

ANSI/NCSL Z540.3

Requirements for the Calibration of Measuring and Test Equipment

Sub Clause 5.3 Assessor Training

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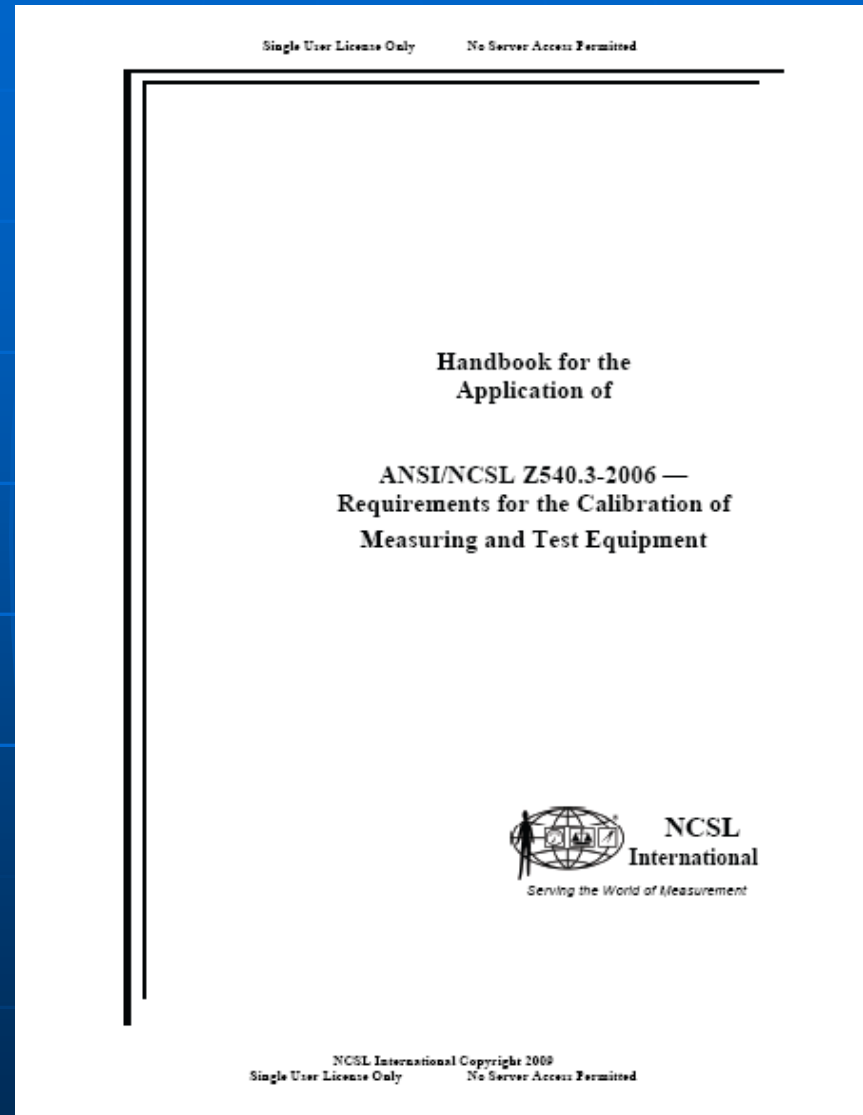
1. Welcome and overview of the session – Steve Doty (5 minutes)
2. Introduction and overview of Z540.3 / Perspectives on cal lab compliance – Del Caldwell (45 minutes)
3. Assessing cal labs to Z540.3, sub-clause 5.3 requirements / Appendix F introduction and use – Steve Doty (45 minutes)

Break - 15 minutes

4. Measurement uncertainty concepts for Z540.3 / Probability of false acceptance, concept and compliance – Dennis Jackson (115 minutes)
5. Wrap-up / Broad Q&A / Availability of Supplemental NCSLI resources [Handbook and bibliography; RP-1 (2009 rev); RP-3 (2007 rev); RP-12 (2009 rev); and RP-18 (2009 new)] – Steve Doty (15 minutes)



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Handbook Content

The Handbook provides:

- Terms and definitions for clarification and common understanding
- Discussion and guidance for sub-clauses of the Standard
- Furnishes representative examples that address key aspects of the topics discussed.
- Five appendices full of helpful examples, with one appendix addressing possible methods for achieving PFA requirements of the Standard.



