Happy Holidays from the Staff at A2LA

A2LA News: The Newsletter of the American Association for Laboratory Accreditation__ *December, Number 83*

Editors: Teresa Barnett and Timothy Rasinski
Web Layout: Daren Valentine

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A2LA News December 2003

Milestones of A2LA

Peter Unger, A2LA President

I thought it would be appropriate to share with you a list of significant milestones and accomplishments of the past 25 years. My apologies for any significant event or person that I have not mentioned.

Month Year **Milestones**

January 1978	ACIL (American Council of Independent Laboratories) sponsored an organizational meeting to establish A2LA
July 1978	Articles of Incorporation signed
July 1978	First Board meeting chaired by Roger Amorosi
July 1978	Stygar-Willis Associates, Inc. selected to manage operations
January 1979	A seven-member Council of Accreditation formed with members from general interest and purchaser-user members
October 1979	Operating expenses $48,800 for past year
March 1980	An accreditation fee of $3,000 established
September 1980	Lou Rossi elected Chair
September 1980	Technical Committees no longer reporting to the Accreditation Council rather a separate body (Criteria Council) reports to the Board
October 1980	First labs accredited: Lancaster Laboratories, Lancaster, PA; Harris Laboratories, Lincoln, NE; Structure Probe, West Chester, PA, Metuchen, NJ, and Fairfield, CT
March 1981	John Magnotti of MACO Associates appointed Executive Director
June 1982	17 laboratories accredited
September 1982	Board approved requirement that each accredited lab must participate in some form of proficiency testing for each field of testing
September 1982	Accreditation criteria established for biological, chemical, electrical, construction materials and geotechnical fields of testing.
March 1983	26 laboratories accredited
April 1983	Board adopted ISO/IEC Guide 25 as the general criteria for accreditation
January 1984	Foster Wilson elected Chair
August 1984	City of Houston requires A2LA accreditation for its contract labs
August 1984	58 laboratories accredited
April 1985	Board adopted ASTM standard E994-84, *Guide for Laboratory Accreditation Systems* as the basis for its operation
December 1985	Total income for 1985 was $100,000
April 1986	78 laboratories accredited
January 1986	Gladys Berchtold elected as Chair
January 1986	Board membership increased to 21 from 14
April 1986	John Locke named Executive Director through his firm CASSI
April 1986	Grants were secured from ASTM and ACIL
April 1986	Lisa Drake joined CASSI as Staff Director
June 1986	Pete Unger joined CASSI as Vice President
December 1986	80 laboratories accredited; total income $149,000
April 1987	Loans secured from ACIL and ASTM
June 1987	Work on bilateral MRA agreements begun with Hong Kong, Australia, and New Zealand
August 1987	Acronym changed from AALA to A2LA
August 1987	John Locke's title changed to President
December 1987	117 laboratories accredited; total income $242,000
October 1987	Public training programs begin including one supported by Defense Industrial Supply Center

April 1988	First assessor conclave held which becomes an annual event to air problems and provide continuing training
August 1988	Calibration laboratory accreditation program established
December 1988	156 laboratories accredited; total income $260,000
January 1989	Chester Grant elected as Chair
April 1989	Fastener lab program started
November 1989	A2LA recognized as one of two accreditation bodies by GM
December 1989	207 laboratories accredited; total income $453,000
January 1990	Roxanne Robinson joins the staff
April 1990	First bilateral mutual recognition agreement signed with HOKLAS, Hong Kong
November1990	MRA signed with NATA, Australia and TELARC, New Zealand
December 1990	270 laboratories accredited; total income $681,500
January 1991	Management firm's staff converted to employees of A2LA
April 1991	Last of three forums to develop cooperation among accreditation bodies held, but there seems to be little interest
December 1991	Accredited labs given one year to meet revised ISO/IEC Guide 25:1990
December 1991	348 laboratories accredited; total income $936,000; 5 person staff
January 1992	Paul Schlecht elected Chair
April 1992	MRA with Naval Sea Systems Command signed
June 1992	Last loan repaid; A2LA debt free
December 1992	460 laboratories accredited; total income $936,000; 8 person staff
May 1993	STERLAB, Netherlands evaluates A2LA for possible MRA which never materializes – lack of confidence in US traceability claims a major issue
November 1993	EPA recognizes A2LA under National Lead Laboratory A ccreditation Program
November 1993	Inspection body accreditation program initiated
December 1993	593 laboratories accredited; total income $1,363,000
January 1994	William Roberts elected Chair
June 1994	MRA for testing signed with SCC, Canada
December 1994	700 laboratories accredited; total income $1,892,000
January 1995	MRA signed with SINGLAS, Singapore
December 1995	774 laboratories accredited; total income $2,186,000
September 1996	APLAC evaluates A2LA, the first peer evaluation for the eventual MRA
April 1996	Pete Unger succeeds John Locke as President
October 1996	A2LA signs ILAC MOU with 43 other accreditation bodies
December 1996	882 laboratories accredited; total income $2,751,000
January 1997	Steve Bowser elected Chair
April 1997	NIST approves A2LA under Fastener Quality Act evaluation program
November 1997	A2LA one of seven signatories to inaugural APLAC MRA
December 1997	A record 300 applicants received for the year
December 1997	987 laboratories accredited; total income $3,853,000; 22 person staff
February 1998	1000 th lab accredited (Mattel Corporate Integrity Lab, El Segundo, CA)
October 1998	Headquarters moved from Gaithersburg to Frederick, Maryland
December 1998	1,195 laboratories accredited; total income $4,340,0 00; 25 person staff.

