



ACCLASS Guidance on Scopes of Accreditation

November 1, 2009

Table of Contents

Purpose.....	3
Definitions.....	3
ACLASS Recommended Practices.....	4
Testing Scope of Accreditation.....	5
Calibration Scope of Accreditation.....	5
Use of the International System of Units.....	6
Scopes of Accreditation Reporting Examples	7
ACLASS Scope of Accreditation	8
Uncertainty Issues.....	8
Scope of Accreditation Flexibility	8
References.....	10
APPENDIX A.....	11
APPENDIX B	12

Purpose

This guidance document is intended to assist both ACLASS assessors and ACLASS customers, both accredited and applicant laboratories, in drafting scopes of accreditation. The recommendations and guidance made here are intended to allow adherence to both ILAC guidance documents and ACLASS requirements, while helping to standardize formats across the range of potential accredited tests and calibrations in the sphere of ISO/IEC 17025 accredited operations.

While a laboratory's scope of accreditation is issued as an ACLASS document and published on the ACLASS 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.¹

It is hoped that this document will outline minimum requirements and set frameworks within which a laboratory may exercise some flexibility in its scope of accreditation, while still allowing ACLASS to meet all requirements set forth in ISO/IEC 17011 and by the international regional co-operations of which ACLASS maintains membership.

Definitions

Accreditation: Third-party attestation related to a laboratory conveying formal demonstration of its competence to carry out specific tasks. The process of verification of laboratory competence to ISO/IEC 17025 and the associated accreditation body requirements, resulting in the issuance of a certificate and scope of accreditation for a defined period of time listing all witnessed and approved tests and/or calibrations.

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. This document may range from a half page to dozens of pages depending on the list length, often with associated uncertainties.

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

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

¹ At the same time, however, it is understood that sometimes there is a need to cooperate with the accredited laboratory regarding terminology and formatting as long as such cooperation does not disadvantage the laboratory or the accreditation body who is striving for consistency and transparency in its operations.

ACLASS Recommended Practices

All scopes of accreditation for ACLASS should as best as possible abide by the following components and associated recommendations.

The scope of accreditation should consist of three main sections.

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

To assist applicant and accredited laboratories, including assessors, in drafting the scope of accreditation, ACLASS provides templates formatted with much of the necessary information.

In the header, there should be the full ACLASS logo, the full accredited laboratory name, the laboratory address, one or two contact persons for the laboratory, the main phone number for contacting the laboratory, the main category or categories of accreditation (calibration, testing, or both), the certificate number, and the expiration date of the certificate/accreditation (“Valid to” date).²

In the table of accredited items, the scope should have headers for each table section corresponding to the general fields of testing or calibration as found in ILAC guidance documents and the ACLASS ISO/IEC 17025 application for accreditation pages entitled “Calibration/Measurement (or Testing) Areas and Parameters.” These include:

For Calibration Scopes of Accreditation:

- Electromagnetic – DC/Low Frequency
- Electromagnetic – RF/Microwave
- Optical/Fiber-Optical Radiation
- Time and Frequency
- Thermodynamic
- Mechanical
- Dimensional
- Ionizing Radiation

For Testing Scopes of Accreditation:

- Acoustics and Vibration
- Biological or Microbiological
- Chemical
- Construction Material

² The full laboratory name and address is to be the physical location of the main laboratory location as identified by the laboratory and the official legal name of the laboratory.

- Dimensional Inspection/Measurement
- Electrical
- Environmental
- Mechanical (or Metallurgical)
- Non-Destructive
- Optical or Photometric or Radiometric
- Thermal

It should be noted that some of these general fields are multi-disciplinary and may have sub-categories or sub-disciplines. Some of these terms may become dividers in the accreditation scope with terms such as “EMC Testing” as part of Electrical Testing, “Ballistics Testing” as part of Mechanical Testing, or “Wastewater Testing” as part of Biological or Microbiological testing.³

The column headings within the table of accredited items should try to follow the calibration and/or testing scope template found in the ACLASS application for accreditation on the ACLASS website.

