R205: SPECIFIC REQUIREMENTS: CALIBRATION LABORATORY ACCREDITATION PROGRAM

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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.

P102 – A2LA Policy on Measurement 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.

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

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

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

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 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);

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 applicable[2])*. 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 Arrangement; or as published in the BIPM key comparison database (KCDB) of the CIPM MRA."

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

[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*

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 – Rules for Making Reference to A2LA Accredited Status*.

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 ***optional*** accreditation to ANSI/NCSL Z540-1-1994 shall also comply with the applicable requirements of that Standard. See Section 6.0 for Z540-1 requirements not found in ISO/IEC 17025 or these Requirements.

1.3 Calibration laboratories seeking ***optional*** accreditation to ANSI/NCSLI Z540.3: 2006 shall also comply with the applicable requirement of that Standard. See Section 7.0 for Z540.3 requirements not found in ISO/IEC 17025 or these Requirements.

2.0 Specific Requirements

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

2.1 Calibration Intervals

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.

2.2 Intrinsic Standards

2.2.1 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).

2.3 Accredited (Endorsed) Calibration Certificates and Reports (Note: Items in italics are taken directly from ILAC P14:11/2010 *ILAC Policy for Uncertainty in Calibration)*

2.3.1 Accredited calibration laboratories shall report the uncertainty of measurement, in compliance with the requirements of this document.

2.3.2 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 ± 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 uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %."*

2.3.3 For asymmetrical uncertainties other presentations than y ± U may be needed. This concerns also cases when uncertainty is determined by Monte Carlo simulations (propagation of distributions) or with logarithmic units.

2.3.4 The numerical value of the expanded uncertainty shall be given to two significant figures. Further the following applies:

1) 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.

2) 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: The above (2.3.4) may be precluded by legal, regulatory or contractual requirements.

2.3.5 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.

2.3.6 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.

2.3.7 An indiscriminate use of the CMC listed on the A2LA scope of accreditation as the uncertainty of an actual calibration is not justified.

2.3.8 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.

2.4 Statements of Compliance

2.4.1 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 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 conditions[3];

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.

2.5 Method or Parameter Observation During an Assessment

2.5.1 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.

2.5.2 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.

2.5.3 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.

2.5.4 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-G8:2009, *Guidelines on Assessment and Reporting of Compliance with Specification*. With agreement from the customer, other decision rules may be used as provided for in this section of the Requirements.

2.6 Review of Calibration Certificates

Note: All new applications received after December 31, 2012 are subject to the new requirements found in Section 2.6 of R205. All currently accredited CABs with an anniversary date of August 31, 2013 or later will be subject to the new requirements found in Section 2.6 of R205.

2.6.1 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):

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

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 for Uncertainty Calculations that support the Calibration and Measurement Capability (CMC) on the Scope of Accreditation

4.1 Terms and Definitions:

4.1.1 For the purpose of this section of the document, the relevant terms and definitions given in the "International Vocabulary of Metrology – Basic and General Concepts and Associated Terms" (VIM) and the following apply:

a) Measurement Uncertainty: "Measurement uncertainty" refers to the measurement uncertainty calculation developed to demonstrate how the claimed Calibration and Measurement Capability (CMC) was derived for the scope of accreditation. It does not refer to the measurement uncertainty calculated as part of the measurement as reported on a calibration certificate.

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

c) Standard Contributor: "standard contributor" refers to those items outlined in section 4.2.1.

4.2 Measurement Uncertainty (CMC) Contributors

4.2.1 Every measurement 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:

a) Repeatability (Type A)
b) Resolution
c) Reproducibility
d) Reference Standard Uncertainty
e) Reference Standard Stability
f) 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.

4.2.2 The measurement uncertainty shall also:

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

4.3 General Considerations

4.3.1 The measurement uncertainty shall represent expanded uncertainties expressed at approximately the 95% level of confidence using a coverage factor of $k = 2$.