January 1999	Douglas Berg elected Chair
September 1999	Bilateral MRA with European cooperation for Accreditation signed
December 1999	1,348 laboratories accredited; total income $5,349,000; 28 person staff.
November 2000	A2LA one of 35 accreditation bodies to sign inaugural ILAC MRA
December 2000	1,491 laboratories accredited; total income $6,694,000; 31 person staff.
September 2001	A2LA one of three signatories to inaugural NACLA MRA
December 2001	1,573 laboratories accredited; total income $6,542,000; 34 person staff.
January 2002	William Kavanagh elected Chair
November 2002	A2LA one of three signatories to inaugural IAAC MLA
December 2002	1,612 laboratories accredited; total income $6,991,000; 33 person staff.
April 2003	2000 th accreditation certificate issued to BOC Gases, Detroit, MI

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FDA Denver District Laboratory Achieves A2LA Accreditation

The Denver District Laboratory of the Food and Drug Administration (FDA) celebrated its status as the first FDA laboratory in the nation to achieve accreditation by A2LA on October 21, 2003. Peter Unger, A2LA President, presented the Certificates of Accreditation for biology and chemistry at a formal ceremony in Red Rocks Conference Center in Morrison, Colorado, attended by the laboratory staff and officials from FDA and related government agencies.

Quoting the FDA press release:

"Accreditation makes FDA's scientific findings more defensible and credible in legal proceedings and is recognized as quality data achieved through an established quality system. Accreditation demonstrates to the nation and to the world that this FDA laboratory has stood by FDA's commitment to excellence. It provides assurance to a laboratory, its peers and industry leaders that the laboratory's processes and procedures are consistent with current best practices in testing. It is a benchmark for performance. Laboratory accreditation is recognized both nationally and internationally as a foundation for technical competency."

FDA has clearly committed itself to using accreditation in the public interest.

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Laboratory Invitation to A2LA Assessor Conclave

A2LA will be hosting its annual Assessor Conclave in March 2004. As part of this yearly event, each of the A2LA Technical Advisory Committees will meet to discuss issues affecting their programs of accreditation. All A2LA-accredited and enrolled laboratories are invited and encouraged to attend.

These meetings will be held on Saturday, March 13, 2004 from 8 a.m. to 5 p.m. and will include:

- The Construction Materials Advisory Committee (Staff Contact: Joe Kane, 301 644 3220 or jkane@a2la.org)
- The Life Sciences Advisory Committee (Staff Contact: Roger Brauninger, 301 644 3233 or rbrauninger@a2la.org)
- The Materials Testing Advisory Committee (Staff Contact: Tim Rasinski, 301 644 3232 or trasinski@a2la.org)

- The Electromechanical Advisory Committee (Staff Contact: Beth Hackett, 301 644 3227 or bhackett@a2la.org)
- The Measurement Advisory Committee (Staff Contact: Tim Osborne, 301 644 3237 or tosborne@a2la.org)

This year's Conclave will be held at:

The Sheraton Columbia Hotel
10207 Wincopin Circle
Columbia, Maryland
http://www.sheratoncolumbia.com

Unfortunately, A2LA is not able to subsidize expenses for laboratories that wish to attend, but your participation is invaluable to the growth and development of our programs. If you are interested in attending, please notify the appropriate A2LA staff contact, and a detailed agenda will be forwarded to you prior to the meetings.