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Handbook Purpose

What it is:

This Handbook is a tool and the information in this *Handbook* should not be viewed as the only means of applying or complying with the requirements of the Standard.

A resource, the Handbook is designed so that you need not read it in its entirety. The reader can go to specific sub-clauses to seek guidance on application.

One comment received: This Handbook is an incredible training manual on Z540.3

What it is not:

This *Handbook* is not an interpretation of the Standard.

This *Handbook* is also not the Standard, and therefore is not a requirements document and organizations can not be audited to the Handbook.



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Appendix F, Comparative Analysis

Introduction

ANSI/NCSL Z540.3-2006, *Requirements for the Calibration of Measuring and Test Equipment*, is the US National Standard that “prescribes the requirements for a calibration system to control the accuracy of the measuring and test equipment used to ensure that products and services comply with prescribed requirements.” Included in the requirements for the calibration system are requirements for components of that system including those of what is typically referred to as a calibration or standards laboratory.

In a collaborative effort to improve benefits to accredited calibration laboratories and minimize any unnecessary redundancies, provision was made in *ANSI/NCSL Z540.3-2006* to accept use of applicable *ANS/ISO/IEC 17025* accreditations to offset part of the *ANSI/NCSL Z540.3-2006*’s requirements. This provision is included in *ANSI/NCSL Z540.3-2006*, sub-clause 5.3, and is repeated here for reference:

Calibration-servicing components may be considered competent to provide calibration services when they have been accredited to meet ANS/ISO/IEC 17025, including the requirements of this sub-clause, 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.

The purpose of this document is to compare the competency demonstration requirements of *ANS/ISO/IEC 17025* to the technical requirements of *ANSI/NCSL Z540.3-2006*, sub-clause 5.3, and determine what additional assessment activity would be required over and above that already required by *ANS/ISO/IEC 17025*.

A summary of the comparative analysis is provided in the next section followed by the topical comparison of requirements.



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Summary

For the comparison shown in the body of this document, *ANSI/NCSL Z540.3-2006* was divided up into about eighty-six separate topics. This set of topics was further grouped these into five broad categories:

Categories	Comments	Qty
1. This is an additional requirement.	An assessment requirement over and above that done for <i>ANSI/ISO/IEC 17025</i> accreditation.	19
2. This may be an additional requirement.	This has some potential for being an additional assessment requirement.	3
3. May not be an additional requirement.	This has some potential for <u>not</u> being an additional requirement.	1
4. No additional requirement.	The assessment requirement for <i>ANSI/ISO/IEC 17025</i> is the same or equivalent.	52
5. Not a requirement.	No direct assessment is needed. This would include NOTE's or related information.	11

Topics from sub-clauses of *ANSI/ISO/IEC 17025* were then compared to the *ANSI/NCSL Z540.3-2006* sub-clause 5.3 topics. In some cases more than one sub-clause or topic from *ANSI/ISO/IEC 17025* were used for a single *ANSI/NCSL Z540.3-2006* topic.

Based on this initial comparison, about 73 % of the total candidate assessment topics do not impose a new assessment requirement over and above that normally addressed during assessment to *ANSI/ISO/IEC 17025*.

