


[Contact Us](#)
[Request Information](#)

A2LA News: The Newsletter of the American Association for Laboratory Accreditation__July 2006, Number 93

Editors: [Teresa Barnett](#) and [Timothy Rasinski](#)

Web Layout: [Daren Valentine](#)

[Adobe PDF Version](#)

In This Issue.....

General Updates, Notices & Press Releases

- Chairman's Message
- 2005 Annual Report Available
- New Fees for 2007
- New Assessors Contracted by A2LA
- Aerospace Prime Recognition Update
- New Aerospace Advisory Committee
- New & Updated Documents
- Fall 2006 Training Schedule

Meeting Summaries

- A2LA Participates in APLAC RMP Workshop

Updates on A2LA Operations & Policies

- Misuse of the A2LA Accredited Symbol
- Keeping Current with A2LA Requirements
- A2LA Policy on Personnel Certification
- Submitting CARs Electronically
- Recalculating Measurement Uncertainty for T9
- How to Interpret the the Estimated Assessment Cost Form
- Software Validation
- Are Accelerometers in Good Condition?

International Activities and Updates

- MRA Members vs. Signatories



Tom Smith, A2LA assessor (left), discusses assessment findings with the staff of the Japan Quality Assurance Organization. A2LA accredits labs in 48 states and 22 foreign countries.

A2LA News July 2006

Chairman's Message

by **Trevor Boyce**

In the last publication of *A2LA News*, I wrote of the excellent condition of the A2LA "house-in-order heartbeat." This is the more important of the two heartbeats that any and all non-subsidized organizations must have in order to be considered healthy.

The house-in-order heartbeat was defined as the strength of today's financial status of the organization. In other words, does the organization have a suitable cash flow that will operate the enterprise today so that the doors will be open tomorrow?

In that light I stated that A2LA is in excellent order.

Now let me focus on the second heartbeat, the "long-term-viability heartbeat." This is defined as all those

activities being performed today that will supply the market demand of the future.

It would be correctly pointed out by a business professor that not every organization needs a long-term-viability heartbeat. If there exist a stable marketplace where supply, demand, and technology remain constant, then a house-in-order heartbeat is all that is needed, but that condition exists only in fairy tales. As we all know, market conditions are always changing, and so A2LA must be prepared.

In this A2LA has identified several areas of interest of which one is the accreditation of medical laboratories. There is talk of several others.

The reason why the house-in-order heartbeat is the more important of the two is that long-term-viability projects cost money in the beginning. Seldom, if ever, does such a project create a positive cash flow from day one. It is necessary to be generating a strong house-in-order heartbeat to afford the luxury of a long-term-viability endeavor. This is no different for A2LA, and happily we are in good shape.

Already A2LA is deep into the study of the medical laboratory accreditation process and market conditions. A few areas of market penetration have been identified that take advantage of our years of accreditation experiences to allow an easy entry. Yet with any such endeavor, there is much to learn and obstacles to overcome.

Looking into the near future and assuming that all goes well with the development of the medical laboratory long-term-viability project and perhaps a few other projects as well, A2LA will be in a position of having expanded its accreditation services, all the while insuring that its two heartbeats are strongly pumping blood through the organization.

I look forward to reporting on this accomplishment.

[return to top](#)

2005 Annual Report Available

The [2005 A2LA Annual Report](#) is now available on our website. If you prefer a hardcopy, please call us at 301 644 3248, and we will be happy to provide one. The annual report provides valuable information regarding participation in our accreditation programs, national recognitions, international agreements and the financial health of the Association. We encourage everyone to read it when they have an opportunity.

[return to top](#)

New Fees for 2007

After a careful review and analysis of needs, A2LA is modestly adjusting its fees in line with the rate of inflation, effective January 1, 2007. A2LA has not increased fees in three years. The impact of the increase will depend upon the time spent by the assessor(s) on the assessment. We are only adjusting the assessment daily rate; the A2LA initial application fee and annual fees established in 2004 will remain the same.

The assessment daily rate is the rate that A2LA charges the applicant for the assessment time. Currently, the assessment daily rate is \$960 per 8-hour day (or \$120/hour), and it will increase to \$1,080 (or \$135/hour). In an effort to have the overall cost of accreditation more closely reflect the size of the laboratory and its requested Scope(s) of Accreditation, the assessment daily rate is the only element of the fee formula to be increased.

The increase is \$120/day (or \$15/hour). So an average of five assessor days per on-site assessment would be a \$600 increase over two years or \$300 budgeted increase per year. This rate is chargeable at the time of assessment, every other year for most accredited applicants. Travel expenses will still be billed at the actual cost.

At its June 2, 2006, meeting the A2LA board of directors approved the following fee schedule effective January 1, 2007, for the laboratory accreditation services. The current 2004 to 2006 fee schedule will remain in effect until December 31, 2006.

