A2LA Receives “Deemed Status” from State of Maryland for Accreditation of Forensic Laboratories

By Karin Athanas, A2LA Senior Accreditation Officer

On May 18, 2012 the State of Maryland published new regulations for the licensure and oversight of forensic laboratories working in or offering to perform work in the State of Maryland. Code of Maryland Regulations (COMAR) Title 10, Subtitle 51 Forensic Laboratories was developed by the Maryland Department of Health and Mental Hygiene (DHMH) with the help of the Maryland Forensic Laboratory Advisory Committee (FLAC - http://www.msa.md.gov/msa/mdmanual/26excom/html/15forensiclab.html), of which A2LA is a member.

To ensure compliance with COMAR 10.51, A2LA staff developed document R221a – Annex A: Specific Requirements for Forensic Facilities Licensed in Maryland, a supplement to A2LA document R221 - Specific Requirements: Forensic Examination Accreditation Program-Testing which includes the general requirements of the A2LA forensic testing laboratory accreditation program. Both documents, as well as an official application, mock assessment and crosswalk of COMAR 10.51 to A2LA requirements, was provided to the State of Maryland, DHMH, for review.

On November 6, 2012, A2LA received recognition as a deemed accreditation organization under the State of Maryland in accordance with COMAR 10.51. As a deemed accreditation organization, forensic laboratories that offer to perform or perform forensic analyses in the State of Maryland can seek out accreditation services from A2LA to meet state licensing requirements. Additionally, proficiency testing providers accredited by A2LA are approved for use by licensed forensic laboratories in meeting proficiency testing requirements found in COMAR 10.51.

Currently A2LA is one of three United States accreditation body signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) that offer accreditation to ISO/IEC 17025 for forensic testing laboratories and the only United States signatory to the Inter-American Accreditation Cooperation (IAAC) MRA that offers accreditation of crime scene units to ISO/IEC 17020.

In addition to accreditation services, A2LA offers assessment to the FBI Quality Assurance Standards (QAS) for Forensic DNA Testing and Databasing Laboratories in accordance with section 15.2 of the QAS which requires: “at least once every two years, an external audit [conducted] by an audit team comprised of qualified auditor(s) from a second agency.”

For additional information regarding the A2LA forensic program or to apply within this program, please contact Karin Athanas at 301 644 3236 or kathanas@A2LA.org.
By Karin Athanas, A2LA Senior Accreditation Officer

It has only been half a year since the 2012 Technical Forum and Annual Meeting and already A2LA staff are hard at work developing meeting agendas, planning events and making contact with new A2LA members and friends that they look forward to meeting in person at the May 2013 Technical Forum and Annual Meeting. As of publication, the following has already been accomplished:

- Technical Advisory Committee Recording Secretaries have drafted their agendas and are accepting suggestions for discussion topics, presentations and new members;
- An A2LA 2013 Technical Forum and Annual Meeting event page has been created on Facebook (http://www.facebook.com/events/331405313615517/) and participants are being encouraged to provide their suggestions for topics ranging from ideas to improve events to discussions on accreditation-related topics to nominations for awards; and
- Diana Gavin has been appointed as 2013 Technical Forum and Annual Meeting coordinator and is currently working to draft announcements and special invitations, scheduling events and overseeing meeting preparations.

All A2LA contracted and potential assessors and accredited and enrolled organizations as well as technical advisory committee, accreditation council, and criteria council members will receive an official invitation to register for the meeting in March 2013. If you do not fall within one of these categories and would like to be invited to attend, please contact your assigned Accreditation Officer, relevant technical advisory committee recording secretary or email A2LA directly at info@A2LA.org to request an invitation.

By Rob Knake, A2LA Program Manager

A2LA’s Rob Knake currently serves as the NCSL International Mid-Atlantic Regional Coordinator. Rob, in partnership with Henry Zumbrun from Morehouse Instrument Company, coordinated a two-day training event that was conducted October 17-18, 2012 at the Morehouse Instrument Company facility located in York, PA. Phil Smith, A2LA Director of Public Affairs, was also present to assist with the training event.

The instructors were Henry Zumbrun and William Lane from Morehouse Instrument Company. The topic was Fundamentals of Force Calibration (A Hands-On Approach). Registration was limited to 12 attendees and the response was overwhelming. Another training event is planned for Spring 2013 for those who were unable to secure one of the 12 available slots, so there will be another opportunity to take advantage of this local training event.

The training included the use of primary standards and various pieces of force calibration equipment. The attendees physically tested measurement and test equipment and were shown the importance of using appropriate calibration adapters and setups as well as the errors introduced by using incorrect calibration adapters and setups. The participants left with a better understanding of proper force calibration techniques. Torque calibration techniques and measurement uncertainty contributors were also covered.

If you were unable to attend this event, watch for the notification of the spring training session which will be posted online in the near future at www.ncsli.org.

