

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18 Page 1 of 29

R205 - SPECIFIC REQUIREMENTS: CALIBRATION LABORATORY ACCREDITATION PROGRAM

2018

© 2018 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.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 2 of 29

Table of Contents

1.0 INTRODUCTION 3

2.0 POLICIES..... 3

3.0 GENERAL CRITERIA 3

4.0 SPECIFIC CRITERIA..... 4

5.0 PROFICIENCY TESTING..... 4

6.0 CALIBRATION PROGRAM CRITERIA 4

6.1 TECHNICAL DECISIONS4

6.2 CALIBRATION INTERVALS4

6.3 ACCREDITED CALIBRATION CERTIFICATES5

6.4 STATEMENTS OF COMPLIANCE5

6.5 METHOD OR PARAMETER OBSERVATION DURING AN ASSESSMENT6

6.6 REVIEW OF CALIBRATION CERTIFICATES7

6.7 REQUIREMENTS FOR CMC UNCERTAINTY CALCULATIONS ON THE SCOPE OF
ACCREDITATION.....8

 6.7.1 CMC Uncertainty Contributors.....8

 6.7.2 Deficiencies and Implementation.....8

 6.7.3 General Considerations.....9

6.8 SCOPES OF ACCREDITATION..... 10

7.0 APPENDICES..... 12

APPENDIX A: ANSI/NCSL Z540-1-1994 REQUIREMENTS (OPTIONAL)12

APPENDIX B: ANSI/NCSL Z540.3-2006 REQUIREMENTS (OPTIONAL)14

APPENDIX C: DUROMETER REQUIREMENTS (OPTIONAL).....19

APPENDIX D: DIMENSIONAL TESTING REQUIREMENTS (OPTIONAL)20

APPENDIX E: EXCERPTS FROM ILAC POLICY FOR UNCERTAINTY IN CALIBRATION ILAC–
P14:01/201321

8.0 DEFINITIONS 25

CIPM MRA.26

9.0 REFERENCES..... 27

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18 Page 3 of 29

1.0 INTRODUCTION

These accreditation requirements are applicable to laboratories applying within the general A2LA Field of Calibration. The Calibration field includes measurements typically conducted by standards and calibration laboratories for a variety of measurement quantities. This program is applicable to all types of calibration laboratories, including those that calibrate reference standards as well as measuring and test equipment (M&TE).

In addition, with the publication of the American National Standard ANSI/NCSL Z540, A2LA offers the option of including **ANSI/NCSL Z540-1** in a calibration laboratory's accreditation, particularly in cases where a laboratory's customers require it. A2LA also offers the option of including **ANSI/NCSL Z540-3** in a calibration laboratory's accreditation, particularly for those seeking to meet the requirements of the United States Navy and NASA. See APPENDIX A and B of this document for more information.

2.0 POLICIES

A2LA has developed policies for all of its accredited laboratories related to measurement traceability, measurement uncertainty and references to accredited status. The following policies apply to the field of Calibration:

- Measurement Traceability:
[P102 - A2LA Policy on Metrological Traceability](#)
- References to Accredited Status:
- *R105 – Requirements When Making Reference to A2LA Accredited Status*
- Measurement Uncertainty: See section 6.0 of this document for both the measurement uncertainty that supports the scope of accreditation and for the uncertainty reported to the customer.
- *P112 – A2LA Flexible Scope Policy* (when applicable)

3.0 GENERAL CRITERIA

The general criteria for accreditation within the field of Calibration are contained in ISO/IEC 17025:2017, or ISO/IEC 17025:2005, “General requirements for the competence of calibration and testing laboratories”. All provisions of these general criteria and the requirements outlined in [R101 - General Requirements: Accreditation of ISO/IEC 17025 Laboratories](#) apply under this field.

Any laboratory performing calibrations in the field (i.e., at other than a permanent laboratory site) may seek accreditation for this field work. In these cases, A2LA has developed additional general criteria for laboratories performing tests in the field. These requirements may be found in [R104 - General Requirements: Accreditation of Field Testing and Field Calibration Laboratories](#).

Calibration laboratories may also be accredited to the American national standard ANSI/NCSL Z540-1-1994 Part I and/or ANSI/NCSLI Z540.3-2006 as an optional accreditation. However, where a Z540-1 or Z540.3 requirement differs from a 17025

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18 Page 4 of 29

requirement, or another A2LA Policy or Requirement, the more stringent requirement will apply.

4.0 SPECIFIC CRITERIA

The A2LA Measurement Advisory Committee (MAC) has developed consensus decisions related to calibration and dimensional testing which apply to the field of Calibration. The relevant consensus decisions are contained in A2LA [P109 - Technical Consensus Decisions from the Measurement Advisory Committee \(MAC\)](#) Where applicable, A2LA assessors will examine a Calibration laboratory's practices to ensure compliance with these consensus decisions.

