
	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 1 of 12

R205: SPECIFIC REQUIREMENTS: CALIBRATION LABORATORY ACCREDITATION PROGRAM


December 2011

© 2011 by A2LA

All rights reserved. No part of this document may be reproduced in any form or by any means without the prior written permission of A2LA.

	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 2 of 12

R205: SPECIFIC REQUIREMENTS: CALIBRATION LABORATORY ACCREDITATION PROGRAM.....	1
I. DESCRIPTION OF THE CALIBRATION PROGRAM.....	3
1.0 SCOPE.....	3
2.0 REFERENCES	3
3.0 DEFINITIONS.....	4
4.0 DESCRIPTION.....	4
4.1 <i>Application for accreditation</i>	4
4.2 <i>Measurement traceability</i>	5
4.3 <i>Uncertainty of Measurement to support the scope of accreditation</i>	5
4.4 <i>Proficiency testing</i>	6
4.5 <i>Use of the A2LA logo and advertising policy</i>	6
4.6 <i>Dimensional testing parameters on scope of accreditation</i>	6
II. REQUIREMENTS FOR CALIBRATION ACCREDITATION	6
1.0 GENERAL REQUIREMENTS.....	6
2.0 SPECIFIC REQUIREMENTS	7
3.0 REQUIREMENTS FOR FIELD CALIBRATION ACCREDITATION.....	10
4.0 REQUIREMENTS SPECIFIC TO ANSI/NCSL Z540-1-1994 - OPTIONAL.....	10
5.0 REQUIREMENTS FOR ANSI/NCSLI Z540.3-2006 OPTIONAL REQUIREMENTS.....	12

	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
	Page 3 of 12	

I. Description of the Calibration Program

1.0 Scope

- 1.1 This document describes the requirements for calibration laboratories seeking A2LA accreditation. The calibration program is based on ISO/IEC 17025-2005, *General requirements for the competence of calibration and testing laboratories*.

Calibration laboratories may also be accredited to the American national standard ANSI/NCSL Z540-1-1994 Part I as an optional accreditation. However, where a Z540-1 requirement differs from a 17025 requirement, or a requirement set forth in this document, the more stringent requirement will apply.

2.0 References

P101 – Reference to A2LA Accredited Status-A2LA Advertising Policy.

P109 – Technical Consensus Decisions from the Measurement Advisory Committee (MAC).

P110 - A2LA Policy on Measurement Uncertainty.

R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories.

P102 – A2LA Policy on Measurement Traceability.

R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories.

R104 – General Requirements: Accreditation of Site Testing and Site Calibration Laboratories.

APLAC TC 004 12/06: Method of Stating Test and Calibration Results and Compliance with Specifications

ANSI/ISO/ASQ Q9000:2000, Quality management systems – Fundamentals and vocabulary.


ANSI/NCSL Z540-1-1994, Part I, Calibration Laboratories and Measuring and Test Equipment- General Requirements.

ANSI/NCSL Z540-2-1997, U.S. Guide to the Expression of Uncertainty in Measurement.

BIPM/IEC/ISO/OIML, International vocabulary of basic and general terms in metrology (VIM): 2007.

ILAC, 2009, 2009-08-20_BMC to CMC Circular

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

	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 4 of 12

ILAC-P8:07/2006, *ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories*

ILAC P10:2002, *ILAC Policy on Traceability of Measurement Results.*

ILAC P14:11/2010 *ILAC Policy for Uncertainty in Calibration*

ILAC G8:03/2009, *Guidelines on Assessment and Reporting of Compliance with Specification.*

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

ISO/IEC 17000: *Conformity assessment – Vocabulary and general principles.*

ISO/IEC 17043:2010 - Conformity assessment -- General requirements for proficiency testing.

NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, Taylor, Barry N., Kuyatt, Chris E., U.S. Government Printing Office, Washington, D.C., 1993.

UKAS, *The Expression of Uncertainty and Confidence in Measurement* (M3003), 2007.

3.0 Definitions


3.1 For the purpose of these Requirements, the relevant terms and definitions given in ISO/IEC 17000 and the VIM apply. General definitions related to quality are given in Q9000, whereas ISO/IEC 17000 gives definitions specifically related to standardization, certification and laboratory accreditation. Where different definitions are given in Q9000, the definitions in ISO/IEC 17000 and VIM are preferred.

