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A2LA News: The Newsletter of the American Association for Laboratory Accreditation __ *April 2006, Number 92*

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Linda Crumpler, RJR, Mitzi Miller, assessor, and Tonya Young, RJR, talk at the A2LA Conclave.

A2LA News April 2006

Chairman's Message

I, Trevor Boyce, have two strengths that I bring to the business table, 1) financial management and 2) an understanding of what an organization must do to have a "long term viability heartbeat." These are the skill sets and perhaps a few lesser ones that I have used to help grow my own business, Microbac Laboratories, Inc., into a nationwide group of highly diversified testing laboratories.

When I came onto the A2LA Board six years ago, my thought was that I was going to have to hold people's hands regarding financial management as few of the other organizations whose boards I have sat on have been any good in this area. However, much to my delight, A2LA was far more in tune with good financial control than had been expected. The reasons for this are several.

First, sometime before I arrived on the scene the A2LA Board wisely set a directive that A2LA's bottom line financials should show at least a 3% surplus. This excellent decision instantly required a culture within the A2LA operations that paid attention to costs as well as sales. This may seem elementary to many readers but it has always amazed me in my business travels just how few organizations actually practice this. Fortunately, the A2LA Board set the foundation for a proper business-like culture with this requirement.

Second, A2LA is blessed and has been for the six years that I have served with the best treasurer I have ever been associated with, Frank Banda of the Reznick Group in Bethesda, Maryland. Frank's job, which he does better than anyone, has been to keep A2LA's financial feet on the ground. Matters of investment

management, money (cash) management, cost versus sales maintenance and all other items related to A2LA's ultimate audited financial statements fall under Frank's domain. A2LA and all associated owe Frank a debt of gratitude for the outstanding job that he does.

Third, is the most senior staff Pete Unger and Roxanne Robinson who, for the leaders of a non-profit organization are surprisingly in tune with financial management. I do not know if this evolved from the 3% board directive or this focus existed prior, but what is pleasing to me is how much they talk about such issues on a regular basis. This is very good.

Finally, the unsung hero in all this is Lisa Drake, who is the staff financial manager. I have found that Lisa accounts for every penny in both sales and costs and has a superb understanding of financial banking covenant type ratios and any other item related to A2LA's "house-in-order" well being related to dollars and cents. She is a credit to the organization.

So, as it stands, A2LA's financial house is in order. The organization has one of its hearts beating solidly and this assures us that A2LA will survive today so that our doors will be fully open tomorrow. What a great position.

In the next newsletter I will write about the second organizational heart, the "long-term-viability" heart. This is the heart that, if beating, assures A2LA of being alive and well over the long haul. Much work is being done in this area, and I look forward to reporting to you.

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First Inspection Body Accreditations Issued

The first two inspection bodies to apply for accreditation have been assessed, found to meet the stringent international requirements, and accredited by A2LA.

The requirements for an inspection body accreditation are stated in ISO/IEC 17020-1998 *General Criteria for the Operation of Various Types of Bodies Performing Inspections* as well as the [IAF/ILAC-A4:2004 Guidance on the Application of ISO/IEC 17020](#). These accreditations demonstrate technical competence for a defined scope and operation of a quality management system.

Congratulations go out to [Gaming Laboratories International, Inc \(GLI\)](#) in Lakewood, NJ and [Progressive Engineering, Inc \(PEI\)](#) in Goshen, IN.

GLI is the world's first private gaming device and systems testing laboratory and inspection body and offers services in inspecting, testing, auditing and consulting for the world wide gaming industry.

PEI serves customers from all parts of the United States and in all phases of the construction industry.

The company works with local contractors and nationally known product suppliers and modular housing and recreational vehicle manufacturers.

For more information about A2LA's inspection body accreditation program, please contact Steve Medellin, A2LA program manager, at 301 644 3228 or smedellin@a2la.org.

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Results of the Board of Directors Election

The results of the 2006 election by the membership of the A2LA Board of Directors have been tabulated. Each of the newly elected members and officers will serve a three-year term. The results are:

- Chairman – J. Trevor Boyce: Mr. Boyce has been president and CEO of Microbac Laboratories, Inc. since 1993. He holds a B.A. in humanities with science from Hampden Sydney College and a master's degree in sports medicine from Old Dominion University.
- First Vice Chairman – James Galipeau: Mr. Galipeau is with Plastics Technologies Laboratory, Inc. He has an extensive background in plastics and graduated from the University of Massachusetts.

