



A2LA News: The Newsletter of the American Association for Laboratory Accreditation___April 2005, Number 88

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John Wehrmeyer, Paul Graboff, Phil Smith, and Gary Cornell take a break during the A2LA Conclave

A2LA News April 2005

Notes from the Editors

We are always striving to make *A2LA News* timely, informative and beneficial to the thousands of laboratories, members, assessors and volunteers that read it each quarter. And we are always receptive to your ideas for making that happen.

As you will note in this issue, two A2LA assessors have contributed articles within their areas of expertise to share their knowledge and experience on issues that they frequently encounter.

A2LA staff are also actively involved not only in suggesting ideas for current issues and areas of discussion but also in submitting articles for inclusion in our newsletter. Rob Miller, A2LA Senior Laboratory Services Officer, and Pamela Wright, A2LA Laboratory Services Officer, each have written their first article in this issue of *A2LA News*. Rob's article on assessments of dimensional testing laboratories to the *A2LA Calibration Program Requirements* is an informative clarification of a nuance that is frequently misunderstood. Pamela's article on conducting a reverse traceability study is both timely and helpful to many laboratories that are facing a finding against the *A2LA Traceability Policy*.

If you have any suggestions or ideas for articles to be included in future issues of *A2LA News* or if you are interested in writing an article for submission, please feel free to contact Teresa Barnett (301 644 3202 or tbarnett@a2la.org) or Tim Rasinski (301 644 3232 or trasinski@a2la.org) at A2LA headquarters.

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A2LA Welcomes Two New Staff Members

A2LA is pleased to welcome two new staff members. The first is Kathleen Pennewill who is joining A2LA as an administrative associate. Ms. Pennewill has a background in insurance and human resources and worked as a benefits and retirement plan administrator in her previous position.

The second is Philip Smith. Phil is joining A2LA as business development manager and has been an A2LA calibration assessor for four years. Most recently he served as a technical sales representative for a firm representing primary reference standards, test equipment, and various sensors from several manufacturers. Prior to this, Phil served in the United States Air Force as the American Metrology Representative on the NATO mobile calibration team. We feel the mixture of technical and sales experience makes him the perfect person to represent A2LA to current and future clients.

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A2LA Partners for Joint Accreditation/Registration Assessments

In an effort to enhance the A2LA approach as a "one-stop-shop" for test and calibration laboratories, A2LA has signed agreements with two management system registrars to allow laboratory accreditation and registration through one on-site visit. These agreements allow testing and calibration laboratories to obtain ISO/IEC 17025 accreditation as well as ISO 9001, TL-9000, AS 9100, ISO 14001 and ISO 13485 management system registration.

Currently accredited A2LA laboratories interested in obtaining management system registration will be put in contact with the two agencies to work out the registration arrangements. Once registered, assessments will be coordinated for simultaneous accreditation and registration activities.

For new applicants, the process will be implemented so that the initial assessment will be coordinated for simultaneous accreditation and registration activities.

For more information regarding this opportunity, please contact A2LA or your Laboratory Services Officer.

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A2LA's Fall 2005 Training Course Schedule

Title: [Introduction to Measurement Uncertainty](#)

- September 26-27, 2005 – Novi, MI
- November 14-15, 2005 – Orlando, FL

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

- September 28 – 30, 2005 – Novi, MI
- November 16-18, 2005 – Orlando, FL

Title: [Control Charting for Metrology Applications](#)

- October 3-4, 2005 – Cleveland, OH

Title: [The World of EMC Standards-Present and Future](#)

- October 5, 2005 – Cleveland, OH

Title: [Assessment of Laboratory Competence](#)

- October 17-21, 2005 – Annapolis, MD

For additional information, please contact Ms. Julie Stevens, A2LA Training Coordinator, at 301 644 3235 or jstevens@a2la.org.

