ADMINISTRATIVE PROCESS RULE:

PREPARING A DRAFT SCOPE OF ACCREDITATION FOR ISO/IEC 17025 CALIBRATION LABORATORIES

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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 accredited calibrations in the sphere of ISO/IEC 17025 accredited operations.

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*

NIST SP 811, *Guide for the Use of the International System of Units (SI)*

NIST SP 330, *The International System of Units (SI)*

ILAC P14, *ILAC Policy for Uncertainty in Calibration*

ILAC G18, *Guideline for the Formulation of Scopes of Accreditation for 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: Document published on an accreditation body website listing the witnessed and approved calibrations and/or tests compliant to ISO/IEC 17025.

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 use 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 assessor or Accreditation Manager.

The format of the example table must be followed. This includes font (Times New Roman), font size (11), column order and column headings, and placement of notes. Page number, the total number of pages, and the date of the draft must be displayed on each page.

ANAB assessors are expected to verify and update the scope document as needed during each assessment visit. The laboratory can request an expansion or reduction of its accredited scope through a change notice. The lead assessor is responsible for updating the scope of accreditation and submitting it to ANAB with the assessment report for review and approval.

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)

In the table of accredited items, the scope should have headers for each section of the table corresponding to the general fields of calibration found in ILAC guidance documents and the ANAB ISO/IEC 17025 application (Calibration/Measurement Areas and Parameters).

Calibration scopes of accreditation include the following **major fields** with related parameters.

- Parameters may be combined for specific equipment types.

Acoustics and Vibration

Accelerometers, Vibration Meters, Sound Attenuators, Sound Level Meters, Noise Dosimeters, etc.

Chemical Quantities

Gas dividers, certified gasses**,** pH/ORP meters & transmitters, conductivity/TDS meters, Refractometers, etc.

Electrical – DC/Low Frequency

Capacitance Source, Capacitance Measure, AC Current Source, AC Current Measure, DC Current Source, DC Current Measure, Meters, RLC Bridges, Inductance Source, Voltage Sources, Voltage

Meters, pH Meters (Millivolt Simulation) Thermocouple Millivolt Sources, Thermocouple Temperature Meters, Process Calibrators, Resistance Artifacts, Decade Resistors, Resistance Meters, RTD Temperature Meters, Thermistor Temperature Meters, Conductivity Meters (Resistance Simulation), Magnetic Fields Measure, Magnetic Fields Source, etc.

Electrical – RF/Microwave

Power; AC/DC Power Meters, RF Attenuators, RF Attenuation Meters, RF Power Meters, RF Power Sensors, etc.

Ionizing Radiation

Dosimetry; Absorbed Dose/Rate, Air Kerma Rate, Dose Equivalent, Surface Emission, Emission Rate, Efficiency, Absorbed Dose, etc.

Length – Dimensional Metrology

External/Internal Cylinders, Angle Blocks, Threaded Devices, Gears, Fixtures, Functional Gages, Calipers, Micrometers, Height Gages, Optical Comparators, CMM's, 3-Axis Vision Systems, Laser Trackers, Pitch Masters, etc.

Mass and Mass Related

Hydrometers, mass & volumetric flow, dynamometers, force meters, load cells, Durometers, Durometer Calibrator, Rockwell Hardness Testers, Rockwell Hardness Specimens, Mass Artifacts, Pressure Gages/Transducers, Vacuum Gages/Transducers to 3kPa (29.5 inHg), Balances, Bench Scales, Torque Wrenches, dynamic & kinematic viscometers, efflux cups, Pipettes, Volumetric Flasks, etc.

Photometry and Radiometry

Luminous Intensity, Illuminance Responsivity, Responsivity (spectral power, spectral irradiance, spectral radiance, laser power, solar power, solar irradiance, blackbody total irradiance, UV broadband irradiance, UV broadband radiant exposure), Distribution Temperature, Correlated Color Temperature, Reflectance, Emissivity, Emittance, BDRF, Reflectance, Radiance, Luminescent Radiance Factor, Wavelength, Gloss, Optical Emission Spectrometers, Optical Power, Optical Wavelength, Optical Attenuation, etc.

Thermodynamic

Infrared Guns, hygrometers sensors, humidity chambers, Thermocouples, Platinum Resistance Thermometers (PRT, SPRT), temperature chambers, Drywells, etc.

Time and Frequency

Clocks**,** Electronic Counters, Stopwatches, Timers**,** bandwidth, rise time, etc.

Some of these general fields are multi-disciplinary and may have sub-categories or sub-disciplines.

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.

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.

UNCERTAINTY

All calibration scopes of accreditation contain a column heading of expanded uncertainty of measurement, and this uncertainty is determined at approximately 95% confidence level, coverage factor of k=2, unless noted otherwise and footnoted.

The calculation of uncertainties for any scope of accreditation should follow the Guide to the Expression of Uncertainty in Measurement (GUM). The calculations and considerations of all relevant factors potentially contributing to measurement variability and “nearly ideal” calibrations are collectively considered the uncertainty budget. ANAB’s policy is to retain a copy of all uncertainty budgets for all accredited scope items for each customer. The calculations of uncertainty are to be provided to the ANAB assessor at assessment visits, including any updates.

CALIBRATION SCOPE OF ACCREDITATION

Calibration and Measurement Capability (CMC) is expressed in terms of the measurement parameter, measurement range, expanded uncertainty of measurement and remarks. Further information can be found in ILAC P14.

