### AGENDA ITEM

#### A2LA Advertising Policy

A PowerPoint presentation was given by Teresa Barnett, A2LA Director of Quality (see Attachment #1). After the presentation, the following issues were clarified:

- Signing the sub-license agreement for use of the combined “ILAC MRA – A2LA Accredited” symbol does not restrict a conformity assessment body (CAB) only to use of the combined symbol. They may also continue to use the “A2LA Accredited” symbol.

- A question was raised regarding whether or not A2LA is actively encouraging more marketing by accredited CABs. In response, staff pointed out that an initial encouragement is offered when a CAB is first accredited but that any ideas or suggestions for encouraging CABs beyond this

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<tr>
<th>AGENDA ITEM</th>
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<th>MOTIONS &amp; ACTION ITEMS</th>
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</table>
| A2LA Advertising Policy | A PowerPoint presentation was given by Teresa Barnett, A2LA Director of Quality (see Attachment #1). After the presentation, the following issues were clarified:  
  - Signing the sub-license agreement for use of the combined “ILAC MRA – A2LA Accredited” symbol does not restrict a conformity assessment body (CAB) only to use of the combined symbol. They may also continue to use the “A2LA Accredited” symbol.  
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<tr>
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<tbody>
<tr>
<td>A2LA Normative Documents</td>
<td>A PowerPoint presentation was given by Joe Ritz, A2LA Accreditation Officer (see Attachment #2). After the presentation, the following were discussed:&lt;br&gt;- If a CAB’s master document list (or equivalent document control procedure) provides a direct link to each of the A2LA documents considered “normative”, this is an adequate indication of the revision status of each document. A link to the general A2LA website, however, is not sufficient.&lt;br&gt;- If a CAB’s master document list (or equivalent document control procedure) links to the correct version of a recently updated A2LA document, yet the CAB’s staff is not aware of or implementing the update, then a deficiency may be cited against the requirement for communication to and implementation by appropriate personnel.</td>
<td>None.</td>
</tr>
<tr>
<td>A2LA Top 10 Deficiencies</td>
<td>A PowerPoint presentation was given by Peter Unger, A2LA President/CEO (see Attachment #3).</td>
<td>None.</td>
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<tr>
<td>Vertical Auditing</td>
<td>A PowerPoint presentation was given by Diana Gavin,</td>
<td>None.</td>
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<tr>
<td>In-House Calibration</td>
<td>A2LA Director of Human Resources (see Attachment #4). A PowerPoint presentation was given by Pam Wright, A2LA Accreditation Manager (see Attachment #5). After the presentation, the following were discussed:</td>
<td><strong>ACTION:</strong> P. Wright to review the language in P102 to ensure that it is clear that a T9-approved lab may not perform commercial calibration work if the calibrations are not listed on their Scope of Accreditation. (By April 30, 2012)</td>
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<tr>
<td>(A2LA T9)</td>
<td>- Retention of calibration data that corresponds to a calibration label.</td>
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<td>- The appropriateness and acceptability of leasing equipment/reference standards for internal calibrations.</td>
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<td>- The acceptability of a “T9-approved lab” performing commercial calibration work for another lab if the calibrations are not on their Scope of Accreditation. Although it was agreed that this is not acceptable, it was pointed out that the wording of P102 may be entirely clear in this regard.</td>
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<td>- The recent requirement prohibiting the reporting of statements of compliance only.</td>
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<td>- Whether using the same measurement uncertainty</td>
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<td>calculations for cases when nothing has changed in the budget is acceptable. It was noted that, in general, this is not allowed.</td>
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<td><em>Post-Meeting Note: This is an acceptable practice; however, it should be noted that, in most cases, when the reference standard is recalibrated it is returned with a revised measurement uncertainty which then must be updated in the uncertainty calculation for the instrument in question.</em></td>
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<td>- Whether every instrument calibrated in-house must have its own measurement uncertainty calculation. It was noted that, ideally, this is the case.</td>
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<td><em>Post-Meeting Note: It is possible to assign the same measurement uncertainty to a group of instruments as long as the instruments have the same characteristics, such as resolution.</em></td>
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<tr>
<td>CAB Web Portal Demonstration</td>
<td>The CAB portal on the A2LA website was briefly described and demonstrated. All CABs were strongly encouraged to use the portal for renewals of accreditation.</td>
<td>None.</td>
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</tbody>
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*Summary prepared by Teresa C. Barnett, A2LA Director of Quality.*
## ATTENDEES