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Feedback From An Accredited Laboratory

Positive feedback from our accredited laboratories is always appreciated and welcomed by A2LA staff. Recently, the following letter was submitted to A2LA from

DH Instruments of Phoenix, AZ:

I wanted to express my appreciation of A2LA. I originally decided to use A2LA accreditation based on its customer service. Everyone was very easy to work with, and I always received answers right away from whomever I came into contact with at A2LA. The other reason was the MRA [Mutual Recognition Arrangements] with EA [European cooperation for Accreditation] and APLAC [Asia Pacific Laboratory Accreditation Cooperation]. I was originally concerned about the technical capabilities of the assessors at A2LA and sent a long letter to you about DHI's history and commitment to quality and our innovative solutions to pressure and flow metrology. This was in some ways an attempt to scare A2LA off if not up to the task. Since then we have been nothing but impressed with the knowledge and helpfulness of the assessors and very pleased with the consistent practices and direction of your organization.

I recently read Peter Unger's letter to NACLA and applauded A2LA's decision not to continue participation in an MRA with NACLA. A2LA is, in my view, the most accomplished and dependable AB [accreditation body] in the United States and ABs that have not come close to the efforts that A2LA has put forth should never have received the same recognition.

Great job and don't let up.

(Printed with permission from Michael Bair, DH Instruments, Inc., Phoenix, AZ)

A2LA takes great pride in the skills and technical expertise of our assessor corps, and we appreciate having their efforts acknowledged. A2LA also is committed to enforcing the obligations of the international MRAs of which we are signatories because of the ultimate benefit they bring to our accredited laboratories – one test accepted everywhere.

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Reminder Regarding Updated Email Addresses

Quite some time ago, A2LA implemented a system for keeping laboratories, assessors, members, etc. up to date on document revisions and Association activities via email. While most of these issues are reiterated in each issue of the A2LA newsletter, notices of newsletter availability are also issued via email. Therefore, it is critical that A2LA maintain on record current email addresses for its constituents, as a significant number of returned and undeliverable mail is received from each notice that is issued.

Please be sure to notify any A2LA staff member of a change to your email address and, if you are in doubt as to whether or not A2LA has on record your current and correct address, please feel free to contact any staff member to confirm this.

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A2LA Holds 2005 Conclave

A2LA held its annual Conclave from March 8 through 14, 2005, in Columbia, Maryland.

This year's series of meetings began with the annual [assessor orientation course](#) from Tuesday morning through Friday afternoon. There were 18 participants in the course, 17 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.

Two additional technical training sessions were given on Friday, March 12. A special meeting and training session was held for the automotive EMC accreditation program to discuss updates and clarifications within the program, and the regular training and refresher session for environmental lead (Pb) assessors was also held.

Individual discipline-specific breakout sessions were held on Friday evening. Sara Weitzel headed a session on various topics for plastic and rubber assessors, and Roger Brauningler led a meeting of food testing assessors. The disciplines and topics covered during these Friday evening meetings typically change from year-to-year depending on developments within the various fields.

Meetings on Saturday started early with the Plenary Session of all Conclave attendees. As in the past, a significant portion of the Plenary Session was devoted to refresher training on the accreditation requirements and A2LA's interpretation of them. Several staff presentations were given during the Plenary Session, including Teresa Barnett's presentation on the current version of the [A2LA Advertising Policy](#), Greg Gogates' presentation on guidance for understanding software verification, Tim Rasinski's presentation on the required depth of assessment to the requirements of the [Traceability Policy](#) for laboratory's performing in-house calibrations, and Trace McInturff's presentation on the [Proficiency Testing Matrix](#) and its use by A2LA assessors. The day's meetings concluded with the Assessor Committee meeting hosted by committee chair, Bob Holcomb. The interactions between A2LA and NACLA were a primary topic of conversation during the Assessor Committee meeting, but time was also reserved for discussion of several new issues (including the new ISO/IEC 17025: 2005) and updated internal A2LA policies. In the evening, the [annual A2LA banquet](#) was held. A2LA vice-president Roxanne Robinson presented assessors with 5, 10, 15, and 20-year service awards. This was the first time this has been done and will be a continuing event at future Conclaves. [Dawn Mettler](#) received the annual Assessor's Choice award as recognition of her skills as an A2LA assessor. Also, Doug Lentz received an award of appreciation for his service as chair of the Accreditation Council, and [Marlin Bussey](#) and Bill Dingeldein received awards of recognition upon their retirement as A2LA assessors.