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Gaining Acceptance by A2LA's Mutual Recognition Agreement Partners

A2LA prides itself on the extent to which our accreditation program has gained national and international acceptance. We routinely undergo extensive, thorough evaluations by our peers around the world to ensure that our process is compliant with internationally accepted standards and practices. The results of these peer evaluations are the numerous mutual recognition agreements (MRAs) A2LA has signed with our counterparts worldwide. In essence, these MRAs attest to the fact that the accreditation issued by any signatory is equivalent to accreditations issued by all other signatories. The MRAs also attest to the fact that each signatory is operating in full accordance with ISO Guide 58 *Calibration and Testing Laboratory Accreditation Systems – General Requirements for Operation and Recognition* and is competently accrediting laboratories to ISO/IEC 17025.

For A2LA-accredited testing and calibration laboratories, these MRAs can provide opportunities for expanding into an international marketplace. Testing or calibration performed by an A2LA accredited lab is considered equivalent to testing/calibration performed by labs accredited by the other signatory accrediting bodies within these various economies. It is important to understand, however, that these MRAs do not necessarily bind organizations (governmental or non-governmental) within these economies to recognize the equivalency of the accredited tests or calibrations. In many cases, though, an open discussion on the matter can bring about greater awareness of the significance of the MRAs and, ultimately, acceptance of data across borders. As a signatory to these MRAs, A2LA is committed and obligated to assist any accredited laboratory in gaining recognition within other signatory economies. If you encounter difficulties in gaining recognition of your A2LA accreditation or have questions about the recognition of other accrediting bodies, please contact your A2LA Laboratory Services Officer.

A list of the MRAs to which A2LA is currently a signatory as well as a list of all current signatories to these MRAs is below.

The Asia Pacific Laboratory Accreditation Cooperation (APLAC) MRA :

For Testing & Calibration -

NATA (Australia)	SCC (Canada)
CNACL (China)	CCIBLAC (PRC)
HKAS (Hong Kong)	NABL (India)
KAN (Indonesia)	JAB (Japan)

JCSS (Japan)
KOLAS (Korea)
SAC -SINGLAS (Singapore)
TLAS (Thailand)
IAS (USA)
VILAS (Vietnam)
JNLA (Japan)
IANZ (New Zealand)
CNLA (Taipei)
A2LA (USA)
NVLAP (USA)

The European Cooperation for Accreditation (EA) MRA :

For Testing –

BMwA (Austria)
CAI (Czech Republic)
FINAS (Finland)
DACH (Germany)
DATech (Germany)
NAB (Ireland)
LA (Lithuania)
NA (Norway)
SNAS (Slovakia)
SWEDAC (Sweden)
UKAS (U.K.)
BELTEST (Belgium)
DANAK (Denmark)
COFRAC (France)
DAP (Germany)
DASMIN (Germany)
SINAL (Italy)
RvA (Netherlands)
IPQ (Portugal)
ENAC (Spain)
SAS (Switzerland)
LATAK (Latvia)

For Calibration –

BMwA (Austria)
CAI (Czech Republic)
FINAS (Finland)
DAR DKD (Germany)
NAB (Ireland)
LA (Lithuania)
NA (Norway)
SNAS (Slovakia)
SWEDAC (Sweden)
UKAS (U.K.)
BKO-OBE (Belgium)
DANAK (Denmark)
COFRAC (France)
SIT (Italy)
LATAK (Latvia)
RvA (Netherlands)
IPQ (Portugal)
ENAC (Spain)
SAS (Switzerland)

The International Laboratory Accreditation Cooperation (ILAC) MRA :

For Testing & Calibration -

NATA (Australia)
BELTEST (Belgium)
INMETRO (Brazil)
CCIBLAC (PRC)
BMwA (Austria)
BKO-OBE (Belgium)
SCC (Canada)
CNACL (PRC)