<table>
<thead>
<tr>
<th>Sarah Adelman</th>
<th>Steve Crupi</th>
<th>Jeff Gust</th>
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<tr>
<td>Marwa Adly</td>
<td>Linda DeWitt</td>
<td>Mike Hart</td>
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<td>Helga Alexander</td>
<td>Mary Alice DerAris</td>
<td>Karl Haynes</td>
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<td>Jim Allred</td>
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<td>Robert Audette</td>
<td>Dave Deaver</td>
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<td>Susan Audino</td>
<td>Tom Doggart</td>
<td>Michele Hoppenrath</td>
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<td>John Ball</td>
<td>King Drake</td>
<td>Bill Inderrieden</td>
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<td>Teresa Barnett</td>
<td>Phil Engler</td>
<td>Brenda Jackson</td>
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<td>Nathan Belsher</td>
<td>Dagmar Epsten</td>
<td>Klaus Jaeger</td>
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<td>Chuck Blank</td>
<td>David Evanson</td>
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<td>Michelle Bradac</td>
<td>Jeff Fisher</td>
<td>Renu Joshi</td>
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<td>Roger Brauningher</td>
<td>Arlene Fox</td>
<td>Ashley Kamauf</td>
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<td>Mike Buzard</td>
<td>Dan Fritz</td>
<td>Paul Keep</td>
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<td>Ryan Carey</td>
<td>Michele Gaabo</td>
<td>Marc Kelemen</td>
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<td>Ashly Carter</td>
<td>Tessie Gamber</td>
<td>Joseph Kellum</td>
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<td>Samantha Carter</td>
<td>Diana Gavin</td>
<td>Mike Kesselmayer</td>
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<td>Justing Cheng</td>
<td>Ray Gil</td>
<td>Alex Klein</td>
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<td>Brian Conner</td>
<td>Chuck Gortakowski</td>
<td>John Knicely</td>
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<td>Vanessa Cook</td>
<td>Ned Gravel</td>
<td>Garett Kokal</td>
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<td>Greg Cooper</td>
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<td>Gary Cornell</td>
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Nicole Kwarteng
Bob Lambert
Diane Lawver
Walt Lehmus
Doug Lentz
Rosa Leonard
Steve Lerman
Billy Liu
Frank Lutze
Dennis McCully
Amanda McDonald
Steve McGeehan
Trace McInturff
Jim Markniese
Jorge Martins
Shawn Mason
Craig Maytrott
Lon Miles
Mitzi Miller
William Mills
Amanda Mitchell
Harry Moody
Ed Morse
Louise Ogden
Susan Oldfather
Tim Osborne
Tom Ouimet
Gail Parker
Bill Peverill
Heidi Phillips
Jason Poore
Beverly Prevette
Vincent Pugh
Randy Querry
Brad Ranch
Tim Reachmack
Joe Ritz
Roxanne Robinson
Chuck Schaefer
Ray Schiltz
Michelle Serafin
Larnell Simpson
Elizabeth Smith
Phil Smith
Tom Smith
Craig Spooner
Brad Stawick
Tom Tefelske
Dan Tholen
Peter Unger
Daren Valentine
Kiran Verma
Lorena Villarreal
John Wehrmeyer
Jane Weitzel
Marie Wright
Pam Wright
Gene Zerlaut
Wayne Ziemer
Niel Zuern
American Association for Laboratory Accreditation
P101 – Reference to A2LA Accredited Status/A2LA Advertising Policy

Presented by Teresa Barnett, Director of Quality
A2LA Annual Technical Forum
Columbia, MD
March 25, 2012
Why does A2LA need an Advertising Policy?

- To fulfill our obligations under the ILAC MRA.
- To ensure consistent references to A2LA.
- To address and prevent chronic complaints.
- To ensure a “level playing field” for all accredited organizations.
How is P101 arranged?

- **Section A:** General requirements applicable to all references to A2LA and all uses of the “A2LA Accredited” symbol (including websites).

- **Section B:** Specific requirements applicable to very specific references to A2LA and uses of the symbol (e.g., reports, clothing, business cards, labels, etc.).

- **Section C:** Requirements only related to use of the combined “ILAC MRA – A2LA Accredited” symbol.
Where do the requirements in P101 come from?

- The bulk of Sections A and B comes from ILAC P8, which includes requirements related to:
  - General accreditation references
  - Reproduction of symbols
  - Reports, certificates & labels
  - Subcontracted tests/calibrations
  - Opinions/interpretations
  - Advertising and publicity materials
- Section C in P101 comes from the licensing agreement between ILAC and A2LA for use of a combined symbol.
- Some additional requirements have been developed and approved to address and prevent chronic complaints and misuse.
What are the most common mistakes?

- Using the “A2LA” logo instead of the “A2LA Accredited” symbol.