The majority of Sunday was devoted to individual technical committee meetings. Five committees (CMT/geotechnical, life sciences, materials testing, electromechanical, and measurement) met throughout the day to discuss issues particular to their fields as well as issues common among all disciplines, including the [A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories](#) and the [A2LA Traceability Policy](#). Late Sunday afternoon, the A2LA Criteria Council and Accreditation Council also met to discuss their activities over the past year and those planned for the future.

The Conclave concluded on Monday with the Annual Meeting of the Membership. Peter Unger presented the President's report, and various committee chairs and staff members presented reports on the weekend's activities as well as general Association activities. Peter Unger also discussed the latest news regarding the revision to ISO/IEC 17025 and 17011. The Board of Directors meeting immediately followed and was the concluding event of the Conclave.

The 2006 Conclave is scheduled to be held from March 6 – 13 at the Columbia Sheraton. We hope to see you there.

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A2LA Attends the 2005 Quality Expo

A2LA attended the 2005 Quality Expo in Chicago, IL from April 19-21. Phil Smith and Tim Rasinski represented A2LA at the show and had a chance to talk to many of our labs. Overall, their experience with A2LA has been positive, but we were happy to answer questions and listen to concerns. Thanks to all of the A2LA labs that attended.

[American Calibration, Inc.](#)
[Advanced Technology Services](#)
[Atlas Weathering Services](#)
[Beta LaserMike](#)
[Cal-Rite Corp.](#)

Carl Zeiss Corp.
Cincinnati Test Systems, Inc.
Mitutoyo
MTS Metrology
Newage Testing Instruments, Inc.
Precision Metrology, Inc.
QC Inspection Services, Inc.
Quality Calibration Service, Inc.
Richard J. Bagan, Inc.
Starrett
Sturtevant Richmond
Supplier Inspection Services, Inc.
Sun-Tec Corp.
Sypris Test & Measurement
Tinius Olsen
Transcat
United Testing Systems, Inc.
Zwick USA

We also answered many questions about laboratory accreditation and our process of assessing labs. The booth featured access to the A2LA website allowing potential lab and calibration customers to learn how the laboratory search engine works and look for accredited labs. We were able to match several visitors with labs to meet their testing and calibration needs. And a large part of the three days was spent just educating people on the difference between accreditation, registration, and certification. We hope those who visited found us useful and helpful.

We will be attending the [2006 Quality Expo](#) in Novi, MI on June 7 & 8. We hope to see you there.

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New & Updated Documents:

On February 8, 2005, A2LA issued its field-specific annexes to the [Policy on Estimating Measurement Uncertainty for Testing Laboratories](#). These annexes contain examples of methods and the categories (I-V) that they relate to. Annexes have been developed and are available on the A2LA website for:

- [automotive and materials testing labs](#);
- [electro-mechanical testing labs](#);
- [construction materials and geotechnical testing labs](#);
- [life sciences testing labs](#).

On April 18, 2005, A2LA replaced the old *Environmental Selection List* and *Environmental Lead (Pb) Selection List* with four template documents that environmental laboratories may use to draft their Scope of Accreditation. Templates have been developed for [Environmental Scopes](#), [Environmental Lead \(Pb\) Scopes](#), [Environmental Kentucky Underground Storage Tank \(KY UST\) Scopes](#), and [Environmental Wyoming Storage Tank Remediation \(formerly the WY LAUST program\) Scopes](#). There is also an [instruction sheet](#) that explains how the templates are to be used in drafting a Scope of Accreditation. All of these templates are available by email upon request and also as links on the A2LA website. Beginning immediately, new and renewal laboratories are to use these templates in place of the selection lists when indicating their desired Scope of Accreditation.