CAI (Czech. Rep.)	DANAK (Denmark)
FINAS (Finland)	COFRAC (France)
DAP (Germany)	DACH (Germany)
PTB (Germany)	DATech (Germany)
DASMIN (Germany)	HKAS (Hong Kong, China)
NABL (India)	KAN (Indonesia)
NAB (Ireland)	SINAL (Italy)
SIT (Italy)	ISRAC (Israel)
JAB (Japan)	IA (Japan)
KOLAS (Rep. of Korea)	RvA (The Netherlands)
IANZ (New Zealand)	NA (Norway)
IPQ (Portugal)	SPRING (Singapore)
SNAS (Slovakia)	SANAS (South Africa)
ENAC (Spain)	SWEDAC (Sweden)
SAS (Switzerland)	CNLA (Taipei)
TLAS (Thailand)	UKAS (United Kingdom)
A2LA (USA)	IAS (USA)
NVLAP (USA)	VILAS (Vietnam)

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SBC Recognizes A2LA ISO/IEC 17025 Accreditation for NEBS Testing

A2LA is now formally recognized by SBC for ISO/IEC 17025 accreditation of Network Equipment Building Systems (NEBS) testing laboratories. On October 1, 2003, SBC issued SBC-TP-76200 *Network Equipment Power, Grounding, Environmental, and Physical Design Requirements* , Issue 5 replacing Issue 4 (May 2003). Section 1.12 of Issue 5 states:

> Starting January 1 st , 2004, SBC will only accept test reports submitted by testing laboratories that are accredited by an accreditation agency (e.g., the American Association for Laboratory Accreditation, National Voluntary Laboratory Accreditation Program) that is, in turn, recognized by the National Cooperation for Laboratory Accreditation. The scope of accreditation must include the test standards referenced in test reports. Where specific tests are not covered by a Laboratory's accreditation, a plan and timetable for obtaining the necessary accreditations must be in place and submitted to SBC for approval prior to January 1st, 2004. Test laboratories located outside of the United States shall be accredited in accordance with ISO/IEC Guide 25 or ISO/IEC 17025. This accreditation must be performed by a nationally recognized accrediting body operating in accordance with ISO/IEC Guide 58. Reports submitted to SBC shall contain accreditation and scope information or a letter of accreditation may be forwarded for our files.

Copies of SBC-TP-76200 Issue 5 and general information about SBC's environmental equipment standards may be found at https://ebiznet.sbc.com/sbcnebs/ .

A2LA can accredit testing laboratories for the full scope of NEBS testing, including BELLCORE GR-63 and GR-1089 as well as other domestic and international NEBS related test methods. Interested applicants in the area of NEBS testing may contact Bethany Hackett at 301 644 3227 or by email at bhackett@a2la.org.

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Owens-Illinois Plastic Group Receives Coca-Cola Acceptance

Owens Illinois Plastic Group Closure Laboratory (1151.02) has successfully completed the Coca-Cola Laboratory Acceptance Program. This program allows suppliers to Coke to provide internal testing data and saves time by bypassing third party evaluation.

Coca-Cola accepted the lab's accreditation to ISO/IEC 17025 as fulfilling the requirements for an internal self assessment and an external audit by Coke saving time and money on the first two steps of acceptance. Owens-Illinois is the second lab to be certified under the new program.

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Spring 2004 Training Schedule

Title: Introduction to Measurement Uncertainty

($895.00/Non-Members), ($845.00/Members)

- February 02-04, 2004 – Phoenix, AZ
- April 05-07, 2004 – New Orleans, LA
- June 07-09, 2004 – Indianapolis, IN

Title: Measurement Uncertainty Workshop

($395.00/Non-Members), ($345.00/Members)

- February 05, 2004 – Phoenix, AZ
- April 08, 2004 – New Orleans, LA
- June 10, 2004 – Indianapolis, IN

Title: ISO/IEC 17025 and Accreditation

($795.00/Non-Members), ($745.00/Members)

- February 05-06, 2004 – Phoenix, AZ
- April 08-09, 2004 – New Orleans, LA
- June 10-11, 2004 – Indianapolis, IN

Title: Assessment of Laboratory Competence

($1,495.00/Non-Members), ($1,445.00/Members)

- May 03-07, 2004 – San Francisco, CA

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

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Inspection Body Workshop Held in Beijing

Steve Medellin of A2LA participated in the APLAC inspection body workshop held in Beijing, China on November 18-20, 2003. The purpose of this workshop was to train and harmonize accrediting bodies (AB) that accredit inspection bodies (IB) to the requirements of ISO/IEC 17020 - *General Criteria for the Operation of Various Types of Bodies Performing Inspection* . The three-day training course focused on many aspects of operating an inspection body accreditation program, including the requirements for the IBs and those for the ABs who administer the accreditation program. Topics such as establishing a program and joining a mutual recognition arrangement (MRA) were also discussed.