4.3.2 The data from which the origin of the measurement uncertainty was determined shall be documented.

4.3.3 The statistical analysis shall be in accordance with the *Guide to the Expression of Uncertainty in Measurement* (GUM).

4.4 Deficiencies and Implementation

4.4.1 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.

4.4.2 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;

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.

5.0 Requirements for Technical Consensus Decisions from the Measurement Advisory Committee (MAC)

5.1 Refer to P109 - Technical Consensus Decisions from the Measurement Advisory Committee (MAC)

6.0 APPENDIX A: 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 information[4]:

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;

[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.

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.

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*.

7.0 APPENDIX B: Requirements Specific to ANSI/NCSLI Z540.3-2006 – Optional

7.1 Scope

1.1 This document describes the requirements for calibration laboratories seeking, in addition to A2LA accreditation for ISO/IEC 17025, an optional accreditation to ANSI/NCSLI Z540.3-2006. However, where ANSI/NCSLI Z540.3-2006 requirement differs from a 17025 requirement, A2LA requirement or A2LA policy, the more stringent requirement will apply.

7.2 References

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

7.3 Definitions

7.3.1 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.

7.4 Requirements Specific to ANSI/NCSLI Z540.3-2006 section 5.3

7.4.0 Calibration of Measuring and Test Equipment

7.4.1 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;

7.4.2 The calibration provider shall ensure that the scope of calibration capability is consistent with the calibration requirements of the customer contracting the service;

7.4.3 The calibration provider shall ensure the levels of measurement risk are acceptable to the customer contracting the service and the supplier of calibration service;

7.4.4 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;

7.4.5 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;

7.4.6 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.

7.4.7 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;

7.4.8 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.

7.4.9 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.

7.4.10 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.

7.5 Calibration Procedures

7.5.1 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.

7.5.2 All calibration procedures shall:

7.5.2.1 Contain sufficient information on requirements for the associated measurements and instructions to perform the calibrations;

7.5.2.2 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;

7.5.3 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;
- Criteria and/or requirements for calibration decisions, such as approval or rejection; and
- Data to be recorded and method analysis and presentation.

7.6 Validation

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.

7.7 Measurement Assurance Procedures

7.7.1 Measurement processes incorporating measurement assurance methods, such as statistical process control, shall use a measurement assurance procedure.

7.7.2 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.

7.7.3 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.

7.7.4 Measurement assurance controls may be based on the use of calibrated check standards, usage, and/or time since the last performance.

7.7.5 The measurement assurance procedure shall include mandatory instructions to preclude the use of the measuring process that exceeds its controls.

7.7.6 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.

7.8 Measurement Uncertainty and Traceability

7.8.1 The uncertainty and traceability of all measurement results associated with processes included in the calibration system shall meet the requirements of their applications.

7.8.2 Measurement uncertainty components which have an influence on such measurement results shall be included in the estimates of measurement uncertainty.

7.9 Expression of Measurement Uncertainty

7.9.1 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.

7.10 Measurement Traceability

7.10.1 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.

7.10.2 This traceability to a national measurement institute other than the National Institute of Standards and Technology is acceptable when:

7.10.3 A mutual recognition agreement, such as the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arragement (MRA), is in effect with the National Institute of Standards and Technology and sufficient equivalence of applicable calibration services exists; or

7.10.4 When the calibration service of the National Institute of Standards and Technology is not available or does not meet the measurement performance requirements.

7.10.5 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.

7.11 Calibration Equipment

7.11.1 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.

7.11.2 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.

7.11.3 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.

7.12 Calibration Records

7.12.1 Records shall be maintained of each item of equipment and software where its use contributes to the results of the calibrations performed;

7.12.2 The records shall include the following:

- As found measurement performance condition of the equipment;
- Calibrations actions taken (adjusted, repaired, new value assigned, limited, derated, modified, etc.);
- Limitations of use;
- Assigned calibration interval;

7.12.3 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.