5.0 PROFICIENCY TESTING

The general proficiency testing requirements for all ISO/IEC 17025 accredited laboratories are contained within [R103 - General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories - 2013 \(pdf\)](#). Additional requirements related specifically to the field of Calibration may be found in [R103a - Annex: Proficiency Testing for ISO/IEC 17025 Laboratories](#).

6.0 CALIBRATION PROGRAM CRITERIA

The additional criteria for accreditation of calibration laboratories are:

6.1 Technical Decisions

The final decision on technical matters is made by A2LA. See A2LA *R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories* for information on appeals.

6.2 Calibration Intervals

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 method¹ 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.

¹ See NCSL International *RP-1: Establishment and Adjustment of Calibration Intervals* and [ILAC G24:2007 Guidelines for the determination of calibration intervals of measuring instruments](#) for more information.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 5 of 29

6.3 Accredited Calibration Certificates

- 1) The laboratory shall meet the requirements of [ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration](#) section 6.1 to 6.5.

By exception, where it has been documented during contract review that:

- Only a statement of compliance with a specification is required; and
- That the reference standard or test and measuring equipment will not be used to calibrate another device; and
- That the calibration certificate is not intended to be used in support of the further dissemination of metrological traceability (i.e. to calibrate another device);

Then the measured quantity value and the measurement uncertainty may be omitted on the calibration certificate, however the requirements found section 6.4 of this document apply.

- 2) Section 6.3 of ILAC-P14:01/2013 may be precluded by legal, regulatory or contractual requirements.
- 3) An indiscriminate use of the CMC listed on the A2LA scope of accreditation as the uncertainty of an actual calibration is not justified.

6.4 Statements of Compliance

Laboratories are permitted to issue certificates with a statement of compliance (e.g., 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;
- 2) the measurements needed to determine conformance are within the accredited scope of the laboratory;
- 3) when parameters are verified 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 conditions;
- 4) the laboratory shall ensure the decision rule used meets the needs of the customer²;

² See ILAC-G8:2009, *Guidelines on Assessment and Reporting of Compliance with Specification*, JCGM 106:2012, *The role of measurement uncertainty in conformity assessment*, ISO/TR 14253-
Footnote continued on next page

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 6 of 29

- 5) when parameters are verified to be within specified tolerance, the calibration laboratory shall determine the uncertainty and take that uncertainty into account when issuing the statement of compliance. In addition, no claim of compliance shall be made when the measurement uncertainty is larger than the tolerance being evaluated.

An exception can be made only in cases where the laboratory indicates in the contract with the client that the calibration results will be reported without factoring in the effect of uncertainty on the assessment of compliance, and the client agrees to the contract.

In this case the uncertainty can be excluded when making that statement of compliance on the calibration certificate. In effect, both parties share the risk that the results may or may not meet the specification since the uncertainty was not included when the results were determined. In these cases, the measurement uncertainty shall still be determined and shall be reported on the calibration certificate.

- 6) In accordance with [ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration](#) section 6.1, the calibration laboratory shall retain documentary evidence of the measured quantity value and the uncertainty of measurement, as specified in ISO/IEC 17025:2005 clauses 5.10.4.2 and 4.13, or ISO/IEC 17025:2017 clause 7.8.4 clause , and shall provide such evidence upon request.
- 7) The certificate relates only to metrological quantities and states which clauses of the specification are verified to have been met.

6.5 Method or Parameter Observation During an Assessment

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.

- 1) 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.
- 2) If a laboratory can demonstrate successful participation in a commercially available proficiency test or a well-organized inter-laboratory comparison that meets the

6:2012, *Generalized decision rules for the acceptance and rejection of instruments and workpieces*, ISO 14253-1:1998, *Decision rules for proving conformance or non-conformance with specifications*, ASME B89.7.3.1-2001, *Guidelines for decision rules: considering measurement uncertainty in determining conformance to specifications* for guidance.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 7 of 29

requirements of ISO/IEC 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.

- 3) 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.