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Dimensional Test Reports as Calibration Certificates

Traceability is typically achieved through calibration services. However, in some instances, traceability can be achieved through test results. When a dimensional testing laboratory (in the mechanical field of testing) is measuring what is commonly referred to as hard tooling or fixed gauges, there are times when that measured tool is going to be used by the laboratory's customer as the reference standard to measure his/her own parts.

In those cases, the dimensional testing laboratory is serving as a link in the traceability chain and must be treated by A2LA and our assessors as a calibration laboratory. In these situations, the calibration program requirements must be applied in order to accredit the dimensional testing laboratory for this

service.

Therefore, a dimensional testing laboratory that has been assessed against the calibration program requirements and issues an accredited test report containing appropriate statements of measurement results, measurement uncertainty, and traceability can be considered as having produced a "calibration" report for the dimensional artifact in question regardless of the title of the document. This can be particularly useful for complex dimensional artifacts that most dimensional calibration laboratories will not be accredited to calibrate.

A note at the bottom of the Scope of Accreditation for those dimensional test labs meeting the calibration program requirements will read, "This laboratory meets the A2LA *Calibration Program Requirements* for the types of dimensional testing listed above. Accredited test reports issued containing appropriate statements of measurement results, measurement uncertainty, and traceability are considered equivalent to a calibration certificate."

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A Beginner's Guide to Reverse Traceability

Here is the scenario: Your laboratory receives a deficiency cited against (T1) of the [A2LA Policy on Measurement Traceability](#) because your equipment was not calibrated by a recognized (accredited by A2LA or a mutual recognition arrangement partner) calibration laboratory. In responding to the deficiency, it was determined that there is no calibration provider that is accredited to perform the calibration you need. Your corrective action reflects this information, but you receive a letter from A2LA asking for a "reverse traceability search." Now you scratch your head and wonder, "What is this?"

First of all, let us explain the concept of traceability. Traceability is the establishment of linkages to the SI (Système International d'unités). "Okay," you may ask, "what is the SI?" The SI is a unit of measurement known and recommended by the [General Conference of Weights and Measures](#) (CGPM) and the [International Committee for Weights and Measures](#) (CIPM). These units of measurement include things such as the gram, the joule, etc. Calibration laboratories that maintain their own primary standard can claim traceability to the SI system only after the standards have been compared, **directly or indirectly**, with other similar standards of a national metrology institute (NMI). The NMI in the United States is the [National Institute of Standards and Technology](#) (NIST). So basically, traceability is the establishment that a calibration laboratory's primary standard has been compared either directly or indirectly with other similar standards of an NMI. **If it is an indirect comparison, then each calibration provider in between the calibration laboratory with the primary standard and the NMI (each link in the chain) must be accounted for.** For calibration laboratories accredited by a recognized accrediting body, this traceability is already established through the assessment and accreditation process, and thus they meet the *Traceability Policy*. For laboratories that are not accredited or whose accrediting body is not recognized by A2LA, this traceability cannot be confirmed, so it then becomes your responsibility to establish all of the indirect comparisons (each link in the chain) between your calibration provider (the laboratory with the primary standard) and NIST (or another recognized NMI). This process is called a "reverse traceability" search.

Here is a practical guide to reverse traceability ([flowchart representation](#)):

1) Begin with your calibration certificate. Review the certificate to determine what standards the calibration laboratory used to conduct the calibration.

For example: ABC Company has a calibration certificate from the original equipment manufacturer (OEM) for a radius arm. The OEM listed a height gage, micrometer, and gage blocks as the standards used for the calibration of the radius arm.

2) Request a copy of the calibration certificate for the exact standard(s) (identified by serial numbers) used to conduct your calibration.

For example: ABC Company requests a copy of the calibration certificate for the height gage s/n 100, micrometer s/n 200, and gage blocks s/n 300 used by the OEM to conduct the calibration of the radius arm.

