American Association for Laboratory Accreditation

A2LA News: The Newsletter of the American Association for Laboratory Accreditation__ *April, Number 84*

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from l to r: Joseph Kane, A2LA LSO; Woodward Vogt, A2LA Board Member; Neil Zuern, A2LA Criteria Council and Accreditation Coucil Member

GE Aircraft Engine Recognizes ILAC Recognized Accreditation Bodies

General Electric Aircraft Engines (GEAE) formally announced recognition of ILAC recognized ISO/IEC 17025 accredited materials testing laboratories as meeting GEAE S-400F in its Autumn/Winter 2003/4 *Metallic Testing Labs* newsletter. As such, once materials testing laboratories get initial approval from GEAE, the lab can now get re-certified for GEAE work by obtaining or maintaining A2LA accreditation.

Laboratories applying for A2LA accreditation or submitting their renewal paperwork should make sure that they clearly request the desire for GEAE recognition. The A2LA assessor will use the *GEAE Supplemental Checklist – AC1.1* as an assessment tool and to record the results of the assessment of the laboratory's Scope(s) of Accreditation. Also, GEAE will provide an auditor test kit containing testing artifacts for chemistry, tensile, hardness, creep rupture, and stress rupture testing and for metallographic examination that the lab will test in the presence of the A2LA assessor. The results of the assessment, along with the results from the artifact testing, will be provided to GEAE by A2LA Laboratory Services staff for continued GEAE acceptance.

This announcement from GEAE on the acceptance of A2LA accreditation is now the second major aerospace prime to recognize A2LA. According to the Sikorsky Aircraft website, "Sikorsky now

recognizes the American Association for Laboratory Accreditation (A2LA) as an alternative to NADCAP. The A2LA accreditation covers eleven specific testing disciplines along with the general requirements for ISO/IEC 17025 for testing and calibration laboratories. Special Process Laboratory Suppliers designated by Approval Source List Note 7, may now use the A2LA accreditation as a direct substitute to NADCAP certification."

A2LA is aggressively working with the rest of the 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.

For further information on the acceptance of A2LA accreditation by GEAE, please contact Trace McInturff, A2LA Operations Manager, at tmcinturff@a2la.org or 301 644 3223.

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FCC Recognition Update

On October 15, 2001, the Federal Communications Commission (FCC) adopted a *Notice of Proposed Rule Making and Order* that proposed a number of changes to FCC Part 15 and other parts of the rules.

One of the proposed changes in the *Notice*, as stated in FCC 03-149, Item 44, is that a test laboratory that has been accredited by an organization recognized by the FCC will no longer have to file a description of its measurement facilities, provided the accrediting organization submits certain information about the laboratory to the FCC. The information required is the laboratory's name, address, contact information, Scope of Accreditation, date of accreditation, and the date on which the accreditation expires.

This proposal is intended to reduce the burden on laboratories by eliminating the need for them to file duplicate information with both the FCC and an accrediting body. As such, A2LA has been working with the FCC to update the information on the FCC website for those testing laboratories that have been accredited by A2LA in the electrical field of testing for FCC Part 15 using ANSI C63.4 and wish to be recognized by the FCC.

Prior to a laboratory's anniversary date an electronic reminder will be forwarded from the FCC notifying the lab of its anniversary date. Based upon the A2LA accreditation process, the laboratory's renewal should be in progress by the time this notification is sent out by the FCC, so a response is not necessary. It is important for A2LA accredited laboratories to meet all application deadlines and keep A2LA informed of any changes in the quality system in order to maintain FCC recognition throughout the A2LA accreditation.

During the laboratory's A2LA on-site renewal assessment, the assessor will verify the information and review the laboratory's compliance with the 47 CFR 2.948 requirements. At the completion of the A2LA accreditation process, A2LA is responsible for updating the information, including the lab's anniversary date, on the FCC website.

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A2LA Holds 2004 Conclave

A2LA held its annual Conclave from March 9 through 15, 2004, in Columbia, Maryland.