8.0 APPENDIX C – Requirements Specific to Dimensional Testing Parameters on Scopes of Accreditation

8.0. Description of the Dimensional Testing Requirements

8.1 Scope

8.1.1 This document describes the requirements for organizations seeking A2LA accreditation for dimensional testing parameters on their scope of accreditation. The dimensional testing requirements are based on ISO/IEC 17025:2005, *General requirements for the competence of calibration and testing laboratories*.

8.2 Background

Some of the organizations accredited under the Mechanical field of testing for dimensional testing are actually performing calibration measurements as part (or all) of the measurements that they make. This situation is especially prevalent in dimensional measurement laboratories using coordinate measuring machine (CMMs) to perform their measurements.

When the dimensional measurement laboratory is measuring what is commonly referred to as "hard tooling" or fixed gauges, there are times when that measured tool is going to be used by the laboratory's customer as the reference standard to measure their own parts. In those cases, the dimensional measurement laboratory is serving as a link in the traceability chain and must be treated by A2LA and our assessors as a calibration laboratory. In these situations the requirements found in *R205 – Specific Requirements: Calibration Laboratory Accreditation Program* must be applied in order to accredit the dimensional measurement organization for this service. Additionally these dimensional testing parameters are also required to meet *R218 – Applications for Calibration Scopes of Accreditation* for presentation on the scope.

It is understood that some of the dimensional measurements are performed as a small part of the mechanical scope or calibration scope of accreditation and that much of the work is taking measurements of automotive parts, for example, to ensure an appropriate fit on the automobile; this is considered dimensional testing.

If a situation arises where a mechanical testing organization desires to include dimensional testing capability for which the unit under test does serve as link in the traceability chain on their scope of accreditation or a calibration organization desires to include dimensional testing capability for which the unit under test does not serve as link in the traceability chain, A2LA will accredit the organization without requiring them to hold a separate Scope of Accreditation.

8.3 Definitions

8.3.1 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.

9.0 General Requirements

9.1 An application for accreditation must be completed in either the Mechanical field of testing or the field of Calibration. In cases where a CAB holds a current accreditation in another field the dimensional testing capability may be added as a second field to a current scope of accreditation (see *R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories*).

9.2 Measurement traceability

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

9.3 Uncertainty of measurement

9.3.1 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)[2] 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)[5]. In accordance with international convention, uncertainties listed on A2LA scopes of accreditation will usually represent expanded uncertainties expressed at approximately the 95% level of confidence using a coverage factor of $k = 2$. The uncertainty quoted on a scope of accreditation will be taken to be the CMC.

9.3.2 CMC as stated on a Scope of Accreditation, implies that within its accreditation a laboratory is not entitled to claim a smaller uncertainty for a particular measurement parameter than the value listed on its scope.

9.3.3 Organizations are not permitted to claim a Calibration and Measurement Capability (CMC) on their scope of accreditation that is lower than the CMC claimed by the National Metrology Institute (as stated in the key comparison database listed on the BIPM website, www.bipm.org) through which traceability is achieved unless allowance is made by A2LA.

[2] As defined in the ILAC P14:11/2010 *ILAC Policy for Uncertainty in Calibration*

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

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

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

9.4 Proficiency testing

9.4.1 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.

9.5 Use of the A2LA accredited symbol and rules for making reference to A2LA accredited status.

9.5.1 See *P101 – Rules for Making Reference to A2LA Accredited Status.*

9.6 Field Testing and Calibration

9.6.1 See *R104 – General Requirements: Accreditation of Field Testing and Field Calibration Laboratories* for requirements pertaining to accreditation of mechanical tests or calibrations performed in the field. Accredited field calibrations shall be identified on the scope of accreditation.

10.0 Specific Requirements for Dimensional Testing

10.1 For all dimensional testing parameters for which the unit under test ***does*** serve as link in the traceability chain (see section 2.0), the following requirements apply:

10.1.1 The CAB shall meet the requirements found in *R205 – Specific Requirements: Calibration Laboratory Accreditation Program and R218a – Annex A: General and Specific Editorial Considerations*.