Mr. Galipeau was originally elected to the position of second vice chair and is filling the position vacated by the passing of William Harral.

- Secretary – Nancy Foncannon: Ms. Foncannon is self-employed as the owner of Quality System Consulting, Inc. She is an A2LA assessor in the mechanical testing area and member of the Accreditation Council. She has a bachelor's degree from Michigan State University in mechanical engineering and a master's degree from Western Michigan University in engineering management.
- Director – George Brammer: Mr. Brammer is currently president of Brammer Standard Company, Inc., a producer of chemical and spectrochemical analytical reference materials. He graduated from Marshall University with a B.S. in chemistry.
- Director – Edward Colbert: Mr. Colbert is a senior scientist with Bayer Material Science, LLC. His experience is in the mechanical testing of polymers, and he is a member of the A2LA Accreditation Council. He holds a B.S. in chemistry from the University of Pittsburgh.
- Director – Arlene Fox: Ms. Fox is the senior director of proficiency testing for AOAC. She is a member of the A2LA Criteria Council and a NACLA evaluator. Her B.S. is in physiology from the University of Chicago.
- Director – Dilip Shah: Mr. Shah is a principal of E=mc³ Solutions, a consulting practice offering training and consulting on quality system issues. He is an active member of the American Society for Quality (ASQ), contributing to the ASQ *Metrology Handbook* and the Statistics and Measurement Quality Division. Mr. Shah has a bachelor's degree in electronics and instrument science and is pursuing a master's degree in applied statistics.

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New Assessors Contracted by A2LA

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

- Jim Allred – calibration
- [Nathan Belsher](#) – electromagnetic compatibility
- [Doug Berg](#) – automotive testing
- [Teresa Carter](#) – materials testing
- Thomas Dickten – telecommunications and electromagnetic compatibility
- [Tom Daggart](#) – materials testing
- [Dorothy Gill](#) – life science
- [J. Brent Snoddy](#) – calibration
- David Waitt – telecommunications and electromagnetic compatibility

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

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A2LA Welcomes New Staff

A2LA has hired three new laboratory service officers.

[Samantha Dizor](#) is working in the calibration program. She is a recent graduate of the University of Jacksonville with a B.S. in physics with minors in mathematics and computer science.

[Adam Gouker](#) is working with mechanical and fastener testing labs in the materials testing program. Adam has a degree in mechanical engineering from the University of Pittsburgh, Johnstown.

[Dana Miller](#) works with automotive labs in the mechanical and chemical fields. She graduated from Kutztown University with a B.S. in sociology and a minor in criminal justice.

We welcome all three to the A2LA family.

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Environmental Chamber Uncertainty Guide Available

The Society of Environmental Engineers in the United Kingdom has published [A Guide to Calculating the Uncertainty of the Performance of Environmental Chambers](#). This document can be downloaded from the web site www.environmental.org.uk. Simply select 'downloads' and locate the document in the list of 'Most Popular - Top 10' downloads.