A2LA is currently developing an inspection body accreditation program, which is expected to be operational in early 2004. If you have any questions regarding the program, please contact Steve Medellin at 301 644 3228 or by email at smedellin@A2LA.org.

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Verifying Traceability Through Non-Accredited Calibration Sources

The A2LA Policy on Measurement Traceability (*Traceabilty Policy*) requires that A2LA-accredited testing and calibration laboratories have their relevant testing or calibration equipment calibrated by either a National Metrology Institute (NMI) within the BIPM - CIPM system, or a calibration laboratory that has been accredited by A2LA or one of our mutual recognition agreement (MRA) partners. This is A2LA's process for verifying traceability of measurements to the SI and is in accordance with international practice.

Conformance with this requirement for traceability is straightforward when calibration certificates from the NMI or from an accredited calibration laboratory carrying the requisite accreditation body logo are provided. When this documentation is not available, however, the situation becomes more clouded.

Occasionally, laboratories request an exception to the *A2LA Traceability Policy* so that they can continue using a calibration vendor that is not appropriately accredited. In these cases, however, the laboratory must still supply evidence that the measurements being made by an unaccredited calibration vendor are truly traceable to the SI. For example, frequently the calibration vendor has had its own reference standards calibrated by another unaccredited calibration laboratory and so the traceability to the SI may not be verified at that point in the traceability chain. In cases such as this, further investigation is needed on the part of the laboratory using that particular unaccredited vendor (including OEMs).

Whenever an exception to the *A2LA Traceability Policy* is requested, the laboratory submitting the request must include (as part of the supporting documentation) evidence of verification of traceability to the SI for each link in the chain for that particular measurement. Granted, this will require time and effort to achieve, but it is essential that this traceability be proven and documented when it cannot be achieved through the use of an NMI or accredited calibration laboratory. A2LA assessors visiting your laboratories will be discussing this important aspect for you to consider when requesting an exception to the Traceability Policy.

If you have any questions about this process, please contact your appropriate A2LA Laboratory Services Officer.

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Reference to ISO 9001/2:1994 On A2LA Certificates of Accreditation

With the transition to ISO 9001/2:2000 complete as of December 15, 2003, the wording of A2LA's current Certificates of Accreditation will be amended. Reference to concurrent conformance with

equivalent requirements within ISO 9001/2:1994 will be removed. A2LA Certificates of Accreditation will now only reference compliance with ISO/IEC 17025:1999.

A further discussion on this subject and the impact it may have on accredited laboratories may be found in the December 2003 Newsletter Article: "ISO/IEC 17025: The ISO 9001 Question".

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New and Updated Documents:

A2LA has issued newly revised *Environmental Program Requirements (EPR)* that are based on the 2001 Edition of the National Environmental Laboratory Accreditation Council (NELAC) standards. The associated assessor checklist is available electronically on the A2LA web site. Assessments in the environmental field conducted as of May 1, 2004, must be conducted against these new requirements. Prior to May 1, 2004, assessment to the new requirements is optional. Environmental laboratories seeking accreditation through the Wyoming Leaking Aboveground and Underground Storage Tank and Kentucky Underground Storage Tank Accreditation Programs are not subject to this policy.

In addition to the "main" assessor checklist that covers the requirements found in the EPR, five specialized checklists cover the technical disciplines found in Appendix D including: chemical, air, microbiological, radiochemical and toxicity testing. Laboratories are required to complete the checklist relevant to the Scope of Accreditation they are seeking.

Two new "mandatory guidance" documents have been finalized for Calibration Scopes of Accreditation, *Mandatory Guidance on Editorial Principles for Calibration Scopes of Accreditation*and *Mandatory Guidance for Calibration Scopes of Accreditation for Hardness Measurements*. Calibration Scopes of Accreditation must follow these guidelines unless there are compelling reasons not to. All Calibration Scopes will be reviewed against these guidelines as on-site assessments occur.