Testing Scope of Accreditation

As defined in ILAC guidance documents and ACLASS requirements, the following elements are recommended to be included in the scope table as a minimum for most testing laboratories, and these should be conveyed as best as possible in the column headings:

- a) identification of the group of products, materials, or items tested
- b) identification of the specific tests or types of tests performed
- c) identification of the specification, standard method, or technique used
- d) identification of the reference standards and key equipment used in the testing
- e) any additional information as practicable related to the range of testing or measurement, limits of detection, etc.
- f) associated uncertainties, if applicable

An example of a typical testing scope of accreditation is shown in Appendix A.

Calibration Scope of Accreditation

As defined in ILAC guidance documents and ACLASS requirements, the following elements are recommended to be included in the scope table as a minimum for most calibration laboratories, and these should be conveyed as best as possible in the column headings:

³ These sub-disciplines play a critical part in a laboratory PT/ILC program. The design of the PT/ILC coverage within the 4 year period needs to address every sub-discipline in the accredited scope. See the ACLASS guidance document on PT/ILC for further details.

- a) identification of the measuring instrument or type of instrument, measuring system, items or reference materials measured or calibrated
- b) identification of the specific calibrations performed (properties measured or the quantities measured)
- c) identification of the specification (where available), standard method or technique used
- d) identification of the specific ranges of measurement recognized
- e) identification of the Calibration and Measurement Capability (CMC) recognized, expressed as an uncertainty with the appropriate confidence levels
- f) identification of the measuring instruments, reference standards, and key accessories used to perform the calibrations
- g) any additional information as practicable such as equipment type or manufacturer

An example of a typical calibration scope of accreditation is shown in Appendix B.

As best as possible, each scope entry should add clarity to the test or calibration capabilities. For calibration scopes, this often means individual listings for line items that have a different or distinct CMC than another item or range of the measurand.

In the scope of accreditation footer, there will be two components, the footnotes (notes) and the approval signature. This section, by the way, is not to be confused with the page footer for all scopes which lists the ACLASS address, contact information, scope version number, and page numbers.

In the ACLASS scope of accreditation, there are already two or more footnotes included. These always include a reference to the scope accreditation number, which corresponds to the accreditation number found in the scope header and the certificate of accreditation. For calibration scopes, there should be a footnote that references the confidence level and k factor for the uncertainties. In addition, any of several other footnotes may be found in the footer including those giving clarification to abbreviations, such as lengths, diameters etc., highlighting tests or calibrations that may be performed in the field and/or in the laboratory, highlighting tests or calibrations performed at multi-site operations or remote laboratory locations with addresses of such, identification of possible contributors not included in CMC calculation, and others. If the laboratory has limited capabilities (less than the full scope of accreditation) either on-site or at satellite/remote sites, the footnotes should make it clear which are or are not available at those locations. This could be done with a statement, superscripts, or asterisks.

Use of the International System of Units

It is the policy of ACLASS to try as best as possible to follow the guidance of NIST 330 and 811 for the listing of all scope entries especially range values and uncertainty (CMC) numbers or expressions. This formatting guidance for the International System of Units (SI) is invaluable but not absolute in countless scope of accreditation listings. Laboratory representatives are encouraged to use this document in their drafts and confer with

ACLASS assessors and Accreditation/Program Managers whenever possible to avoid lengthy redrafts.

ACLASS scopes of accreditation are drafted to meet NIST 811, *Guide for the Use of the International System of Units (SI)*, as best as possible. This guide has been prepared by the National Institute of Standards and Technology (NIST) to assist those who may have need of such assistance in the use of the SI in their work, including the reporting of results of measurements. NIST 811 can be accessed on the ACLASS website at <http://aclasscorp.com/guidancedocs.cfm>

Scopes of Accreditation Reporting Examples

It is clear to those who work with electrical calibration scopes that many complicated listings are found. Combinations of parameters often are defined and traditional scope formats have often tried to separate parameters, one into the “Range” column heading and another still in the “Parameter” column heading. ACLASS attempts, whenever possible, to list in the Range column the primary parameter whose same units of measure are also listed in the uncertainty column. Often this is accomplished by listing, for example, AC voltage and current listings, the voltage or current left-aligned in the Range column and all the frequency ranges below it in the same column but all as centered entries.