If you are interested in hosting future training events, if you have topics that you would like to see covered during an upcoming training event or if you are interested in serving as a MD or VA Section Coordinator for NCSL International, please contact Rob Knake at rknake@A2LA.org for more details.
A2LA Visits Frederick Animal Health Laboratory

By Lauren Smith, A2LA Accreditation Officer II

On Friday, November 23, 2012, the Maryland Secretary of Agriculture, Earl “Buddy” Hance, and the Deputy Secretary, Mary Ellen Setting, visited the Maryland Department of Agriculture’s Frederick Animal Health Laboratory in Frederick, MD. The Assistant Secretary for Marketing, Animal Industries and Consumer Services, Patrick McMillan, was also in attendance. The purpose of the Secretary’s visit was to congratulate the laboratory on successfully becoming accredited to ISO/IEC 17025:2005 and to the World Organisation for Animal Health (OIE) Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases (2008) through A2LA’s Veterinary Laboratory Accreditation Program. A2LA Accreditation Officer, Lauren Smith, and President/CEO, Peter Unger, were invited to take part in the meeting which included a tour of the laboratory.

The Secretaries had visited the Maryland Department of Agriculture’s Salisbury Animal Health Laboratory earlier in the month to congratulate them on the same achievement as their sister location in Frederick. Together, Salisbury and Frederick have become the seventh and eighth certificates under A2LA’s Veterinary Laboratory Accreditation Program, respectively. It was a pleasure for A2LA to take part in this organization’s celebration and witness the sense of achievement that the staff felt for accomplishing their goal of becoming accredited.

Peter Unger stated, “I am very pleased to recognize the two Maryland animal health facilities for their achievement of A2LA accreditation. The support provided by the State Department of Agriculture officials to complete the accreditation process is exemplary. The laboratories join a small but select group of outstanding, accredited laboratories in the veterinary field.”

The A2LA Veterinary Laboratory Accreditation Program accredits laboratories in the commercial, academic, and government sectors. The requirements combine the ISO/IEC 17025:2005 standard with language from the OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases to create a program that specifically addresses the needs of an organization performing infectious disease diagnostics, disease surveillance, virology, pathology, microbiology, or immunology on commercially or privately owned animals. Lauren Smith is A2LA’s point of contact for the Veterinary Program. For further information, she can be reached at (240) 575 7482 or lsmith@A2LA.org.

A2LA Named a Future 50 Winner for the Second Year in a Row

By Teresa C. Barnett, A2LA Director of Quality

SmartCEO Magazine named A2LA as one of the 50 fastest growing companies in the greater Baltimore area for the second year in a row. The criteria for being named one of Smart CEO’s “Future 50” are combined growth rates of revenues and employees over a three-year period. Each company named was determined to be steadily growing while remaining true to their missions to provide exceptional products and services to their customers.

“The companies we are honoring this year are growing in spite of the economic hardships we have all been facing. These companies are investing in themselves, and investing in their people and are rising above the rest. They deserve to be recognized and celebrated because they are moving our economy and this region forward,” said Craig Burris, founder and president of SmartCEO magazine. “We are proud to recognize them for their achievements and growth.”

A gala dinner is planned in downtown Baltimore on January 10, at which A2LA will be presented with a plaque. A2LA is one of only a very few non-profit organizations identified as recipients of this award. A profile of each “Future 50” company will be presented in the January 2013 issue of Baltimore SmartCEO magazine.
### Winter/Spring 2013 Training Schedule

#### Course:

**Title: Understanding ISO/IEC 17065**
- NEW Course!!!!!
  - January 22-24, 2013 - Frederick, MD (Understanding 17065)
    - Holiday Inn
    - Frederick, MD 21703
    - 301 694 7500
    - Rate: $99.00 per night
    - (room rate cut-off: January 1, 2013)

**Title: ISO 17020 and Accreditation**
- NEW Course!!!!!
  - February 7-8, 2013 - Las Vegas, NV (ISO 17020 and Accreditation)
    - Courtyard Las Vegas South
    - Las Vegas, NV 89118
    - 702 895 7519
    - Rate: $139.00 Per Night
    - (room rate cut-off: February 6-8, 2013)

**Title: Introduction to Measurement Uncertainty**
- February 17-22, 2013 - Savannah, GA (Intro to MU, ISO/IEC 17025 and Accreditation)
  - Marriott Savannah Riverfront
  - 100 General McIntosh Blvd.
  - Savannah, GA 31401
  - 912 233 7722
  - Rate: $155.00 per night
  - (room rate cut-off: February 17, 2013)

**Title: ISO/IEC 17025 and Accreditation**
- February 20-22, 2013 - Savannah, GA
  - $995.00 non-members, $945.00 members
  - April 8-9, 2013 - San Diego, CA
    - $995.00 non-members, $945.00 members
    - (Note that this is a 2-DAY COURSE at this venue)
  - June 19-21, 2013 - Columbus, OH
    - $995.00 non-members, $945.00 members

**Title: ISO 15189:2012 and Accreditation**
- UPDATED Course!!!!!
  - March 4-5, 2013 - San Antonio, TX
    - $975.00 non-members, $945.00 members
  - April 21-26, 2013 - Chicago, IL (Assessment of Laboratory Competence)
    - Chicago Marriott O’Hare
    - 8535 West Higgins Road
    - Chicago, IL 60631
    - Rate: $189.00 Per night
    - (room rate cut-off: April 21-26, 2013)

