	<i>The American Association for Laboratory Accreditation</i>	
	R205a: Annex to Specific Requirements: ANSI/NCSLI Z540.3-2006	Document Issued: June 11, 2010
	Page 1 of 5	

I. Description of the ANSI/NCSLI Z540.3-2006 Optional Requirements

1.0 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.

2.0 References

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


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

5.3 Calibration of Measuring and Test Equipment


- a. 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;
- b. *The calibration provider shall ensure that the scope of calibration capability is consistent with the calibration requirements of the customer contracting the service;*
- c. *The calibration provider shall ensure the levels of measurement risk are acceptable to the customer contracting the service and the supplier of calibration service;*
- d. *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;*
- e. *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;*

	<i>The American Association for Laboratory Accreditation</i>	
	R205a: Annex to Specific Requirements: ANSI/NCSLI Z540.3-2006	Document Issued: June 11, 2010
	Page 2 of 5	

- f. *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.*
- g. *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;*
- h. 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.
- i. 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.
- j. *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 Calibration Procedures

- a. Calibrations shall be performed using calibration procedures that:
 - 1. Address the measuring and test equipment performance requirements;
 - 2. Are acceptable to the customer;
 - 3. Are current and appropriate for the calibrations; and
 - 4. Provide reasonable assurance that the calibration results are as described.
- b. All calibration procedures shall:
 - 1. Contain sufficient information on requirements for the associated measurements and instructions to perform the calibrations;
 - 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;

	<i>The American Association for Laboratory Accreditation</i>	
	R205a: Annex to Specific Requirements: ANSI/NCSLI Z540.3-2006	Document Issued: June 11, 2010
	Page 3 of 5	

5.3.1.1 Calibration Procedures

Calibration procedures shall include the following information:


- a) identification and document controls information;
- b) scope and/or description of item to be calibrated;
- c) measurement quantities and ranges to be determined for the item to be calibrated and any associated tolerances;
- d) minimum performance requirements of the equipment to be used for calibration, including measurement and reference standards, and reference materials;
- e) environmental conditions required and any stabilization period needed;
- f) description of steps associated with the calibrations to be performed;
- g) criteria and/or requirements for calibration decisions, such as approval or rejection; and
- h) data to be recorded and method analysis and presentation.

5.3.1.2 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.

5.3.2 Measurement Assurance Procedures

- a. Measurement processes incorporating measurement assurance methods, such as statistical process control, shall use a measurement assurance procedure.
- b. 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.
- c. 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.
- d. Measurement assurance controls may be based on the use of calibrated check standards, usage, and/or time since the last performance.
- e. The measurement assurance procedure shall include mandatory instructions to preclude the use of the measuring process that exceeds its controls.
- f. 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.

	<i>The American Association for Laboratory Accreditation</i>	
	R205a: Annex to Specific Requirements: ANSI/NCSLI Z540.3-2006	Document Issued: June 11, 2010
	Page 4 of 5	

5.3.3 Measurement Uncertainty and Traceability

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

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

- a. sources of measurement uncertainty;
- b. estimation and combining of uncertainties;
- c. conditions and assumptions;
- d. documentation and reporting criteria; and
- e. bibliography.

5.3.3.2 Measurement Traceability

- a. 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.
- b. This traceability to a national measurement institute other than the National Institute of Standards and Technology is acceptable when:
 1. 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
 2. when the calibration service of the National Institute of Standards and Technology is not available or does not meet the measurement performance requirements.
- c. 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.

	<i>The American Association for Laboratory Accreditation</i>	
	R205a: Annex to Specific Requirements: ANSI/NCSLI Z540.3-2006	Document Issued: June 11, 2010
	Page 5 of 5	

5.3.4 Calibration Equipment

- a. 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*.
- b. 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.
- c. 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.

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;
 - f) calibrations actions taken (adjusted, repaired, new value assigned, limited, derated, modified, etc.);
 - h) limitations of use;
 - i) 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.

Document Revision History

Date	Description
May 5, 2010	Creation of new document.
June 11, 2010	Update with section 5.3.9