Service	Current Fees	Effective January 1, 2007
Initial Application Fee	\$600	\$600
Initial Application Fee, additional facilities	\$600	\$600
Annual Fee, First Field	\$1,200	\$1,200
Annual Fee, Additional Fields	\$1,000	\$1,000
Assessment Daily Rate	\$960	\$1,080
Assessor Deposit, First Field	\$2,000	\$2,000
Assessor Deposit, Each Additional Field	\$2,000	\$2,000

For renewal laboratories with an anniversary date after January 1, 2007, invoices for 2007 fees (generated approximately 6 months prior to the anniversary date) will reflect the same annual fee(s) and assessor deposit(s). Assessments for those laboratories will be charged at the new daily assessment rate of \$1,080.

Also, any interim assessment and follow up assessment from an action taken in 2006 but conducted in 2007 will remain at the \$960 rate until April 30, 2007. Effective May 1, 2007, all interim or follow up assessments will be at the rate of \$1,080.

Any new applications for accreditation received after January 1, 2007, will be subject to the new fees. Any laboratories submitting new applications prior to December 31, 2006, must have their on-site assessment completed by April 30, 2007, to receive the daily assessment rate in effect at the time of application (\$960 day). After May 1, 2007, all initial assessments will be charged the new \$1,080 daily assessment rate.

For any laboratory that achieves initial accreditation between now and December 31, 2006, the daily assessment rate for the surveillance visit in 2007 will remain at \$960.

The refund policy remains unchanged.

For any questions regarding this change, please contact A2LA at 301 644 3248.

[return to top](#)

New Assessors Contracted by A2LA

The following assessors have been given contracts by A2LA and have started performing assessments:

[Howard "Buck" Barker](#) – construction materials

[Brendan Cryns](#) – materials testing

[P.W. "Woody" Tramel](#) – calibration

A2LA would also like to thank the laboratories that allow A2LA staff to accompany the new assessors on their first assessments as part of our evaluation process. The A2LA assessor training program would not be a success without the cooperation of our laboratories.

[return to top](#)

Aerospace Prime Recognition Update

A2LA has received encouraging reports that accredited materials testing laboratories (MTLs) are actively enjoying the recognition A2LA has obtained from various aerospace primes. Listed below are the aerospace primes that currently recognize A2LA accreditations to ISO/IEC 17025.

- GE – GE has made the following statement, "With the incorporation of ISO 17025 in S-400, GE allows more flexibility in the approval process. Subsequent to initial approval by GE, a laboratory can get re-certified for GE work by: 1) a GE on site audit, 2) a SNECMA or AIRBUS audit, 3) an ISO 17025 performed per GE additional requirements by NADCAP recognized accreditors, e.g.

A2LA etc. or 4) a Pri-Nadcap audit.”

- Sikorsky – Sikorsky's *Approved Source List (ASL)* contains a statement recognizing A2LA as an alternative to NADCAP. “Sikorsky now recognizes the American Association for Laboratory Accreditation (A2LA) as an alternative to NADCAP. Special Process Laboratory Suppliers designated by Approved Source List Note 7, may now use the A2LA accreditation as a direct substitute to NADCAP certification.”
- Boeing - Boeing's document D1-4426 (NADCAP Information revision EJ) under the heading “Exceptions When NADCAP Accreditation is Not Required” states, “Nadcap accreditation for MTL is not required for companies holding ILAC recognized accreditations for the applicable test methods.”
- Pratt & Whitney – Pratt & Whitney has made a formal announcement to waive its NADCAP mandate for material test labs accredited by A2LA.
- Hamilton Sundstrand – Hamilton Sundstrand has made a formal announcement to waive its NADCAP mandate for material test labs accredited by A2LA.

A2LA is currently working with other aerospace primes to gain their acceptance of A2LA accreditation and/or acceptance of the ILAC MRA. Updates and announcements will be posted on the A2LA website as they develop.

For further information on the acceptance of A2LA accreditation by aerospace primes, please contact Robert Miller, senior laboratory services officer, at rmiller@a2la.org or 301 644 3239.

[return to top](#)

New Aerospace Advisory Committee

A2LA has scheduled its inaugural Aerospace Advisory Committee meeting for Tuesday, September 26, 2006, from 9:00 AM until 5:00 PM at the Sheraton Columbia Hotel. This committee will be open to the public and will include specifiers (primes), material testing laboratories (MTLs) and other interested parties.

General meeting information (including hotel and transportation arrangements) can be found at www.a2la.org/aerospace/AAC_attendance_confirmation.pdf. You may register to attend on our web site at www.a2la.org/aerospace/aacconfirm.cfm.

A2LA sets up advisory committees for certain fields or program areas if advice is needed beyond that which can be obtained from existing consensus standard writing and industry committees. Each advisory committee provides advice on the development of program requirements and the interpretation and/or amplification of ISO/IEC 17025 requirements for particular fields. A2LA will use the advice generated by this committee to advance its aerospace program.