**Title: ISO/IEC 17025 for Accredited Laboratories**
- NEW Course!!!!!
  - March 11, 2013 - Charleston, SC
    - $495.00 non-members, $445.00 members
  - June 16-21, 2013 - Columbus, OH (Intro to MU, ISO/IEC 17025 and Accreditation)
    - Hilton Columbus at Easton
    - 3900 Chagrin Drive
    - Columbus, OH 43219
    - Rate: $189.00 per night
    - (room rate cut-off: May 26, 2013)

**Title: Internal Auditing**
- March 18-19, 2013 - Columbus OH
  - $795.00 non-members, $745.00 members

**Title: Root Cause Analysis and Corrective Action**
- April 10, 2013 - San Diego, CA
  - $495.00 non-members, $445.00 members

**Title: Assessment of Laboratory Competence**
- April 22-26, 2013 - Chicago, IL
  - $1595.00 non-members, $1545.00 members

#### Venues:

**January 22-24, 2013 - Frederick, MD (Understanding 17065)**
- Holiday Inn
- Frederick, MD 21703
- 301 694 7500
- Rate: $99.00 per night
- (room rate cut-off: January 1, 2013)

**February 6-8, 2013 - Las Vegas, NV (ISO 17020 and Accreditation)**
- Courtyard Las Vegas South
- Las Vegas, NV 89118
- 702 895 7519
- Rate: $139.00 Per Night
- (room rate cut-off: February 6-8, 2013)

**February 17-22, 2013 - Savannah, GA (Intro to MU, ISO/IEC 17025 and Accreditation)**
- Marriott Savannah Riverfront
- 100 General McIntosh Blvd.
- Savannah, GA 31401
- 912 233 7722
- Rate: $155.00 per night
- (room rate cut-off: February 17, 2013)

**March 3-5, 2013 - San Antonio, TX (ISO 15189 and Accreditation)**
- The Westin Riverwalk
- 420 West Market Street
- San Antonio, TX 78205
- 210 224 6500
- Rate: $219.00 per night
- (room rate cut-off: February 1, 2013)

**March 10-11, 2013 - Charleston, SC (ISO/IEC 17025 for Accredited Laboratories)**
- Courtyard by Marriott Charleston
- Historic District
- 125 Calhoun Street
- Charleston, SC 29401
- 843 805 7900
- Rate: $179.00 per night
- (room rate cut-off: February 11, 2013)

For additional information, please contact Julie Collins, A2LA Training/Membership Administrator, at 301 644 3235 or jcollins@A2LA.org.
January 14, 2013 and March 11, 2013 - 1:00 - 3:00 PM
Introduction to Measurement Uncertainty (2 Hours)
This 2-hour web event will cover:
- Measurement Uncertainty definitions.
- Why Measurement Uncertainty is required.
- Minimum Measurement Uncertainty contributors.
- Simplified process for determining Measurement Uncertainty.
- Measurement Uncertainty references.
$299.00. (A2LA Members $249.00 - Discount Code: A2LAWIN)
Registration URL: https://student.gototraining.com/rt/3459093613974248960 (Select the date from the web menu.)

January 15, 2013 and March 12, 2013 - 1:00 - 3:00 PM
Practical Methods for Reporting Measurement Uncertainty on a Calibration Report per ILAC P14 Guidelines (2 Hours)
This 2-hour web event will cover:
- Understanding ILAC P14 requirements.
- Metrological traceability.
- Measurement Uncertainty contributors.
- Reporting customer’s Measurement Uncertainty.
- Test Uncertainty Ratio (TUR) and compliance statements.
- Helpful spreadsheet techniques.
$299.00 (A2LA Members $249.00 - Discount Code: A2LAWIN)
January 15, 2013: Registration URL: https://student.gototraining.com/rt/7913931000164580096
March 12, 2013: Registration URL: https://student.gototraining.com/rt/4105954996292707840

January 16, 2013 and March 13, 2013 - 1:00 - 3:00 PM
Basic Statistics for Metrology with Excel (2 Hours)
This 2-hour web event will cover:
- Excel basic statistical functions.
- Basic statistics required for Measurement Uncertainty.
- Developing a Measurement Uncertainty spreadsheet.
- Validation of a spreadsheet.
$299.00 (A2LA Members $249.00 - Discount Code: A2LAWIN)
Registration URL: https://student.gototraining.com/rt/8116628167768392960 (Select the date from web menu.)
The following documents have been updated within the controlled A2LA management system. All of these documents are available on the A2LA website (www.A2LA.org) through the “Search A2LA Site” tool unless otherwise indicated.