4.0 Description

4.1 Application for accreditation

4.1.1 To apply for A2LA accreditation in the field of Calibration, the applicant must complete *F101 - Application for Accreditation: ISO/IEC 17025 Laboratories*, which is available from A2LA (www.A2LA.org). A complete application for accreditation contains the following:

- a) Complete laboratory information as requested on page 6 and 7 of the application;
- b) A signed Conditions for Accreditation form (pages 8 and 9 of the application);
- c) Complete supporting information requested on page 10 and 11 of the application including organizational charts, all relevant proficiency testing information, and a list of standards

	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 5 of 12

used to support the calibrations for which accreditation is sought and which indicates the calibration source for each standard;

- d) A completed technical staff matrix as requested on page 12 of the application;
 - e) A completed fee schedule as requested on page 13 of the application;
 - f) A completed *F204 – Scope of Accreditation Selection List: Calibration Laboratories* defining the calibrations for which accreditation is sought.
 - g) Complete uncertainty budgets to support the claimed uncertainties for the calibrations listed in the completed selection list (see Section 4.3);
 - h) A completed *C207 – Specific Checklist: Calibration Laboratory Accreditation Program* which includes references to the quality system documentation where required.
- 4.1.2 Assessor assignments will not normally be made for incomplete applications. The applicant will be notified that the application is incomplete and required information will be requested. Once the application is complete, an appropriate assessor or team of assessors will be assigned.

4.2 Measurement traceability

- 4.2.1 Detailed information concerning measurement traceability and specific requirements pertaining to measurement traceability can be found in A2LA's *P102 – A2LA Policy on Measurement Traceability*.


4.3 Uncertainty of Measurement to support the scope of accreditation

- 4.3.1.1 For each measurement parameter and associated range(s), the laboratory shall provide with the application an uncertainty budget showing how the claimed Calibration and Measurement Capability (CMC) was derived. The assumptions made for the determination of the uncertainty budgets, if any, must be specified and documented. A2LA accredited and enrolled calibration laboratories shall calculate measurement uncertainties using the method detailed in the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM)¹, *GUM supplement documents and/or ISO Guide 35 (as applicable²)*. In accordance with international convention, CMCs listed on A2LA scopes of accreditation will usually represent expanded uncertainties expressed at approximately the 95% level of confidence using a coverage factor of $k = 2$.

- 4.3.1.2 As defined in ILAC P14:11/2010, Section 3.2, the *Calibration and Measurement Capability* is "a calibration and measurement capability available to customers under normal conditions, as described in the laboratory's scope of accreditation granted by a signatory to the ILAC

¹ Guidance documents based on the GUM include Expression of the Uncertainty of Measurement in Calibration, NIST Technical Note 1297, and UKAS M3003, The Expression of Uncertainty and Confidence in Measurement, 2007.

² ILAC P14:11/2010 *ILAC Policy for Uncertainty in Calibration*

	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
	Page 6 of 12	

Arrangement; or as published in the BIPM key comparison database (KCDB) of the CIPM MRA.”

4.3.1.3 CABs shall also meet all additional requirements as found in the A2LA Measurement Advisory Committee (MAC) consensus document *P109 - Technical Consensus Decisions from the Measurement Advisory Committee (MAC)*.

4.3.2 Uncertainty budgets shall be reviewed and approved by A2LA before a laboratory is granted accreditation.

4.3.3 Calibration laboratories can be accredited for the calibration or verification of testing machines to industry tolerances. The industry standard shall be referenced on the scope of accreditation. Calibration laboratories accredited for such verifications must still calculate measurement uncertainties in accordance with the GUM. The uncertainty calculations shall be documented in an uncertainty budget that will be reviewed and approved by A2LA prior to accreditation.

4.4 Proficiency testing

4.4.1 See *R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories* and the associated *R103a – Annex: Proficiency Testing for ISO/IEC 17025 Laboratories* for proficiency testing requirements for calibration laboratories.

4.5 Use of the A2LA symbol and advertising policy

4.5.1 See *P101 – Reference to A2LA Accredited Status-A2LA Advertising Policy* (Section XIII of the “General Requirements for Accreditation of Laboratories”).

4.6 Dimensional testing parameters on scopes of accreditation


4.6.1 Refer to *R205c: Annex - Specific Requirements: Dimensional Testing Parameters on Scopes of Accreditation*.

II. Requirements for Calibration Accreditation

1.0 General Requirements

1.1 Calibration laboratories shall comply with all applicable requirements of ISO/IEC 17025:2005 and A2LA’s *R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories*.

1.2 Calibration laboratories seeking accreditation to ANSI/NCSL Z540-1-1994 shall also comply with the applicable requirements of that Standard. See Section 4.0 for Z540-1 requirements not found in ISO/IEC 17025 or these Requirements.