6.6 Review of Calibration Certificates

The laboratory shall have and shall implement a procedure for issuing accredited (endorsed) calibration certificates. The procedure shall ensure that these calibration certificates are evaluated for compliance with ISO/IEC 17025 and A2LA requirements before being issued to the customer including (but not limited to):

- Review of items required from the contract (e.g. method agreed on, indication of limited calibration when applicable, provision of data, accredited symbol etc.);
- Inclusion of before and after data when the instrument requires adjustment or repair;
- Identification of sub-contracted results and/or non-accredited results (e.g. those not included in the scope of accreditation);
- The measurement uncertainty is not smaller than the CMC claim on the scope of accreditation.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 8 of 29

6.7 Requirements for CMC Uncertainty Calculations on the Scope of Accreditation

6.7.1 CMC Uncertainty Contributors

1) Every CMC uncertainty shall take into consideration the following standard contributors, even in cases where they are determined to be insignificant, and documentation of the consideration shall be made:

- Repeatability (Type A)³
- Resolution
- Reproducibility
- Reference Standard Uncertainty
- Reference Standard Stability
- Environmental Factors

Note: It should be noted that scope components such as resolution, may also contribute to other components such as repeatability. Therefore, simply combining all components on an equal basis could result in an overstatement of the measurement uncertainty.

2) The CMC uncertainty shall also:

- Include those significant contributors that apply to the measurement.
- Include those significant contributors required by a method/procedure associated with the measurement.

For Guidance on uncertainty contributors for electrical parameters on the scope of accreditation see A2LA [G110 - Guidance on Uncertainty Budgets for Electrical Parameters](#).

6.7.2 Deficiencies and Implementation

1) For those uncertainty records documented after implementation of this policy (implementation as of January 1, 2012), including those revisions to existing records, a deficiency shall be written where objective evidence demonstrates that this policy has not been met.

2) For those measurement uncertainty records documented prior to implementation of this policy (before January 1, 2012), a deficiency shall only be written:

- a) Where objective evidence reveals a “standard” contributor to be significant and is not documented and/or;

³ As required by ILAC-P14:01/2013 section 5.4.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 9 of 29

- b) Where objective evidence demonstrates any other contributor to be significant and is not documented and/or;
- c) Where the statistical analysis is not in accordance with the GUM.

Note: “standard” and “significant” as defined in section 4.1 of this document.

6.7.3 General Considerations

- 1) The data from which the origin of the CMC uncertainty was determined shall be documented and the assumptions made for the determination of the uncertainty shall be specified and documented.
- 2) The statistical analysis shall be in accordance with the *Guide to the Expression of Uncertainty in Measurement* (GUM)⁴.
- 3) The laboratory shall meet the requirements of [ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration](#), section 4.2, 5.3, and 5.4.
- 4) **The exclusion of the uncertainty from the “best existing device” is allowed under the following conditions:**
 - a) Documentation of the contribution to the CMC from the device shall be included as part of the record of CMC calculation.
 - b) Documentation of the justification for the exclusion of the contribution of the “best existing device” from the CMC shall be included as part of the record of the CMC calculation.
 - c) The scope of accreditation shall contain a footnote that clearly identifies that the contributions to the uncertainty from the device are not included.

Example Footnote1: “The contributions from the “best existing device” are not included in the CMC claim.”

Example Footnote2: “The CMC for this Parameter/Equipment applies for performance verification of the “best existing” device under test and not for the assignment of reference values, and therefore certain characteristics of the “best existing” device under test (e.g. resolution) are not included in this CMC estimate.”

⁴ BIPM JCGM 100:2008, *Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM 1995 with minor corrections)*.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 10 of 29

6.8 Scopes of Accreditation

1) The laboratory shall meet the requirements of [ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration](#) section 5.1 to 5.4.

2) Organizations are not permitted to claim a Calibration and Measurement Capability (CMC) on their scope of accreditation that is smaller than the CMC claimed by the National Metrology Institute (as stated in the key comparison database listed on the BIPM website) through which traceability is achieved unless allowance is made by A2LA. For those parameters approved, the laboratory shall use the following footnote on the scope of accreditation:

“The CMC claim is smaller than that of the expanded uncertainty claim for (*insert name of NMI*) as listed in the BIPM Key Comparison Database. A2LA has evaluated the laboratory’s CMC claim and has verified this information to be correct and appropriate.”

A2LA may also accept uncertainties smaller than the NMI’s “commercial” uncertainty that is provided to its own customers on a case-by-case basis.

3) The numerical value of the CMC shall be expressed on the scope of accreditation in accordance with [ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration](#) section 6.3.

4) The final decision on what constitutes “ambiguity” on expression of the CMC and on all content and editorial concerns of the scope of accreditation is made by A2LA. For more information on Calibration Scopes of Accreditation see A2LA [G118 - Guidance for Defining the Scope of Accreditation for Calibration Laboratories](#).