- **G106 – Guidance on Scopes of Accreditation for PCBs under the TCB Accreditation Program** was updated on August 29, 2012.
- **C650 – General Checklist: ISO 15189 Medical Testing Laboratory Accreditation Program** was updated on September 17, 2012.
- **I106 – Available Proficiency Testing Programs** was updated on September 25, 2012.
- **Software Validation in Accredited Laboratories** by Greg Gogates was updated on July 23, 2012.
- **P604 – Policy for Medical Record and Material Retention** was updated on September 17, 2012.
- **A 2013 version of R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories** (dated January 1, 2013) is in transition with the 2009 version of this document, as explained in the **R103 – Transition Memo** (dated September 17, 2012).
- **A 2013 version of C106 – General Checklist: Proficiency Testing for ISO/IEC 17025 Laboratories** (dated January 1, 2013) is in transition with the 2011 version of this document, as explained in the **R103 - Transition Memo** noted above.
- **R104 – General Requirements: Accreditation of Field Testing and Field Calibration Laboratories** and the associated **C103 – General Checklist: Accreditation of Field Testing and Field Calibration Laboratories** were updated on September 6, 2012.
- **R215 – Specific Requirements: Texas DOH Indoor Air Quality Testing Laboratory Accreditation Program** was updated on September 15, 2012.
- **R310a – Annex: Clark County Nevada Special Inspection Agencies** was updated on September 25, 2012.
- **R310b – Annex: New York NY Special Inspection Agencies** was updated on September 25, 2012.
- **I102 – Instructions for Responding to the Assessor Deficiency Report** was updated on October 10, 2012.
- **R205 – Specific Requirements: Calibration Laboratory Accreditation Program** and the associated **C207 – Specific Checklist: Calibration Laboratory Accreditation Program** were updated on November 16, 2012. (Please see the related article in this issue of A2LA Today.)
- **R205a – Annex to Specific Requirements: ANSI/NCSLI Z540.3-2006, R205b – Annex to Specific Requirements: Calibration Measurement Uncertainty Software, R205c – Annex to Specific Requirements: Dimensional Testing Parameters on Scopes of Accreditation, C207b – Annex to Specific Checklist: Calibration Measurement Uncertainty Software and P110 – A2LA Policy on Measurement Uncertainty in Calibration** have been made obsolete. The content of all of these documents have instead been incorporated within the 11/16/12 version of R205. (Please see the related article in this issue of A2LA Today.)
- **F235 – Application for Assessment to the FBI Quality Assurance Standards for DNA Testing and Databasing Facilities** is a new document dated November 16, 2012.
- **F236 – Pilot Program Post Assessment Questionnaire – FBI DNA QAS Pilot Program** is a new document dated November 16, 2012.
ISO/IEC 17065 Published for Certification Bodies

By Rob Miller, A2LA Accreditation Manager

The International Accreditation Forum (IAF) 26th annual general assembly and associated committee meetings were held in Rio De Janeiro, Brazil on October 16-26, 2012. During this annual meeting there was one critical resolution adopted that would immediately impact A2LA’s Product Certification Accreditation Program.


ISO/IEC 17065:2012 became publicly available on September 15, 2012; as such, all IAF Multi-lateral Recognition Arrangement (MLA) signatories (including A2LA) must have all of their Product Certification Bodies (PCBs) accredited to ISO/IEC 17065:2012 no later than September 15, 2015.

For A2LA to successfully assess and provide accreditation to each of its accredited and enrolled PCBs within our two-year assessment cycle, A2LA has published an official transition memorandum outlining the target dates for transitioning to this new standard. The transition memorandum titled R307 - Transition Memorandum to ISO/IEC 17065 is available on the A2LA website at www.A2LA.org.

A2LA will begin accepting applications or scope expansion requests for Product Certification Bodies to be assessed against this new standard beginning March 31, 2013. Any Product Certifier currently accredited to ISO/IEC Guide 65 will be required to undergo an on-site assessment to the new standard in accordance with the R307 - Transition Memorandum to ISO/IEC 17065 mentioned above.

For further information, please feel free to contact A2LA at 301 644 3248 or info@A2LA.org.

Note: A2LA has generated a number of new documents in response to the release of this standard, which are currently undergoing review by the A2LA Criteria Council for approval. It is our intent to have these publicly available on our website at www.A2LA.org no later than February 28, 2013.
On March 1, 2012 the ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission) released the second edition of requirements for accreditation of inspection bodies, ISO/IEC 17020:2012 Conformity assessment — Requirements for the operation of various types of bodies performing inspection. This second edition cancels and replaces the first edition, ISO/IEC 17020:1998- General criteria for the operation of various types of bodies performing inspection.

To promote the transition from the first edition to the second edition, the International Laboratory Accreditation Cooperation (ILAC) issued the following resolution:

The ILAC membership agrees to a three-year transition period for the implementation of ISO/IEC 17020:2012 Conformity assessment - Requirements for the operation of various types of inspection bodies performing inspection, from the date of publication of the English language version of the standard. The standard was published on 1 March 2012, therefore the three year transition period will conclude on 1 March 2015.

The ILAC resolution means that all A2LA-accredited inspection bodies (IBs) shall be accredited to the 2012 version no later than March 1, 2015. As an ILAC mutual recognition arrangement signatory, A2LA must ensure that we fulfill this obligation by the March 1, 2015 deadline. To minimize the financial impact of the transition on an IB, the goal is to conduct an assessment to the new version during a regularly schedule renewal assessment. Since A2LA accredited IBs are on a 2-year accreditation cycle, the changeover process must begin in 2013.

A2LA has revised a number of documents related to this transition, all of which will be publically released in the near future. To help with the transition process, A2LA is offering to provide all currently accredited inspection bodies with a desk audit of their quality system documentation against the 2012 version of the standard prior to the accredited inspection body’s renewal assessment. This desk audit is optional and would be done free-of-charge.

