



A2LA News: The Newsletter of the American Association for Laboratory Accreditation____July 2005, Number 89

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A2LA News July 2005

A2LA Offering Accreditation to SAE AS7101

In an effort to assist our A2LA accredited materials testing laboratories (MTL) in gaining prime aerospace manufacturers' acceptance, A2LA has begun offering accreditation to SAE AS7101b – *National Aerospace and Defense Contractors Accreditation Program (NADCAP) General Requirements for Materials Test Laboratory Accreditation Program*. This endeavor is being undertaken with the end goal of elimination of redundant prime contractor assessments and is currently being endorsed by a number of prime contractors. This accreditation is not meant to be a substitution for prime contractor approval, but can be utilized, upon acceptance, as a prime contractor tool to increase MTL efficiencies and decrease overall costs for clients and vendors. A2LA continues to pursue aerospace prime AS7101 accreditation collaboration as an ongoing effort to make "one standard, one accreditation" a reality.

The SAE AS7101 requirements are essentially the elements of ISO/IEC 17025 plus an assortment of technical requirements for the significant test technologies covered by the MTLs – namely chemical, mechanical, metallography and microhardness, hardness, corrosion, fastener testing (plus mechanical testing specimen preparation), differential thermal analysis, and X-ray diffraction. (Please note that heat treating will not be included under this accreditation.) The main deltas of these requirements are prescribed equipment calibration and proficiency testing participation intervals and a requirement for the test laboratory to have a procedure for 're-testing' non-conforming specimens. As these requirements are regularly covered by the customary A2LA assessment process, additional assessor time to add SAE 7101 to a laboratory's Scope of Accreditation should not be extensive. However, the assessor will need to complete the *AS7101 Assessor Checklist* as a record that all applicable sections of the standard are assessed.

Once the assessment process is complete, the laboratory's Scope of Accreditation will include the following verbiage:

"In recognition of the successful completion of the A2LA evaluation process (also including an

assessment of the laboratory's compliance with SAE AS7101), accreditation is granted to this laboratory to test: ..."

If your laboratory is interested in obtaining accreditation to SAE AS7101, please download the [AS7101 Fax Confirmation Form](#) available on the A2LA web site. Upon receipt of the form, A2LA will provide you with a copy of the *AS7101 Assessor Checklist* that your laboratory will need to complete and provide to A2LA prior to the assessment of these requirements. If you have any questions, please contact A2LA Sr. Laboratory Services Officer [Robert Miller](#) at 301 644 3229.

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Cannon Instrument Company, an A2LA Accredited Laboratory, Begins NIST Alliance

The [National Institute of Standards and Technology](#) (NIST) has designated [Cannon Instrument Company](#) to provide U.S. national measurement standards and to issue calibration and measurement certificates for certified liquid viscosity reference standards. Cannon Instrument Company will participate on behalf of the U.S. in key comparisons organized by the [Comite Internationale de Poids et Mesures](#) (CIPM). CIPM key comparisons establish levels of equivalence of national measurement standards realized by the national measurement institutes (NMI) of various nations and support calibration and measurement certificate capability claims found in the BIPM [Key Comparison Database](#).

Cannon's responsibilities pursuant to the agreement include realization of liquid viscosity measurements standards at the highest level of technical competence and experience. Cannon will also assume responsibilities for dissemination of U.S. national measurement standards for liquid viscosity and for compliance with the requirements of the CIPM *Mutual Recognition Arrangement*. To meet these requirements, the company will work closely with NIST to maintain appropriate quality controls and documentation of measurement uncertainty of primary standards and their dissemination. The agreement with NIST includes a required performance review of Cannon's measurement assurance program control data every two years.

Cannon Vice President and General Manager Pat Maggi said that he viewed the new NIST relationship as "indicative of a high level of confidence in the quality processes that have enabled Cannon Instrument Company, as an ISO/IEC 17025 accredited and world-renowned viscosity calibration laboratory, to achieve international prominence as a preferred supplier of viscosity-related products and services."