3) When you receive a copy of the certificate:

- **Review it to ensure that the serial number(s) for the standard(s) match the ones listed on your original calibration certificate. If it does not match, request the correct certificate.**
- **Determine whether the calibration certificate is from a mutually recognized accrediting body or NMI (such as NIST). If it is, then you have established traceability, and you may go to step 5. If it is not, then you must establish the next "link in the chain" by going to step 4.**

For example: ABC Company receives the calibration certificates for the standards used to conduct the calibration of the radius arm. The serial numbers all match; however, the height gage calibration certificate is from company X, and the micrometer and gage blocks certificates are from company Y. Neither company is accredited. Now ABC Company must request a copy of the calibration certificate from company X for the standard used to calibrate the height gage and from company Y for the standards used to calibrate the micrometer and gage blocks, being specific about serial numbers.

4) For the next link in the chain:

- a) Request a copy of the calibration certificate for the exact standard(s) used to conduct the previous calibration in the chain.**
- b) When you receive a copy of the certificate:**

- **Review it to ensure the serial number(s) for the standard(s) used matches the one(s) listed on the previous calibration certificate in the chain. If it does not match, request the correct certificate.**
- **Determine whether the certificate is from a mutually recognized accrediting body or NMI (such as NIST). If it is, then you have established traceability and you may go to step 5. If it is not, then you must establish the next link in the chain by repeating step 4.**

For example: ABC Company receives a copy of the calibration certificates from company Y for the micrometer and gage blocks and company X for the height gage. The serial numbers all match the calibration certificate from the OEM. While company Y's calibration certificates for the micrometer and gage blocks are from NIST, company X sent its height gages to John Doe Calibration Company. While this establishes the reverse traceability for the micrometer and gage blocks, it does not for the height gage. ABC Company repeats step 4 and requests and receives a copy of John Doe's calibration certificate for the gage blocks that were used to calibrate the OEM's height gage that was used to calibrate ABC Company's radius arm. Since John Doe's laboratory is accredited by NVLAP, all the calibrations between ABC Company's primary calibration provider and the recognized accredited calibration laboratory have been accounted for. ABC Company can now move to step 5.

5) Send a copy of all the calibration certificates that establish traceability as your follow-up response to A2LA.

Keep in mind that exceptions to the *Traceability Policy* are only valid until the next assessment. If your laboratory is still not in compliance at that time, then a deficiency will be again cited against (T1). Another reverse traceability search will be needed before another exception is granted as the calibration provider(s) in between the calibration laboratory with the primary standard and the NMI may change.

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Traceability of pH Measurements

Did you know that pH traceability to the SI is possible?

The [International Union of Pure and Applied Chemistry](#) (IUPAC) updated previous recommendations in 2002. The update incorporated the definition of primary standards from BIPM as published in *Com. Cons. Quantité de Matière* **4** (1998). See also: *Metrologia* **38**, 289 (2001). This definition and the document from IUPAC in 2002 demonstrate the traceability of pH measurements and the associated uncertainty.

The definition of primary standards for pH as determined by a primary method (cell without transference, Harned cell) allows the conventional quantity to be incorporated within the internationally accepted system of measurement, the International System of Units (SI). Furthermore, incorporation of the uncertainties for the primary method, and for all subsequent measurements, permits the uncertainties for all procedures to be linked to the primary standards by an unbroken chain of comparisons.

The IUPAC papers and reports present the definitions, procedures, and terminology relating to pH measurements in dilute aqueous solutions in the temperature range 5–50 °C. Details are given relating to the primary and secondary methods for measuring pH and the rationale for the assignment of pH values with appropriate uncertainties to selected primary and secondary substances. The IUPAC recommendations are found in "[Measurement Of pH, Definition, Standards, And Procedures,](#)" *Pure Appl. Chem.*, Vol. 74, No. 11, pp. 2169–2200, 2002, (IUPAC Recommendations 2002).