Each inspection body is required to review ISO/IEC 17020:2012 and revise their quality management system as necessary prior to their next on-site assessment. Those inspection bodies wishing to take advantage of the free desk audit of their updated quality management system are invited to complete the updated C301 checklist, cross-referencing the requirements of the updated standard with the corresponding sections of their quality management system. The IB’s revised quality manual may then be provided to A2LA along with the C301 checklist, at which time A2LA staff will conduct the desk audit. While A2LA cannot provide consulting services, our staff will identify potential deficiencies so that the inspection body may make any necessary changes prior to their renewal assessment.

A2LA is also pleased to announce a new ISO/IEC 17020 training class, ISO 17020 and Accreditation. The first class is scheduled for February 7-8, 2013 in Las Vegas, NV. The course is a comprehensive look at ISO/IEC 17020:2012, its documentation, and its internal auditing requirements. In this course, attendees will gain critical insight into the interpretation of the requirements of this inspection body standard and will also receive a detailed review of the accreditation process. Attendees will learn what information a quality manual should contain and how to keep documents and the quality manual up-to-date.

This course also gives attendees the knowledge needed to establish an internal audit program, as required by ISO/IEC 17020, including aspects such as scheduling, planning, conducting, reporting on and closing out internal audits. Attendees will receive practical instructions on the development, implementation and long-term maintenance of an effective ISO/IEC 17020 management system. For more information on this course, please visit our web site http://a2la.org/training/ISO17020.cfm?private=no or contact Julie Collins, A2LA Training and Membership Administrator, at jcollins@A2LA.org or 301.644.3235.

For further information regarding inspection body accreditation, please contact Steve Medellin, A2LA Accreditation Manager (301 644 3228, smedellin@a2la.org), or Elizabeth Carbonella, A2LA Senior Accreditation Officer (301 644 3219, ecarbonella@a2la.org).
Changes to A2LA R205: Specific Requirements: Calibration Laboratory Accreditation Program and A2LA R218: Requirements for Calibration Scopes of Accreditation

What You Need to Know

By Pam Wright, A2LA Accreditation Manager

Upon review and approval by the A2LA Measurement Advisory Committee (MAC) and the A2LA Criteria Council (CC), A2LA’s R205: Specific Requirements: Calibration Laboratory Accreditation Program was published with a revision date of November 16, 2012. While most of the changes are simply a consolidation of various requirements and policies into a single document, there is one addition as well. The addition and changes to R205 are noted below:

- R205 has been revised to add a new requirement in Part II Section 2.6. This new requirement calls for the laboratory to develop and implement a procedure for issuing accredited (endorsed) calibration certificates. The procedure must ensure that accredited (endorsed) calibration certificates are evaluated for compliance with ISO/IEC 17025 and A2LA requirements before being issued to the customer.
- An additional change to R205 relates to significant figures for the expanded uncertainty that is reported on an accredited (endorsed) calibration certificate and reads as:
  2.3.4 The numerical value of the expanded uncertainty shall be given to two significant figures. Further the following applies:
  1) The numerical value of the measurement result shall in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result.
  2) For the process of rounding, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided i.e. in Section 7 of the GUM.

Note: The above (2.3.4) may be precluded by legal, regulatory or contractual requirements.

Implementation of these new changes will be as follows:

- At this time, all currently accredited calibration laboratories and new applicants will be subject to the requirements of R205 with the exception of Section 2.6.
- All new calibration laboratory applications received after December 31, 2012 will be immediately subject to the new requirements found in Section 2.6 of R205.
- All currently accredited calibration laboratories with an anniversary date of August 31, 2013 or later will be subject to the new requirements found in Section 2.6 of R205 by the time of their renewal assessment.

R205 was also reorganized and consolidated in the following manner with no changes to any requirements:

- The former section 4.0 from R205 was moved to APPENDIX A: Requirements Specific to ANSI/NCSL Z540-1-1994 – Optional.
- The contents of A2LA P110 – A2LA Policy on Measurement Uncertainty in Calibration were moved to the new section 4.0 and P110 has been withdrawn.
- The contents of A2LA R205a - Annex to Specific Requirements: ANSI/NCSLI Z540.3-2006 were moved to APPENDIX B: Requirements Specific to ANSI/NCSLI Z540.3-2006 – Optional and R205a has been withdrawn. The corresponding checklist, C207a is still available.
- The contents of A2LA R205c – Specific Requirements for Dimensional Testing Parameters on Scopes of Accreditation were moved to APPENDIX C – Requirements Specific to Dimensional Testing Parameters on Scopes of Accreditation and R205c has been withdrawn. Furthermore, the scope examples from R205c were also updated.

What does this mean for you?

On the implementation of R205 (11/16/2012 version):

- The 11/16/2012 version must be implemented immediately, with the exception of Section 2.6.
- Section 2.6 must be implemented immediately for all calibration laboratory applications for accreditation received after December 31, 2012.
- Section 2.6 must be implemented by the time of an accredited calibration laboratory’s renewal assessment beginning with all anniversary dates of August 31, 2013.

On the master documents list:

Calibration laboratories no longer need to include P110, R205a and R205c as controlled documents in the master documents list. The laboratory does need to update its master document list for the new November 16, 2012 revision of R205.

On the requirements of P110, R205a and R205c, now part of R205:

Nothing has changed. These requirements have simply been

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embedded into R205 in order to place all the applicable requirements within a single document.