- Implying accreditation for items not on the Scope.

- Implying accreditation for locations other than that listed on the Scope.

- Not including the A2LA cert number/entity with *every* use of the combined symbol.
It is just too complicated...the policy is:

- Lengthy? – Yes.
- Specific? – Yes.
- Complicated? – It does not have to be...

**A2LA staff is available & ready to help navigate through P101 and develop marketing and advertising materials that meet an organization’s needs.**

- Time-consuming? – No...

**A2LA staff is committed to an immediate turn-around on requests for review and approval of marketing materials.**
How does the review and approval process work?

- Submit proposed A2LA references and/or uses of the “A2LA Accredited” symbol to the A2LA Director of Quality.

- A2LA reviews the proposals and responds with “ok” or “not quite”....If the response is “not quite”, it does not end there. Rather we:
  - explain exactly how the proposal does not meet P101; and
  - outline options and suggestions to bring the proposal in line with P101 with minimal revisions and work needed.

An organization will never be simply told “NO”....A2LA staff will always help to determine & point out any needed adjustments as quickly as possible.
What have others said about the A2LA review and approval process?

- “The approval process is not time consuming at all. You have always made it extremely easy for me to work through getting approval and have always been extremely quick in turning around needed corrections and approvals.”
- “To date we haven’t had any delay in releasing marketing materials due to delays in approval. You have no idea how helpful you have been!”
- “The review and approval process has been so simple for us.”
- “Once we realized it didn’t involve forms or committees or overnighting proofs, just an email, it has really become a non-issue.”
- “Every question I had was promptly answered in a way I could understand. Several answers included guidance so I didn’t have to email back and forth for every detail.”
What have others said about the A2LA review and approval process?

- “The length and detail of the policy...might make people think the approval process is difficult, but we have found the policy and the process to be very different.”
- “There are no tricks and hidden agendas, just fair and honest comparison with the policy which is made available to us.”
- “We were afraid of bureaucracy and long delays, but it has been very easy for us so far...We just aren’t used to that kind of response from other organizations.”
- The process to get items approved is pretty straightforward. I have found no delays in getting marketing items approved.”
But improvements can always be made…

- Developing an area of the A2LA website where proposed marketing materials may be uploaded for immediate review. P101 will be revised to describe this.

- P101 recently revised with instructions to contact the Director of Quality to initiate the approval process.
Anyone needing help in developing materials to promote their A2LA accreditation...

Feel free to contact:

Teresa Barnett  
A2LA Director of Quality  
tbarnett@A2LA.org
A2LA Normative Documents

Presented by Joe Ritz
A2LA Annual Technical Forum
Columbia, MD
March 25, 2012

American Association for Laboratory Accreditation
Overview

- What are normative documents?
- What A2LA normative documents are required for a CAB’s quality system?
- Meeting the requirements of ISO/IEC 17025, Clause 4.3.2.1.
ISO/IEC 17025:2005, Clause 4.3.1 states,

“The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents...”
What are Normative Documents?

- Normative documents are those that provide rules, guidelines or characteristics for activities or their results.

- Standards, technical specifications, codes of practice and regulations.

- Vital to CABs maintaining their accreditation.
What are Normative Documents?

- In addition to ISO/IEC 17025, normative documents include general A2LA policy documents and specific A2LA program requirements.

- Confusion – what A2LA policies and/or requirements are required?
A2LA Website – CAB Access Portal

- All A2LA CABs have access to Portal.

- How does a CAB login?

- How will this help with required A2LA normative documents?

- Example –
ISO/IEC 17025:2005, Clause 4.3.2.1 states,

“All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to use. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be made readily available…”
Meeting the Requirements of ISO/IEC 17025, Clause 4.3.2.1

- All A2LA normative documents are required on master list of documents.

- Or, they are to be referenced in a CAB’s document control procedure.

- Current revision status and distribution must be addressed.
Master List of Documents

- Current revision status not identified.
- Relevant documents on CAB Portal Page have current revision date.
Master List of Documents

- Hardcopy Master List – Each required A2LA normative document must list current revision date.

- Reminder – Relevant documents on CAB Portal Page have current revision date.
Document Control Procedure

- Document control procedure can point user to A2LA website.

- Procedure must be clear and concise.