	American Association for Laboratory Accreditation	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 7 of 12

1.3 See Section 3.0 for requirements pertaining to accreditation of calibrations performed in the field. Accredited field calibrations shall be identified on the scope of accreditation.

2.0 Specific Requirements

2.1 In addition to the requirements of ISO/IEC 17025 the following requirements shall be satisfied by all calibration laboratories:

2.1.1 Calibration intervals for each measuring instrument or standard shall be established to control the probability of calibrations being out-of-tolerance at the end of the calibration interval. The method used to establish and adjust intervals shall be documented and based upon a determination of the standard's performance. Equipment records shall include the measured value for each parameter found to be out of tolerance during calibration or verification.


2.1.2 Where an intrinsic standard or system is used as a standard, the following requirements apply:

- a) direct intrinsic standard or system-to-intrinsic standard or system comparison with NIST or an accredited laboratory shall be conducted at appropriate intervals to ensure the correct realization of the measurand;
- b) documented calibration history of the device used to measure differences between intrinsic standard or system and unknown values shall be maintained;
- c) documented calibration history of the intrinsic standard or system components (e.g., the time base of the reference frequency counter in a Josephson voltage array system) shall be maintained;
- d) documented evidence of periodic checks on system precision and stability (e.g., leakage currents, ground loops, thermal emf's, step integrity, trapped magnetic flux, noise, and microwave power impinging on a Josephson voltage array) shall be maintained.

Note: For those laboratories using saturated salt solutions for the purposes of traceability, those solutions mixed on demand from reagent grade salts and distilled water may be treated as comparable to an intrinsic standard. In these instances, the laboratories are not required to meet item (a) as listed above, but must be able to provide evidence of meeting (b) through (d).

2.1.3 Accredited (endorsed) calibration certificates and reports (Note: Items in italics are taken directly from ILAC P14:11/2010 *ILAC Policy for Uncertainty in Calibration*)


- a) *Accredited calibration laboratories shall report the uncertainty of measurement, in compliance with the requirements of this document.*
- b) *The measurement result shall normally include the measured quantity value y and the associated expanded uncertainty U . In calibration certificates the measurement result should be reported as $y \pm U$ associated with the units of y and U . Tabular presentation of*

	American Association for Laboratory Accreditation	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 8 of 12

the measurement result may be used and the relative expanded uncertainty $U / |y|$ may also be provided if appropriate. The coverage factor and the coverage probability shall be stated on the calibration certificate. To this an explanatory note shall be added, which may have the following content:

“The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %.”

- c) *For asymmetrical uncertainties other presentations than $y \pm U$ may be needed. This concerns also cases when uncertainty is determined by Monte Carlo simulations (propagation of distributions) or with logarithmic units.*
- d) *The numerical value of the expanded uncertainty shall be given to two significant figures and in the final statement the numerical value of the measurement result shall always be rounded up.*
- e) *Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer’s device. Where applicable the uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except that uncertainty components evaluated for the best existing device shall be replaced with those of the customer’s device. Therefore, reported uncertainties tend to be larger than the uncertainty covered by the CMC. Random contributions that cannot be known by the laboratory, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory anticipates that such contributions will have significant impact on the uncertainties attributed by the laboratory, the customer shall be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.*
- f) *The uncertainty of reported measurements shall be stated as the actual uncertainty of the measurement, not as the accredited CMC unless that CMC actually applies.*
- g) *An indiscriminate use of the CMC listed on the A2LA scope of accreditation as the uncertainty of an actual calibration is not justified.*
- h) *As the definition of CMC implies, accredited calibration laboratories shall not report a smaller uncertainty of measurement than the uncertainty of the CMC, as stated on a Calibration laboratory’s Scope of Accreditation, for which the laboratory is accredited.*
- i) *Laboratories are permitted to issue certificates with a statement of compliance (i.e., conformance to a specification) relating to the metrological aspects of specifications. In such cases the laboratory shall ensure that:*
 - 1) *the specification is a national or international standard or one that has been agreed to or defined by the customer;*

	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 9 of 12

- 2) the measurements needed to determine conformance are within the accredited scope of the laboratory;
- 3) when parameters are certified to be within specified tolerance, the associated uncertainty of the measurement result is properly taken into account with respect to the tolerance by a documented procedure or policy implemented by the laboratory that defines the decision rules used by the laboratory for declaring in or out of tolerance conditions³;
- 4) when parameters are certified to be within specified tolerance, the associated uncertainty of the measurement is recorded and maintained for future reference;
- 5) the certificate relates only to metrological quantities and states which clauses of the specification are certified to have been met.