On October 1, 2003, A2LA finalized a revision to the *Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories*. Hard copies of this document are also available from A2LA. Important changes were made to this document to facilitate monitoring of the requirement that all accredited laboratories participate in proficiency testing such that their entire Scope is covered over a four-year period. All laboratories are encouraged to familiarize themselves with the revised document, as it will be implemented in full as of January 1, 2004.

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ISO/IEC 17025: The ISO 9001 Question

(Reprinted with permission from UKAS Update 31, Autumn Edition 2003, written by Roger Brockway, UKAS External Affairs Director)

The current version of ISO/IEC 17025:1999 – the standard for laboratories on which accreditation is based – relates to ISO 9001/2:1994 in its quality system or management requirements (section 4).

This was done for two reasons: first, it seemed sensible, where a quality system was to be specified, to make use of ISO's standard for quality systems, ISO 9001/2; second, so that laboratories in conformity with ISO/IEC 17025 could demonstrate, if required, that their quality system also operates in accordance with ISO 9001/2, the standard better known to specifiers (clause 1.6).

In practice this approach has not stood the test of time well. ISO/IEC, on publishing ISO/IEC 17025:1999, insisted that it be reviewed when ISO 9001/2:1994 were updated, which was known to be going to happen with the publication of ISO 9001:2000. This has caused ISO/IEC 17025 to go into

revision before the laboratory community has settled down to get used to it.

More significantly, the 1999 formula has blurred expectations about the status of ISO/IEC 17025. Because of the linkage with the 1994 versions of ISO 9000, the standard makes the claim that laboratories conforming to its requirements also meet the equivalent requirements of ISO 9001/2. This has led laboratories to make this claim in response to specifier demand. Naturally, laboratories want to maintain this facility. In practice, the current draft revision of ISO/IEC 17025 does not fully incorporate all the requirements of ISO 9001:2000, and would not do so without major revision, so the provision in the 1999 standard allowing for claims of conformity with ISO 9001/2 cannot be maintained.

According to many, the mistake was to build so much on the alignment with ISO 9001/2 in the 1999 standard. It has allowed laboratories, asked whether they conform to ISO 9001/2, to claim that they do. A more honest approach may have been for laboratories conforming to ISO/IEC 17025, and accredited accordingly, to tell specifiers requiring ISO 9001/2 that ISO/IEC 17025 is the specific standard for them, and includes appropriate quality system requirements specifically designed for laboratories. Laboratories responding to questionnaires that ask about conformity with ISO 9001 do not in practice lose out if they cross out "ISO 9001" and clarify that ISO 17025 is the quality system standard for them. Educated specifiers respect this, and uneducated ones tend to be impressed rather than otherwise.

It is perhaps a pity that the standards system ever led us into pretending that conformity with the proper standard for laboratories could be passed off as conformity with the more fashionable, but, for laboratories, less relevant ISO 9001. Perhaps the time is right for a bolder assertion of the virtues for laboratories of ISO/IEC 17025 and accreditation over the more generic ISO 9001 in terms of the quality system as well as of the more obvious deeper requirements for technical aspects.

In the longer term, we need to give thought to which way ISO/IEC 17025 ought to develop. Should it in its next revision fully incorporate ISO 9001, possibly by simple cross-reference, thereby making use of ISO's quality management system standard rather than reinventing the wheel, and enabling claims of conformity with both standards to be made by accredited laboratories, or is there reason for it to maintain its own specialized quality management system requirements and for there to be no linkage to ISO 9001? The first route is being tried out in the development of ISO/IEC 17021, the draft new standard for management system certification bodies, while draft ISO/IEC 17011, the proposed new standard for accreditation bodies has taken the "self-contained" management system approach.

The final solution for each standard will be for decision by ISO and IEC, not by the accreditation or laboratory community alone.

(A2LA is active in representing the United States in this international standardization work. We welcome feedback from any interested parties. Please send any comments to the newsletter editors, Teresa Barnett at tbarnett@a2la.org *or Tim Rasinski at* trasinski@a2la.org*.)*

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TUR & Decision Rules

The International Laboratory Accreditation Cooperation (ILAC) has prepared a guide, ILAC-G8: 1996 *Guidelines on Assessment and Reporting of Compliance with Specification*, to assist laboratories on the method for stating test results and assessment of compliance with specifications for testing and calibration laboratories. A2LA accredited and applicant laboratories are encouraged to obtain this guide and apply its principles when making statements of compliance with a specification.

