Understanding and Complying with Metrology Requirements

Evan Doughty
Referenced Standards

- Mil-Std 45662(a)
- ANSI/NCSL Z540-1
- ISO/IEC 17025:2005
- ANSI/NCSL Z540.3
So, how many **car** guys and gals do we have here with us today?

Yes, I could have said **space** or **airplanes**...
Mil-Std 45662(A)
Mil-Std 45662(A)

• A U.S. military standard
• First issued as a Mil-C in early 1960’s
• Requirements for establishing and running a Calibration “System”
• Rescinded 1995, replaced by ANSI/NCSL Z540-1
• Defined-
  Calibration  Consensus Standard
Measuring and Test Equipment, MT&E
Measurement Standard  Traceability
• Established Requirements for-
  QMS  Environmental Controls
  Cal Intervals  Cal Procedures
  Subcontracting  Handling
ANSI/NCSL Z540-1
ANSI/NCSL Z540-1

- A U.S. **national** standard
- First issued 1994
- Requirements for operating a Calibration Laboratory (part I)
- Compliance of suppliers to customer requirements (part II)
- Withdrawn 2007, replaced by ISO/IEC 17025 (part I) and ANSI/NCSL Z540.3 (part II)
• Part I, General requirements, quality system and technical
  • How to run a lab was a carryover from the Mil-Spec
• Part II, Supplies, Services, and Customer Requirements
  • New approach that added the view that the customers had a shared risk in the calibration of their equipment
ISO/IEC 17025
ISO/IEC 17025

- An international standard
- First issued 1999 (1995 as a guide)
- Requirements for the competence of a Testing or Calibration Laboratory
- Includes quality system requirements of ISO 9001
- Current version is 2005, but in revision
• Contained three main pillars in establishing competence-
  • Metrological Traceability, specifically to the SI unit
  • Measurement Uncertainty, the “accuracy of a calibration”
  • Assuring the validity of results, all accredited labs must do Inter-laboratory Tests to validate their processes
ANSI/NCSL Z540.3
ANSI/NCSL Z540.3

- A U.S. national standard
- First issued 2006
- Requirements for establishing the technical requirements of a Calibration Lab
- Current version is 2013
• Similar to Z540-1 except for one major difference-
  • Introduced the idea that pass/fail to a specification was not sufficient
  • Providing an accuracy ratio was not sufficient
  • Providing measurement uncertainty was not sufficient
• That the possibility that an item could pass calibration but still actually be out of tolerance.

• Probability of False Acceptance
Recap of the Standards

• Mil-Std 45662(a) Dead and buried
  • From the 60’s replaced by Z540-1
• ANSI/NCSL Z540-1 On life support
  • From the 90’s replaced by 17025 and Z540.3
• ISO/IEC 17025:2005
  • Current international standard
• ANSI/NCSL Z540.3
  • Current U.S. national standard
Similarities

- All have the requirement for a basic quality system
- All require good measurement technology
  - Competent suppliers
  - Appropriate equipment
  - Traceability
  - Calibration procedures
  - Trained technical staff
  - Calibration reports
Key Differences

• Each standard tried different ways to establish accuracy requirements
• 17025 focused on international confidence
• 17025 built in ISO9001 QMS requirements
• 17025 requirement for inter-laboratory comparisons and other quality verifications
• 3rd party verification/ accreditation
• Scope of Accreditation
Key Technical Difference

- Mil-Std 45662(a) used a TAR approach
- Z540-1 uses a TUR approach
- 17025 uses the approach that the lab must calculate measurement uncertainty (Mu)
- Z540.3 says the lab must maintain a not exceed a minimum probability of false acceptance risk (PFA)
TAR – TUR – Mu - PFA

- Test Accuracy Ratio
  - Ratio of the accuracy of the standard to the accuracy of the UUT
  - Easy comparison
  - Lab must maintain 4:1 ratio or better
  - If a 4:1 is not achievable the lab must report the actual TAR
TAR – TUR – Mu - PFA