In examining the remaining 27 % assessment topics, most of the additional requirements should not pose a significant burden on assessment activities. Initially, however, several would require additional knowledge, clarification, and additional assessment effort. These are listed in the following:

<i>ANSI/NCSL Z540.3-2006</i>	Topic
Sub-clauses 5.3 and 5.3 b)	Measurement decision risk, probability of false acceptance, and test uncertainty ratio evaluation and parameter calculation, including guard band application.
Sub-clauses 5.3 and 5.3.4	Calibration system concept, requirements, and application to calibration laboratory standards and equipment.
Sub-clauses 5.3 and 5.3.4	Calibration interval evaluation to measurement reliability and uncertainty requirements.

Of additional interest is the use of information from clauses and sub-clauses other than 5.3 for the assessment process. Besides the application noted in the second item above, use of terms and definitions from Clause 3 as well as prescriptive material for calibration intervals and outside suppliers are needed, for example.



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Comparative Analysis

<i>ANSI/NCSL Z540.3-2006 Sub-clause 5.3 Topics</i>	<i>ANS/ISO/IEC 17025 Relevant Sub-clauses and 171 Committee Comments</i>
<p>5.3 Calibration of measuring and test equipment Calibration of measuring and test equipment 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 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.</p>	<p>For the purpose of this comparison, the customer is the organization submitting the M&TE and the supplier is the calibration laboratory.</p> <p>17025 is a test and calibration laboratory competency demonstration requirement.</p> <p>Z540.3 is a technical requirements document that applies to M&TE used by an organization, including the calibration component which may be an internal or external calibration laboratory.</p> <p>The application of Z540.3 to the calibration laboratory may be by contractual agreement with the customer or be self-imposed by the laboratory itself.</p> <p>(Note: This applies throughout this analysis)</p> <p>The calibration laboratory is to demonstrate their capability to determine measurement decision risk (MDR) for a specific calibration scope. This capability may be self imposed and requires assessment before it can be placed on a scope of accreditation.</p> <p>This is an additional requirement.</p>



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5.3b) Where 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. Where it is not practicable to estimate this probability, the test uncertainty ratio shall be equal to or greater than 4:1.

17025 does not address competency demonstration requirements for the probability of incorrect acceptance decisions (false accept) (typically called probability of false accept, PFA), or test uncertainty ratio (TUR). It's also noted that TUR is not the same as test accuracy ratio (TAR) used in other standards, such as Z540.1. The calibration laboratory must demonstrate competence and capability to determine PFA and TUR for both the customer supplied M&TE; any stated scope of capability; and for the calibration of their own standards. (See sub-clauses 5.5.)

This is an additional requirement.



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5.3 Calibration of measuring and test equipment

All measuring and test equipment included in the calibration system, 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.

17025, 5.6.1, requires periodic calibration of the calibration laboratories equipment and this equipment be included in an established program and procedure.

Z540.3 specifically requires recalibration of all M&TE in the calibration system, including calibration equipment, at predetermined intervals and the meeting of measurement uncertainty and reliability requirements. 17025 requires the calibration equipment to meet specifications and includes the requirement for scheduled checks. (Sub-clauses 5.5.2, 5.6.3.1, and 5.6.3.3.)

For Z540.3, the calibration laboratory must demonstrate how their program and procedure determines the calibration intervals and meets the uncertainty and reliability requirements for its calibration equipment, reference standards and material. See Z540.3, 5.3.4.

Most requirements are addressed by 17025;

measurement reliability targets for tolerance tested calibration standards and equipment would be an additional requirement.

See also Z540.3 sub-clause 5.3.4.



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5.3.1 Calibration procedures

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:

Z540.3 requires “procedures” to be used for calibrations and those procedures are required to include certain information. 17025, 5.4.2 requires “appropriate methods” with little firm guidance on what that is.

Z540.3 requires the calibration procedure to address the measuring and test equipment (M&TE) performance requirements. 17025 does not address specific M&TE performance requirements.

Z540.3 requires calibration procedures to be acceptable to the customer. 17025, sub-clause 5.4.2, requires the customer to be informed as to the method chosen.