- If you are an A2LA calibration laboratory, then the former requirements of P110 (now found in Section 4.0 of R205) still apply.
- If you are a calibration laboratory accredited for Z540-1 then the former requirements of Section 4.0 of R205 (now found in APPENDIX A of R205) still apply.
- If you are a calibration laboratory accredited for Z540.3 then the former requirements of R205a (now found in APPENDIX B of R205) still apply.
- If you have dimensional testing on your calibration Scope of Accreditation then the former requirements of R205c (now found in APPENDIX C of R205) still apply.

It is important to note that A2LA does not plan to further amend R205 in 2013.

Upon review and approval by the A2LA Measurement Advisory Committee (MAC) and the A2LA Criteria Council (CC), A2LA’s R218: Requirements for Calibration Scopes of Accreditation has been published with a revision date of November 19, 2012. There are no significant changes to these requirements. The changes to R218 are summarized below:

- A2LA’s R218a – Annex A: General and Specific Editorial Considerations has been added to R218 as APPENDIX A: General and Specific Editorial Considerations. R218a has been withdrawn. Changes to Appendix A were made to document current practice within A2LA Accreditation Services; therefore, nearly all calibration Scopes of Accreditation should already be in compliance with these additional items:
  1. Added to Item 9: This simple rule is supported, in part, by the GUM, Section 7.2.6.
  2. Added to Item 13a: This is always given as footnote 1 on the Scope of Accreditation.
  3. Added to Item 13b: This is always given as footnote 2 on the Scope of Accreditation.
  4. Added to Item 13c: This is always given as footnote 3 on the Scope of Accreditation unless the laboratory does not offer field calibration service. In addition, where the footnote to indicate field service is used, it must always be placed on the parameter to designate those that are applicable from those that are not, even in cases where all the parameters are applicable.
  5. Added Item 15: For dimensional parameters, the range cannot begin with zero, rather the term “Up to…” is used instead.
  6. Added Item 16: Use of the term “Generate” is restricted to Electrical – DC/Low Frequency and RF/Microwave parameters. All other parameters use the term “Measuring Equipment” instead.
  7. Added Item 17: A dash is used when denoting “Generate”, “Measure”, or “Measuring Equipment”. For example: DC Voltage – Generate, DC Current – Measure, Frequency – Measuring Equipment.
  8. Added Item 18: Use of the term “and” or the symbol “&” may be used but must be used consistently throughout the document. Use of the symbol “&” is required when indicating the Discipline of “Time & Frequency”.
  9. Added Item 19: The information captured in the comments must line up with the range indicated.
  10. Added Item 20: A forward slash “/” is always used between DC/Low Frequency and RF/Microwave.

- A2LA’s R218b – Annex B: Presentation of Durometers on a Scope of Accreditation was added to R218 as APPENDIX B: Presentation of Durometer Calibration on a Scope of Accreditation. R218b has been withdrawn. There are no material changes to APPENDIX B.

- A2LA’s R218c – Annex C: Presentation of Hardness on a Scope of Accreditation was added to R218 as APPENDIX C: Presentation of Hardness Calibration on a Scope of Accreditation. R218c has been withdrawn. There are no material changes to APPENDIX C.

What does this mean for you?

On the implementation of R218 (11/19/2012 version):

- The 11/19/2012 version must be implemented immediately. For new items found in APPENDIX A, A2LA staff has already been implementing these changes; therefore, very few calibration Scopes of Accreditation should be affected by them. The Scopes affected are currently being updated during routine renewal assessments.
- For APPENDIX B and APPENDIX C items, these have already been implemented for calibration laboratories with anniversary dates of May 31, 2012 or later and are currently being updated with ongoing renewal assessments.

On the master documents list:

This means that a calibration laboratory no longer needs to include R218a, R218b and R218c as controlled documents in the master documents list. The laboratory does need to update its master documents list for the new November 19, 2012 revision of R218.

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Changes to P102b - Annex: Policy on Requesting an Exception to Measurement Traceability – What You Need to Know

By Pam Wright, A2LA Accreditation Manager

There have been some changes to the process for granting an exception to the A2LA traceability policy. These changes have been implemented as of November 28, 2012. A summary of the changes are as follows:

Exceptions are now granted for the current calibration interval instead of the time between assessments.

This means that the accredited organization must provide A2LA with evidence of or information regarding the calibration interval that has been set for the reference standard or measuring and test equipment in question as part of the exception request.

When the calibration interval is set at less than two years a further exception approval is not required by A2LA until the renewal application is made available to the accredited organization.

This means that, when an accredited organization sets a calibration interval at one year, for example, A2LA does not require an exception request until the next renewal assessment has been initiated. At that point if the accredited organization does not submit a further exception request with their renewal application and obtain approval prior to the on-site assessment or if a traceable calibration has not been performed by the time of the assessment, a deficiency will be cited.

In cases where the calibration interval of the reference standard or measuring and test equipment is set at greater than two years, and it exceeds the manufacturer's recommended interval, documented evidence (e.g. records of intermediate checks) indicating that the reference standard or measuring and test equipment continues to remain within the manufacturer (or applicable) specifications is also required.