• Test Uncertainty Ratio
• Similar to the 4:1 TAR ratio
• Introduced the realization that the calibration process itself could influence the calibration results
• Must maintain 4:1 ratio or better
• Not easy to calculate because the lab must calculate uncertainties to determine TUR
TAR – TUR – **Mu** - PFA

- Measurement Uncertainty
- Shifted the focus from a test ratio to understanding your calibration process and the contributors to the uncertainty or inaccuracies of the calibration
- Measurement Uncertainty, **Mu**, must be reported for each calibration test point
• Measurement Uncertainty

• The concept was that by knowing the Mu the lab established more confidence in their measurements

• Left the laboratories customer the responsibility to understand uncertainties and what it meant for their tests
The Measurement Uncertainty Problem

• Statistics can be manipulated to make a lab look better than it is or a lab that does not understand their uncertainties look bad
• Two very different laboratories with very different Mu could calibrate the same item and still call it accredited as long as they reported the uncertainties
• Confused Customers
• Created the need for -

Customer Education
TAR – TUR – Mu - PFA

• Probability of False Acceptance
• A Z540.3 lab must maintain a PFA of less than 2%
• An attempt to return to less need for customer education
Key Differences

- When is TAR “good enough”
- Is 4:1 sufficient or is 10:1?
- TAR is very easy to determine
- What about TUR
  - Do you understand the meaning of process uncertainty. Does the lab?
  - The lab must calculate or at least understand uncertainties to determine TUR
Key Differences

- ISO 17025 has two basic uncertainties
- Scope of Accreditation CMC
- Best the lab is capable of achieving
- Reported Measurement Uncertainty Mu
- The actual uncertainty of the calibration of your piece of MT&E
Key Differences

- When are 17025 uncertainties a good idea
- Do you understand how these uncertainties should be used to determine the accuracies of your own tests?
- Can I just use their published scope CMCs?
  - Simple answer is yes but think about them plus the equipment listed on the scope as labs may have the same equipment but different uncertainties

Be an Educated Consumer
Key Differences

- ANSI/NCSL Z540.3
- What does PFA give me?
- Did they guardband or modify my equipment's tolerances?
- Should I worry about PFR?
Questions to Ask Yourself

• Do I have a choice on what standard to use?
• Do I have someone imposing a requirement on me?
  • NASA
  • U.S. Navy
  • Accredited 17025 lab
• Does that person understand the imposition in cost and time?
Questions to Ask Yourself

• When do I have a choice on what standard to place on my PO?
• Am I passing on traceability, am I performing internal calibrations?
• Am I the end or the traceability chain?
• Do I want to go and audit my calibration providers
• Confidence in my provider
Key Audit Points

• 17025 Accredited labs accredited by a properly recognized 3\textsuperscript{rd} party requires minimal or no 2\textsuperscript{nd} party audits
  • Audit requirements outside of 17025 such as;
    • Specific customer requirements
      o Special tolerances
      o Special reporting
    • Regulatory requirements
    • Safety requirements
Key Audit Points

• Many ISO 17025 Accredited labs are also verified for Z540-1 compliance
• Adds very few additional questions to the 17025 checklist
• Since the 17025 Scope of Accreditation for an accredited lab is published it is easy to find Z540-1 compliant labs
• Parameters on the accredited labs scope may not be all the tests the lab can perform
Mil-Std 45662(A)....
No reason to keep using, replaced with a good standard, Z540-1, buried

ANSI/NCSL Z540-1
Even though rescinded it is still widely used, TUR was easily understood
life support

ANSI/NCSL Z540.3
It hasn’t been widely accepted, PFA is not well understood

ISO/IEC 17025:2005
Uncertainties vary greatly between providers and are not well understood
CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board
500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that
Evan’s Calibration
123 Shore Line Dr., Merritt Island, FL 32952

has been assessed by ANAB
and meets the requirements of international standard
ISO/IEC 17025:2005
and national standard(s)
ANSI/NCSL Z540-1-1994
& ANSI/NCSL Z540.3-2006

while demonstrating technical competence in the field(s) of
CALIBRATION

Refer to the accompanying Scope(s) of Accreditation for information regarding the types of calibrations to which this accreditation applies.