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New & Updated Documents

- The [Automotive EMC Laboratory Accreditation Program Requirements](#) have been updated to a February 2, 2006, version. It has been revised to reference the fourth revision (01/27/2006) of the AEMCLRP program requirements and is effective immediately.
- The *Assessor Checklist: General Criteria (ISO/IEC 17025 - Full Text Incorporated with A2LA'S Environmental Program Requirements)* containing the full text of ISO/IEC 17025 and the A2LA environmental program requirements has been updated to a January 25, 2006, version and is available by request only. This version will be implemented for laboratories with a September 30, 2006, anniversary date or later. Laboratories wishing to upgrade to this version sooner may do so upon request. For more information or to request a copy of the checklist, please contact Atefeh Fathi at 301 644 3210 or afathi@a2la.org.
- The five environmental program appendix checklists (for [chemistry](#), [radiochemistry](#), [microbiology](#), [toxicity](#), and [air](#)) have been updated to January 25, 2006, versions. They will also be implemented for laboratories with a September 30, 2006, anniversary date or later. Laboratories wishing to upgrade to this version sooner may do so upon request. Please contact Atefeh Fathi for more information at 301 644 3210 or afathi@a2la.org.
- The [A2LA Wyoming Storage Tank Remediation \(STR\) Laboratory Accreditation Program Requirements](#) have been updated to a February 28, 2006 version. They are available on our website and will be implemented for laboratories with a September 30, 2006, anniversary date or later. Laboratories wishing to upgrade to this version sooner may do so upon request. The associated [environmental Wyoming STR scope template](#) document has been updated to a February 28, 2006, version. It should be used by laboratories within this program to develop their proposed draft Scope of Accreditation. Please contact Atefeh Fathi for more information at 301 644 3210 or afathi@a2la.org.
- The [Accreditation Program for Reference Materials Producers Application Form](#) and the [A2LA Program for the Accreditation of Reference Materials Producers Procedures Manual](#) have been updated to a March 2, 2006, version. They are available on our website and will be implemented immediately. The associated *Reference Material (RM) Producer Accreditation Requirements - Assessor Checklist* has also been updated to a March 2, 2006, version but is available upon request only. Please contact Randy Querry for more information at 301 644 3221 or rquerry@a2la.org.
- The *Assessor Checklist: General Criteria for Accreditation of Inspection Bodies (ISO/IEC 17020 and IAF/ILAC A4 - Full Text)* has been updated to a March 2, 2006, version to incorporate IAF/ILAC A4. It will be used for all inspection body assessments as of this date, and it is available upon request only. Please contact Steve Medellin for more information at 301 644 3228 or smedellin@a2la.org.
- Section 2 ("[Printed Application](#)") of the inspection body application forms has been updated to a March 2, 2006, version. It will be used for all future inspection body applicants.

- The [General Requirements for Accreditation Of Product Certification Bodies](#) have been updated to a February 13, 2006, version, primarily to address special circumstances for TCB applicants. It is available on our website and will be implemented immediately.
- A new [A2LA Texas Department of Health Indoor Air Quality Laboratory Accreditation Program \(TXDOH IAQ\) Requirements](#) document has been established, dated March 6, 2006. If you have any questions or are interested in pursuing accreditation to these requirements, please contact Randy Query at 301 644 3221 or rquery@a2la.org.
- The [A2LA Program for the Accreditation of Proficiency Testing Providers – Procedures Manual](#) has been updated to a March 22, 2006, version. The changes are effective immediately as they simply bring the document in line with the procedural requirements for other A2LA programs.
- The [A2LA Environmental Program Requirements](#) have been updated to a March 22, 2006, version. The change is effective immediately, as it simply removed the text of the NELAC criteria and instead references where the current criteria may be obtained directly from the EPA.
- A new [ISO Guide 34:2000 Confirmation – Fax Form](#) has been developed, dated March 24, 2006. The form is to be completed by any reference material producer (RMP) interested in obtaining a checklist of the full text of ISO Guide 34. The form is simply a written confirmation from the RMP that it owns an official copy of the standard itself.
- The [Annex to the A2LA Policy on Measurement Uncertainty For Life Sciences Testing Laboratories](#) has been updated to an April 1, 2006, version.
- The [ISO/IEC 17025 Confirmation – Fax Form](#) has been updated to an April 7, 2006, version to include all checklists that combine 17025 with other specific program requirements.

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Fall 2006 Training Schedule

Title: [Introduction to Measurement Uncertainty](#)

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

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

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

Title: [Assessment of Laboratory Competence](#)

- TBD

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

- TBD

Locations and dates for all classes will be posted at the [training course schedule page](#) of the A2LA website as soon as the information becomes available. An updated schedule will also appear in the July newsletter. For additional information, please contact Julie Stevens, A2LA training coordinator, at 301 644 3235 or jstevens@a2la.org.

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A2LA Holds 2006 Conclave

A2LA held its annual Conclave from March 7 through 13, 2006, 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 (including 3 new A2LA staff members), 16 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 10. A special meeting of FCC EMC assessors was held and a training session was offered for inspection body assessors to support our newly announced inspection body accreditation program.

Meetings on Saturday started early with the individual technical advisory 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 Policy on Measurement Traceability](#).

Saturday's meetings concluded with the Assessor Committee meeting, hosted by [Committee Chair Ray Schiltz](#). Ideas for improvement and clarification from the assessors were discussed and A2LA staff accepted several action items to streamline and elaborate on the current practices of our assessors. Time was also reserved for discussion of several issues and updated policies from within our Financial Services and Laboratory Services departments.

