



## **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** A calibration curve shall be constructed with a minimum of three (3) calibration standards, which bracket the expected sample concentrations. 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 shall be documented.

#### **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.