5) Scopes of accreditation must contain the information required by ISO/IEC 17011:2017 section 7.8.3. However, A2LA’s Flexible Scope Policy P112 allows for the name/title of the method or procedure to be omitted from a calibration laboratory’s scope of accreditation. The name/title of the method or procedure is recorded as part of the assessment and retained by A2LA for future reference. ISO/IEC 17011:2017 section 7.8.4 requires that any information not included on the scope of accreditation per section 7.8.3 be available upon request.

As such, by participating in the A2LA Calibration Program organizations have consented to permit A2LA to provide the name/title of the method or procedure to requesting parties. If the name/title of the method and/or procedure is not included on the scope of accreditation A2LA will provide the name/title of the method or procedure used to support that measurement parameter to the requesting party. No confidential information is provided regarding the method or procedure, only the name/title which would have appeared on the scope of accreditation per ISO/IEC 17011:2017 section 7.8.3.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 11 of 29

Please note that this is a new requirement and all Accreditation Bodies compliant to the new standard will have to meet this requirement. A2LA will transition all Scopes of accreditation not containing a method/procedure to a flexible Scope in conjunction with the transition to ISO/IEC 17025:2017.

Note: The remaining requirements in this document pertain to optional items. If you do not want Z540-1-1994, Z540.3-2006, Durometer or Dimensional Testing on your scope of accreditation then you may stop here.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 12 of 29

7.0 APPENDICES

APPENDIX A: ANSI/NCSL Z540-1-1994 Requirements (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 calibration.

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.
- 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.
- 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 information⁵:

⁵ 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.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 13 of 29

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;

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.

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.

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.*

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 14 of 29

APPENDIX B: ANSI/NCSL Z540.3-2006 Requirements (Optional)

- 1) In addition to A2LA accreditation for ISO/IEC 17025, an optional accreditation to ANSI/NCSLI Z540.3-2006 is available. However, where ANSI/NCSLI Z540.3-2006 requirement differs from a 17025 requirement, A2LA requirement or A2LA policy, the more stringent requirement will apply.
- 2) The laboratory shall meet the following requirements specific to ANSI/NCSLI Z540.3-2006 section 5.3 (**note: items in *italics* are from A2LA, numbering is that of Z540.3**):

5.3 Calibration of Measuring and Test Equipment

- Calibration of measuring and test equipment [*M & TE*] shall be in accordance with the requirements of this National Standard. Calibration may be performed within or outside a designated calibration facility, e.g. in situ, on-site, or at a customer's facility, provided compliance with the requirement of this National Standard is maintained;
- The calibration provider shall ensure that the scope of calibration capability is consistent with the calibration requirements of the customer contracting the service;
- The calibration provider shall ensure the levels of measurement risk are acceptable to the customer contracting the service and the supplier of calibration service;
 - a) In cases where a request for reporting measured values is made by the customer, the calibration provider shall ensure that the measurement uncertainty is acceptable to the customer and shall document the acceptance;
 - b) In cases where a request for verification that measurement quantities are within specified tolerances is made by the customer, the calibration provider shall ensure that the probability that incorrect acceptance decisions, also known as probability of *false accept (PFA)*, that result from calibration tests do not exceed 2% and shall document the findings;

Where the customer requests verification that the measurement quantities are within specified tolerances, the calibration provider shall establish, define and implement decision rules used for determining the associated probability of false accept (PFA) does not exceed two percent with respect to the tolerance in a documented procedure or policy;

In cases where it is not practicable to estimate the probability that incorrect acceptance decisions (PFA) do not exceed 2% the calibration provider shall ensure that the test uncertainty ratio is equal to or greater than 4:1.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 15 of 29

- All measuring and test equipment [M & TE] included in the calibration system of the calibration provider, including measuring systems, calibration equipment, reference standards and material, and other inspection and monitoring equipment, shall be calibrated prior to use and recalibrated at predetermined intervals to ensure acceptable measurement uncertainty, traceability, and reliability. Intervals may be based on usage or time since last calibration.
- When there is doubt as to the suitability of an item for calibration, when an item does not conform to the description provided, or the calibration required is not specified in sufficient detail by the customer, the calibration provider shall consult with the customer for further instructions before proceeding and shall record the discussion.

The calibration certificate issued to the customer shall indicate that either all of the ISO/IEC 17025 accredited results were also achieved in accordance with ANSI/NCSLI Z540.3 or shall suitably identify the applicable ISO/IEC 17025 accredited results that were also achieved in accordance with ANSI/NCSLI Z540.3.

5.3.1 Calibrations shall be performed using calibration procedures that:

- Address the measuring and test equipment performance requirements;
- Are acceptable to the customer;
- Are current and appropriate for the calibrations; and
- Provide reasonable assurance that the calibration results are as described.

