians shall complete a training course (an in-house course is acceptable) for the applicable analysis prior to performing unsupervised analysis on laboratory samples. Courses on sample preparation and instrument analysis may be taken separately or combined. The criteria and training requirements for laboratory personnel shall be clearly defined, documented and maintained on file. The



laboratory must maintain a description of the training program content, duration of the training, qualifications of the trainer, and objective evidence that the analyst/technician has successfully analyzed unknown reference samples of the matrices/analytes of concern within specified acceptance criteria. The dates of authorization to perform specific tasks shall be recorded.

**2B.3.2.2** All analysts and technicians shall have demonstrated ability to produce reliable results through accurate analysis of certified reference materials (CRMs), proficiency testing samples, or in-house quality control samples. This demonstration shall be done at a minimum of every six (6) months and documented.

**2B.3.2.3** All analysts and technicians shall have a minimum of twenty (20) business days of hands-on experience conducting analyses in an industrial hygiene laboratory before initiation of independent work on customer samples.

#### **2B.4 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.4.1** 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.4.2** 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.4.3** 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.4.4** For industrial hygiene testing, a calibration curve shall be constructed with a minimum of three (3) calibration standards (ICP-AES is an exception) which bracket the expected sample concentrations and a calibration blank. The calibration curve must 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.4.5** 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. Such samples are analyzed applying the same set of standard calibration data. This analytical standard is used to verify an accurate analyte response in the presence of possible interfering materials present in samples. Acceptance criteria shall be documented.



**2B.4.6** 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.4.7** 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.4.8** Multiple matrix-based quality control spikes shall be analyzed with each batch of samples. The spike level shall be at a concentration level within the calibration curve of the applicable analysis. The Laboratory Control Samples (LCS-LCSD) are carried through the entire procedure, from preparation to analysis. Acceptance criteria shall be documented for LCS-LCSD recoveries and precision.

## **2B.5 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.4 (as applicable), in addition to the following management system requirements:

### **2B.5.1 Phase Contrast Microscopy (PCM) Analysis**

**2B.5.1.1** U.S. laboratories performing airborne asbestos analysis must 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 Graticule diameter using a NIST-traceable, or equivalent, stage micrometer
- c) Frequency and results of HSE/NPL test slide checks
- 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 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 fiber counting round robin program in compliance with or equivalent to AIHA-PAT, LLC's program.

**2B.5.1.1.2** Fiber counting round robin results shall be posted in the laboratory for analysts' viewing.

**2B.5.1.1.3** Final PCM reports must include:

- a) Both fiber density and fibers/cc (or total fibers per sample)



b) Applicable intra-laboratory Sr value(s)

**2B.5.1.2** 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 must include dates of training, course outline, contact hours, and record of examination.

**2B.5.1.3** All laboratories are required to participate in a fiber counting round robin program consistent with the requirements outlined in Policy Module 6.

**2B.5.2** Polarized Light Microscopy (PLM) Analysis

**2B.5.2.1** U.S. laboratories performing bulk asbestos analysis under the Asbestos Hazard Emergency Response Act (AHERA) must 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.5.4.

**2B.5.2.2** 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.5.2.3** The laboratory shall have a stereo microscope (~ 7-40x mag.) and HEPA-filtered hood with appropriate flow documented for sample preparation.

**2B.5.2.4** The laboratory shall have sample preparation tools, including a mortar and pestle or other grinding equipment.

**2B.5.2.5** 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.5.2.6** 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.5.2.7** The laboratory shall have standards – NIST 1866 and 1867 (six regulated asbestos types and fibrous glass) or equivalent.

**2B.5.2.8** 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.5.2.9** The Quality Assurance program shall address:

- a) Reanalysis by same and different analyst, including frequency and acceptance criteria
- b) Calibration of 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.5.3** Transmission Electron Microscopy (TEM) Analysis

**2B.5.3.1** 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.5.3.2** The laboratory shall have a clean bench or clean room (Class 100).

**2B.5.3.3** 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.5.3.4** 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.5.3.5** 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.5.3.6** 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.5.3.7** 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 must be  $\leq 1.5$
- 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.6 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 and this program specific Module 2B, Sections 2B.1 through 2B.4 (as applicable) with the following exceptions:

**2B.6.1** 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.6.2** 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 must 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.4.4.

## **2B.7 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.4 (as applicable).

**2B.7.1** Refer to the AIHA-LAP, LLC guidance document, *Beryllium Accreditation Guidance Document*, maintained on the AIHA-LAP, LLC web site ([www.aihaaccreditedlabs.org](http://www.aihaaccreditedlabs.org)) for additional information.

**2B.7.2** Follow appropriate health and safety regulations to prevent employee exposure.

## **2B.8 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.4 (as applicable) maintained on the AIHA-LAP, LLC web site ([www.aihaaccreditedlabs.org](http://www.aihaaccreditedlabs.org)).

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.8.1 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 client 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.