This year's series of meetings began with the annual assessor orientation course from Tuesday morning through Friday afternoon. There were 17 participants in the course, 15 of whom passed the exam administered on Friday. A2LA would like to welcome the new assessors and wish them luck as

they enter the next phase of training by performing laboratory assessments.

On Friday, March 12, the American National Standards Institute (ANSI) hosted its second annual meeting of accredited product certification representatives, Accreditation Committee members, and assessors/technical experts in conjunction with the Conclave. After the dinner break, Reinaldo Figueiredo of ANSI led a training seminar on ISO/IEC 17020, *General Criteria for the Operation of Various Types of Bodies Performing Inspection.*

Individual, discipline-specific breakout sessions were held on Friday evening. Sara Weitzel headed a session on various topics for plastic and rubber testing assessors, and Joe Kane led a meeting of non-destructive testing assessors. We expect to continue the Friday evening meetings at future Conclaves although the disciplines and topics covered are likely to change depending on developments within the various fields over the course of the coming year.

Saturday was devoted to assessor meetings. Five committees (CMT/geotechnical, life sciences, materials testing, electromechanical, and measurement) met throughout the day to discuss issues particular to the fields. In the evening, the annual A2LA banquet was held, during which John Wehrmeyer was recognized as A2LA Assessor of the Year.

Meetings on Sunday started early with the Accreditation Council and Criteria Council meetings. These were followed by the Plenary Session. This year, the plenary session was devoted entirely to assessor refresher training on ISO/IEC 17025 and A2LA's interpretations for many of the requirements contained within. The day's meetings concluded with the Assessor Committee meeting hosted by committee chair, Bob Holcomb. Several staff presentations were given during the Assessor Committee meeting, including Trace McInturff's presentation on the use of a new *Proficiency Testing Matrix* form to capture those PT results reviewed on-site by the assessor, Teresa Barnett's presentation on the distinction between a method and a procedure, Dana Leaman's presentation on common calibration certificate issues, and Tim Rasinski's presentation on the content and quality of assessor deliverables.

The Conclave concluded on Monday with the Annual Meeting of the Membership. Peter Unger presented the President's report, and the various committee chairs presented reports on the weekend's activities. Peter Unger also discussed the latest news regarding the upcoming revision to ISO/IEC 17025 and 17011, which will supersede Guide 58. The Board of Directors' meeting immediately followed and was the concluding event of the Conclave.

The 2005 Conclave is scheduled to be held from March 8 – 14 at the Columbia Sheraton. We hope to see you there.

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IEEE EMC Society / SAE

On February 3-4, 2004, A2LA attended the IEEE EMC Society / SAE Automotive EMC Standards Workshop at the Henry Ford Convention Center, Dearborn, MI. Trace McIntuff and Brad Moore represented A2LA during the workshop and enjoyed meeting all of the IEEE members who took time to stop by the A2LA exhibit.

The first day's activities were broken down into a four-part presentation. A number of SAE EMC test methods were discussed during the presentations. Each presenter identified the scope of the procedure, the critical aspects of the procedure, interpretations, any changes made, and the future outlook of the procedure. A copy of the presentations is available to members through IEEE at http://emcsociety.org/Auto2004/.

The second day's activities consisted of a range of presentations. Among them, Russell Carstensen of The National Association of Radio and Telecommunications Engineers (NARTE) gave a presentation on the NARTE personnel certification program, followed by Mr. Daniel Hoolihan with an overview of

ISO 17025 and its relationship to laboratories within the automotive EMC field.

The Automotive EMC Laboratory Recognition Program (AEMCLRP) Committee had a chance to discuss the present status of the AEMCLRP recognition program. Part of the presentation described how implementation was viewed from the OEM's perspective. Validation testing must be performed using AEMCLRP recognized test methods. A2LA's AEMCLAP accreditation program is currently the only program in North America that is recognized by AEMCLRP.

To finish the workshop, Daimler Chrysler, Ford, and GM presented the new requirements for the AMCLRP recognition program. It is of note that the AEMCLRP committee is planning to phase out SAE J1113-25, *Radiated Immunity - Tri-plate Test Method*, from the program over the next two years.