All calibration procedures shall:

- a) Contain sufficient information on requirements for the associated measurements and instructions to perform the calibrations;
- b) In addition, the number of different measurement quantities and values in a calibration procedure shall be sufficient to ensure conformity of the measuring and test equipment to determined requirements.

5.3.1.1 Calibration procedures shall include the following information:

- Identification and document controls information;
- Scope and/or description of item to be calibrated;
- Measurement quantities and ranges to be determined for the item to be calibrated and any associated tolerances;
- Minimum performance requirements of the equipment to be used for calibration, including measurement and reference standards, and reference materials;
- Environmental conditions required and any stabilization period needed;
- Description of steps associated with the calibrations to be performed;

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 16 of 29

- Criteria and/or requirements for calibration decisions, such as approval or rejection; and
- Data to be recorded and method analysis and presentation.

5.3.1.2 *The calibration provider shall ensure that* calibration procedures and their modifications, are validated. The validation shall be as extensive as is necessary to meet the needs of the procedure's application.

5.3.2 Measurement Assurance Procedures

- Measurement processes incorporating measurement assurance methods, such as statistical process control, shall use a measurement assurance procedure;
- This procedure shall be systematically applied and include stated measurement uncertainty or reliability goals, control criteria, and methodology to verify that the goals and criteria are being attained;
- The controls shall be adjusted when the results of the previous measurements indicate that such action is appropriate to maintain acceptable measurement uncertainty or reliability;
- Measurement assurance controls may be based on the use of calibrated check standards, usage, and/or time since the last performance;
- The measurement assurance procedure shall include mandatory instructions to preclude the use of the measuring process that exceeds its controls;
- The measurement assurance procedure and any associated measuring and test equipment shall be documented as a calibration procedure in accordance with the provisions of this National Standard.

5.3.3 Measurement Uncertainty and Traceability

- The uncertainty and traceability of all measurement results associated with processes included in the calibration system shall meet the requirements of their applications;
- Measurement uncertainty components which have an influence on such measurement results shall be included in the estimates of measurement uncertainty.

5.3.3.1 Expression of Measurement Uncertainty

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 17 of 29

A documented procedure shall be used to estimate and express the uncertainty of measurement for all calibrations. As a minimum, the procedure shall address:

- Sources of measurement uncertainty;
- Estimation and combining of uncertainties;
- Conditions and assumptions;
- Documentation and reporting criteria; and
- Bibliography.

5.3.3.2 Measurement Traceability

- The results of a calibration or measurement shall be traceable through a controlled, unbroken chain of competent calibrations to and through the National Institute of Standards and Technology to the SI units of measurement;
- This traceability to a national measurement institute other than the National Institute of Standards and Technology is acceptable when:
 - a) A mutual recognition agreement, such as the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA), is in effect with the National Institute of Standards and Technology and sufficient equivalence of applicable calibration services exists; or
 - b) When the calibration service of the National Institute of Standards and Technology is not available or does not meet the measurement performance requirements;
- Where traceability to SI units through national metrology institutes is not available, or SI units are not established, a consensus standard including a reference standard and related calibration procedures, which are clearly specified and mutually agreed upon by all parties concerned, shall be applied.

5.3.4 Calibration Equipment

- All measuring and test equipment required for the correct performance of calibrations and related measurements, including calibration and reference standards and reference material, shall be available to the calibration provider;
- In those cases where the calibration provider needs to use equipment outside its permanent control, it shall ensure that the requirements of this National Standard are met;
- Measuring and test equipment that may affect the results of the calibrations shall be calibrated and included in a calibration system meeting the requirements of this National Standard.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 18 of 29

5.3.9 Calibration Records

- Records shall be maintained of each item of equipment and software where its use contributes to the results of the calibrations performed;
- The records shall include the following:
 - a) As found measurement performance condition of the equipment;
 - b) Calibrations actions taken (adjusted, repaired, new value assigned, limited, derated, modified, etc.);
 - c) Limitations of use;
 - d) Assigned calibration interval;
- Generation, amendment, issuance, and deletion of records shall be authorized. In addition, the reason for an amendment or deletion of a record shall be documented.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18 Page 19 of 29

APPENDIX C: Durometer Requirements (Optional)

For those laboratories that include durometers on their scope of accreditation:

For an endorsed (accredited) calibration requested to meet ASTM D2240 the calibration certificate must also include the following information in addition to the requirements of this document:

- Date of calibration;
- Date of last calibration;
- Calibration due date (as determined by the user);
- Manufacturer, type, model, and serial number of the instrument, and a notation when a maximum indicator or timing device is present;
- Values obtained for measurement parameters identified on the scope of accreditation (pre- and post-calibration results), including notation of the effect of a maximum indicator, if present. The method of reporting the calibrated value shall be attained by the arithmetic mean of the determinations: Ambient temperature; Relative humidity; Technician identification;
- Applicable standards to which the instrument is calibrated;
- Calibrating instrument information to include type, serial number, manufacture, date of last calibration, calibration due date (determined by calibration service provider), and a statement of traceability of standards to the SI through NIST or another acceptable national metrology institute (NMI)⁶.