Since this meeting is intended to seek input from all interested parties, we are currently accepting ideas for additional discussion topics. If you have an issue or topic for discussion at this meeting or have questions regarding the meeting, please contact Rob Miller at rmiller@a2la.org. The agenda will be posted on the A2LA website at www.a2la.org by August 25, 2006.

[return to top](#)

New & Updated Documents

- The *Accreditation Program for Providers of Proficiency Testing (PT) Programs – Application Form* has been updated to a 5/16/06 version. It is available on the A2LA website and is in effect for any PT provider applicant as of 5/15/06.

- The [General Requirements for Accreditation of Proficiency Testing Providers](#) has been updated to a 5/9/06 version to require an on-site, first-year surveillance visit for all newly accredited proficiency testing providers. The document is available on the website and is in effect for all applicants to this program as of 5/9/06.

For questions about the A2LA proficiency testing provider accreditation program, please contact Randy Query at 301 644 3221 or rquery@a2la.org.

- The [General Requirements for the Accreditation of Reference Material Producers](#) has been updated to a 5/9/06 version to require an on-site, first-year surveillance visit for all newly accredited reference material producers. The document is available on the website and is in effect for all applicants to this program as of 5/9/06.
- The [Accreditation Program for Reference Material Producers – Application Form](#) has been updated to a 5/1/06 version. It is available on the website and is in effect for any reference material producer applicants as of that date.

For questions about the A2LA reference material accreditation program, please contact Randy Query at 301 644 3221 or rquery@a2la.org.

- The [A2LA Policy on Measurement Traceability](#) has been updated to a 5/19/06 version and is available on the website. Clarifications to several sections have been made and a substantial change to the requirements of T9d has also been made. A note has been added to T9d that the new requirement is in effect for in-house calibrations performed as of 8/1/06. Laboratories will not be assessed to this new requirement for any in-house calibrations done prior to that date.
- The *Assessor Checklist: General Criteria (ISO/IEC 17025-2005 - Full Text)*, the *Combined Assessor Checklist: A2LA Animal Drug Testing Program and ISO/IEC 17025 General Criteria – Full Text*, the *Combined Assessor Checklist: A2LA Food Testing Program and ISO/IEC 17025 General Criteria – Full Text* and the *General Criteria (ISO/IEC 17025 - Full Text Incorporated with A2LA's Environmental Program Requirements)* checklist have all been updated to 5/19/06 versions. All of these contain the relevant changes to the [A2LA Policy on Measurement Traceability](#) and are available upon request only.

In addition, all of these checklists have undergone a format change whereby laboratories are only required to complete the "document reference" section for shaded requirements. It is now the assessor's responsibility to complete the "compliance" column and the "comments" column, as these have been separated into an "assessor use only" section. Use of these new checklists will begin with each laboratory's next scheduled on-site assessment.

All remaining, relevant assessor checklists have been updated to reflect the format change noted above. All are available on the website, unless otherwise noted. These include:

- [Assessor Checklist: Animal Drug Testing Program](#);
- [Assessor Checklist: A2LA Food Testing Program Requirements](#) (available upon request only);
- [NELAC Proficiency Testing Provider ISO/IEC 17025-2005 and NELAC Chapter 5 Assessor Checklist](#) (available upon request only);
- [Assessor Checklist: Environmental Lead \(Pb\) Program Requirements](#);
- [Assessor Checklist: A2LA Calibration Program Requirements](#);
- [Assessor Checklist: A2LA Kentucky UST Laboratory Accreditation Program Requirements](#);
- [Assessor Checklist: A2LA Requirements for the Accreditation of Site Testing and Site Calibration Laboratories](#);
- [Assessor Checklist: Veterinary Diagnostic Program Requirements](#);
- [Assessor Checklist: A2LA Wyoming Storage Tank Remediation \(STR\) Laboratory Accreditation Program Requirements](#);

- [SAE AS7101 Assessor Checklist](#) (available upon request only);
 - [Assessor Checklist: A2LA Environmental Program Requirements](#);
 - [Assessor Checklist: A2LA Environmental Program Requirements – Appendix D](#) (for radiochemistry, air, chemistry, microbiology, and toxicity);
 - [Assessor Checklist: 21 CFR Part 210 & 211: Current Good Manufacturing Practice \(cGMP\)](#);
 - [Proficiency Testing Provider Requirements Assessor Checklist](#);
 - [NELAC Chapter 2 Proficiency Testing \(PT\) Provider Requirements Assessor Checklist](#);
 - [NELAC Proficiency Testing \(PT\) Provider Requirements \(ISO Guide 43 and ISO Guide 34\) Assessor Checklist](#) (available upon request only);
 - [National Standards for Water Proficiency Testing Studies Criteria Document: A2LA Assessor Checklist](#);
 - [Reference Material \(RM\) Producer Accreditation Requirements: Assessor Checklist](#) (available upon request only).
- The [A2LA Construction Materials Testing Assessment Checklist](#) has been updated to a 6/6/06 version to reflect current requirements of the relevant ASTM standards. It is available on the A2LA website. For construction materials laboratories, use of this checklist will begin for new or renewal applications received as of 6/6/06.
 - A stand-alone policy document for branch systems (the [A2LA Branch System Policy](#)) has been written (dated 6/1/06) to reflect special requirement for branch applicants. It is located on the website for reference by all parties and is also reflected in the "ISO/IEC 17025 Application" forms.
 - The [Putting Green Materials Testing Program](#) requirements have been updated to a 6/8/06 version. It is available on the website. The revisions made to this document are effective as of 9/15/06.

