SUPPLEMENTAL ACCREDITATION REQUIREMENTS:
ANSI/NCSL Z540.3, SUBCLAUSE 5.3, CALIBRATION LABORATORIES (NON-FORENSICS)

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INTRODUCTION

This document is to establish supplemental accreditation requirements defined by ANAB. This document is written to help laboratories develop and implement a laboratory management system in compliance with ANSI/NCSL Z540.3-2006, subclause 5.3, that is suitable for the laboratory’s size and workload, and that will meet clients’ needs.

For laboratories that are contractually bound to control their measuring and test equipment or that of their customers, the requirements of this standard are applicable. All requirements of the standard can be superseded by the requests of the customer.

Calibration laboratories are considered competent to provide calibration services when they have been accredited to meet ISO/IEC 17025, including the requirements of ANSI/NCSL Z540.3, specifically subclause 5.3.

REFERENCES

ANSI/NCSL Z540.3-2006, Requirements for the calibration of measuring and test equipment
Handbook for the Application of ANSI/NCSL Z540.3-2006 Requirements for the calibration of measuring and test equipment
ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories
ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
International Vocabulary of Basic and General Terms in Metrology (VIM)

DEFINITIONS (FROM ANSI/NCSL Z540.3:2006)

Calibration: Set of operations that establish under specified conditions the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Calibration system, calibration program: Set of interrelated or interacting elements necessary to maintain the measurement performance of measuring and test equipment to defined requirements.

Guard band: Offset of a measurement decision value from a stated specification or tolerance.

Measurement assurance: Result of a process to provide adequate confidence that a measurement will satisfy stated requirements.

Measurement decision risk: Probability that an incorrect decision will result from a measurement.

Measurement process: Set of operations to determine the value of a measurement quantity.

Measurement quantity: Attribute of a phenomenon, artifact, or substance that can be distinguished qualitatively and determined quantitatively.

Measurement reliability: Probability that all the applicable measurement quantities of measuring and test equipment are within tolerance.
Measuring and test equipment: Measuring instrument, measurement standard, reference material, or auxiliary apparatus, or a combination thereof, necessary to realize a measurement process.

M&TE: Abbreviation for “measuring and test equipment.”

NIST: National Institute of Standards and Technology, the U.S. National Metrology Institute.

Organization: Group of people and facilities with an arrangement of responsibilities, authorities, and relationships.

PFA: Abbreviation for “probability of false acceptance”.

Test uncertainty ratio: Ratio of the span of the tolerance of a measurement quantity subject to calibration, to twice the 95% expanded uncertainty of the measurement process used for calibration.

Tolerance: Extreme values of an error permitted by specifications, regulations, etc., for a given measuring instrument, test, or measurement application.

Validation: Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled. General requirements above and beyond ISO/IEC 17025.

1. CALIBRATION OF MEASURING AND TEST EQUIPMENT

1.1. Calibration of measuring and test equipment shall be in accordance with the requirements of ANSI/NCSL Z540.3. Calibration can 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 requirements of this National Standard is maintained. The scope of the calibration capability shall be consistent with the calibration requirements and provide levels of measurement decision risk acceptable to both the customer and supplier.

1.1.1. When calibrations provide for reporting measured values, the measurement uncertainty shall be acceptable to the customer and shall be documented through the contract review process.

1.1.2. When calibrations provide for verification that measurement quantities are within specified tolerances, the probability that incorrect acceptance decisions (false accept) will result from calibration tests shall not exceed 2% and shall be documented. When it is not practicable to estimate this probability, the test uncertainty ratio shall be equal to or greater than 4:1.

1.2. Calibration-serving components are considered competent to provide calibration services when they have been accredited to meet ISO/IEC 17025, including the requirements of ANSI/NCSL Z540.3 subclause 5.3, or otherwise found to be in conformance by an authority acceptable to the customer. Competence shall be confirmed for the required calibration services and reflected in a scope of accreditation or in a similar listing of calibration capability and conformity in the non-accredited laboratory.