As indirect verification of durometers is not supported by ASTM D2240, therefore, it is not permitted on A2LA Scopes of Accreditation.

See also A2LA [G118 - Guidance for Defining the Scope of Accreditation for Calibration Laboratories](#) for scope examples.

⁶ See A2LA *P102 – A2LA Policy on Metrological Traceability* for information on acceptable NMIs.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 20 of 29

APPENDIX D: Dimensional Testing Requirements (Optional)

For those laboratories that have dimensional testing on their scope of accreditation where the unit under test is used to calibrate another device:

In addition to the requirements of this document:

- For all dimensional testing parameters for which the unit under test ***does*** serve as link in the traceability chain and where an endorsed (accredited) test report is issued, the organization shall identify on the test report that the test(s) conducted is performed in accordance with *R205 – Specific Requirements: Calibration Laboratory Accreditation Program* and is deemed equivalent with a calibration. Furthermore, they shall also identify this on the scope of accreditation.
- For dimensional testing parameters for which the unit under test ***does*** serve as link in the traceability chain for some parameters but ***does not*** serve as a link in the traceability chain for others, where an endorsed (accredited) calibration certificate or test report is issued the organization shall distinguish those results that ***are*** performed in accordance with R205 and deemed equivalent to a calibration from those that ***are not*** deemed equivalent to a calibration. Use of an asterisk with language to this effect is acceptable.

See also A2LA [G118 - Guidance for Defining the Scope of Accreditation for Calibration Laboratories](#) for scope examples.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 21 of 29

APPENDIX E: Excerpts from ILAC Policy for Uncertainty in Calibration ILAC–P14:01/2013

Below are excerpts from ILAC P14:01/2013⁷ from section four through six for reference purposes:

4. ILAC Policy on the Estimation of Uncertainty of Measurement

4.1 Accreditation bodies that are full members of or are applicants to the ILAC Mutual Recognition Arrangement (the ILAC MRA) **shall** require their accredited calibration laboratories to estimate uncertainties of measurement for all calibrations and measurements covered by the scope of accreditation.

4.2 Calibration laboratories accredited by the accreditation bodies **shall** estimate uncertainties of measurement in compliance with the “Guide to the Expression of Uncertainty in Measurement” (GUM), including its supplement documents and/or ISO Guide 35. To make sure that its accredited calibration laboratories estimate uncertainty of measurements in line with the GUM and/or ISO Guide 35, the accreditation body may use documents published by other organizations or publish its own document containing practical guidance and mandatory requirements. These mandatory requirements should be in accordance with the reference documents mentioned above.

5. ILAC Policy on Scopes of Accreditation of Calibration Laboratories

5.1 The scope of accreditation of an accredited calibration laboratory **shall** include the calibration and measurement capability (CMC) expressed in terms of:

- a) measurand or reference material;
- b) calibration/measurement method/procedure and/or type of instrument/material to be calibrated/measured;
- c) measurement range and additional parameters where applicable, e.g., frequency of applied voltage;
- d) uncertainty of measurement.

5.2 There **shall** be no ambiguity on the expression of the CMC on the scopes of accreditation and, consequently, on the smallest uncertainty of measurement that can be expected to be achieved by a laboratory during a calibration or a measurement. Particular care should be taken when the measurand covers a range of values. This is generally achieved through employing one or more of the following methods for expression of the uncertainty:

⁷ © Copyright ILAC 2013

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 22 of 29

- a) A single value, which is valid throughout the measurement range.
- b) A range. In this case a calibration laboratory should have proper assumption for the interpolation to find the uncertainty at intermediate values.
- c) An explicit function of the measurand or a parameter.
- d) A matrix where the values of the uncertainty depend on the values of the measurand and additional parameters.
- e) A graphical form, providing there is sufficient resolution on each axis to obtain at least two significant figures for the uncertainty.

Open intervals (e.g., “ $U < x$ ”) are not allowed in the specification of uncertainties.

5.3 The uncertainty covered by the CMC **shall** be expressed as the expanded uncertainty having a specific coverage probability of approximately 95 %. The unit of the uncertainty **shall** always be the same as that of the measurand or in a term relative to the measurand, e.g., percent. Usually the inclusion of the relevant unit gives the necessary explanation.