[return to top](#)

Fall 2006 Training Schedule

Title: [Introduction to Measurement Uncertainty](#)

- September 18-19, 2006 – Boulder, CO (\$795.00 for non-members, \$745.00 for members)
- November 13-14, 2006 – Las Vegas, NV (\$795.00, \$745.00)

Title: [ISO/IEC 17025 and Accreditation](#)

- September 20-22, 2006 – Boulder, CO (\$995.00, \$945.00)
- November 15-17, 2006 – Las Vegas, NV (\$995.00, \$945.00)

Title: [Assessment of Laboratory Competence](#)

- October 2-6, 2006 – Cleveland, OH (\$1595.00, \$1545.00)

Title: [Quality Assurance Analysis Tools for Calibration and Testing Laboratories](#)

- October 23-24, 2006 – Cleveland, OH (\$795.00, \$745.00)

Venues:

September 18-22, 2006

Hotel Boulderado
2115 13 th Street
Boulder, CO 80302
303 440 2880
Rate: \$149.00

October 2-6, 2006

Radisson Hotel Cleveland Airport
25070 Country Club Blvd.
North Olmsted, OH 44070
440 734 5060
Rate: \$84.00

October 23-24, 2006

Radisson Hotel Cleveland Airport
25070 Country Club Blvd.
North Olmsted, OH 44070
440 734 5060
Rate: \$84.00

November 13-17, 2006

Treasure Island
3300 Las Vegas Blvd. South
Las Vegas, NV 89109
702 894 7711
Rate: \$129.00

For additional information, please contact Julie Stevens, A2LA training coordinator, at 301 644 3235 or jstevens@a2la.org.

[return to top](#)

A2LA Participates in APLAC RMP Workshop

Two A2LA staff members participated in a reference material producers workshop sponsored by the [Asia Pacific Laboratory Accreditation Cooperation](#) (APLAC). Roxanne M. Robinson, vice president, served as one of three instructors by presenting two lectures for the three-day course. Mr. W. W. Wong, Hong Kong, convener, APLAC MRA council, and Dr. Ed de Leer, Netherlands NMI, rounded out the instructors for the workshop. Randy Querry, A2LA program manager, also participated in the April 2006 workshop. The China National Accreditation Board for Laboratories (CNAS) hosted the event, which was held at the Friendship Hotel in Beijing, China.

Reference materials play a crucial role in the laboratory accreditation process. ISO/IEC 17025 advises that reference materials are to be used for development of non-standard methods (5.4.4), validation of methods (5.4.5), and for the calibration of instruments (5.6.1). Additionally, ISO/IEC 17025 emphasizes the use of certified reference materials (CRMs) for establishing traceability for calibrations that currently cannot be made in SI units (5.6.2.1.2 and 5.6.2.2.1). Also, reference materials aid in assuring the quality of test and calibration results (5.9) as certified reference materials and secondary reference materials for use in internal quality control checks.

In November 2005, the [International Laboratory Accreditation Cooperation](#) (ILAC) General Assembly approved two resolutions: 1) the acknowledgement "that assessing the technical competence of bodies producing reference materials with assigned values is accreditation of conformity assessment activities;" and 2) resolving "that accreditation of technically competent bodies producing reference materials with assigned values will be conducted against harmonized criteria based on ISO Guide 34 and ISO/IEC 17025 in combination."

The purpose of the training course was to support the extended APLAC MRA to include accreditation of reference material producers. The course was designed for participants who are experienced accreditation body staff and are or will be involved in the accreditation of reference material producers or experienced technical assessors who will be involved in the assessment of reference material producers.

The main elements of the course included discussing the requirements of ISO Guide 34:2000 *General Requirements for the Competence of Reference Material Producers*; key components in developing an accreditation program for reference material producers and approaches to the assessment of reference material producers; planning of assessments; the requirements of ISO Guides 30, 31 and 35 (all of which are referenced in ISO Guide 34); and the extension of the APLAC MRA to include reference material producers. The objective was to foster a consistent approach to the assessments of reference material producers by accrediting bodies around the world.

The participants greatly benefited from the use of hands-on exercises during the course to support the themes discussed during the class. For example, the group broke out into teams and established plans for assessments and discussed different approaches to the assessment process that would likely need to be applied based on the varying case studies provided.