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IAS Recognized Under APLAC

At its April 25, 2005, meeting in Tokyo, the [Asia Pacific Laboratory Accreditation Cooperation](#) (APLAC) voted to admit [International Accreditation Services, Inc.](#) (IAS) to its *Mutual Recognition Arrangement* (MRA) for calibration laboratory accreditation. IAS was already an APLAC MRA signatory for its testing laboratory and inspection body accreditation programs.

As a signatory to the MRA for its calibration laboratory accreditation program, calibration labs accredited under IAS's APLAC *Scope of Recognition* are acceptable for the purposes of meeting the [A2LA Policy on Measurement Traceability](#). Any questions regarding this should be directed to A2LA Laboratory Services.

Our congratulations to IAS for this achievement!

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A2LA Transition to ISO/IEC 17025:2005

It does not seem that long ago that the laboratory accreditation world was putting a plan in place to transition from ISO/IEC Guide 25 to ISO/IEC 17025:1999 – a significant transition. Well, here we go again as ISO/IEC 17025:2005 was released on May 15, 2005. This time around, however, the transition should be less painful as the deltas of the two documents (the new sections being 4.1.5k, 4.1.6, 4.2.3, 4.2.4, 4.2.7, 4.7.2, 4.10 and 5.9.2) are not that substantial – dealing primarily with how management ensures effective communication and how the effectiveness of the management system is continually improved.

ISO/IEC 17025:1999 was created and documented to harmonize with ISO 9000:1994. Soon after that document was implemented, ISO 9001:2000 was released, and it could no longer be claimed that the management system aspects of ISO/IEC 17025 met the intent of ISO 9000:2000.

With ISO/IEC 17025:2005 the laboratory, once accredited, will be able to state that the management system requirements of ISO/IEC 17025:2005 (Section 4) are written in a language relevant to and meeting the “principles” of ISO 9001:2000 and are aligned with its pertinent requirements. The [International Standards Organization \(ISO\)](#), [International Laboratory Accreditation Cooperation \(ILAC\)](#), and [International Accreditation Forum \(IAF\)](#) will be releasing a joint communiqué that will give those testing and/or calibration laboratories that are 17025:2005 accredited an official attestation on their management system to provide to their customers that are requiring ISO 9001 registration.

ILAC has confirmed the transition period of two years for the implementation to ISO/IEC 17025:2005. Therefore, A2LA is implementing a transition plan as follows:

- A2LA will purchase and distribute to **every** A2LA applicant and accredited laboratory copies of ISO/IEC 17025:2005 as soon as it is publicly available;
- A2LA will begin performing assessments or gap assessments to the 2005 version on October 1, 2005, according to the laboratory’s usual assessment schedule. If laboratories meet the new requirements, they will be accredited to the 2005 version. If they do not, they will be re-accredited to the 1999 version until acceptable corrective action to the gap requirements is provided (with acceptable resolution required at least by the laboratory’s annual review);
- Beginning October 1, 2006, **all** assessments will be performed to the 2005 version, and the laboratories will follow the usual corrective action process;
- For those currently accredited laboratories seeking accreditation to the new version prior to their on-site assessment, the laboratory will need to provide objective evidence that they have implemented the new requirements, and A2LA staff will perform a desk audit of the submitted documentation. A2LA will charge a flat fee of \$400 for this service and will update the laboratory’s accreditation once all requirements are deemed adequately implemented.

For additional information and guidance on implementing these new requirements and the objective evidence required to meet the 2005 version, please visit [Understanding ISO/IEC 17025: A2LA Specific Applications of the Standard](#).

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New & Updated Documents:

- On May 6, 2005, an “Observation Record Form” was developed for assessors to use in documenting observations during routine laboratory assessments. Agreement and written authorization must be obtained from each laboratory before any observations are included as part of the formal assessment record. Those laboratories that do wish to have observations included as part of their report should expect to see them documented on this form.
- In May 2005, the A2LA website was revised to include up-to-date descriptions of how A2LA applies various sections within ISO/IEC 17025: 1999 (with cross-references to the associated clauses in ISO/IEC 17025: 2005). Discussion of specific clauses and ways in which laboratories may meet the requirements are included.
- In July 2005, the A2LA website was revised to include A2LA’s applications of the new sections of ISO/IEC 17025: 2005. Several new requirements are contained in the 2005 iteration of the

standard, and our website now discusses each of these additional clauses and how laboratories may meet the new requirements.