This means that, when an organization sets a calibration interval at five years (for example) and, by doing so, they exceed the manufacturer-recommended interval of one year (for example), the organization must provide documented evidence that the reference standard or measuring and test equipment in question is still in tolerance or in compliance with the manufacturer or applicable specification. An example of documented evidence would be intermediate check data.

Circumstances surrounding the exception will be re-evaluated during the organization’s next full assessment. A deficiency will be cited if a new calibration interval was assigned to the reference standard or measuring and test equipment, the calibration provider does not meet the A2LA Traceability Policy, and approval of an additional exception request was not obtained.

This means that, if (during the on-site visit) the assessor finds that the calibration interval has ended and the organization obtained another non-accredited, non-traceable calibration and did not request another exception from A2LA prior to the assessment, a deficiency will be cited.

If you have any questions regarding these changes to P102b, please speak with your Accreditation Officer (AcO) or Pam Wright at pwright@A2LA.org or 301-644-3201. ✮

On the requirements of R218a, R218b and R218c, now part of R218:

Minor changes have been made. The majority of these requirements have simply been embedded into R218 in order to place all the applicable requirements in a single document.

• If you are an A2LA calibration laboratory, then the former requirements of R218a (now found in APPENDIX A) still apply.

• If a Durometer parameter is present on your Scope of Accreditation then the former requirements of R218b (now found in APPENDIX B of R218) still apply.

• If a Hardness parameter is present on your Scope of Accreditation then the former requirements of R218c (now found in APPENDIX C of R218) still apply.

Should you have any questions on the changes to R205 or R218, please contact your Accreditation Officer or Pam Wright at 301-611-3201 or pwright@A2LA.org ✮
Revised Explanations of ISO/IEC 17025 Requirements

By Teresa Barnett, A2LA Director of Quality

In September 2012, the A2LA Criteria Council voted to approve three revised explanations of the ISO/IEC 17025:2005 requirements. These and other explanations may be found on the A2LA website under “Accreditation Programs”, “Explanations for the ISO/IEC 17025 Requirements”.

QUESTION: Our lab maintains one controlled & centrally-located copy of every document in the management system. Is a master list outlining distribution really required in this case?

REVISED Response: No, a master list is not necessary. Section 4.3.2.1 requires a “master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system...”. Many laboratories now maintain their management system through a lab file server or from within a content management system (CMS). In both of these cases, the user accessible file directory or CMS cabinet provides adequate metadata to satisfy this clause of ISO/IEC 17025. If a laboratory maintains a controlled paper copy of documents within their management system, it is assumed that each is also maintained as a word-processed object in a server file directory. The directory itself may then serve as the master list required by this clause of the Standard, as long as the document control procedure also specifies the location/distribution of any controlled hardcopies.

QUESTION: Is the master list my lab created to meet Section 4.3.2.1 of the Standard considered a record or is it considered a document that would be subject to document control requirements?

REVISED Response: A2LA considers a laboratory’s “master list” to be a record and not a document that is subject to document control requirements. Section 4.3.2.1 of ISO/IEC 17025 indicates that the clause can be met by use of either a master list (subject to requirements associated with record management) OR an equivalent document control procedure (subject to document control requirements). If the master list is an online file directory or a screen from an intranet Content Management System (CMS), it is considered to be an electronic record that is a living list reflecting the online status of each document.

QUESTION: What is considered an “equivalent measure” for avoiding loss or change of original data that is stored electronically?

REVISED Response: “Electronic records” are records whose original (or source) data is entered electronically – either automatically by test equipment or by hand. Appropriate measures are to be implemented by the laboratory to safeguard against loss or change of the originally recorded data. The “equivalent measure” pertains to the “initial/date/cross-out” concept. To ensure against the loss or change of original data that is stored electronically, “audit trails” are used so as not to obscure the original observation(s). Audit trails provide an indelible history of the data from original observation to the final value. The metadata required for each change are a timestamp and record the identity of the person capturing or changing the data, thus allowing the records to show when and by whom each original entry was made and when and by whom each subsequent change was made. Electronic datasets generated automatically by test equipment are typically not a concern, since any revisions would be automatically regenerated by the test equipment with the assumption that the dataset is not subject to datapoint manipulation.

This “equivalent measure” to the “initial/date/cross-out” concept also requires the additional concept of “session time”. This is the time allowed for the user to maintain the data in an editable state prior to “committing” or “checking-in” the data. This time should be reasonably short to ensure that the history of changes is captured but not so short as to capture every backspace. Suggested timeframes are end of shift, end of logical portions of tests, or end of day.

There are mature software tools and techniques that may be used to avoid loss or change of electronic source data, such as:

- The use of Document Management, Content Management, or Code Management applications that require named users to “check-in” and “check-out” documents, spreadsheets, etc. These tools retain all versions in history and identify when and by whom the new versions were saved.
- The use of a database that “expires” data rather than deleting it. This is a standard feature of SQL databases that also manage the “who and when” via user IDs.
- The removal of the “modify” permission in the file directory containing the data files. This will require the user to “save-as” the data file, thereby creating unique filenames of each instance of revision or change.
- Printing out the data and saving the paper copy as the original observation.