The annual A2LA banquet was held on Saturday evening. [A2LA Vice-President Roxanne Robinson](#) presented assessors with 5, 10, 15, and 20-year service awards. [Gene Zerlaut](#) received the annual Assessor's Choice Award as recognition of his skills as an A2LA assessor. Also, A2LA's first president, [John Locke](#), received the first John W. Locke Award to honor his commitment of time and services to A2LA towards the advancement of laboratory accreditation (nationally and internationally) and to recognize his extensive expertise, innovative ideas, demonstrated leadership, achievement of a high degree of respect from his peers, and attainment of an impeccable reputation for statesmanship, diplomacy and fairness.

This award will be given in future years to those individuals who meet these same criteria as agreed to by the A2LA Board of Directors.

Sunday morning began with meetings of the A2LA Criteria Council and Accreditation Council to discuss their activities over the past year and those planned for the future.

The remainder of Sunday was devoted to 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 official applications of them, particularly the amendments of ISO/IEC 17025:2005. Two staff presentations were given during the Plenary Session, including [Daren Valentine's](#) presentation on the procedure for allowing deficiencies to be closed on site during the course of an organization's assessment, and Roxanne Robinson's presentation on the newly organized and updated *Assessor Instruction Manual*.

The Conclave concluded on Monday with the Annual Meeting of the Membership. Newly elected chairman of the A2LA Board of Directors, Trevor Boyce, offered opening comments and a presentation on his vision for A2LA in the coming years. Dr. William G. Kavanagh was honored for his many years and levels of service to A2LA, particularly as outgoing chairman of the A2LA Board of Directors. Peter Unger presented the president's report, and the chairmen of the Criteria Council and Accreditation Council presented reports on the weekend's activities as well as general Association activities. The Board of Directors meeting immediately followed and was the concluding event of the Conclave.

The 2007 Conclave is scheduled to be held from March 20 to 26 at the Columbia Sheraton. We hope to see you there.

Special thanks to Nancy Berg for supplying the Conclave photographs.

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IEEE 2006 EMC Workshop

On January 30 – 31, 2006, A2LA attended the [IEEE/SAE 2006 Automotive EMC Standards Workshop](#) at the University of Michigan at Dearborn. 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 with each presenter identifying the scope of the procedure, the critical aspects of the procedure, interpretations, any changes made, and the future outlook of the procedure. You may request a copy of the presentations by contacting IEEE Southeastern Michigan Chapter webmaster at scott@emcsociety.org.

The second day's activities consisted of a range of presentations. Among them, Phil Fanson, A2LA assessor, presented on his A2LA assessment experiences, followed by an overview presented by Brad Moore on the revisions identified in ISO/IEC 17025:2005.

The Automotive EMC Laboratory Recognition Program (AEMCLRP) Committee was given an opportunity to unveil the new [AEMCLRP revision 4 program requirements](#). Part of the presentation described how implementation was viewed from the OEM's perspective. Validation testing must be performed using AEMCLRP recognized test methods.

If you have any questions or concerns regarding the AEMCLAP program or any other aspect of the automotive EMC program, please contact Brad Moore, senior laboratory services officer, at 301 644 3226 or bmoore@a2la.org.

A2LA will again be exhibiting at the [2006 IEEE Symposium on Electromagnetic Compatibility](#) August 14-18, 2006, in Portland, Oregon. We look forward to seeing you there.

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Uncertainties Estimates of Microbiology Labs

by Marlene Moore (Advanced Systems, Inc.) – A2LA Assessor

The Life Sciences Advisory Committee is in the process of compiling and reviewing examples for estimating the uncertainty of microbiological testing. Microbiological uncertainty estimates are being implemented for methods that use counting for their measurements.

Qualitative microbiological methods (presence/absence results) do not require an estimate of uncertainty according to the policies of A2LA and other accreditation bodies. Some discussion has involved the possibility of a need to estimate the uncertainty at the measurement point for determination of presence or absence. (If you are interested in this type of discussion – please join the A2LA Life Sciences Advisory Committee.)

The following example for microbiology laboratories presents the use recommended in ISO standard 19036, *Microbiology of Food and Animal Feeding Stuffs – Guide on Estimation of Measurement Uncertainty for Quantitative Determinations*. The example is for methods that use counting for determination of the number of colonies in a test sample. This requires the use of lognormal transformations and is not calculated in the same manner as in chemical measurements where a normal distribution of the data is developed and applied.

