



**ADMINISTRATIVE PROCESS RULE:
PREPARING A DRAFT SCOPE OF
ACCREDITATION FOR ISO/IEC 17025
TESTING LABORATORIES**

AUTHORITY: VICE PRESIDENT

EFFECTIVE DATE: 2017/03/29

DOCUMENT NUMBER: PR 2350

TABLE OF CONTENTS

Introduction.....	3
References	3
Definitions.....	3
Draft Scope of Accreditation.....	4
Preparation of Scope of Accreditation	4
Scope of Accreditation Flexibility.....	6
Use of International System of Units.....	6
Testing Scope of Accreditation	6
Revision History	8
Annex A. Example of Testing Scope of Accreditation.....	9

INTRODUCTION

This document is intended to assist in drafting scopes of accreditation, and to clarify ILAC guidance documents and ANAB requirements, while helping to standardize formats across the range of potential ISO/IEC 17025 accredited tests.

While a laboratory's scope of accreditation is issued as an ANAB document and published on the ANAB website, it is also understood to be a marketing document for the accredited laboratory. As such, the entries on the scope of accreditation need to be well understood by potential customers and users of the accredited laboratory.

This document outlines minimum requirements and sets frameworks within which a laboratory can exercise flexibility in its scope of accreditation while allowing ANAB to meet the requirements set forth in ISO/IEC 17011 and by the international regional cooperations of which ANAB is a member.

REFERENCES

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

DEFINITIONS

Accreditation: Third-party attestation that a laboratory has demonstrated competence to carry out specific tasks. The process of verification of laboratory competence to ISO/IEC 17025 and any associated accreditation body requirements, resulting in the issuance of a certificate and scope of accreditation for a defined period of time.

Assessment process: Operations carried out by an accreditation body to ensure with an adequate degree of confidence that the laboratory has the competence to provide reliable services within the defined scope of accreditation.

Calibration: Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

ILAC: International Laboratory Accreditation Cooperation, the international body that helps standardize and recognize accreditation systems worldwide and publishes documents to support these efforts.

Scope of accreditation: The document published on an accreditation body website listing the witnessed and approved calibrations and/or tests compliant to ISO/IEC 17025.

Testing: Determination of one or more characteristics of an object of conformity assessment, according to a procedure.

DRAFT SCOPE OF ACCREDITATION

ANAB customers are expected to draft an initial scope table listing as part of the application process. In addition, customers are expected to follow the ANAB scope of accreditation template (Annex A) to draft the initial accreditation assessment scope document for submission prior to the accreditation visit. Customers are encouraged to seek clarification as needed from an ANAB Accreditation Manager.

PREPARATION OF SCOPE OF ACCREDITATION

To assist laboratories and assessors in drafting scopes of accreditation, ANAB provides templates formatted with much of the necessary information. All scopes of accreditation for ANAB should abide by the following guidelines as much as possible.

The scope of accreditation should consist of three main sections:

- Scope header
- Table of accredited items
- Scope footer (notes)

The scope header should include:

- ANAB logo
- Laboratory name and address
- Conformity assessment activity (calibration, testing, inspection, etc.)
- Certificate number
- Expiration date of the accreditation (“valid to” date)

Accredited items should be grouped by table according to the corresponding major fields of testing identified below. Testing scopes of accreditation include the following major fields:

Acoustics

Acoustic Performance, Field Measurement of Sound, Sound Absorption, Sound Transmission Loss etc.

Vibration

Acceleration, Vibration Performance, Dynamic Balancing, Shock, etc.

Biological

Aquatic Biology, Cell Culture, Seed Testing, DNA Analysis, Ecotoxicology, etc.

Microbiological

Bacteriology, Mycology, PCR, Phycology, Tests on Food and Food Products, etc.

Chemical

Spectroscopy, Microscopy, Chromatography, Wet Chemistry Measurements, etc.

Construction Material

Cement & Cementitious Materials, Cement, and Clay Based Products, Refractories, Aggregates, etc.

Dimensional Measurement/Testing

Fixture/Gauge layout, CMM, etc.

Electrical

Measure, AC, DC, Capacitors, NEBS, Cells and Batteries, etc.

Electromagnetic Compatibility (EMC) (methods must include date/version/revision information on scope)

Conducted Emissions (Voltage), Conducted Emissions (Current), Radiated Emissions (E-Field), Radiated Emissions (H-Field), Conducted RF Immunity/Susceptibility, Conducted AF Immunity/Susceptibility, Radiated Immunity/Susceptibility (H-Field), Radiated Immunity/Susceptibility (E-Field), Transient Immunity, Power Input, etc.