- The requirements of ISO/IEC 17025: 2005 have been incorporated into a “full-text checklist” for use by laboratories and assessors. An official copy of the 2005 version of the standard will be provided to all accredited and enrolled laboratories within the coming weeks and so the full-text checklist will be made available to them at that time. Future applicants to the accreditation program will be asked to provide a signed affidavit attesting to the fact that they own a copy of the standard before the checklist will be provided.
- The Annex to the [A2LA Measurement Uncertainty Policy for Automotive and Materials Testing Laboratories](#) has been updated to a July 19, 2005, version. The revision expands upon the list of methods and their respective uncertainty categories and includes additional opening remarks. The updated document is available on the A2LA website and also as a hardcopy upon request.
- A2LA has updated [Typical Steps in Preparing for Initial Accreditation/Renewal of Accreditation/Annual Review of Accreditation](#) to a July 19, 2005, version. The document is available on the A2LA website and also as a hardcopy upon request.

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Closing Deficiencies On Site

A2LA allows assessors to close a deficiency during the course of an assessment. In order to do this, the lab must submit its corrective action to the assessor for review before the closing meeting with evidence that it has followed its corrective action procedure and fully implemented the corrective action. This process is not intended as a quick fix. If the assessor is satisfied with the corrective action, s/he will indicate in the deficiency report that the deficiency is closed. Once a deficiency is indicated, however, it will not be removed from the report, even if closed during the assessment. If the assessor is unsure of the adequacy of the response, s/he may choose not to close the deficiency and instead ask the lab to submit the response to A2LA along with its corrective actions for other deficiencies. The assessor will then forward a copy of the corrective action response **and all evidence of implementation** to A2LA with the assessment package.

Once the corrective action process is complete for all remaining open deficiencies, the assessment package will be sent to the A2LA president or to the Accreditation Council (AC) depending on the nature and number of deficiencies. The president or AC makes the final determination of the adequacy of all responses, including those closed on site. A2LA staff will contact the lab for follow-up information if the corrective action is considered to be inadequate.

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Control and Ownership of Normative Documents

During our annual Assessor Conclave held in Columbia, MD, an issue arose from the Plenary Session regarding which normative documents laboratories are required to own and to have under their document control system.

Normative documents are those that provide rules, guidelines or characteristics for activities or their results. It is a generic term that covers such documents as standards, technical specifications, codes of practice and regulations. ISO/IEC 17025-1999 contains roughly thirty references to other published requirement and guidance documents. Each of the referenced documents then refers to additional normative documents, and on and on. And so the questions arise: Are laboratories required to own and control these documents in addition to ISO/IEC 17025? At what point is the line drawn?

After much consideration, A2LA has concluded that accredited laboratories are required to own or have direct access to the normative documents that are vital to maintaining their accreditation. These documents have been determined to be ISO/IEC 17025, general A2LA policy documents, and the specific A2LA program requirement documents relating directly to their field of accreditation.

For example, an on-site calibration laboratory would be expected to possess (or have direct access to) and have under its document control system ISO/IEC 17025-1999, [General Requirements for](#)

[Accreditation of Laboratories](#), [A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories](#), [A2LA Policy on Measurement Traceability](#), and [A2LA Advertising Policy](#). In addition to these general policy documents, the calibration lab would be expected to have under its document control [Calibration Program Requirements](#), [A2LA Policy for Claims for Measurement Uncertainty for On-Site Calibrations on Scopes of Accreditation](#), and the [A2LA Specific Criteria for the Accreditation of Site Testing and Site Calibration Laboratories](#).

If there are any questions as to which normative documents are specific to your laboratory's accreditation, please contact your Laboratory Services Officer.

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Z Scores and Small Samples

In order to meet the requirements of the [A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories](#), many labs participate in small inter-lab or intra-lab programs when no commercial testing programs are available for the parameters being tested. This is allowed under section G of the *Proficiency Testing Requirements*, which states, "Acceptability of such programs will be made on a case-by-case basis by the assessor, and will be based on the design of the program, its frequency, the suitability of the samples, and **defined written criteria for data analysis** (emphasis added) and corrective action." Further, section 5.9 of ISO/IEC 17025, upon which the *Proficiency Testing Requirements* are based states, "where practicable, statistical techniques shall be applied to the reviewing of the results."