AC-1498
Certificate Number

ANAB Approval

Certificate Valid To: 12/25/2016
Version No. 001 Issued: 12/25/2014

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated January 2007).
# Scope of Accreditation

## I. Dimensional

<table>
<thead>
<tr>
<th>PARAMETER / EQUIPMENT</th>
<th>RANGE</th>
<th>CALIBRATION AND MEASUREMENT CAPABILITY [EXPRESSED AS UNCERTAINTY(σ)]</th>
<th>REFERENCE STANDARD OR EQUIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micrometers</td>
<td>Up to 60 in</td>
<td>54 μin</td>
<td>Grade 2 and 3 Gauge Blocks</td>
</tr>
<tr>
<td>Calipers</td>
<td>Up to 72 in</td>
<td>72 μin</td>
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<tr>
<td>2 Point Dimensional</td>
<td>Up to 10 in</td>
<td>2.5 μin</td>
<td>F&amp;W Labmaster</td>
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<td>0.017 lbf</td>
<td>Morehouse Proving Rings</td>
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<tr>
<td>Torque</td>
<td>Up to 500 lbf-ft</td>
<td>1.7 % RDQ</td>
<td>Torque Transducers and Indicator</td>
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III. Thermodynamic

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**Notes:**
1. Calibration and Measurement Capabilities (Expanded Uncertainties) are based on approximately a 95% confidence interval, using a coverage of $k=2$.
2. This scope also covers calibrations made at customer designated locations (on-site).
3. Calibrations covered under this scope can only be performed during the months of June through August.
4. This scope is part of and must be included with the Certificate of Accreditation No. AC-4321.

_Signed_

Vice President
Specific Thoughts

• Many calibration labs offer different levels of service. Other than the current ISO 17025 and Z540.3 levels many labs offer Z540-1 or other lower levels of service.

• Some customers just want a simple “is my caliper accurate?” They do not want data, actual readings or care about how good the calibration is.

• Many do not understand calibration or the risk of not getting a good calibration.
Specific Thoughts

• Risk-
  • A lab is accredited to 17025 but that does not include Z540-1 or Z540.3
  • You must perform a 2\textsuperscript{nd} party audit of all other pertinent areas
  • Parameters on the 17025 accredited labs scope may not be all the tests the lab can perform
  • You’ll need to verify technical competence of these additional areas
Specific Thoughts

• Risk-
  • Risk is a two way street. The laboratories have the risk that they must maintain proper traceability, do good technical work and give the customer the data they require in a way they can use it.
  • The customer must ensure they are asking the lab for what they truly need and then verify they get what they ask for in a way they can use it.
Risk

• Ensure that you know the requirements you need to meet
  • What level of service
  • What deliverables, data, uncertainties, special traceability, special presentation
  • Contract or Purchase Order?
• Ensure you are clear to your calibration provider
  • Are there exceptions to the contract?
• Review what you receive or contract for
Risk

• Traceability-
  • Where is the top of the traceability chain?
  • Natural constant or consensus standards
  • NMI (NIST) or SI Units (BIPM)

• Calibration accuracy and equipment tolerance-
  • TAR - TUR - Mu - PFA

• Assuring measurement results through PT-
  • Has the lab proven they can do quality work?
Thank You

• I know that for some of you this is confusing information.

• If you have questions please ask.

• My contact information is:
  Evan Doughty
  edoughty@anab.org
Additional Training

- I know that for some of you this is confusing information.
- Internal Auditor ISO 17025- overview of accreditation
- Lead Assessor ISO 17025- In-depth course
- Practical Measurement Uncertainty

- Her contact information is:
  Caroline Trenner
trenner@anab.org