Radio (methods must include date/version/revision information on scope)

Power Output, Frequency Stability - Delta Voltage, Frequency Stability - Delta Temperature, Occupied Bandwidth, Spurious Emissions – Radiated, Spurious Emissions - Antenna Conducted, Transient Frequency Response, Modulation Characteristics, Occupancy Time - Channel Spacing, Power Spectral Density, Coexistence, etc.

Environmental

Toxicity Testing, Asbestos Testing, Organic Testing, Radiochemical Testing, Inorganic Testing, etc.

Mechanical

Tension, Compression, Environmental Conditioning, Color, Corrosion, Creep/Creep Rupture, Displacement, Environmental Simulation, etc.

Non-Destructive

Radiographic, Ultrasonic, Acoustic Emission Testing, Magnetic Particle Testing, Thermography, etc.

Optical or Photometric or Radiometric

Radiant flux, Broad-Band Irradiance, Luminous Intensity, Distribution of Luminous Intensity, Luminous Flux, etc.

Thermal

Determination of Thermal Properties of Materials, Flammability, DSC, TGA, Tests on Fire Protection Equipment, etc.

Information Technology

Information Security Evaluation, Gaming Software Tests, Acceptance Tests, Functionality Tests, Software Products, Compatibility, etc.

SCOPE OF ACCREDITATION FLEXIBILITY

The level of detail on a scope of accreditation often represents a balance between generic methods used and the precise day-to-day requirements of all sample types, device types, customer requirements, and technology advances encountered. ANAB abides by ILAC G18, Guideline for the Formulation of Scopes of Accreditation for Laboratories, which reviews aspects of the flexibility warranted in the scopes of accreditation.

In areas such as NDT, EMC, and chemical testing, laboratories often may need to modify or amplify more generic methods to determine minimum detection levels or configuration designs to obtain good measurements. In such cases, laboratories are often granted the flexibility of accreditation to more generic methodologies and the freedom to modify their previous methods. This still obligates the affected laboratories to maintain customer awareness and agreement with the modified methods and to ensure adherence to the requirements for method validation according to ISO/IEC 17025.

USE OF INTERNATIONAL SYSTEM OF UNITS

ANAB laboratories are to follow as closely as possible the guidance of NIST SP 330 and NIST SP 811 for listing all scope entries for range values and uncertainty values or expressions. This formatting guidance for the International System of Units (SI) is invaluable but not absolute in the countless scope of accreditation listings. Laboratory representatives are encouraged to use this document in their drafts and confer with ANAB assessors and Accreditation Managers whenever possible to avoid lengthy re-drafts.

TESTING SCOPE OF ACCREDITATION

1. MOST MAJOR FIELDS

For most major fields, it is recommended that at a minimum the following elements be included in the scope table, and be conveyed as best possible in the column headings:

Major Field

Each table is labeled with the Major Field as designated by: Acoustics, Vibration, Biological, Microbiological, Chemical, Construction Material, Dimensional, Electrical, Electromagnetic Compatibility (EMC), Radio, Environmental, Mechanical, Non-Destructive, Optical or Photometric or Radiometric, Thermal, and Information Technology.

Specific Tests and/or Properties Measured

Define the specific types of testing performed and, when relevant, identify the properties or ranges measured. You may provide the lower and upper bounds for the range of the property. Care must be taken when zero is the lower bound and the uncertainty is given as a function of the range; in this case, the function must be in a form such that the uncertainty at zero is itself not equal to zero. The capabilities of the laboratory need to be clearly expressed in an easy to understand format.

Specification, Standard, Method, or Test Technique

Enter all the test methods you use when performing tests in the technology related in the first column. The test method may be an internationally recognized test method such as ASTM, ISO, SAE, MIL, ANSI, or other accepted methods. This may also be a customer-specified method or internal method. Whichever method(s) is stated on the scope, the laboratory is expected to have available the most current version of that method and will be assessed to them. For internal methods, the laboratory must have the appropriate method validation documentation as required by ISO/IEC 17025 available for the ANAB assessor(s).

Items, Materials, or Products Tested

Define the items, materials, products that you test using this column. For example, Metals, Alloys, Fasteners, Wastewater, Seat Belts, Interior Components, and Elastomers are all types of products tested.

Key Equipment or Technology

In this field, the entry may identify the key equipment utilized to perform the specific testing or identify the test technology. For example, the test technology may include: Hardness, Ultimate Tensile Strength, Izod Impact, Gas Chromatography (GC), Thermogravimetric Analysis (TGA), Specific Gravity, Static Load, and Dynamic Load, etc.