The participants quickly realized that there are several different modes of operation to cover the reference material product tasks, such as, producing reference materials, handling all activities of reference material production, and relying on collaborators to carry out the homogeneity and stability studies or to provide support on the characterization of the sample. As a result, the assessment body must approach these assessments differently to effectively ascertain the technical competence of the applicant organization to ISO Guide 34 in combination with ISO/IEC 17025.

Currently, an APLAC technical committee working group is preparing guidance on the approaches for assessing the different scenarios, including what requirements within ISO/IEC 17025 are relevant for a given case. It is expected that this guidance document will be finalized and available by December 2006. A2LA will provide a link to this document from our reference material producers documents that are currently available on our web site once the guidance document is approved.

For additional information about our reference material producer accreditation program, please contact Randy Querry at (301) 644-3221 or via email at rquerry@A2LA.org.

[return to top](#)

Misuse of the A2LA Accredited Symbol

A2LA is very diligent in addressing any and all instances of misuse of the "A2LA Accredited" symbol of which we become aware. We notice these misuses in magazine advertisements, organization websites, test and calibration certificates, brochures, etc. However, it is not possible for us to police every use of the symbol by every organization out there.

In large part, we rely on our laboratories and assessors to inform us of instances of fraudulent or misleading use of the "A2LA Accredited" symbol. Accredited laboratories expend significant effort and resources in obtaining and maintaining their accreditation and, therefore, their right to display the symbol, so we fully understand the importance of maintaining the integrity of the symbol and taking any actions possible to correct cases of misuse.

Occasionally, we receive word of a fraudulent use of the symbol but no evidence of this can be provided. This becomes a very difficult (if not impossible) situation to pursue and investigate, particularly if we are notified of the misuse by a competitor. Whenever possible, we ask that actual evidence of the misuse be provided when A2LA is notified. We will make every effort not to divulge the source of the complaint or to jeopardize any business relationships.

Frequently, cases of misuse of the symbol turn out to be simple misunderstandings or instances of human error. That being said, if you receive a test or calibration certificate containing the "A2LA Accredited" symbol that does not fully meet your needs or A2LA's requirements for displaying the symbol, we do encourage you, as the client, to contact the laboratory first. This enables the laboratory to enact its own complaint-handling and/or corrective action procedures to remedy the problem. If it is a blatant and outright example of fraudulent use of the symbol, however, or if resolution cannot be achieved between you and the laboratory, you are encouraged to contact A2LA immediately.

[return to top](#)

Keeping Current with A2LA Requirements

As part of the initial application and with each renewal of accreditation, each laboratory is required to read and sign the A2LA *Conditions for Accreditation*. Item #13 of the *Conditions* states that, in order to attain and maintain accreditation, an applicant must agree to:

Carry out any adjustments to its procedures in response to due notice (by A2LA newsletter, email and/or hardcopy) of any intended changes by A2LA to the criteria, requirements, or conditions for accreditation, in such time as in the opinion of A2LA is reasonable.

A2LA occasionally hears through the grapevine that laboratories are not inclined to read the A2LA newsletter for updates and changes that may affect them. Also, some laboratories claim never to receive email notices of updates or notices of the availability of our newsletter, which is issued quarterly.

It is the responsibility of all applicant and accredited organizations to remain up to date on the criteria and requirements for attaining and maintaining their accreditation. Neglecting to read the A2LA newsletter and/or emails and react to updates posted there are violations of the *Conditions for Accreditation*.

If you believe you are not receiving email notices of changes to our program or notices of newsletter availability, please contact your laboratory services representative. It may be a matter of our having an incorrect or outdated email address on record. Likewise, it could also be related to an issue with your email server capturing and/or deleting our bulk email notices. If this is the case, only your IT department can determine a resolution.

[return to top](#)

A2LA Policy on Personnel Certification

A2LA would like to clarify that we do not and will not require personnel certification for a laboratory to obtain or maintain accreditation unless it is required by regulatory authorities or included in the standards for the specific technical field or required by the user. ISO/IEC 17025 section 5.2.1 states, "The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required."

Personnel certification programs offered by many organizations are an excellent way of acquiring knowledge and training in a specific field of testing or calibration. Laboratory staff that have taken the extra effort to obtain certification(s) reflect their commitment to continuous improvement and desire to excel. Certifications are looked upon favorably but are not a specific requirement for accreditation.

[return to top](#)

Submitting CARs Electronically

Laboratories submitting corrective actions to A2LA have the option of doing so electronically as e-mail attachments or on CD. We do not recommend floppy discs as disc drives are no longer common on computers, but we can work with them if necessary. E-mail attachments are limited to about 7 megabytes in size.

When receiving corrective actions and other documents electronically, we prefer to have the document as one large document, pdf or word format, instead of many small documents. This saves us time in opening and printing many small documents and ensures the order that the documents are intended to

be read in is maintained.

