MODULE 2E
UNIQUE SCOPES LABORATORY ACCREDITATION PROGRAM
ADDITIONAL REQUIREMENTS

2E.1 SCOPE

The AIHA-Laboratory Accreditation Programs (AIHA-LAP), LLC offers a Unique Scope accreditation for those laboratories wishing accreditation under AIHA-LAP, LLC and ISO/IEC 17025:2017. 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 shall be in compliance with the requirements found in appropriate AIHA-LAP, LLC Policy Modules including Modules 2A and 6. All applications of this Unique Scopes accreditation are subject to approval by the AAB.

2E.2 FACILITIES

Laboratory facilities supporting unique scope testing shall be equipped and designed to meet the needs of the specific testing.

2E.3 ANALYTICAL METHODS

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

2E.3.1 For quantitative testing procedures, the laboratory shall establish and verify the minimum reporting limit(s) and linear ranges annually. This shall be completed and documented for each test and matrix.

2E.3.2 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.3.3 All analytical reagents shall be of ACS grade or better.

2E.3.4 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 calibration blank shall be used to construct the calibration curve. For those technologies and software packages requiring fewer calibration standards, follow the manufacturer's recommendations (e. g., the instrument operations manual). 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.4 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 shall be completed with each set of samples having less than 20 samples, and within each batch of 20 samples. The laboratory shall 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.5 TRANSFER OF ACCREDITATION

2E.5.1 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.5.2 Laboratories wishing to substitute their current AIHA-LAP, LLC 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.