5.4 Calibration laboratories **shall** provide evidence that they can provide calibrations to customers in compliance with 5.1 b) so that measurement uncertainties equal those covered by the CMC. In the formulation of CMC, laboratories **shall** take notice of the performance of the “best existing device” which is available for a specific category of calibrations.

A reasonable amount of contribution to uncertainty from repeatability **shall** be included and contributions due to reproducibility should be included in the CMC uncertainty component, when available. There should, on the other hand, be no significant contribution to the CMC uncertainty component attributable to physical effects that can be ascribed to imperfections of even the best existing device under calibration or measurement.

It is recognized that for some calibrations a “best existing device” does not exist and/or contributions to the uncertainty attributed to the device significantly affect the uncertainty. If such contributions to uncertainty from the device can be separated from other contributions, then the contributions from the device may be excluded from the CMC statement. For such a case, however, the scope of accreditation **shall** clearly identify that the contributions to the uncertainty from the device are not included.

NOTE: The term “best existing device” is understood as a device to be calibrated that is commercially or otherwise available for customers, even if it has a special performance (stability) or has a long history of calibration.

5.5 Where laboratories provide services such as reference value provision, the uncertainty covered by the CMC should generally include factors related to the measurement procedure as it will be carried out on a sample, i.e., typical matrix effects, interferences, etc. shall be considered. The uncertainty covered by the CMC will not generally include contributions arising from the instability or inhomogeneity of the

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18 Page 23 of 29

material. The CMC should be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

Note: The uncertainty covered by the CMC for the reference value measurement is not identical with the uncertainty associated with a reference material provided by a reference materials producer. The expanded uncertainty of a certified reference material will in general be higher than the uncertainty covered by the CMC of the reference measurement on the reference material.

6. ILAC Policy on Statement of Uncertainty of Measurement on Calibration Certificates

6.1 ISO/IEC 17025 requires calibration laboratories to report, in the calibration certificate, the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

Accredited calibration laboratories **shall** report the measured quantity value and the uncertainty of measurement, in compliance with the requirements in 6.2 – 6.5 of this section.

By exception, and where it has been established during contract review that only a statement of compliance with a specification is required, then the measured quantity value and the measurement uncertainty may be omitted on the calibration certificate. The following **shall** however apply:

The calibration certificate is not intended to be used in support of the further dissemination of metrological traceability (i.e. to calibrate another device);

As specified in ISO/IEC 17025:2017 clause 7.8.4 or ISO/IEC 17025:2005 clauses 5.10.4, the laboratory shall determine the uncertainty and take that uncertainty into account when issuing the statement of compliance; and

The laboratory shall retain documentary evidence of the measured quantity value and the uncertainty of measurement, as specified in ISO/IEC 17025:2017 clause 7.8.4 or ISO/IEC 17025:2005 clauses 5.10.4.2 and 4.13 and shall provide such evidence upon request.

6.2 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 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

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18 Page 24 of 29

uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %.”

Note: *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.*

6.3 The numerical value of the expanded uncertainty **shall** be given to, at most, two significant figures. Further the following applies:

- a) The numerical value of the measurement result **shall** in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result.
- b) For the process of rounding, the usual rules for rounding of numbers **shall** be used, subject to the guidance on rounding provided i.e in Section 7 of the GUM.

Note: *For further details on rounding, see ISO 80000-1:2009^[7].*

6.4 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 should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.

6.5 As the definition of CMC implies, accredited calibration laboratories **shall not** report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 25 of 29

8.0 DEFINITIONS

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.

Accreditation Body (AB) (ISO/IEC 17000 clause 2.6): Authoritative body that performs accreditation.

Accredited: When a Conformity Assessment Body (CAB) is granted accreditation by an accrediting body (e.g. A2LA) that is a signatory to the ILAC mutual recognition arrangement (MRA).

Best Existing Device: is defined as a device to be calibrated that is commercially or otherwise available for customers, even if it has a special performance (stability) or has a long history of calibration⁸.

Bureau International des Poids et Mesures (BIPM)

<http://www.bipm.org/en/home/>): The task of the BIPM is to ensure world-wide uniformity of measurements and their traceability to the International System of Units (SI). It does this with the authority of the Convention of the Metre, a diplomatic treaty between fifty-five nations, and it operates through a series of Consultative Committees, whose members are the national metrology laboratories of the signatory States, and through its own laboratory work.

The BIPM carries out measurement-related research. It takes part in, and organizes, international comparisons of national measurement standards, and it carries out calibrations for Member States.