If you have any questions about the process for submitting your corrective action electronically, please contact your laboratory services officer or A2LA at 301 644 3248.

[return to top](#)

Recalculating Measurement Uncertainty for T9

Laboratories that perform in-house calibrations of their own equipment must meet the requirements of section T9 of the [A2LA Policy on Measurement Traceability](#). One of the requirements (part d) requires that the lab have and apply procedures for evaluating the measurement uncertainty of the calibration process. As of August 1, 2006, the lab must maintain records of the uncertainty calculations, usually in the form of uncertainty budgets.

Uncertainty budgets are not static and must be reevaluated when any of the contributors to the uncertainty change. For example, if any of the reference standards used in the calibration are sent out for recalibration (T9e) and return with a different uncertainty, the uncertainty must be reevaluated, especially if the uncertainty increases. If the ability and skill of the technician performing the calibration is critical to the calibration, a new repeatability study should be performed if the calibration technician changes. Not all factors contributing to the uncertainty are significant enough to alter the value of the uncertainty to the two significant figures at which measurement uncertainty is usually reported, so the reevaluation may consist only of a review of the relevance of the change on the final uncertainty value. A full recalculation may not be required if the effect of the change is insignificant. If a recalculation is required, a spreadsheet or uncertainty calculator may necessitate that only the value of a single cell be changed to recalculate the uncertainty.

If an assessor finds a situation where uncertainty should have been reevaluated due to a change in one of the contributors but was not, the assessor will cite a deficiency against T9d of the [A2LA Traceability Policy](#).

[return to top](#)

How to Interpret the Estimated Assessment Cost Form

The *Estimated Assessment Cost Form* (EACF) is given to an organization's authorized representative by the assessor at the end of an on-site assessment whether it is a pre-, initial, surveillance, renewal, follow-up or interim assessment. When the form is given to the authorized representative for approval, it is important that all details on it be reviewed and discussed with the assessor before the end of the assessment. This is an opportunity for the lab to question any items listed that it feels are excessive, and the authorized representative may question any charge on the EACF without fear of repercussion. If, however, an organization's representative is not comfortable approaching the assessor directly regarding the expenses charged, s/he is encouraged to contact A2LA immediately to discuss the matter further. A2LA makes every effort to control and minimize the cost of assessments, as we are a non-profit association with the goal of providing a high quality assessment at an affordable price.

The following is a breakdown of the EACF and the meaning of the different sections:

The top of the form consists of the master code (assigned by A2LA) of the organization assessed and the master code of the main location if the organization assessed is a branch lab or is under the direction of an overall corporate representative. Also listed are the assessment number, assessment type, and the field(s) being assessed. Below that is the organization's name, address, contact person, assessor(s) assigned to perform the assessment, and the A2LA staff person responsible for working with the organization.

The next section is broken down into four areas of assessor expenses. The organization has some control over the expenses identified here. When the assessor is scheduling the assessment with the organization, there should be conversations regarding the dates and the amount of time the assessor is expected to spend on the assessment. This is also a good time to work out preliminary costs with the assessor or discuss possible expenses such as airline tickets, rental car rates, and hotel cost. Any suggestions from

the organization to the assessor with regard to less expensive options may be helpful to both parties. It is important to remember that all but the "assessment services" area on the form are simply estimates. However, they should ultimately be reasonably close to the final cost charged. A receipt must accompany any single expenditure in excess of \$25.

The "assessment services" area documents the assessor's time and should match what is listed on the invoice submitted by the assessor to A2LA for payment. If there is a discrepancy, A2LA will contact the assessor for clarification. The billable time in this section includes preparation time, travel time, on-site assessment time, report time, and expected post assessment time.

The "travel cost" area includes airfare, car rental, taxi, limo, parking, tolls, gasoline, and mileage (at the IRS rate). The organization being assessed has some control over the cost in this area as it may wish to, for example, provide transportation for the assessor to and from the lab and/or airport. The "hotel and meal expense" area is also one over which the organization may exercise some control. For example, the organization may book the hotel for the assessor.

The "miscellaneous expense" area includes phone, Internet, and postage related to communicating with the organization, other assessors on the team, and A2LA. Finally, there may be a charge for something that does not fall under one of the above areas. In such a case, it is to be included as "other". The total for the "miscellaneous expense" section is not to exceed \$25.

There is a section at the bottom of the form labeled "IMPORTANT!" The organization's authorized representative should read this section before signing and approving the form for further processing. The organization must be proactive in discussing expenses and costs with the assessor before and/or during the assessment or with A2LA immediately following the assessment. There should be no surprises when the organization receives the final invoice from A2LA stating the amount still owed or the refund due. The process requires everyone's participation to assure the cost efficiency of the assessment. If there are ever any questions regarding a final invoice, please contact Teresa McCarthy at (301) 644-3229 or tmccarthy@a2la.org for assistance.