The document also notes that traceability to SI is not always necessary and may not be practical due to economic constraints. Laboratories and assessors should review this document to determine the need and application for the various contributors to uncertainty estimation for pH measurements.

The IUPAC document provides examples of uncertainty calculations for primary substances as produced by NMIs and for second standard solutions that may be produced by calibration laboratories using any one of five cell types. The descriptions on the factors resulting in larger uncertainties due to different solutions or other factors are presented in detail.

The Harned cell is the primary method for the absolute measurement of pH. This method has been accepted worldwide as the primary method used by NMIs to assign values to primary standards of solid substances. These solid substances are available from NIST as a standard reference material (SRM)

(e.g., 186g) with stated uncertainties.

Accredited laboratories use the primary standard buffers for assigning secondary pH values to secondary standard buffers. For practical pH measurements, the application of the secondary buffers is more convenient. The primary standards require very specific preparation and should be the same nominal composition as the pH of the unknown in order to reduce the uncertainty. The cells used for the comparison are defined in the document and the associated uncertainty for each is described. Three cells are recommended for the assignment of secondary values to buffer solutions, and the typical uncertainty is presented in the document.

The assignment of secondary values is to be carried out by NMIs or accredited calibration laboratories, which are to issue certificates containing the actual pH values and uncertainties for the secondary standards for each lot. A detailed description and examples of uncertainty budgets are presented in the IUPAC document.

The majority of pH measurements are conducted in cells referred to as combination or single rod electrodes (liquid in glass with a reference electrode). Because of systematic and random effects of glass electrodes and liquid junction potentials, these cells must be calibrated. The document recommends three types of calibration, the one-point, two-point, and five or multi-point calibration procedures, each of which has a characteristic uncertainty. The appropriate calibration procedure depends on the required target uncertainty of the measurement, and the type of cells and materials to be measured.

The measurement uncertainties ($k = 2$) discussed in the document provides target uncertainties using secondary buffers for glass electrode calibration.

- Expanded uncertainty (pH units): 0.01 - 0.03 for multipoint (5) calibration;
- Expanded uncertainty (pH units): 0.02 – 0.03 for 2 point calibration by bracketing;
- Expanded uncertainty (pH units): 0.3 for one point calibration within 3 pH units of the value and using an assumed slope.

The document provides various notes and considerations for determination of pH. The document presents the information necessary for laboratories performing calibrations of pH meters and providing certified standard (buffer) values to allow traceability and uncertainty estimates for pH.

Written by:

Marlene Moore, Advanced Systems, Inc. – Assessor for A2LA since 1993

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Improving the Interface Between Laboratories and Their Customers

Measurements and tests are essential to all modern life. Whether one buys a gallon of gasoline, is concerned with a radiation exposure limit during a medical examination, depends upon an honest measure of a product from a grocery store, worries about the lead content in paint, requires an accurate measurement to launch a shuttle spacecraft, or assures the adequacy of measurements used in nuclear safety related equipment testing and assessment - competency and quality in measurements are expected and necessary.

A significant element, perhaps the foundation of measurement adequacy at both testing and calibration laboratories, is adequate calibration of measurement and test equipment essential for the required measurement.

As frequently observed during on-site assessments, a common problem is the inadequate calibration of an instrument to meet the **requirement for a specific test or measurement method or application**. To a lesser extent, problems are also found in subcontracted tests and calibrations that may not meet the specific requirements for the supported methods. The root cause of the problem is often traceable to inadequate contract review at the supporting laboratory, insufficient definition of technical and quality requirements by the customer or end user, inappropriate method selection, or a combination of these. A lack of communication of actual requirements and expectations by both parties is often found.

When a measurement problem is found, the feedback often includes the following:

- The procuring lab or customer says, "The calibration laboratory is expected to be an expert, especially if it is accredited, so the fault is with the calibration lab for not properly calibrating my

instrument for my specific test.”