BIPM Key Comparison Database (KCDB) (<http://kcdb.bipm.org/>): supports the Mutual Recognition Arrangement of the [CIPM](#) (CIPM MRA) of national measurement standards and of calibration and measurement certificates issued by national metrology institutes. The technical basis of the arrangement is the set of results obtained in the course of time through key comparisons carried out by the [Consultative Committees](#) of the CIPM, the BIPM and the regional metrology organizations ([RMOs](#)), and published by the BIPM and maintained in the [key comparison database](#). Detailed technical provisions are given in the [Technical Supplement](#) to the arrangement.

Calibration and Measurement Capability (CMC)⁹: A CMC per the CIPM MRA-D-04, *Calibration and Measurement Capabilities in the context of the CIPM MRA* is a calibration and measurement capability available to customers under normal conditions:

⁸ Adapted from ILAC P14:01/2013 *ILAC Policy for Uncertainty in Calibration*

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 26 of 29

a) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement; or

b) as published in the BIPM¹⁰ key comparison database (KCDB) of the CIPM MRA¹¹.

Calibration and Measurement Capability Uncertainty (A2LA): The uncertainty of measurement described on a scope of accreditation under normal conditions.

Conformity Assessment Body CAB)¹²: a body that performs conformity assessment activities and that can be the object of accreditation.

Note: Whenever the acronym "CAB" is used, it applies to both the applicant and accredited CABs unless otherwise specified.

Dimensional Testing (A2LA): the measurement of geometric characteristics of parts or products to determine compliance with design specifications.

ILAC Mutual Recognition Arrangement (MRA) (<http://ilac.org/ilac-mra-and-signatories/>): The ILAC Arrangement provides significant technical underpinning to international trade. The key to the Arrangement is the global network of accredited testing and calibration laboratories and inspection bodies that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence. Now that the ILAC Arrangement is in place, governments can take advantage of it to further develop or enhance trade agreements. The ultimate aim is increased use and acceptance by industry as well as government of the results from accredited laboratories and inspection bodies, including results from facilities in other countries. In this way, the free-trade goal of "a product tested or inspected once and accepted everywhere" can be realized.

Measurand (VIM3 clause 2.3): Quantity intended to be measured.

Metrological Traceability¹³: property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

⁹ Per the CIPM MRA-D-04, *Calibration and Measurement Capabilities in the context of the CIPM MRA*, Version 4 October 2013.

¹⁰ For the BIPM KCDB see

http://kcdb.bipm.org/AppendixC/country_list_search.asp?page=1&pge=4&CountSelected=US&type=T

¹¹ For the CIPM MRA see <http://www.bipm.org/en/cipm-mra/>

¹² ISO/IEC 17011:2017

¹³ Per JCGM 200:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM) 3rd edition.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18 Page 27 of 29

Significant (A2LA): “significant” further means a contributor whose contribution increases the CMC by five percent (5%) or greater.

Standard Contributor (A2LA): “standard contributor” refers to those items outlined in section 6.7.1.1 of this document.

9.0 REFERENCES

R105 – Requirements When Making Reference to A2LA Accredited Status

[P102 - A2LA Policy on Metrological Traceability](#)

[P109 - Technical Consensus Decisions from the Measurement Advisory Committee \(MAC\)](#)

[R101 - General Requirements: Accreditation of ISO/IEC 17025 Laboratories](#)

[R103 - General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories \(pdf\)](#)

[R104 - General Requirements: Accreditation of Field Testing and Field Calibration Laboratories](#)

P112 – Flexible Scope Policy

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.*

ANSI/NCSL Z540.3-2006 *American National Standard for Calibration – Requirements for the Calibration of Measuring and Test Equipment.*

BIPM JCGM 200:2012, *International vocabulary of metrology - Basic and general concepts and associated (VIM) 3rd edition (2008 version with minor corrections).*

CIPM MRA-D-04, *Calibration and Measurement Capabilities in the context of the CIPM MRA* Version 4 October 2013

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 28 of 29

BIPM JCGM 100:2008, *Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM 1995 with minor corrections)*.

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 P10:01/2013, *ILAC Policy on Traceability of Measurement Results*.

ILAC P14:01/2013 *ILAC Policy for Uncertainty in Calibration*

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

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*.

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.

ANSI/NCSL Z540.3-2006, Sub-clause 5.3, *Requirements for the Calibration of Measuring and Test Equipment*.

	A2LA	
	R205 - Specific Requirements: Calibration Laboratory Accreditation Program	Document Revised: 10/11/18
		Page 29 of 29

Document Revision History

Date	Description
3/5/18	<ul style="list-style-type: none"> • Updated to the new version of ISO/IEC 17025:2017.
10/11/18	<ul style="list-style-type: none"> • Added provisions on flexible Scopes. • Added transition policy for Scopes that do not reference method and/or procedure.