Z540.3 requires calibration procedures to be current and appropriate. 17025, sub-clause 5.4.2 requires use of the latest edition of a standard associated with the calibration. Sub-clause 5.4.1 requires documentation be kept up to date. Z540.3 requires calibration procedures provide reasonable assurance that the calibration results are as described.

This is an additional requirement.

Except for use of current procedures, the remaining items reflect additional requirements.



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5.3.1a) 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;

The principal difference is again Z540.3 procedure vs. 17025 method. The assessment has to include the demonstration that the number of measurement quantities and values are sufficient to ensure conformity to the performance requirements. (See 5.3.1)

This is an additional requirement.



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5.3.1.1 Contents

Calibration procedures shall include the following information:

17025, 5.4.4, requires, under method selection, that standard methods be used, or if not, non-standard methods approved by the customer. 17025 then lists, in a note, what should be contained in the non-standard method.

Although the list of requirements in sub-clause 5.4.4 is similar, they are not required to be included in a method. Z540.3 requires a procedure and specific elements in the procedure. The two standards differ in that Z540.3 requires a procedure and 17025 requires a standard method. Per the VIM, the two (procedure and method) can differ.

Also, Z540.3 requires specific elements to be included in the procedure and the elements are not required by 17025 for standard methods. Elements are addressed in 17025 for non-standard methods but are optional. If the assessment always included the elements then a comparison is appropriate.

However, it is an additional requirement for assessment but the topics are not new to the assessors or calibration laboratories.

This is an additional requirement.



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5.3.1.2 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.

17025, 5.4.5 defines validation and requires validation of methods other than those considered "standard."

Z540.3 has a similar view as to what "validation" is but requires the calibration procedures to be validated and does not require methods to be validated.

This is an additional requirement. See Z540.3, 5.3.1.1.



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5.3.2 Measurement assurance procedures

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. 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.

17025, 5.9, requires planned quality control procedures and allows for the use of different methods that are appropriate for the type and volume of work.

Z540.3 requires the measurement assurance method be documented as a calibration procedure.

The two requirements address similar topics. However, it is an additional requirement for assessment but the topics are not new to the assessors or calibration laboratories.

This is an additional requirement.



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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.

Z540.3 requires the “uncertainty and traceability of all measurement results...shall meet the requirements of their applications.”

17025, 5.4.6.3, “requires all uncertainty components which are of importance...be taken into account.”
17025, 5.6.2.1.1, requires “the programme for calibration of equipment...to ensure calibrations and measurements made by the laboratory are traceable to the...SI.”

Both standards address measurement uncertainty and traceability at this top level. However, Z540.3 directly requires that the uncertainty and traceability meet the application requirements.

This is an additional requirement.



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5.3.3.1a) sources of measurement uncertainty;

17025, 5.1.1, identifies factors that influence a calibration result and relates those factors to sub-clauses in the standard. 17025, 5.1.2, requires that these factors be taken into account in developing calibration methods and procedures.

Z540.3 requires the procedure address sources of uncertainty while 17025 extends this to require a set of factors and relates them to sub-clauses in the standard.

17025, 5.4.6.3 Note 1, also identifies factors to be considered.

In related areas, Z540.3, 5.3.3 requires including components “having an influence on measurement results” while 17025, 5.4.6.3 requires “all uncertainty components that are of importance...”

The two requirements address similar topics.

However, it is an additional requirement in assessing the uncertainty procedure, but the topics are not new to the assessors or calibration laboratories.



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5.3.3.1b) estimation and combining of uncertainties;

17025, 5.4.6.3, requires that “all uncertainty components of importance in the given situation shall be taken into account using appropriate methods of analysis.”

Z540.3, 5.3.3.1, (b) requires that any process of estimating and combining of uncertainties be included in the procedure.

Both standards refer to the GUM as a non-normative standard.

The two requirements address similar topics.