Note: In accordance with R218, one minimal element on the scope of accreditation is "identification of the measuring instrument or type of instrument, measuring system, items calibrated; or reference materials or standards measured or calibrated, or parameters being calibrated." Therefore, the use of the term "length" without a qualifier is not permitted.

10.1.2 The organization shall use a footnote in the scope of accreditation identifying that the organization meets R205 – *Specific Requirements: Calibration Laboratory Accreditation Program* for the types of dimensional tests listed and is considered equivalent to that of a calibration.

10.1.3 See *P101 – Rules for Making Reference to A2LA Accredited Status* section B5 for requirements when issuing an endorsed, accredited calibration certificate.

Example <u>Mechanical Testing Scope or Calibration Scope</u> presentation when the dimensional test *does* serve as a link in the traceability chain:

I. Dimensional Testing/Calibration[1]

Parameter/Equipment	Range	CMC[2, 4] (±)	Comments
One Dimensional[3] – Length Radius	 Up to 6 in Up to 6 in	 320 µin 280 µin	Optical comparator
Length Standards (1D)[3]	(0.01 to 25) in	(75 + 2*L*) µin	CMM

[1] This laboratory offers commercial dimensional testing/calibration service.

[2] Calibration and Measurement Capability (CMC) is the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation when performing more or less routine calibrations of nearly ideal measurement standards or nearly ideal measuring equipment. Calibration and Measurement Capabilities represent expanded uncertainties expressed at approximately the 95 % level of confidence, usually using a coverage factor of $k = 2$. The actual measurement uncertainty of a specific calibration performed by the laboratory may be greater than the CMC due to the behavior of the customer's device and to influences from the circumstances of the specific calibration.

[3] This laboratory meets R205 – *Specific Requirements: Calibration Laboratory Accreditation Program* for the types of dimensional tests listed above and is considered equivalent to that of a calibration.

[4] In the statement of CMC, L is the numerical value of the nominal length of the device expressed in inches.

10.2 For all dimensional testing parameters for which the unit under test does *not* serve as link in the traceability chain (see section 2.0), the following requirements apply:

10.2.1.1 See *P101 – Rules for Making Reference to A2LA Accredited Status section B5* for requirements when issuing an endorsed, accredited test report.

10.2.2 The following requirements apply for the presentation of the scope:

10.2.2.1 The parameter, range, CMC, and Technique and/or Test Method (Standard) are identified on the scope (4 column scope).

102.2.2 Units for Angle measurements degrees, minutes and seconds, use the following corresponding symbols: °, ’, ’’

10.2.2.3 Normally the range cannot begin with zero. Instead “Up to” or a number greater than zero is used.

10.2.2.4 The CMC must apply across the range and be identified as the uncertainty that corresponds to the largest point in the range.

10.2.2.5 The CMC cannot be listed as a range.

10.2.2.6 A “0.00” uncertainty is unacceptable. There is uncertainty in every measurement unless it’s a functional check.

10.2.2.7 For Parameters, each word is capitalized.

10.2.2.8 For Techniques, only first word is capitalized.

10.2.2.9 Only two (2) significant figures are allowed to represent CMCs and they are always rounded up. Example:

- Incorrect: 0.0215 mm
- Correct: 0.022 mm

10.2.2.10 The following footnote shall be included in the scope of accreditation “This test is not equivalent to that of a calibration.”

Note: Where the footnote applies for all parameters it may be listed either with the CMC header or with the actual parameter.

Example <u>Mechanical Testing or Calibration</u> Scope Presentation when dimensional testing does *<u>not</u>* serve as a link in the traceability chain:

I. Dimensional Testing[1]

Parameter	Range	CMC[2] (±)	Technique / Method
Angle[3]	1° to 360°	4.1’	Optical comparator
Radius[3]	(0.005 to 3) in	0.0022 in	Optical comparator

[1] This laboratory offers commercial dimensional testing service only.