If you have any questions or concerns regarding the AEMCLAP program or any other automotive EMC concern, please contact Trace McInturff, Operations Manager, or Brad Moore, Laboratory Services Officer, at A2LA Headquarters.

A2LA will again be exhibiting at the 2004 IEEE Symposium on Electromagnetic Compatibility August 9-13, 2004 in Santa Clara, California . We look forward to seeing you there.

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A2LA Exhibits at SAE 2004 World Congress

The Society of Automotive Engineers (SAE) held its 2004 World Congress March 8 through 11, 2004, at COBO Hall in Detroit, MI. A2LA exhibited at the World Congress for the 5th straight year with Trace McInturff and Steve Medellin representing the Association. Attendance at the show has appeared to improve over the past couple of years. Also exhibiting were a number of A2LA accredited test and calibration laboratories, including:

Agilent Technologies, Akron Rubber Development Laboratory, Atlas Testing Laboratories, Bruel & Kjaer, Chomerics Test Services, Cincinnati Sub Zero Products, Dayton T. Brown, Inc., Detroit Testing Laboratory, Inc., ESSC Test Laboratory, MGA Research Corporation, MTS, Nondestructive Testing Group, PCB Piezotronics, Reliable Analysis, Inc., Sensor Developments, Inc., Southwest Research Institute, TEC Materials Test Lab, Trialon Corporation, Vacuum Technology, Inc., and Underwriters Laboratories, Inc.

We had a fairly steady flow of booth traffic all four days, networked nightly and enjoyed speaking with all who took time to stop by our exhibit.

If you have any questions or concerns regarding A2LA accreditation, please contact Trace McInturff or Steve Medellin at A2LA Headquarters.

A2LA will be exhibiting at the 2004 Quality Expo June 9 & 10, 2004, in Novi, Michigan . We hope to see you there.

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On-Site Assessment Time

When a laboratory applies for accreditation providing a complete application with supporting information, an appropriate number of assessors are assigned to perform an on-site assessment. The number of assessors is determined by the Scope of Accreditation requested by the laboratory. The assessor(s) assigned must have the expertise to cover the technical content of the proposed Scope. In

accordance with A2LA policy, the assessors must then conduct the assessment within 60 days of receipt of the assignment, unless the laboratory requests or otherwise agrees to schedule outside of this time frame.

The on-site assessment time scheduled by the assessor or assessor team is dependent upon several important factors. The breadth of the Scope is one of the most important. In applying for accreditation, a laboratory must define those tests or calibrations for which it is seeking accreditation. During the on-site assessment, an A2LA assessor must witness these items in an effort to determine the competency of the laboratory to perform those activities. Further review of the traceability, procedures, and measurement uncertainty relating to these items is also included to determine whether the laboratory meets the requirements of ISO/IEC 17025 and other various A2LA program requirements. Thus, as a Scope grows to include more tests/calibrations, additional assessment time is needed to complete a review of the activities.

Currently, A2LA requests some of the assessment documentation with the application in an effort to limit the need to review these during the on-site assessment. The quality manual and supporting quality documentation as well as any required measurement uncertainties are requested with the application so that the assessor may review the information and become familiar with the laboratory's system. This prior document review also allows the assessor to formulate any questions or concerns and discuss these with the laboratory before the assessment, thus eliminating the need to spend a large amount of time on-site. This also gives the laboratory time to correct any concerns prior to the scheduled visit.

If you would like an estimate regarding the amount of time needed for the on-site assessment of your laboratory, please contact us at 301 644 3248 with your proposed Scope of Accreditation and one of our Laboratory Services Officers will be happy to assist you.

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Recent Staff Changes at A2LA

A2LA lost a seasoned veteran in Laboratory Services last month when Christy Urban departed to take on one of the most challenging, yet rewarding jobs there is – motherhood. Christy had been with A2LA for almost five years and served as a Laboratory Services Officer managing approximately 120 test laboratories. Christy also served as mentor for a number of staff added over the past couple of years.

While we are sad to see Christy leave the Association, we wish her all the best in her new endeavors.