Additionally, for most electromagnetic low frequency parameters, ACLASS attempts to use the standard terms on the scope of accreditation of “Source” and “Measure” whenever possible alongside voltage, current, resistance, power, etc. whether it be DC or AC parameters.

On testing scopes, ACLASS attempts, whenever possible, to list the test type and/or the sample type in the first or second column. For example, with chemical testing, the use of the sample matrix being tested or extracted for testing (e.g. soil, water, air, grease, wastewater, etc.) is the preferred descriptor. Of course, often there is a combination of matrices for many test procedures, and this can sometimes get complicated and lose its value.

One issue of confusion in scope categories is the overlap of thermodynamic and electrical calibrations related to temperature. The ACLASS policy for resolving this confusion is usually settled by determining whether there is any “dynamic” thermal operation during the calibration. If temperature indicators and controllers are being calibrated, for example, with the use of a multifunction calibrator, and the temperature is only being “simulated” via voltage or other parameter without the use of a temperature bath or chamber of any type, it is considered an electrical calibration. If, however, a bath or chamber is used and real temperatures are measured, it is considered thermodynamic.

ACCLASS Scope of Accreditation

All ACLASS customers are expected to draft an initial scope table listing as part of their application. They are then expected to utilize the ACLASS scope of accreditation templates to draft their accreditation scope document and submit it prior to the accreditation visit. They are encouraged to seek clarification as needed from their respective assessors or one of the ACLASS Accreditation/Program Managers.

ACCLASS assessors performing assessments are expected to verify and update as needed the respective scope of accreditation document during each assessment visit. At many assessments, a laboratory may expand or reduce its accredited scope. The lead assessor assumes the responsibility to update the scope of accreditation and submit it to ACLASS alongside the assessment report for review and approval.

Uncertainty Issues

It should also be noted that essentially all calibration scopes of accreditation will have a column heading of Calibration and Measurement Capability (CMC) or uncertainty, and that this uncertainty will be determined at roughly the 95% confidence level ($k=2$) unless noted otherwise and footnoted. It should also be noted that many testing laboratories' scopes of accreditation may need and have uncertainty column headings as well. In the case of testing laboratories, the term Best Measurement Capability (BMC) will be used. For a determination on those testing scopes that have such requirements, readers are referred to the ACLASS Guidance on Uncertainty for Testing Laboratories.

The calculation of uncertainties, as CMCs or BMCs, for any scope of accreditation is presumed to follow the ISO Guide to the Expression of Uncertainty in Measurement (GUM) or NIST 1297 guidance and practices. The calculations and considerations of all relevant factors potentially contributing to measurement variability and “nearly ideal” calibrations are collectively considered the “uncertainty budget.” It is ACLASS policy to retain a copy of all uncertainty budgets for all accredited scope items for each customer. These need to be provided to the ACLASS assessors at assessment visits if they have not already been sent to the ACLASS office.

Scope of Accreditation Flexibility

The level of detail on a scope of accreditation is often a balance between generic methods used and the precise day-to-day requirements of all the sample types, device types, customer requirements, and technology advances encountered. ILAC has published ILAC G18: 2002, “The Scope of Accreditation and Considerations of Method and Criteria for the Assessment of the Scope in Testing,” a guidance document that reviews aspects of the flexibility warranted in the scopes of accreditation. In short, ACLASS abides by this guidance.

Often, in areas such as NDT, EMC, and chemical testing, laboratories may need to modify or amplify more generic methods in order 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 along with the freedom to modify their previous methods. This still obligates the affected laboratories to maintain customer awareness and agreement with the modified methods and assure adherence with the ISO/IEC 17025 requirements for method validation in accordance with section 5.4 of that standard. Laboratories in this situation will be witnessed and assessed for these capabilities.