- The calibration lab says, “The customer provided no details of what was required. All that was asked for was a calibrated instrument, so I calibrated the instrument with one of the available methods or my own standard procedure.”
- The procuring lab for subcontracted tests or calibrations says, “The supplier is accredited. I should not have to tell him what to do, and he knew I wanted the work done under the lab's Scope of Accreditation.”
- The supplying lab or subcontractor says, “Yes, our sales staff, website, letterhead, and other communications did confirm this is an accredited lab, but the customer never submitted a purchase order requesting an accredited calibration or test.”

The root cause for the problem is often found to be failure to communicate requirements on the part of the client and failure to understand client needs on the part of the calibration laboratory or subcontractor. The three clauses within ISO/IEC 17025-1999, *General Requirements for the Competence of Testing and Calibration Laboratories* that relate to the issue are clause 4.4, “Review of Requests, Tenders and Contracts,” clause 4.6, “Purchasing Services and Supplies,” and clause 5.4, “Selection of Methods.”

Following are the provisions from these clauses that address the customer-supplier interface:

“The laboratory shall have a policy and procedure(s) for the selection and purchasing of services ... that affect the quality of the tests and/or calibrations;”

“These services ... shall comply with specified requirements;”

“Records of actions taken to check compliance shall be maintained;”

“Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services ... ordered;”

“...reviews leading to a contract for testing and/or calibration shall ensure that the requirements, including the methods to be used, are adequately defined, documented and understood;”

“...the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements;”

“When the client does not specify the method to be used, the laboratory shall select appropriate methods;”

“The laboratory shall use test and/or calibration methods ... which meet the needs of the client and which are appropriate;”

“When the client does not specify the method to be used, the laboratory shall select appropriate methods;”

“Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use...”

In practice, the laboratory and its customer each want a positive relationship that is both cost and time effective and that results in minimal risk to their own organizations.

When an individual is ill and procures the services of an “accredited, licensed, or certified” medical doctor, the interface still includes a definition of the requirement or concern on the part of the client/patient (“I need a blood test to get married” or “I’m having chest pains”), or the doctor may indicate the need for a full examination in order to identify areas of concern and select proper diagnostic methods. The doctor or his/her staff does not perform services without having first defined and understood the requirements of the patient (e.g., by investigation to determine what hurts, what the medical appointment is for, etc.).

In business, the understanding between customer and supplier is defined in procurement documents that include specifications for technical and quality requirements. Although many definitions of the term “quality” exist, perhaps the most applicable in this situation is the definition that quality is “defining the requirement and then meeting the requirement.” Phil Crosby included this in his first principle for quality: “Quality is defined as conformance to requirements, not as ‘goodness’ or ‘elegance.’”

In fact, all calibrations and compliance testing are done to defined requirements which are to be met in

order to indicate (1) pass or fail, (2) in-tolerance or out-of-tolerance, (3) compliance or non-compliance by comparing measurement results to specifications or requirements - whether done by the laboratory or the customer.

To assist the user, customer, laboratory, accreditation body, regulator, and others, A2LA has established on its website many useful guidance documents. Four of them are templates or models for procurement and acceptance of competent calibration or testing:

- [Technical & Quality Specification to Assure Competent Calibration Services](#)
- [Calibration Acceptance Checklist](#)
- [Technical & Quality Specification to Assure Competent Test Services](#)
- [Test Acceptance Checklist](#)

Feedback from users indicates that these are useful documents, especially as they relate to assuring adequacy under and compliance with accreditation requirements. The most used document is the *Technical & Quality Specification to Assure Competent Calibration Services* that is currently in revision 12 and undergoing further revision. Readers are referred to the A2LA website to review these documents for usefulness and are encouraged to modify and adopt them for their own purposes. Any comments for improvement are welcome by the author at LGradin@Integrity-Solutions.org as the purpose remains to assist all parties in enhancing the interface between customer and laboratory as part of a process of assuring adequate test and calibration services.

Written by:

Larry Gradin, Integrity Solutions Group, Inc. – A2LA Assessor