Other Changes:

A2LA has added Laboratory Services Officer Kimberly Miller to take over the day-to-day laboratory functions that were previously assigned to Christy. Ms. Miller completed her B.A. degree in 1998, majoring in chemistry and minoring in physics at Hood College, Frederick, Maryland. One of her internships included derivatization and organic synthesis of gunshot residues followed by analysis using MECE at the microfluidics division of the National Institute of Standards and Technologies (NIST). She was employed at Alcoa EastalcoWorks in the Analytical Process Control and Environmental Monitoring Laboratory from 1997-1999 as a chemical analyst. She most recently worked at Bio Whittaker in the Quality Control LAL, Quality Control Raw Material, and Quality Control Analytical Service departments from 2000-2003.

Also, A2LA has added a new Laboratory Services Officer, Tiffany White, to fill a void in the calibration group. Ms. White is a native of Columbia, SC and has lived in Maryland for the last 13 years. She is a recent graduate of Temple University in Philadelphia where she obtained a degree in biology. She plans to further her education at the George Washington University. Her leisure interests include forensics, photography, reading and traveling.

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New and Updated Documents:

- On January 1, 2004, A2LA made additional revisions to the *A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories*. The major revision is to include sub-disciplines within the calibration field for the purpose of determining compliance with the requirement that a laboratory's entire Scope be covered by some form of proficiency testing over a four-year period.

- On January 9, 2004, revisions were made to the A2LA *Environmental Lead (Pb) Program Requirements* and its associated checklist. The primary difference between this and the prior version is the inclusion of a requirement that management reviews be conducted annually. Assessments in the environmental lead (Pb) field of testing are now being conducted against this version of the requirements.

- A2LA developed the formal, written *A2LA Policy on Laboratory Relocation* dated January 27, 2004. The document addresses the actions required on the part of a laboratory to maintain its accreditation in good standing in preparation for and subsequent to a change in location.

- A2LA replaced its interim policy with a formal *Policy on Estimating Measurement Uncertainty for Testing Laboratories* on March 8, 2004. The policy discusses A2LA's expectations for the development of measurement uncertainty estimates for new and renewal testing laboratories and is to be fully implemented as of May 1, 2004.

- On April 1, 2004, A2LA issued *Estimation of Uncertainty of Measurement Results for Calibrations and Tests in Construction Materials and Geotechnical Testing* for laboratories within the construction materials field of testing. The document is guidance only, but laboratories within this field are encouraged to refer to it when evaluating and determining their measurement uncertainties.

- Minor revisions were made to the A2LA *Calibration Program Requirements* and the associated assessor checklist in March 2004. Due to the minor nature of the changes made, the revised documents are being implemented immediately.

- The *Assessors Checklist: General Criteria (ISO/IEC 17025 - Full Text)* containing the full text of the 17025 standard has been updated to include the October 2003 version of the *A2LA Policy on Measurement Traceability* as an addendum. The full text checklist is only available to those laboratories that sign an affidavit attesting to their ownership of ISO/IEC 17025.

- The A2LA *Nondestructive Program Requirements* were revised on April 27 and are being implemented immediately. Specific requirements were removed in this revision and laboratories are now given an option to seek accreditation for ASTM E543 by completing the checklist found in ASTM E1359.

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General vs. Specific Deficiencies

A2LA likes to have its assessors classify deficiencies into two categories – general and specific. The purpose of this is to inform the laboratory of its options in addressing the deficiencies at the time of the assessment. General deficiencies are non-conformances that affect the overall implementation of the lab's quality system - for example, a deficiency cited against section 4.4.1 of ISO/IEC 17025 on contract review. The lack of a procedure for contract review would impact virtually every test or calibration performed by the lab. A corrective action response must address the deficiency and provide

evidence of implementation of the corrective action before the lab becomes eligible for accreditation or re-accreditation. General deficiencies become clearer when compared to specific deficiencies.