References

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC 17011:2004, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

ISO GUM, 1995, *Guide to the Expression of Uncertainty in Measurement*, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, and OIML

NISTIR 811, 1995, *Guide for the Use of the International System of Units (SI)*

NISTIR 330, 2001, *The International System of Units (SI)*

NIST TN 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*

ILAC G-4:1994. *Guidelines on Scopes of Accreditation* - (used as a guide. Precedes ILAC G-18:2002)

ILAC G-18:2002, *The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing* (supersedes ILAC G-4.)

EA-4/02, 2002, *Expression of the Uncertainty of Measurement in Calibration*

APPENDIX A - Example of ACLASS Scope of Accreditation: Testing

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

ZYX Test Labs, Inc.

Street Address – City, State Zip Code
 Contact Name Phone: 555-555-5555

TESTING

Valid to: Certificate Number: AT – xxxx

I. Chemical

ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*DETECTION LIMIT/RANGE/EQUIPMENT
Antimicrobial Adhesive	Quantitation of Adhesive	USP<197> USP<851> And customer equivalent	UV/Visible Spectrophotometer
Metered Dose Inhaler (MDI)	Particle Size	USP<601> And customer equivalent	Andersen Cascade Impactor
Tap Water	Total Organic Carbon	USP<643>	Total Organic Carbon Analyzer

II. Microbiological

ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	*DETECTION LIMIT/RANGE/EQUIPMENT
Water for Pharmaceutical Purpose, Purified Water	Aerobic Plate Count, E.coli, Pseudomonads	USP<1231> Membrane Filtration	N/A
Cream, Gel, Lotion	Bioburden	USP<61>	N/A

Notes:

1. * = As Applicable
2. This scope is part of and must be included with the Certificate of Accreditation No. AT-xxxx

APPENDIX B - Example of ACLASS Scope of Accreditation: Calibration

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Calibration Unlimited, Inc.

Street Address – City, State Zip Code
 Contact Name Phone: 555-555-5555

CALIBRATION

Valid to: Certificate Number: AC – xxxx

I. Dimensional

PARAMETER/ EQUIPMENT	RANGE	CALIBRATION AND MEASUREMENT CAPABILITY [EXPRESSED AS UNCERTAINTY(+)]	REFERENCE STANDARD OR EQUIPMENT	METHODS
Calipers ³	Up to 24 in	(0.6R +12L) μin	Grade 2 Gage Blocks	OEM and GIDEP Sourced Procedures
Cylindrical O.D. ³	(0.01 to 1.15) in	30 μin	Mitutoyo LSM XXX Set Plugs	

II. Mechanical

PARAMETER/ EQUIPMENT	RANGE	CALIBRATION AND MEASUREMENT CAPABILITY [EXPRESSED AS UNCERTAINTY(+)]	REFERENCE STANDARD OR EQUIPMENT	METHODS
Force Tension ³	Up to 60 lbf (60 to 600) lbf	0.01 lbf 0.06 % of reading	Class F Weights Lebow 3136-600	OEM and GIDEP Sourced Procedures
Torque Standards	(1 to 500) in-oz (30 to 2 000) in-lb (150 to 1 000) ft-lb	0.1 in-oz 0.03 in-lb 0.05 ft-lb	Torque Wheel w/ Class F Weights Torque Arm w/ Class F Weights	
Torque Wrenches	(10 to 200) in-oz	0.58 % of reading + 0.6R	Lebow 2120-200	

PARAMETER/ EQUIPMENT	RANGE	CALIBRATION AND MEASUREMENT CAPABILITY [EXPRESSED AS UNCERTAINTY(±)]	REFERENCE STANDARD OR EQUIPMENT	METHODS
Scales / Balances ³	(5 to 150) lb (150 to 600) lb (600 to 2 000) lb	0.07 lb 0.15 lb 1.64 lb	Class F Weights	OEM and GIDEP Sourced Procedures

Notes:

1. Calibration and Measurement Capabilities (Expanded Uncertainties) are based on approximately a 95% confidence interval, using a coverage of $k=2$.
2. This laboratory's capabilities include both in-laboratory and on-site calibration services. Since 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. On-site calibration service is available for this calibration
4. The term (L) represents Length in inches and (R) represents Resolution of the unit under test.
5. This scope is part of and must be included with the Certificate of Accreditation No. AC – xxxx.