2.1.4 Method or parameter observation during an assessment

- a) At a minimum, all of the parameters or all of the method(s) on the draft scope of accreditation must be observed by the assigned assessor during the assessment at least once in a four-year period.
- b) If a parameter or method is not observed by the assigned assessor within a four-year period, that method or parameter will be removed from the scope of accreditation until such a time as it can be observed.
- c) If a laboratory can demonstrate successful participation in a commercially available proficiency test or a well organized inter-laboratory comparison that meets the requirements of 17043 ***at the level of uncertainty being claimed on the draft scope of accreditation*** the laboratory may rely on this demonstration in lieu of an observed parameter during the assessment.
- d) In cases where it is not possible to observe a parameter or method an exception request may be submitted to A2LA for consideration.

Note 1: Equipment out for repair or calibration is not sufficient reason to grant an exception request.

Note 2: Exception requests granted by A2LA are only granted until the next renewal assessment.

³ The default decision rule is found in ILAC-G8:1996, *Guidelines on Assessment and Reporting of Compliance with Specification*, section 2.5. With agreement from the customer, other decision rules may be used as provided for in this section of the Requirements.

	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 10 of 12

3.0 Requirements for Field Calibration Accreditation

3.1 Refer to *R104 – Specific Requirements: Accreditation of Field Testing and Field Calibration Laboratories*.

4.0 Requirements Specific to ANSI/NCSL Z540-1-1994 - Optional

In addition to the requirements of ISO/IEC 17025, the following are the requirements of Z540-1 not found in ISO/IEC 17025 or otherwise addressed in these Requirements. The numbering of these additional requirements follows the numbering of Z540-1. Italic type is used to indicate where Z540-1 differs from ISO/IEC 17025 in otherwise similar requirements.

5.2 h) The quality manual and related quality documentation shall contain the laboratory's scope of calibrations.

5.4 The quality system adopted to satisfy the requirements of this Standard shall be reviewed *at least once a year* by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.


10.2 a) Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.

10.4 Where it is necessary to employ methods that have not been well-established, these shall be subject to agreement with the customer, be fully documented and validated, and be available to the customer *and other recipients of the relevant reports*.

11.5 Tamper-resistant seals shall be affixed to operator accessible controls or adjustments on measurement standards or measuring and calibration equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.


13.2 Each certificate or report shall include at least the following information⁴:

⁴ Many of these items are included in 17025, but to eliminate the possibility of confusion, section 13.2 of Z540-1 is reproduced here in its entirety.

	<i>American Association for Laboratory Accreditation</i>	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 11 of 12

- a) a title, e.g. "Calibration Report", or "Calibration Certificate";
- b) name and address of laboratory, and location where the calibration was carried out if different from the address of the laboratory;
- c) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;
- d) name and address of customer, where appropriate;
- e) description and unambiguous identification of the item calibrated;
- f) characterization and condition of the calibration item;
- g) date(s) of performance of calibration where appropriate;
- h) identification of the calibration procedure used, or unambiguous description of any non-standard method used;
- i) reference to sampling procedure, where relevant;
- j) any deviations from, additions to or exclusions from the calibration method, and any other information relevant to a specific calibration, such as environmental conditions;
- k) measurements (including where applicable "as found" data), examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;
- l) a statement of the estimated uncertainty of the calibration results (where relevant);
- m) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;
- n) where relevant, a statement to the effect that the results relate only to the items calibrated;
- o) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.
- p) special limitations of use; and
- q) traceability statement.

13.6 b) The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out-of-tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.

	American Association for Laboratory Accreditation	
	R205: Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: December 8, 2011
		Page 12 of 12

14.1 Where a laboratory sub-contracts any part of the calibration, *this work shall be placed with a laboratory complying with the requirements of this Standard [ANSI/NCSL Z540-1-1994].* The laboratory shall ensure and be able to demonstrate that its sub-contractor is competent to perform the activities in question *and complies with the same criteria of competence as the laboratory with respect of the work being sub-contracted.*

16.2 Where a complaint, or any other circumstance, raises a concern regarding the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Standard or otherwise concerning the quality of the laboratory's calibrations, the laboratory shall ensure that complaints in those areas of activity and responsibility involved *are promptly resolved.*

5.0 Requirements for ANSI/NCSLI Z540.3-2006 Optional Requirements

5.1 Refer to *R205a: Annex to Specific Requirements: ANSI/NCSLI Z540.3-2006.*

Document Revision History

Date	Description
December 8, 2011	Removed “as of December 1, 2011” from section 4.7; combined sections 4.7 and 2.1.3; added section 4.6 to the table of contents; added “is recorded and maintained for future reference” in section 2.1.3.i.3; changed “measurement result” to “measurement uncertainty” in section 2.1.3.d.