Specific deficiencies affect only a single or very limited number of testing procedures for which the lab is accredited or seeks to become accredited. The deficiency does not indicate a systemic nonconformance of the lab's quality system - for example, a deficiency cited against ASTM B117 (salt spray) for not having type IV water available for the salt spray chamber or a deficiency cited against section 5.6.1 of ISO/IEC 17025 for having a non-calibrated piece of equipment in use. In the case of specific deficiencies, the laboratory has two options. One is to address the deficiency with a corrective action as mentioned above. The other is to request the affected testing or calibration procedure be removed from the Scope of Accreditation. This allows the accreditation process to move forward if corrective action is taking an inordinate amount of time or the corrective action required is disproportionate to the need to have the procedure included on the Scope of Accreditation. If the second option is chosen, the procedure can be returned to the lab's Scope at a later time through the same process used to add new procedures.

Multiple specific nonconformances can result in a general deficiency. For example, if the assessor finds multiple incidences of non-calibrated equipment being used as given in the previous example, he/she will cite a general deficiency against section 5.6.1. The problem of having non-calibrated equipment in service is systemic, impacting a broader range of testing and indicating a repeated failure to implement a requirement of ISO/IEC 17025.

The determination of when a deficiency slips from being a specific deficiency to becoming a general deficiency is left to the discretion of the assessor. Assessors must be careful to place deficiencies in the proper category since a general deficiency indicates the need for a more thorough root cause analysis and corrective action and will affect the way staff and Accreditation Council members view the corrective action.

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In-House Calibrations and the A2LA Traceability Policy

Many laboratories perform in-house calibrations of their equipment and there are many benefits to adopting this approach – reduced costs, less down time, and convenience. However, in-house calibrations must meet all of the traceability requirements of contracted calibrations. These requirements are listed in the *A2LA Policy on Measurement Traceability* and note T9. A2LA is now asking laboratories to provide a list of in-house calibrations performed as part of the accreditation application. This applies to both new and renewal labs. Only calibrations relating to testing listed on the Scope of Accreditation is of interest. A2LA is not concerned with calibrations of equipment for testing not listed on the Scope or calibration of equipment used by other parts of the facility, such as production, final inspection, etc. Laboratories performing many or complicated in-house calibrations may have a calibration assessor review the in-house calibrations as part of the assessment process.

Note T9 has 5 requirements:

- The in-house laboratory shall maintain documented procedures for the in-house calibrations and the in-house calibrations shall be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records shall be retained for an appropriate, prescribed time;

The procedures may be developed in-house or may be published procedures. Some published testing procedures require that equipment be calibrated in a defined way. ASTM D935 and D573, for example, require ovens to be calibrated according to ASTM E145. Section 5.10 of ISO/IEC 17025 should be referenced for the type of information commonly reported on a calibration certificate. Any documents and/or records associated with the calibration are part of the laboratory's quality system and must meet the requirements of sections 4.3, 4.12, 5.5, and any other applicable sections.

- The in-house laboratory shall maintain training records for calibration personnel and these records shall demonstrate the technical competence of the personnel performing the calibrations;
- The in-house laboratory shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from accredited calibration labs or a national metrology institute;

At some point, the equipment and/or reference standards used for calibrations must be traceable to a primary reference standard (perhaps indirectly) or some intrinsic value. In the United States, traceabilty is commonly to a NIST reference standard. However, any recognized national metrology institute (NMI) is acceptable. This may involve purchasing items with an accredited, traceable calibration certificate or directly from an NMI, or having a calibration performed by a recognized, accredited calibration provider.

- The in-house laboratory shall have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be taken into account when statements of compliance with specifications are made;

Uncertainty calculations are required for all in-house calibrations. Uncertainty of the calibration is not the same as the uncertainty of the associated testing. For example, any laboratory performing dimensional inspection has the uncertainty for the inspection published on its Scope of Accreditation. However, this number is not the uncertainty of the calibration of the dimensional inspection equipment. The uncertainty of the testing must take into account the uncertainty of the calibration. Also, even though the testing itself may not require an uncertainty budget because it is considered Type I or II as defined in the A2LA *Policy on Estimating Measurement Uncertainty for Testing Laboratories*, the calibration of the equipment involved in the testing will.

- Reference standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals shall be based on the historical behavior of the reference standard.

Although it may sound obvious, be sure not to use reference standards to calibrate measuring equipment and the measuring equipment to calibrate the reference standards. At some point the chain of traceability must leave the laboratory.