[2] Calibration and Measurement Capability (CMC) is the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation when performing more or less routine measurements of nearly ideal measurement standards or nearly ideal measuring equipment. Calibration and Measurement Capabilities represent expanded uncertainties expressed at approximately the 95 % level of confidence, usually using a coverage factor of $k = 2$. The actual measurement uncertainty of a specific measurement performed by the laboratory may be greater than the CMC due to the behavior of the customer’s device and to influences from the circumstances of the specific measurement.

[3] This test is not equivalent to that of a calibration.

10.3 For dimensional testing parameters for which the unit under test *<u>does</u>* serve as link in the traceability chain for some parameters but *<u>does not</u>* serve as a link in the traceability chain for other parameters, the following requirements apply:

10.3.1 For those parameters that *do* serve as a link in the traceability chain, sections 6.1.1 through 6.1.5 from this document apply.

10.3.2 For the dimensional test that *does not* serve as link in the traceability chain, the scope of accreditation must be presented in accordance with section 6.2.2 of this document.

10.3.3. See *P101 – Rules for Making Reference to A2LA Accredited Status,* section B5 for requirements when issuing an endorsed, accredited calibration certificate or test report.

Example Scope Presentation when dimensional testing *does* and *does not* serve as a link in the traceability chain:

I. Dimensional Testing/Calibration[1]

Parameter/Equipment	Range	CMC[2] (±)	Comments
Length Standards (1D)[3]	Up to 25 in	(75 + 2*L*) µin	CMM
Gridplates (2D)[3]	(6 x 8) in	(60 + 5*L*) µin	Vision CMM
Fixture Gages (3D)[3]	(20 x 25 x 15) in	(200 + 5*L*) µin	CMM

II. Dimensional Testing[4]

Parameter	Range	CMC[2, 6] (±)	Technique/ Method
Angle[5]	1° to 360°	4.1’	Optical comparator
Workpiece Measurement[5]			
1D	Up to 25 in	(125 + 3.5*L*) µin	CMM
2D	(20 x 25) in	(150 + 4*L*) µin	CMM
3D	(20 x 25 x 15) in	(200 + 5*L*) µin	CMM
1D	Up to 8 in	(50 + 10*L*) µin	Vision CMM
2D	(6 x 8) in	(100 + 15*L*) µin	Vision CMM

[1] This laboratory offers commercial dimensional testing/calibration service.

[2] Calibration and Measurement Capability (CMC) is the smallest uncertainty of measurement that a

laboratory can achieve within its scope of accreditation when performing more or less routine calibrations of nearly ideal measurement standards or nearly ideal measuring equipment. Calibration and Measurement Capabilities represent expanded uncertainties expressed at approximately the 95 % level of confidence, usually using a coverage factor of $k = 2$. The actual measurement uncertainty of a specific calibration performed by the laboratory may be greater than the CMC due to the behavior of the customer's device and to influences from the circumstances of the specific calibration.

[3] This laboratory meets R205 – *Specific Requirements: Calibration Laboratory Accreditation Program* for the types of dimensional tests listed above and is considered equivalent to that of a calibration.

Note: This footnote must be identified with a parameter.

[4] This laboratory offers commercial dimensional testing service only.

[5] This test is not equivalent to that of a calibration.

Note: This footnote must be identified with a parameter.

[6] In the statement of CMC, L is the numerical value of the nominal length of the device measured in inches.

Document Revision History

Date	Description
November 16, 2012	• Added "optional" to section 1.2. • Added section 1.3 for Z540.3. • Renumbered section 2.0 to 10.0 and added appropriate headers. • Changed section 2.3.4 with the exact language from ILAC P14:2010 section 6.3 and added a note that this may be precluded by legal, regulatory or contractual requirements. • Added section 2.6 for review of calibration certificates. • Added the requirements from P110 to section 4.0. • Removed Section 4.0 to APPENDIX A. • Added R205a as APPENDIX B. • Added R205c as APPENDIX C. • Updated table of contents. • Updated references to P101 and its reference to section B5. • Updated all references to the current version