- Must directly access each required A2LA normative document.
Questions?
American Association for Laboratory Accreditation

Excellence in Accreditation, Commitment to Service
Top Ten Deficiencies (NCs) From February 1, 2011 to January 31, 2012

March 2011

Peter Unger
A2LA President & CEO
Top Ten NCs for All Labs
8149 NCs from 1231 assessments

1. Specific tests or calibrations  20%
2. 5.5 Equipment                  13%
3. Other standards               13%
4. 5.4 Methods & validation      12%
5. 4.3 Document control          12%
6. Traceability policy           9%
7. 4.13 Control of records       7%
8. 4.14 Internal audits          6%
9. 4.6 Purchasing service/supply 6%
10. Proficiency testing policy    5%
NCs for All Labs

- Top ten NCs represent over 75% of all types of NCs
- 67% are technical in nature
- Rest are related to lab’s management system or A2LA policies
- 10% of assessments have no NCs
- Average number per assessment = 7
### Top Ten NCs for Mechanical Labs

2057 NCs from 397 assessments

<table>
<thead>
<tr>
<th>Rank</th>
<th>Topic</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>1</td>
<td>Specific tests</td>
<td>23%</td>
</tr>
<tr>
<td>2</td>
<td>5.5 Equipment</td>
<td>17%</td>
</tr>
<tr>
<td>3</td>
<td>Traceability policy</td>
<td>12%</td>
</tr>
<tr>
<td>4</td>
<td>4.3 Document control</td>
<td>12%</td>
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<tr>
<td>5</td>
<td>5.4 Methods &amp; validation</td>
<td>8%</td>
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<tr>
<td>6</td>
<td>4.6 Purchasing service/supply</td>
<td>7%</td>
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<td>7</td>
<td>4.14 Internal audits</td>
<td>6%</td>
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<td>8</td>
<td>4.13 Records</td>
<td>5%</td>
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<tr>
<td>9</td>
<td>4.2 Management system</td>
<td>5%</td>
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<tr>
<td>10</td>
<td>Proficiency testing policy</td>
<td>5%</td>
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Top Ten NCs for CMT Labs
417 NCs from 45 assessments

1. Specific tests 45%
2. 4.3 Document control 9%
3. 5.5 Equipment 9%
4. 4.6 Purchasing service/supply 8%
5. 5.2 Management system 7%
6. Proficiency testing policy 6%
7. 5.10 Reporting the results 5%
8. Traceability policy 4%
9. 4.14 Internal audits 4%
10. 4.15 Management reviews 4%
Top Ten NCs for Geotechnical Labs
223 NCs from 23 assessments

1. Specific tests 46%
2. 5.5 Equipment 8%
3. 4.3 Document control 8%
4. 4.6 Purchasing service/supply 8%
5. Proficiency testing policy 7%
6. 5.2 Management system 7%
7. Traceability policy 5%
8. 4.13 Control of records 4%
9. 5.10 Reporting the results 4%
10. Advertising policy 3%
Top Ten NCs for EMC Labs
1080 NCs from 169 assessments

1. Specific tests 30%
2. 5.5 Equipment 17%
3. 4.3 Document control 12%
4. Traceability policy 8%
5. 4.6 Purchasing service/supply 7%
6. 5.9 Assuring quality of results 6%
7. 4.14 Internal audits 6%
8. 5.4 Methods & validation 5%
9. 4.2 Management system 5%
10. Advertising policy 4%
Top Ten NCs for Calibration Labs
1075 NCs from 334 assessments

1. 5.4 Methods & validation 19%
2. Specific calibrations 17%
3. Traceability policy 11%
4. 4.3 Document control 11%
5. 5.5 Equipment 9%
6. Proficiency testing policy 8%
7. 5.10 Reporting the results 8%
8. 4.14 Internal audits 7%
9. Advertising policy 6%
10. 5.6 Measurement traceability 5%
Top Ten NCs for Environmental Labs
749 NCs from 52 assessments

1. Other standards 30%
2. 5.4 Methods & validation 15%
3. 4.3 Document control 9%
4. 5.5 Equipment 8%
5. 4.13 Control of records 7%
6. Specific tests 6%
7. Traceability policy 6%
8. 4.2 Management system 4%
9. 4.14 Internal audits 3%
10. 4.11 Corrective action 3%
Top Ten NCs for Food Labs
740 NCs from 77 assessments

1. Other standards 20%
2. 5.4 Methods & validation 15%
3. 4.13 Control of records 12%
4. 4.3 Document control 12%
5. 5.9 Assuring quality of results 8%
6. 5.5 Equipment 8%
7. Proficiency testing policy 7%
8. 4.2 Management system 6%
9. 4.14 Internal audits 6%
10. 5.2 Personnel 6%
Hope this helps on future assessments!

Questions???

punger@A2LA.org
www.A2LA.org
VERTICAL AUDITS

Presented by: Diana S. Gavin, A2LA Director of HR
Overview

- Define a vertical audit
- What areas are covered
- Recognize the benefits of a vertical audit
- How to conduct a vertical audit
What Is A Vertical Audit?