Finally, be sure to make a distinction between intermediate checks, verifications, standardizations, and calibrations. If you are merely verifying, as with daily verifications of Rockwell hardness equipment or standardizing, as with pH meters, the requirements of T9 do not apply. Since these terms are used interchangeably in many cases, be sure to discuss any questions as to the applicability of T9 with A2LA or the assessor.

The purpose of T9 is not to make in-house calibrations burdensome on the laboratory. However, traceable, accurate equipment is the key to reliable testing. A2LA cannot accredit a laboratory if the test results are suspect. Each lab must weigh the cost/benefit of performing in-house calibrations and proceed accordingly.

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Is Measurement Uncertainty Necessary on Certificates of Calibration for Testing Laboratories?

In order to properly address this issue, the testing laboratory should ask itself a few questions. What does ISO/IEC 17025 require of me? Do I need measurement uncertainty on the calibration certificates I receive? If so, what information should I request and how do I interpret that information? If I do not have it, but I need it, can I get it? This article will summarize the presentation from the 2004 A2LA Assessor's Conclave.

Testing laboratories need to identify for themselves the importance of having measurement uncertainty for the calibrations they receive. But first we have to look at the requirements of the international standard, ISO/IEC 17025. Clause 5.6.2.2.1 states:

"For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed."

The next step would be for the testing laboratory to investigate the methods that it performs to determine if the estimation of measurement uncertainty is required for analyzing its own results. For example, the EPA (through MARSSIM – NUREG 1575 and HASL-300) requires that measurement uncertainty be calculated for radioactive environmental sample analysis. To calculate the uncertainty, the testing laboratory has to apply sampling statistics to the testing method and algebraically add those results to the contributors from the measurement process, one of which would include the uncertainty of calibration of, for example, a balance or pipette. This is the premise behind A2LA's published *Policy on Estimating Measurement Uncertainty for Testing Laboratories* (effective May 1, 2004). The applicable measurement uncertainty category (I-V) for the tests identified on the lab's proposed Scope of Accreditation should dictate whether or not the testing laboratory would require measurement uncertainty on the calibration certificates it receives. A testing laboratory that has evaluated its test methods and rated them as either Category V, most of Category IV and Category III should receive calibration certificates with data and accompanying uncertainties. For additional information, please review the applicable program requirements for your field of testing. Most of the A2LA Advisory Committees have either developed or are developing guidance in this area for specific tests.

Calibration certificates or reports can present measurement uncertainty either explicitly or implicitly. Explicit statements are straight forward and are either applied to each data point or to the calibration process across the range of the calibration. Implicit statements typically appear as either a ratio or as a statement referencing a specification with defined uncertainties. The test uncertainty ratio (TUR) is probably the most common statement of uncertainty and is defined as the ratio of the tolerance of the unit under test (calibrated item) to the expanded uncertainty of the measurand or calibration process. If one knows the tolerance of the unit under test (found primarily in manufacturer's operating manuals and/or method specifications) and the ratio is presented on the calibration certificate, one can algebraically determine the expanded uncertainty. However, the calibration laboratory still has to prove that it meets the criteria, otherwise it cannot claim that ratio. If the calibration laboratory references a specification for defining uncertainties, it is important for the testing laboratory to determine if the specification actually defines the uncertainties for the calibration or if the uncertainty claims describe the standard deviation of a population of instruments that will be "in calibration" within the OEM defined calibration interval. This is a difficult task not only for the testing laboratory but also for the calibration laboratory. Therefore, it is important that the testing laboratory and the calibration laboratory come to an agreement on the definition of the instrument specifications before services are requested and that the agreement is documented.

If the accredited calibration laboratory did not provide measurement uncertainty on the traceable certificate, the service provider should be able to make it available if you request it as required by ISO/IEC 17025 clause 5.10.4.2 which states in summary:

"When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference."

In summary, testing laboratories should take the **3-D** approach:

1. Determine the category of the test you are performing to identify if measurement uncertainty is necessary from your calibration provider;
2. Define with the service provider the information you require on the report;
3. Document the discussion.

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