A similar approach has been used and demonstrated for similar bacteriological techniques by the [Canadian Association for Environmental Analytical Laboratories](#) in *Measurement Uncertainty for Microbiology Testing*, rev 1.7, appendix 3, p. 19.

The example is not the only possible method for determining the estimate of uncertainty of counting methods.

This example illustrates the use of "reproducibility replicates" to estimate uncertainty for the same type of samples analyzed. This technique attempts to capture various sources of uncertainty that can affect routine customer samples by having "replicates" produced independently under as many different conditions as normally occur in the laboratory. This is different than the commonly used procedure where

replicates are produced for every dilution. Those replicates will capture only variability due to pipetting, counting, and organism growth. It does not capture dilution variability or individual analyst differences.

1. The sample is analyzed using all steps of the test method.
2. Samples are set up on 20 different days in duplicate, **analyzed by different analysts on different days, using different equipment (incubators, pipettors) on the different days and possibly using different batches of reagents on each day.**
3. Example of table of reported data for the sample results.

Raw Data (actual CFU recovered) – First Replicate Col 1	Data transformed Col 2	Raw Data (actual CFU recovered) – Second Replicate Col 3	Data transformed Col 4	Difference between replicates (transformed) Col 5	Difference between replicates squared Col 6
131	2.117	142	2.152	-0.035	0.001
69	1.839	90	1.954	-0.115	0.013
45	1.653	76	1.881	-0.228	0.052
40	1.602	55	1.740	-0.138	0.019
31	1.491	20	1.301	0.190	0.036
33	1.519	40	1.602	-0.084	0.007
31	1.491	62	1.792	-0.301	0.091
37	1.568	50	1.699	-0.131	0.017
186	2.270	167	2.223	0.047	0.002
218	2.338	258	2.412	-0.073	0.005
200	2.301	243	2.386	-0.085	0.007
39	1.591	54	1.732	-0.141	0.020
217	2.336	180	2.255	0.081	0.007
119	2.076	133	2.124	-0.048	0.002
28	1.447	46	1.663	-0.216	0.046
106	2.025	112	2.049	-0.024	0.001
107	2.029	89	1.949	0.080	0.006
45	1.653	62	1.792	-0.139	0.019
98	1.991	128	2.107	-0.116	0.013
240	2.380	220	2.342	0.038	0.001

4. Calculations defined in ISO19036 for estimating the uncertainty of measurement:

Step 1 – transform the raw data by taking the base 10 log of the data (column 2, 4);

Step 2 – calculate the difference between the transformed replicates (column 5);

Step 3 – square the differences between the transformed replicates (column 6);

Step 4 – add the differences together (column 6) and divide by 2n, where n = the total number of pairs of duplicates (for this example n = 20) to get 0.00919;

Step 5 – take the square root of the result in step 4; this equals the pooled repeatability standard deviation, which is 0.0956;

Step 6 – apply the coverage factor (k=2 for 95% confidence level) to the repeatability standard deviation to get the estimate of the uncertainty of 0.192 (note: this is the log value). The sample result is converted to the log and then the 0.192 is added and subtracted. These resulting values are the log of the sample measurement estimate of uncertainty;

Step 7 - convert the log value for the sample measurement to base units (cfu) for the laboratory for the reported result;

Step 8 – it is presumed that the sample used in this study is representative of the samples analyzed by the laboratory and therefore this estimate may be used to estimate the uncertainty for any sample. This is useful for food or feed production laboratories where the same types of samples are analyzed for products to determine conformance to product

specifications. Assuming a sample result of 100 CFU, the estimate of uncertainty is 64 to 156 CFU.

A significant portion of the information in this article was developed by Mr. Dan Tholen and Ms. Dawn Mettler, assessors for A2LA.

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Oven Calibrations to ASTM E145

Within the rubber industry, there are several test methods that specify the use of an oven meeting the requirements of ASTM E145, *Standard Specification for Gravity-Convection and Forced-Ventilation Ovens*. These rubber test methods include ASTM D395, *Compression Set*, ASTM D471, *Effect of Liquids*, and ASTM D573, *Deterioration in an Air Oven*. For temperatures through 70 °C, these methods state to use an oven conforming to the specification for a Type IIB oven given in ASTM E145. For higher temperatures, a Type IIA oven is required.