Parameter/Equipment

The entry in this field needs to represent the measurement, which is being provided by the laboratory, for example, Accelerometry, AC Volts, DC Volts, AC Current, Force, Flow, Hardness, Humidity, Mass, Optical, Pressure, Vacuum, Surface Texture, Thermal, Time & Frequency, Vibration, Volume, Torque. Range modifiers, such as a frequency range for AC Voltage, may be listed in the Parameter column. The modifying terms “generate” and “source” when listed in this field describe a capability to calibrate measuring devices. The modifying term “measure” describes a capability to calibrate artifacts or devices that “generate,” “source,” or “provide” the listed parameter.

Range

Provide the lower and upper bounds for the range of the parameter. 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. For example, if the uncertainty is given as “10 μV/V”, then this implies that at zero volts the uncertainty is zero volts since 10 μV/V of zero volts is zero. In this case, a constant, or “floor spec” is included with the proportional part (e.g., “10 μV/V + 1 μV”). The capabilities of the laboratory need to be clearly expressed in an easy to understand format.

Range modifiers, such as a frequency range for an AC Voltage or Current range are typically noted in the Range column and must always accompany the defined range of the measurand; e.g., (1 to 10) V followed by (20 to 100) Hz, alternatively, the frequency modifier, in this case, could be listed in the Parameter column as AC Voltage, (20 to 100) Hz.

Particular care should be taken when reporting uncertainty as a percentage of the reading and having the lower limit of the range as 0. For example, if a range was “0 to 100 psi” or “Up to 100 psi”, the uncertainty can’t be “0.25% of reading” as the uncertainty at zero can’t be zero. The uncertainty would need to include a floor spec (e.g., “0.01 psi + 0.25% of reading”).

The parameters should be grouped together to allow a smooth flow of the discipline(s) being defined.

Expanded Uncertainty of Measurement

ANAB grants accreditation on a laboratory’s capability to make a measurement. This capability is defined in the scope of accreditation and that capability is further defined by the calibration and measurement capability (CMC) associated with that measurement capability. The uncertainty of measurement expressed as an expanded uncertainty in the proposed scope is may be defined as the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation. The uncertainty of measurement is expressed in, at most, two significant figures (digits).

The CMC displayed on the Client Proposed Scope of Accreditation must be achievable by the laboratory when calibrating a nearly ideal unit under test, and shall be supported or confirmed by experimental evidence. Note: The uncertainty budgets of the organization must support the CMC claimed by the applicant per ANAB AR 2251.

Reference Standard, Method, and/or Equipment

The remarks entry is to be used to define any useful information with respect to the measurement being provided by the laboratory, for example, type of equipment used in the calibration (not the manufacturer, type) and/or other relevant information useful for understanding the measurement capability of the laboratory. Detailed and specific notes should be added as comments under the table with footnote listed in the table if remarks column is not large enough to fully define any limitations or other noteworthy considerations associated with the parameter.

In the ANAB calibration scope of accreditation, notes are included at the end of the last table at a minimum, as follows:

- Calibration and measurement capability (CMC) is expressed in terms of the measurement parameter, measurement range, expanded uncertainty of measurement and remarks. The expanded uncertainty of measurement is expressed as the standard uncertainty of the measurement multiplied by a coverage factor of 2 (k=2), corresponding to a confidence level of approximately 95 %. This scope is formatted as part of a single document including Certificate of Accreditation No. AC-XXXX.
- Additional notes should be added as needed to clarify the information in the body of the scope.

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

REVISION HISTORY

Revision Level	Description
Original Release	Original release.
1	Modified the Mass major field name to include “and Mass Related.” Modified the scope example to align with the proposed scope template.

2	Under Calibration Scope of Accreditation, added language describing use of the terms “generate,” “source,” and “measure” in the parameter field of scopes.

ANNEX A. EXAMPLE OF CALIBRATION SCOPE OF ACCREDITATION

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Company Name
Street Address
City, State, Zip Code
Point of Contact (optional) Contact Phone Number (optional)
POC Email (optional) Web Site (optional)

CALIBRATION

Valid to: **Month dd, yyyy** Certificate Number: **AC-XXXX**

Length – Dimensional Metrology

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) [1]	Reference Standard, Method and/or Equipment
Calipers	(0 to 6) in	(60 + 3*L*) µin	Gage Blocks
Thread Plugs Pitch Diameter Major Diameter	 (4 to 80) tpi Up to 4 in	 (70 + 7*L*) µin (64 + 3*L*) µin	Thread Wires and ULM

Mass

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) [1]	Reference Standard, Method and/or Equipment
Indirect Verification of Rockwell Hardness Testers[1]	HRC Low Middle High	 0.32 HRC 0.36 HRC 0.4 HRC	ASTM E18

Electrical - DC/Low Frequency

Parameter / Equipment	Range	Expanded Uncertainty of Measurement (+/-) [1]	Reference Standard, Method and/or Equipment
AC Current - Source	**(22 to 220) µA** (10 to 20) Hz	0.7 nA/A + 25 nA	Multifunction Calibrator
	(20 to 40) Hz	0.36 nA/A + 20 nA	
	40 Hz to 1 kHz	0.14 nA/A + 16 nA	
	(1 to 5) kHz	0.6 nA/A + 40 nA	
	(5 to 10) kHz	1.6 nA/A + 80 nA	

Notes:

1. Calibration and Measurement Capability (CMC) is expressed in terms of the measurement parameter, measurement range, expanded uncertainty of measurement and remarks. The expanded uncertainty of measurement is expressed as the standard uncertainty of the measurement multiplied by a coverage factor of 2 (k=2), corresponding to a confidence level of approximately 95%.
2. On-site calibration service is available for this parameter; because on-site conditions are typically more variable than those in the laboratory, larger measurement uncertainties are expected on-site than what is reported on the accredited scope.
3. This scope is formatted as part of a single document including Certificate of Accreditation No. AC-XXXX.