- **Vertical audits** explore a sample from inception through final reporting
  - Review of Sample #123 from receipt through report

- It differs from **horizontal auditing**, which focuses on one aspect of the QMS
  - Review training records for Jon, Jane, and Joe
Progression of the Audit

Sample #1

- Request, Tenders, Contracts
- Sample Handling
- Testing/Calibration
- Reporting Results
- Record Retention
Requirements for Vertical Audit

• Many of the ISO standards are streamlining audit trail requirements
• ISO/IEC 17025 section 4.13.2.1 requires records to establish an audit trail
• The AIM 500.13 – Steps of an Assessment
• In-house procedures may require it
Benefits of a Vertical Audit

- Ensures that all activities contributing to final report comply with the applicable requirements
- Test the interfaces between areas of laboratory
- Increase efficiency of assessment
- Decrease deficiencies from outside assessments.
How to Conduct a Vertical Audit

Three Basic Ways:
A. Start with contract review and pick a few job/project numbers
B. Start with the test reports/calibration certificates and move back to contracts
C. Start with the internal audit & management review to identify projects via CAR, NCF, etc.
How to Conduct a Vertical Audit

After you select a method that works for you, then you can:

- Check the applicable records for each section as you come across them, or;
- Ask the laboratory to supply all the records for those numbers at one time.
Ask Questions

• What method was used?
• Was the equipment calibrated?
• Were environmental conditions met?
• Were the reference materials traceable?
• Were quality checks performed?
• Was the technician trained?

These questions should be answered by the CAB’s record management system.
Closing Thoughts

- Vertical audits are helpful in determining overall compliance and effectiveness.
- There are many methods to get through the vertical audit.
- They shall be used in conjunction with horizontal auditing techniques.
Questions?
American Association for Laboratory Accreditation

Excellence in Accreditation, Commitment to Service
T9: In-house Calibration

2012 Plenary Session

Presented by: Pam Wright – Accreditation Manager
What T9 “Is” and “Isn’t:

- T9 is the minimal set of requirements a CAB must meet in order to ensure proper traceability for those Measuring and Test Equipment (M &TE) calibrated in house.

- T9 is not a determination of compliance with ISO/IEC 17025
CAB Requirements for T9

- Documented procedure
- Evidence of calibration
- Retain records
- Evidence of training
- Evidence of traceability
- Measurement Uncertainty
- Calibration Interval
Documented Procedure

Expectations for Procedure:

- Part of the quality management system
- Technically valid method
Evidence of Calibration

- Can be calibration report, calibration certificate, calibration sticker, other method

Expectations for the evidence:

- Cannot contain A2LA accredited symbol or make reference to A2LA accreditation or 17025
- May contain the data and/or the measurement uncertainty
- Should retain the data in the case of calibration sticker
Retain Records

- Must be retained for an appropriate, prescribed time

Expectations for retaining records:
- Per R102 – at least the time between assessments

Which records?
- Calibration report, certificate, sticker
- Training
- Calibration certificates of reference standards
- Measurement uncertainty calculations
- Calibration interval information
Evidence of Training

- Must retain training records for calibration staff
- Record must include the technical competence of calibration staff
  - Example: record indicating the outcome of an audit of staff when performing the calibration per the procedure
Evidence of Traceability

- Traceability for the reference standards – not the M&TE
- Must be traceable to NIST/acceptable NMI or ILAC signatory

Expectations for Traceability:

- CAB must own the appropriate reference standard to perform the in-house calibration of the M&TE
- Calibration certificate must meet A2LA P102 - either endorsed by NIST, an acceptable NMI or by an ILAC MRA partner
Measurement Uncertainty

- Must have a procedure for calculating measurement uncertainty (MU)
- Must apply the procedure
- Must calculate MU and record result
- In the case of statements of compliance with specifications the MU must be taken into account

Expectations for MU:
- Procedure must be technically valid
- MU calculated per the GUM
Calibration Interval

- Pertains to reference standard – **not** M&TE
- Reference standards must be recalibrated at an appropriate interval

Expectation for calibration interval:
- Have a policy and procedure for establishing and changing the interval
- Interval determined must be based on the historical behavior of the reference standard
- Strongly recommend retaining a record of the interval established
True or False?

- A calibration that is covered by the CAB’s calibration scope of accreditation is an in-house calibration
  
  FALSE

- In-house calibration is only for those items:
  1. not covered by the scope
  2. not sent out for an external calibration
  3. used to support a parameter/test on the scope
Questions?