1.3. Laboratories applying for accreditation to ANSI/NCSL Z540.3, subclause 5.3, are required to apply the requirements of subclause 5.3 to their own measuring and test equipment (M&TE) and calculate the probability of false acceptance (PFA) for their own M&TE.

1.4. Laboratories that calibrate equipment internally and are not accredited to calibrate those particular items are required to calculate PFA for those supporting calibrations.
2. CALIBRATION PROCEDURES

2.1. Laboratories shall ensure that all testing and calibration results are traceable whenever possible, through NIST or another National Metrology Institute (NMI) to the International System of Units (SI units). Acceptable sources of traceability are available within the Calibration Accreditation Requirements document.

2.2. Calibrations shall be performed using calibration procedures that:
   
   2.2.1. Address the measuring and test equipment performance requirements;
   
   2.2.2. Are acceptable to the customer;
   
   2.2.3. Are current and appropriate for the calibrations; and
   
   2.2.4. Provide reasonable assurance that the calibration results are as described.

2.3. All calibration procedures shall:

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

   2.3.2. Provide for determining and recording the as-found performance of the measuring and test equipment being calibrated; and

   2.3.3. Be suitable for use by the calibration staff to perform and reproduce a calibration to the established performance criteria. Deviation from calibration procedures shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

2.4. When a calibration procedure proposed by the customer is considered to be inappropriate, the customer shall be notified as part of the contract review process.

2.5. Contents: Calibration procedures shall include the following information:

   2.5.1. Identification and document control information;

   2.5.2. Scope and/or description of item to be calibrated;

   2.5.3. Measurement quantities and ranges to be determined for the item to be calibrated and any associated tolerances;

   2.5.4. Minimum performance requirements of the equipment to be used for calibration, including measurement and reference standards, and reference materials;

   2.5.5. Environmental conditions required and any stabilization period needed;

   2.5.6. Description of steps associated with the calibrations to be performed;

   2.5.7. Criteria and/or requirements for calibration decisions, such as approval or rejection; and

   2.5.8. Data to be recorded and method of analysis and presentation.

2.6. Validation: Calibration procedures and their modifications shall be validated. The validation shall be as extensive as is necessary to meet the needs of the procedure’s application.
3. MEASUREMENT ASSURANCE

3.1. Laboratories shall meet the minimum participation as defined within the Calibration Accreditation Requirements document.

3.2. Measuring 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.

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

3.4. The measurement assurance procedure and any associated measuring and test equipment shall be documented as a calibration procedure in accordance with the provisions of ANSI/NCSL Z540.3, subclause 5.3.

4. UNCERTAINTY OF MEASUREMENT

4.1. Laboratories shall meet the uncertainty of measurement requirements within the Calibration Accreditation Requirements document.

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

   4.2.1. Sources of measurement uncertainty;
   4.2.2. Estimation and combining of uncertainties;
   4.2.3. Conditions and assumptions;
   4.2.4. Documentation and reporting criteria; and
   4.2.5. Bibliography.

5. TRACEABILITY

5.1. Laboratories shall meet the traceability requirements within the Calibration Accreditation Requirements document.

5.2. Results of a calibration or measurement shall be traceable through a controlled, unbroken chain of competent calibrations to and through NIST to the SI units of measurement. This traceability to a national measurement institute other than NIST is acceptable when:

   5.2.1. Mutual recognition agreement, such as the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA), is in effect with NIST and sufficient equivalence of applicable calibration services exists; or
   5.2.2. The calibration service of NIST 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.

### REVISION HISTORY

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<td>Original Release</td>
<td>2017/05/23</td>
<td>Initial release of ANSI/NCSL Z540.3, subclause 5.3, supplemental accreditation requirements.</td>
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<td>1</td>
<td>2018/05/02</td>
<td>Added ISO/IEC 17025:2017 as a reference.</td>
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