[return to top](#)

Software Validation

by Greg Gogates, A2LA Assessor

Software use is quite pervasive in the testing and calibration laboratory arena. Much of the test equipment used today contains computing components or is connected to separate computerized controllers that are essentially some sort of PC. Another type of software exists, called firmware, which resides permanently inside a piece of test equipment. It is usually managed by the manufacturer and is typically verified or checked during the equipment calibration activity. It is important to note, however, that any firmware updates done without re-calibration "expire" the current calibration.

ISO/IEC 17025 does us a disservice in using the term software in multiple ways. Clause 4.3.1 discusses software as a document control item and clause 5.5.5 treats software as equipment. The distinction, though, is quite simple. Document control software is really talking about software "objects" such as MSOffice documents or other documentation (not data) files generated by the various software applications throughout the lab. It is not the same as the testing software (that may or may not produce technical records) that is covered under 4.13.2. The note under 5.4.7 also states that word-processing and database software typically used for reporting and storage is considered acceptable as-is.

True testing software evokes multiple 17025 clauses, which must be addressed.

Software, in general per 5.5.5, is considered equipment and, if significant to testing, shall be included on the equipment list as part of or associated with the hardware records. It is also important to note that each instance of the software must be treated separately as it is physically installed on unique hardware. It must, per 5.5.2, be verified or (calibrated) checked prior to being placed in service. This is typically in the form of some simple acceptance testing by the technicians. This holds true for both purchased and custom software.

A distinction must be made between types of testing software being used. Per 5.4.7.2(a), if the software is purchased, then no software validation is required. If the software is coded or modified in-house, then software validation is required. This also includes the modifications and configurations to purchased software. These validations can be considered "software calibrations" in keeping with normal equipment

calibration methodologies used within the lab.

There are many methodologies for both the checking/verification, (user acceptance) and the validation of software. There is a simple methodology available from the <ftp://ftp.fasor.com/pub/iso25/validation> directory as well as other resources valuable to labs.

There is an effort being finalized by the European EUROLAB¹ software validation sub-committee, in which I participated, to put forth a position paper on this subject showing the laboratory community expectations with regard to software use in the accredited laboratory. The current status is that the paper has been approved by PLG², TCQA³ and the EUROLAB General Assembly with minor changes. It will be published as a EUROLAB paper (technical report) with the possibility that the other organizations may adopt or recommend it. I foresee a publication of the EUROLAB Technical Report during the summer 2006. A2LA will strongly consider the adoption of this technical paper when published to ensure consistency within the ILAC⁴ community.