The process one follows given a measurement result and a specification to arrive at a determination of compliance or noncompliance with a specification is called a "decision rule." ILAC-G8 explains several decision rules which we need not restate in detail here. Instead we will provide an overview of the most common rules and situations.

One of the most common decision rules involves ensuring that the measurement uncertainty is relatively

small compared to the specification. For example, when a specification describes an interval with an upper and lower limit and if the ratio of the uncertainty of measurement to the specified interval is reasonably small (e.g., 1:3 or 1:4), then a statement of compliance can be made if the measurement result falls within the specification limits and a statement of noncompliance can be made if it falls outside of the specification limit. If the measurement result falls on one of the specification limits, then neither compliance nor noncompliance can be stated.

The simplest decision rule is "if the measurement result lies within the specification limits, then the product meets the specification, otherwise it fails to meet the specification." Although this rule explicitly ignores measurement uncertainty, seemingly in contradiction of ISO/IEC 17025 requirements (sections 5.10.3.1 and 5.10.4.2), it is allowed per ILAC-G8:

> *More often, the specification requires a compliance statement in the certificate or report but makes no reference to taking into account the effect of uncertainty on the assessment of compliance. In such cases it may be appropriate for the user to make a judgment of compliance, based on whether the test result is within the specified limits* ***with no account taken of the uncertainty*** *. This is often referred to as* ***shared risk*** *since the end-user takes some of the risk that the product may not meet the specification after being tested with an agreed measurement method. In this case there is an implicit assumption that the uncertainty of the agreed measurement method is acceptable and it is important that it can be evaluated when necessary. National regulations can overrule the* ***shared risk*** *principle and can put the uncertainty risk on one party.*
>
> *An agreement between the client and the laboratory or a code of practice or specification may state that uncertainty can be ignored when judging compliance. Similar considerations as for* ***shared risk*** *(above) apply in such circumstances.*

Accreditation bodies cannot dictate to accredited laboratories which decision rules must be used in a specific situation since the basis for making statements of compliance is ultimately a matter to be decided upon by the laboratory and customer. For that reason, it is vitally important that the laboratory understand the needs of the customer and that the customer clearly state to the laboratory how compliance decisions should be made.

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Document Control

Section 4.3.1 of ISO/IEC 17025 requires a document control policy for all documents that form part of the quality system. These documents include "regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals." The note to section 4.3.1 goes on to say that the following may also be considered: "policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc" in various mediums including hard copies and electronic. Considering the wide array of documents that must be included in the document control system, it is easy to see that something may get overlooked and become a cause for citing a non-conformance.

Not every document in a laboratory, in whatever form, falls under section 4.3. A2LA's position is that any type of document as listed above must be covered if the document contains information or instructions on any type of lab equipment or operation. For example, a log (the form itself) for daily entries of the date, time, and temperature of the laboratory environment is not considered to fall under section 4.3. There should be an SOP on how and when to record the temperatures, and that SOP is the controlled document. Changes to the format of the log are not critical, and anyone following the SOP knows which three pieces of information must be recorded. However, a log that contains instructions on how, when, or where the temperature measurements are taken is a controlled document. Changes to the document may have a crucial effect on the operation of the lab and need to be reviewed and approved.

Simple electronic spreadsheets or databases acting only as a place to record data are similar to the uncontrolled log mentioned above. However, if the spreadsheet or database is used to perform data analysis, it needs to become a controlled document. That is, the specific spreadsheet with the functions in place becomes the controlled document, not the spreadsheet program itself. As a parallel, consider word processing software. The SOP's generated using the program are the controlled documents, not the word-processing program itself. Furthermore, computer software must meet the requirements of section 5.4.7.2.

Does your laboratory have "cheat sheets" hanging on walls or bulletin boards near equipment? Perhaps these contain common values or simplified procedures for using the equipment. Have these been through the review and approval process to ensure the information is accurate? You can see the potential is there for serious problems if not. Therefore, this type of document must be considered a controlled document subject to review and authorization.

One final note on document control, section 4.3.2.3 lists several identification features that must be included on internally generated quality system documents. These items are not required on externally generated documents. A laboratory has no control on the document identification features included on operating manuals, testing methods, etc., received from third parties and is not expected to make any notations on the documents to meet section 4.3.2.3.