However, it is an additional requirement in assessing the uncertainty procedure, but the topics are not new to the assessors or calibration laboratories.



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5.3.3.1c) conditions and assumptions;

17025 does not explicitly address conditions and assumptions as a requirement for uncertainty analysis. However some are included in the GUM which is a non-normative reference to the standard.

Z540.3 requires that the topic be included in the procedure.

This is an additional requirement.



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5.3.3.1d) documentation and reporting criteria;
and

17025, 4.3, addresses overall control of documentation, including procedures that would apply to this requirement but the topic is not specifically required in the procedure for expression and estimation of uncertainty.

Z540.3 requires both documentation and reporting criteria to be included in the procedure. NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results* serves as an example of an organization's policy on this topic.

The two address the subjects of documentation and reporting.

However, it is an additional requirement in assessing the uncertainty procedure, but the topics are not new to the assessors or calibration laboratories.



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5.3.3.1e) bibliography.

17025, 4.3, addresses overall control of documentation, including references that would apply to this requirement.

17025, 5.4.1, also addresses availability of current reference documentation. However, the source list of documents is not specifically required in the procedure for expression and estimation of uncertainty.

The two address the subjects of reference documentation.

However, it is an additional requirement in assessing the uncertainty procedure, but the topics are not new to the assessors or calibration laboratories.



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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.

Both Z540.3 and 17025, 5.6.2.1.1, require traceability to the SI utilizing competent calibration sources.

Z540.3 additionally requires this be through the US NMI, the NIST.

17025, allows but does not require traceability through a NMI and supports the idea of traceability to a primary standard in NOTES 2 and 3 of 5.6.2.1.1.

Control of exceptions to use of the NIST or an NMI is addressed in subsequent paragraphs of Z540.3.

17025 appears to address primary standards and use of NMI's in the series of NOTES in 5.6.2.1.1 but NOTES are not a requirement.

This is an additional requirement.



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5.3.3.2a) 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

BIPM activities are those described in the CIPM MRA, which includes the Calibration and Measurement Capabilities database and the supporting Key and Supplemental Comparison database.

17025, 5.6.2.1.1, infers the use of the country's NMI or use of an external NMI that participates in the activities of BIPM.

Z540.3 specifically requires the alternate NMI have be a signatory of the CIPM MRA and sufficient equivalence of applicable calibration services exist.

Most of the 17025 guidance is in the form of NOTES in 6.6.2.1.1, not requirements.

This is an additional requirement.



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5.3.3.2b) when the calibration service of the National Institute of Standards and Technology is not available or does not meet the measurement performance requirements.

17025, 5.6.2.1, NOTE 7 allows for use of another country's NMI but the thrust is addressed in (a) regarding by use of one that has the appropriate MRA.

Z540.3 specifically allows use of another NMI when the NIST doesn't have an appropriate calibration service. However, traceability to the SI is still required by 17025 and Z540.3 (see below for exception).

While it is an additional requirement for assessment to Z540.3, it may be not an additional requirement for US accreditors.



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5.3.4 Calibration equipment

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.

17025, 5.5.2, requires that the calibration equipment be calibrated and refers to “calibration programmes being established...” 17025, 5.6, addresses requirements for that programme.

Z540.3 requires that the program for calibration of M&TE that “affect the results of calibration shall be...included in a calibration system meeting the requirements of this National Standard,” Z540.3.

Both standards require calibration programs for equipment used for the calibration. However, 17025 provides general requirements and guidance for the elements of the program;

Z540.3 provides technical requirements for a calibration system to control the accuracy of M&TE, including calibration standards and equipment.

This is an additional requirement.



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5.3.9 Calibration records

5.3.9f) calibration actions taken (adjusted, repaired, new value assigned, limited, derated, modified, etc.);

17025, 5.5.5 f), includes recording adjustments; doesn't address the broad scope of the requirement.

This is an additional requirement.



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Questions, Comments, Thoughts?



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