2. ELECTROMAGNETIC COMPATIBILITY AND RADIO MAJOR FIELDS

For the Electromagnetic Compatibility (EMC) and Radio major fields, the scope must include the following elements be included in the scope table and be conveyed as best possible in the column headings:

Test Method

Identify the specific published test method(s) *with* date/revision information.

Test Specification(s)

Identify the test(s) conducted within the listed method.

Range

Enter information regarding the range in which the tests are conducted is identified (i.e., frequency range).

Comments

Identify any additional information necessary (i.e., equipment types, test limitations, etc.).

3. ENVIRONMENTAL MAJOR FIELD

For the Environmental major field, the scope must include the following elements be included in the scope table and be conveyed as best possible in the column headings:

Technology

In this field, the entry needs to represent the test technology you are utilizing to perform the test. The entry needs to be specific and not generic.

Specification, Standard, Method, or Test Technique

Enter all the test methods you use when performing tests in the technology related in the first column. The test method may be an internationally recognized test method such as EPA, SM, or other accepted methods. This may also be a customer specified method or internal method. Whichever method(s) is stated on the scope, the laboratory is expected to have available the most current version of that method and will be assessed to them. For internal methods, the laboratory must have the appropriate method validation documentation as required by ISO/IEC 17025 available for the ANAB assessor(s).

Analyte

Provide the exact listing of all analytes that are to be included within the accreditation.

Matrix

The scope tables will be separated by the following test matrices: Drinking Water, Air, Non-Potable Water, Solid and Chemical Materials, and Biological Tissue.

An example of a typical testing scope of accreditation is provided in Annex A.

REVISION HISTORY

Revision Level	Effective Date	Description
Original Release	2017/03/20	Original release.
1	2017/03/29	Removed language in the Appendix A about specific scope formatting. Scope tables remain the same.

ANNEX A. EXAMPLE OF TESTING SCOPE OF ACCREDITATION TABLES

Chemical

Specific Tests and / or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Mercury (Hg)	EPA 245.1 7471B (Modified)	Potable water, Wastewater, Waste	Atomic Absorption
Phosphorus	EPA 365.3	Wastewater, Wastes	Spectrophotometry UV/VIS

Microbiological

Specific Tests and / or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Heterotrophic Plate Count (1 to 300) CFU / mL	SM 9215B	Drinking Water	Plate
Listeria Species Present / Absent	AOAC 2004.06	Food Products; Ingredients; Swabs	Vidas

Mechanical

Specific Tests and / or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ultimate Tensile Strength (0 to 60 000) lb	ASTM E8	Flat, Round, Tubular, Fasteners, Metal Products	Tensile Testing Machine
Rockwell Hardness HRC; HRB, HR15T; HR30T	ASTM E18	Metal Products	Hardness Tester
High / Low Temperature (-200 to 1 200) °C	MIL-STD 810C - Section 501.1, 502.1	Metal Products	Environmental Chamber

Electromagnetic Compatibility (EMC)

Test Method	Test Specification(s)	Range	Comments
ANSI C63.4:2014	Conducted Emissions (Voltage)	9 kHz to 40 GHz	Unlicensed Devices
IEC 61000-4-5:2014	Conducted RF Immunity/Susceptibility		Surge Immunity

Radio

Test Method	Test Specification(s)	Range	Comments
IEC 61204-3:2016	Power Output		Low Voltage Power Supplies
EN 300 113-1 V1.7.1	Modulation Characteristics		Land Mobile Equipment

Environmental

Non-Potable Water		
Technology	Specification, Standard, Method, or Test Technique	Analyte
ICP	EPA 200.7	Zinc
ICP/MS	EPA 200.8	Aluminum
Preparation	Specification, Standard, Method, or Test Technique	Type
Preparation	EPA 3520C	Continuous Liquid-Liquid Extraction
TCLP preparation	EPA 1311	Toxicity Characteristic Leaching Procedure

Environmental

Drinking Water		
Technology	Specification, Standard, Method, or Test Technique	Analyte
LC/MS/MS	EPA 537	Perfluorohexanoic Acid
LC/MS/MS	EPA 537	Perfluoroheptanoic Acid
Preparation	Specification, Standard, Method, or Test Technique	Type
Organic Preparation	EPA 608; EPA 610; EPA 625	Separatory Funnel Liquid-Liquid Extraction
Volatile Organic Preparation	SW836 5030B	Closed System Purge and Trap