Often, (especially among testing labs) z scores are used to evaluate the performance of individual participants in a proficiency testing program. A z score is a ratio of the lab's difference from the mean to the standard deviation ($z = (\text{result} - \text{mean})/\text{standard deviation}$). The resulting z score is a number that corresponds to the number of standard deviations the lab's results fall from the mean. A z score of 1.5 means the results are 1.5 standard deviations above the mean, a -2.3 is 2.3 standard deviations below the mean. Section H of the *Proficiency Testing Requirements* states, "...A2LA considers a test result outside of three standard deviations of the mean of the test results to be an outlying result..."

Here is an interesting experiment to try on a spreadsheet. Set up a fictitious proficiency testing program with four participants - say measuring a 5 cm artifact with a pair of micrometers. Three of the participants get the same value, 5.000 cm. The fourth is off by 10%, 5.500 cm. Obviously, the fourth participant is doing something wrong. If you calculate the z score for the 4th participant, you will get 1.5, which is not indicating an outlier. Next, change the fourth participant's result to 50.000 cm - maybe the decimal was written in the wrong place - and calculate the z score. You will get the same result, 1.5. Here is a result ten times greater than all others, and it is not indicated as an outlier. If you change the 4th participant's result to 500.000 cm, you will again get the same z score. If you consider a second round of proficiency testing with a 10 cm artifact under similar conditions, you will find that the z score is the same. What this implies is that, under these circumstances, all results the same except for one outlier, the z score is independent of the value of the results. This is only true as long as there are not negative test results.

If you continue this same experiment for increasingly large numbers of participants, all participants getting the same result except for one outlier, you will find that the z score grows as the number of participants increases but does not become greater than three until there are at least 11 participants. It turns out that the maximum z score for a given number of participants, n, can be expressed by the formula $(n-1)/\text{square root of } n$. **This implies calculation of z scores for proficiency testing programs with less than eleven participants is an unacceptable method for evaluating performance if the criteria for an outlier is a z score greater than 3.** With ten participants or less, there will never be an outlier.

This leads to the question, if z-scores are not an acceptable way to evaluate programs with a small number of participants, what is? ASTM E178 provides several methods for determining if a result is an outlier. In each case, you must arrange the results from lowest to highest and "eyeball" the results to determine where the outlier(s) is likely to be. If you suspect a single outlier, one method applies. Other methods apply if you suspect two outliers, both high or low, or two outliers, one high, one low. Be sure to review the different methods to determine which is the correct application.

In analyzing the results of proficiency testing, it is important to remember the purpose of proficiency testing. While statistical analysis will assign a value to help determine unacceptable results,

reasonableness of the results should always be considered, especially in small groups.

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Applying the Requirements of ISO/IEC 17025:

A2LA has recently updated its website to include current policies and recommendations with regard to applying the requirements of ISO/IEC 17025 within a laboratory. The link, "[Understanding ISO/IEC 17025](#)", was updated in May 2005 from a previous version to contain up-to-date perspectives and suggestions for how a laboratory may implement the requirements for accreditation. The link has also been updated to cross-reference the ISO/IEC 17025: 1999 clauses with those contained in ISO/IEC 17025: 2005.

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Understanding the New Clauses of ISO/IEC 17025: 2005

The 2005 revision of ISO/IEC 17025 contains several new clauses and requirements that accredited laboratories must implement. However, many of the new clauses are worded in such a way that determining the best means of complying with them could be a challenge. A2LA management and the A2LA Criteria Council have, therefore, agreed upon an approach for applying the new clauses of ISO/IEC 17025: 2005 to accredited laboratories. These applications are now available on the A2LA website and can be viewed at the following link: <http://www.a2la.org/faq/faqfinder170252005.cfm>.

We strongly encourage all accredited and enrolled laboratories to review this link carefully, as transition to the new standard has begun and laboratories will be expected to comply with these additional requirements in the near future.

A2LA Now Accepts



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at 301-644-3229
if you would like to pay by credit card.