A2LA is also considering training classes with regard to software verification/validation techniques for laboratories. Details will follow dependent on interest.

~~~~~  
<sup>1</sup> EUROLAB: The European Federation of National Associations of Measurement, Testing and Analytical Laboratories ([www.eurolab.org](http://www.eurolab.org))

<sup>2</sup> PLG: Permanent Liaison Group between EUROLAB, EA and Eurachem ([www.eurachem.ul.pt](http://www.eurachem.ul.pt)) (EUROCHEM: A network of organizations in Europe having the objective of establishing a system for the international traceability of chemical measurements and the promotion of good quality practices.)

<sup>3</sup> TCQA: EUROLAB Technical Committee of Quality Assurance in Testing

<sup>4</sup> ILAC: International Laboratory Accreditation Cooperation ([www.ilac.org](http://www.ilac.org))

[return to top](#)

## Are Accelerometers in Good Condition

"Are Accelerometers in Good Condition" was presented by Wayne Tustin of the [Equipment Reliability Institute](#) at the 2006 A2LA Conclave to the Materials Testing Advisory Committee as part of his hour-long presentation on accelerometers.

### Introduction

As an A2LA assessor, you are going to evaluate the vibration test capabilities of a laboratory. You are going to look at a device under test (DUT) attached to a fixture which is attached to the armature (which will soon commence to move) of an electrodynamic (ED) shaker. You are going to speak with test personnel as well as to laboratory management.

In future articles, we'll discuss fixtures as well as ED shakers (including their armatures), shaker power amplifiers, electronic controllers and other elements of the vibration test system. In this first article, let's think about the accelerometer (sometimes plural) that is probably attached to the fixture alongside the DUT.

**What's an accelerometer?** An accelerometer is a device for converting motion (not the displacement, not the velocity, but the acceleration of that motion) into an electrical signal. Measuring that electrical signal allows measurement of shaker vibration.

**Which is the control accelerometer?** Ask the test engineer/technician to identify it. During the test, look at a meter or other display; compare measured vibration with what the test spec calls for. That signal also goes to the computer that regulates vibration intensity.

**What is its sensitivity?** Ask the test engineer/technician to show you the record of the accelerometer's most recent calibration, probably in mv/g.

**Cause for rejecting an accelerometer?** We are indebted to Craig Aszkler of PCB for the following photographs. When accelerometers come back to PCB for recalibration, the base sometimes looks like

### Figure 1.\*

Any such damage will interfere with calibration (as well as with subsequent usage), so don't allow a damaged accelerometer to be used.

In this instance, PCB sought the customer's permission to take a minimum lap cut (machining) off the base, restoring the appearance as in [Figure 2](#).

Other calibration laboratories pull the accelerometer across sheets of successively finer-grit abrasive paper, in order to get a smooth (and hopefully flat) surface.

**Are these marks serious?** Yes, indeed. Remember that vibratory displacements are very small, a few microinches at high test frequencies. The accelerometer must mate flat and smooth against the structure it monitors.

**How was it damaged?** How do you suppose the accelerometer of Figure 1 was damaged? Possibly it had been cemented to a shaker, a fixture or a test item. Better to use a proper 10/32 attachment screw with an appropriate shoulder or a manufactured attachment device.

Possibly someone used a pocketknife and scraped off the old cement, inadvertently scratching the base. Never allow that. Direct test personnel to dissolve cyanoacrylate adhesives (superglues), etc. with acetone (fingernail polish remover).

These scenarios could account for the long gouges. But what caused the indentations into the base? Possibly the accelerometer was stud-tightened onto a surface littered with hard particles. Or was stored loose in a drawer and impacted by other hardware. Or several accelerometers were carried dangling on their cables and striking each other.

### Laboratory policy manual

Ask to see the laboratory's test procedure manual. The situation described above should be forbidden by the manual.

\*These two figures appear in Chapter 7, "Acceleration and Force Sensors," of the 2005 *Random Vibration & Shock Testing* text, ISBN 0-9741466-0-9. This text is used in the short courses that are listed at [www.equipment-reliability.com](http://www.equipment-reliability.com).

[return to top](#)

## MRA Members vs. Signatories

The [A2LA Policy on Measurement Traceability](#) states that:

Accredited test and calibration results, reported by laboratories that are accredited by the accreditation bodies recognized by any of these multi-lateral agreements [ILAC, APLAC, EA or IAAC], and reported in a test or calibration report endorsed by the accrediting body's logo, or which otherwise makes reference to accredited status...are recognized by A2LA as satisfying the requirements pertaining to measurement traceability.

The A2LA website contains links to the websites for each of these four organizations but, once there, it can be difficult to determine which are considered full signatories to these mutual recognition arrangements. Each offers varying levels of participation for an accreditation body (AB) or anyone else interested in involvement - from "stakeholder" to "member" to "signatory". But what is the difference between these levels of participation? How does one sort through the list of organizations provided on each of these websites to determine which are considered acceptable by A2LA for the purposes of meeting the traceability policy? It can be a frustrating exercise.

Take, for example, the [ILAC](#) website. Accessing the first page, one must then click on "Members List" from the menu on the left. From there, a region of the world is selected by clicking on the map that appears. In the case of the Americas, a list of "ILAC Members" results. One might think that any AB that then appears on this list would be acceptable for meeting the traceability policy. Not necessarily so. You will note that some ABs are designated as "Full Member (MRA Signatory)" in the right-hand column. Other ABs are designated as "Affiliates". Only those with the "Full Member (MRA Signatory)" designation are acceptable for the purposes of meeting the traceability policy. Any AB that wishes to participate in ILAC meetings, discussions, etc. may do so and be classified as an "affiliate". Only those that undergo a

rigorous and successful peer evaluation are then considered a "Full Member (MRA Signatory)".

Similarly, the [APLAC](#) website discusses "[Full Members](#)," "[Associate Members](#)," "[Related Bodies](#)," and "[Signatories of the APLAC MRA](#)." As long as you select the latter from the menu options, the resulting list will contain ABs that are acceptable for the purposes of meeting the A2LA traceability policy.

For [EA](#), you must select the portion of the website that describes "[The EA MLA](#)." The resulting page is a very straightforward listing of ABs that are signatories to the EA multi-lateral arrangement for both calibration and testing. Any AB on the calibration list is acceptable for the purposes of meeting the A2LA traceability policy.

Finally, the [IAAC](#) website also gives a list of its "[members](#)" but, again, full members, associate members, and stakeholders are all included on the same list. To further complicate matters, not all full members are signatories to the IAAC MLA. One must review the entire list provided to identify those that are specially designated as an "IAAC MLA Signatory". Only those are acceptable for the purposes of meeting the A2LA traceability policy. Chapter 4 of the [IAAC Bylaws](#) gives a good definition of the various levels of participation and what each level entitles an organization to do.

If you are ever in doubt as to whether or not an organization listed on any of these websites is, indeed, a signatory to the relevant recognition arrangement (and, therefore, acceptable for the purposes of meeting the A2LA traceability policy), please do not hesitate to contact us for clarification.

[return to top](#)

#### A2LA Now Accepts



Please call Teresa McCarthy  
at 301-644-3229  
if you would like to pay by credit card.