Use of less mature software tools and techniques is not encouraged but certainly is not prohibited by the Standard. This may include:

- Retaining a register of changes/revisions in electronic records that detail the changes made and by whom.
- Using revision control features of the application that is used to generate the electronic record (e.g., “track changes” in MS Word) but only in combination with removal of the “modify” permission in the file directory so that the “track changes” are not inadvertently incorporated and turned off, thereby obliterating the original information. ✴
The ILAC Sixteenth General Assembly met in Rio de Janeiro from 16 – 26 October 2012.

The ILAC Arrangement Council extended the ILAC Arrangement to include the accreditation of inspection bodies. The following regional cooperation bodies were part of the inaugural signing of the ILAC Arrangement to include the accreditation of inspection bodies:

- Asia Pacific Laboratory Accreditation Cooperation (APLAC)
- European Cooperation for Accreditation (EA)
- Inter-American Accreditation Cooperation (IAAC)

There were 39 inaugural signatories to the extension of the ILAC Arrangement for the accreditation of inspection bodies. A2LA was the first USA accreditation body to sign the extension to inspection body accreditation. For a list of these signatories, visit www.ilac.org.

The following organizations were accepted as Associates:

- Organismo De Acreditacion Ecuatoriano (OAE), Ecuador
- Organismo Nacional de Acreditacion (ONA), Paraguay

The following new signatories to the ILAC Arrangement for laboratory accreditation scopes were approved:

- Cyprus Organisation for the Promotion of Quality (CYS) Cyprus Accreditation Body (CYSAB), Cyprus for testing
- Organismo De Acreditacion Ecuatoriano (OAE), Ecuador for calibration and testing
- Oficina Guatemalteca de Acreditacion, Guatemala for extension of scope to include calibration
- Office Luxembourgais d’Accreditation et de Surveillance (OLAS), Luxembourg for extension of scope to include calibration
- Mongolian Agency for Standardization and Metrology, Accreditation Department (MNAS), Mongolia for calibration and testing
- Organismo Nacional de Acreditacion (ONA), Paraguay for testing

Accreditation Board of Serbia (ATS), Serbia for calibration and testing
- Sri Lanka Accreditation Board for Conformity Assessment (SLAB), Sri Lanka for extension of scope to include calibration
- IARM, The Accreditation Institute of The former Yugoslav Republic of Macedonia for calibration and testing

The following organizations were admitted as Affiliates:

- Accreditation Education Research & Scientific Services Center (AERSSC), Nepal
- Accreditation Commission for Conformity Assessment Bodies (ACCAB), India
- Joint Stock Company Scientific Technical Center “Industrial Safety” (STC-IS), Russian Federation

The Nuclear Energy Institute and the United Kingdom National External Quality Assessment Service (UK NEQAS) were admitted as Stakeholders.

As ISO Guide 34:2009 includes normative references to ISO/IEC 17025 and ISO 15189, the General Assembly decided that accreditation of reference material producers is to be conducted in accordance with ISO Guide 34:2009 alone. Noting the results of the ISO ballot completed for ISO FDIS 15189 on 11 October 2012, the General Assembly agreed that, by 1 March 2016, all references to ISO 15189 in accreditation certificates (as defined and described in ISO/IEC 17011) shall refer to the latest edition of ISO 15189. Compliance will be determined during normal surveillance or reassessment activities or as a separate activity. At the end of the transition period, accreditation of a laboratory to ISO 15189:2007 will not be recognized under the ILAC Arrangement.

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The transition period for the implementation of ISO/IEC 17020: 2012 Conformity assessment – Requirements for the operation of various types of inspection bodies performing inspection will expire on 1 March 2015. At this time, all accreditation certificates issued (as described and defined in ISO/IEC 17011) must reference the 2012 edition of ISO/IEC 17020. Compliance will be determined during normal surveillance or reassessment activities or as a separate activity. After 1 March 2015, inspection bodies accredited to the previous version of ISO/IEC 17020 will not be recognized under the ILAC Arrangement.

The Proficiency Testing Consultative Group has been disbanded and reconstituted as a Proficiency Testing Working Group under the Accreditation Committee (AIC). Commencing in 2013, meetings of the working group will occur annually in conjunction with the AIC mid-year meetings and participation will be open to all interested ILAC members and stakeholders as well as PT providers.

The General Assembly received reports from the Bureau International des Poids et Mesures (BIPM) and the World Anti-Doping Agency (WADA).

IAF and ILAC signed a trilateral MoU with the International Telecommunications Union (ITU) during the meeting to support ITU efforts in the development of its conformity assessment program.

The following officers to the ILAC Executive Committee were elected for 2013-14:

- **Chair** - Peter Unger
- **Vice-Chair** - Merih Malmqvist Nilsson
- **Arrangement Committee** - Ileana Martinez
- **Accreditation Committee** - Regina Robertson
- **Inspection Committee** - Lal Ilan
- **Marketing & Communications Committee** - Jon Murthy
- **Joint Development Support Committee** - Liliane Somma
- **Arrangement Management Committee** - Andreas Steinhorst
- **Unaffiliated Representative** - Etty Feller
- **Laboratory Committee** - Steve Sidney

Finally, at the Joint General Assembly, IAF and ILAC chairs signed an updated Agreement on Closer Cooperation between IAF and ILAC. ★

Happy Holidays!