



## MODULE 2E

### PROGRAM SPECIFIC REQUIREMENTS FOR LABORATORIES SEEKING ACCREDITATION UNDER UNIQUE SCOPES

#### 2E.1 SCOPE

The American Industrial Hygiene Association Laboratory Accreditation Programs (AIHA-LAP, LLC) offers a Unique Scope accreditation for those laboratories wishing accreditation under AIHA and ISO/IEC 17025:2005. A unique scope accreditation can only be applied to an area of testing that is not addressed under an existing AIHA-LAP, LLC program. Laboratories seeking this accreditation must be in compliance with the requirements found in appropriate AIHA Policy Modules including Modules 2A and 6A. The unique scope testing procedures must produce data that is used to evaluate exposures that impact health and / or natural resources. The PT program selected and applied to each unique scope must be compliant with the requirements of Module 6E and are subject to approval by the AAB and / or the TAP.

#### 2E.2 FACILITIES

Laboratory facilities supporting unique scope testing must be equipped and designed to meet the needs of the specific testing. If the unique scope testing is performed in a mobile and / or field operation, the laboratory shall maintain records of the locations where analyses are performed.

#### 2E.3 PERSONNEL

Laboratory personnel shall consist, at a minimum, of a Technical Manager (TM) and a qualified individual not directly involved with the analysis of the samples set. They are to review and concur on the data for use in the final report. See Policy Module 9 for definition of “*Qualified Individual (for data review).*”

##### 2E.3.1 Technical Manager

Qualifications of the TM in addition to those in 2A are at least three (3) years of nonacademic analytical laboratory experience in the field of testing similar to or equivalent to the unique scope.

##### 2E.3.2 Laboratory Analytical Staff

The unique scope program distinguishes two titles for those conducting analytical procedures within the laboratory. An analyst is one who has a bachelor’s (or higher) degree in an applicable science. A technician is one who does not have a bachelor’s degree in an applicable science.

**2E.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.

**2E.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, and/or in-house quality control samples. This demonstration shall be done during initial training and at a minimum of every six (6) months. Demonstrations must be documented and show the acceptance criteria for evaluation purposes.

**2E.3.2.3** All analysts and technicians shall have a minimum of twenty (20) business days of hands-on experience conducting the unique scope analyses before initiation of independent work on customer samples.

## **2E.4 ANALYTICAL METHODS**

In addition to the requirements in Module 2A, the following requirements apply to unique scope testing procedures.

**2E.4.1** For quantitative testing procedures, the laboratory shall establish and verify the minimum reporting limit(s) and linear ranges annually. This must be completed and documented for each test and matrix.

**2E.4.2** Laboratories shall only report levels below the minimum reporting limit as "<" (less than) or with a "ND" (not detected) and reference the reporting limit. The reporting of zero concentration is not permitted.

**2E.4.3** All analytical reagents shall be of ACS grade or better.

**2E.4.4** Daily working calibration curves, as specifically described in the applicable SOP, shall fall within the established linear calibration range. A minimum of three (3) calibration standards and a blank shall be used to construct the calibration curve. All calibration curves shall be dated and labeled with applicable method, instrument identification, analysis date, analyte concentrations, and instrument response. Acceptance criteria in terms of relative percent difference (RPD) of response factors or correlation coefficient shall be stated. New calibration curves shall be prepared whenever an out of control condition is indicated and/or after new calibration standards and/or reagents are prepared.

## **2E.5 INTERNAL QUALITY CONTROL PROCEDURES**

As part of the quality assurance program for each unique scope procedure, the laboratory shall adhere to all stated QA/QC requirements as published in the method(s) used. At a minimum, the laboratory shall analyze laboratory control spike samples, duplicate samples, matrix spiked samples, and blanks with each batch of samples, as appropriate. These QC samples must be completed with each set of samples having less than 20 samples, and within each batch of 20 samples. The laboratory must define the acceptance criteria for the evaluation of each of these quality control samples. Acceptance criteria shall be statistically determined if the method does not define such criteria.



## **2E.6 TRANSFER OF ACCREDITATION**

**2E.2.1** Laboratories wishing to add an accreditation under Module 2E to their existing accreditation certificate shall be required to coordinate their new application and site assessment with those from the other programs. Laboratories may choose to seek early reaccreditation for their existing programs to enable submission of a combined application package.

**2E.2.2** Laboratories wishing to substitute their current AIHA accreditation with accreditation under Module 2E may do so at the end of their current accreditation cycle when their next review and site assessment shall be based on a new application package. Laboratories may choose to submit their reaccreditation early to quicken this process.

## **2E.7 LEVY OF FEES**

The AIHA reserves the right to levy fees for additional activities associated with accreditation under Module 2E including, but not limited to, auditing proficiency test sample providers, assessing proficiency test programs, and handling data.