Document control is not very exciting and does not produce income. However, properly implemented document control saves time and money by preventing costly mistakes. Time spent on document control means less time spent on corrective actions.

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Including the UUT in Best Uncertainty Estimates

"Best uncertainty" is defined as the smallest uncertainty of measurement that a laboratory can achieve within its Scope of Accreditation when performing more or less routine calibrations of nearly ideal measurement equipment.

"More or less routine calibrations" means the laboratory shall be able to achieve the stated uncertainty in the normal work that it performs under its accreditation. Obviously, there are instances where the laboratory would be able to do better as a result of extensive investigations and additional precautions, but these cases are not covered by the definition of best uncertainty unless it is the outspoken policy of the laboratory to perform such rigorous investigation (in which case these become the "more or less routine" type calibrations of the laboratory).

Inclusion of the qualifier "nearly ideal" in the definition means that best uncertainty should not be dependent on the characteristics of the device to be calibrated. Inherent in the concept of being nearly ideal is that there should be no significant contribution to the uncertainty of measurement attributable to physical effects that can be ascribed to imperfections of the device being calibrated. However **, it should be understood that such a device should be available** . If it is established that, in a particular case, even the most ideal available device contributes to the uncertainty of measurement, this contribution shall be included in the determination of the best uncertainty, and a statement should be made that the best uncertainty refers to calibration of that type of device.

Best uncertainty is, therefore, not a theoretical estimate of the smallest uncertainty a laboratory could possibly achieve. It is based on the behavior of real (albeit "nearly ideal") devices under test and should be supported by experimental evidence. For example, in interlaboratory comparisons calibration laboratories are usually asked to perform the calibration under the conditions necessary to achieve their best uncertainty. This cannot be done if the best uncertainty estimate is based on a hypothetically perfect UUT (e.g., with infinite resolution or zero repeatability).

It is worth emphasizing that the best uncertainty relates to the laboratory's normal measurement process and that the laboratory must be able to achieve its claimed best uncertainty in the normal

course of its work. Again, best uncertainty is not the very smallest uncertainty that can be achieved under extraordinary circumstances when calibrating a hypothetical, perfect device. When best uncertainty is estimated based on the laboratory's normal processes and conditions and real UUTs, potential customers then have a valid basis for comparing calibration laboratories based on their best uncertainties.

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What Should be in a Proficiency Testing (PT) Plan?

While the requirement regarding a documented plan for monitoring the quality of tests and/or calibrations is found in ISO/IEC 17025, Section 5.9, A2LA has further specified the content of the laboratory's documented plan to ensure an applicable proficiency testing program covering the laboratory's entire Scope of Accreditation. In the A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories document released on October 1, 2003, it is stated that the plan shall outline those proficiency testing activities that a laboratory undertakes to address the major sub-disciplines and materials/matrices/product types on its Scope within a four-year time frame.

So what exactly constitutes a plan? A plan should include an outline of the tests or calibrations that are included in a laboratory's Scope of Accreditation. In some specific areas, major sub-disciplines and materials/matrices/product types have been identified to eliminate redundant testing activities. For example, in the mechanical testing field, these areas have been defined in the *A2LA Proficiency Testing Requirements* document. A2LA is currently working within the calibration area to define the major sub-disciplines to reduce the redundancy of proficiency testing activities in this field. This additional information is expected by January 1, 2004. Laboratories should reference the appropriate sections of the *Proficiency Testing Requirements* for specific information pertaining to the laboratory's field of accreditation.

Now that the areas that the laboratory needs to participate in have been defined, the plan needs to further document what type of proficiency test the laboratory will participate in for each area and, of course, when the participation is expected to occur. A2LA encourages the use of commercial proficiency testing programs and requires the use of these programs in some fields when the parameters of the commercial program match the lab's normal testing parameters. A list of proficiency testing providers is available on the A2LA website. The participation shall ensure that the laboratory will perform a minimum of two proficiency tests per year as well as ensure that all testing or calibration activities are covered in the four-year time frame.

Another area that needs to be addressed in the plan is the process for submitting the proficiency testing activity information to A2LA. Currently, this information is requested quarterly.

In conclusion, a laboratory's proficiency testing plan should detail the areas in which the laboratory will conduct proficiency testing, the means of conducting the testing, when it will occur, and how the results will be distributed to A2LA.

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