ASTM E145 specifies three criteria for oven calibrations: temperature uniformity, airflow (or rate of ventilation), and time constant. However, some calibration laboratories that are accredited for oven calibrations are only reporting temperature uniformity on their reports. The testing laboratories need to contact these calibration vendors to determine the actual parameters within ASTM E145 that the calibration lab has the capability to (and is accredited to) perform.

Per Section 4.6.3 of ISO/IEC 17025:2005, it is the lab's responsibility to indicate in its purchasing document to the calibration vendor that its oven be calibrated to ASTM E145. Also, once the calibration is completed, the lab must verify that the calibration certificate includes temperature uniformity, airflow, and time constant, per Section 4.6.2 of ISO/IEC 17025:2005.

On a final note, some may consider ASTM E145 to be too stringent for many of the rubber test methods that require an oven to meet this specification. However, this issue needs to be addressed with the ASTM Technical Committee for Rubber for possible method revision. A2LA instructs its assessors to assess to the requirements of the test methods as written, and as long as the method still specifies the use of an oven meeting the requirements of ASTM E145, the lab's oven must be calibrated accordingly.

Please contact Sara Weitzel, A2LA laboratory services officer, with any questions or comments at 301 644 3224 or sweitzel@a2la.org.

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ISO/IEC 17025 INTERNAL AUDIT AND MANAGEMENT REVIEW REQUIREMENTS

Internal audits and management reviews are two of the most critical management system functions performed by a laboratory. Although requirements for these activities have been in place within both iterations (1999 and 2005) of ISO/IEC 17025, as well as within their predecessor ISO/IEC Guide 25, questions and confusion often still arise regarding the difference between these two functions and what a laboratory must do in order to comply with the requirements in the standard.

Internal Audit

Section 4.14.1 (ISO/IEC 17025:2005) requires an internal audit to "verify that its (the laboratory's) operations continue to comply with the requirements of the **management system and this international standard** (ISO/IEC 17025). The internal audit programme shall address **all** elements of the management system, **including the testing and/or calibration activities** (emphasis added)." In these two sentences ISO/IEC 17025 defines three items that must be covered by a complete internal audit: compliance with ISO/IEC 17025; compliance with the laboratory's own quality system (defined in section 4.2.1 as its "policies, systems, programmes, procedures and instructions"); and competence in its testing and/or calibration methods as defined in its Scope of Accreditation.

Section 4.14.3 (ISO/IEC 17025:2005) requires, "The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded." As a record of the assessment to conformance to ISO/IEC 17025, our assessors use the *Assessor Checklist: General Criteria (ISO/IEC 17025)*. Many labs also use it as guidance and documentation of their own internal audits. However, it only covers one of the three items required for an internal audit. Our assessors also use the *Test Method Review Matrix* as a record of observations of test or calibration methods. In auditing the methods, it is important that individuals actually be observed performing the testing or calibration. Since our assessors only spend a few days in a lab, it may not always be practical for them to observe the entirety of a long-term or a rarely performed method, but this should not be a problem for an internal audit where time is less of a constraint. A2LA does not require the use of these documents by laboratories and any format that records the same basic information is acceptable.

While a review to ISO/IEC 17025 will audit the conformance of internally generated documents to the format and requirements of the standard, it does not verify that the lab actually follows its own procedures. This is the final item that must be covered by the internal audit. Since management systems are highly individualized, there is no standard form used by A2LA as a record of a review. One option is a checklist of SOPs with room for a date, sign off, and observations.

Finally, included with records and findings of the audit the lab should include records of corrective actions (as defined in section 4.11 of ISO/IEC 17025:2005) taken as a result of the internal audit.

Management Review

ISO/IEC 17025:2005 only requires that the findings, both positive and negative, of the management review and consequent actions be recorded. However, it is very specific in addressing the items that must be taken into account during a management review. Section 4.15.1 lists eleven specific items that the lab "shall" take into account. Section 4.2.2 of the standard adds a twelfth item. The question an A2LA assessor will then ask is, "How did you take account of these items?" We cannot dictate how this is answered, but one of the easiest ways is to have an agenda or minutes showing that each of the items was covered.

A2LA is well aware that many labs that are part of a production facility are also functioning under one of the ISO 9000 standards. With the focus on production it is easy for the lab's internal audit and management review to get swallowed up as part of the company-wide audit/review process. However, it is still required that all of the items above be addressed **as related to the laboratory**. This does not mean that the lab's internal audit and management review cannot be part of a larger, company-wide review, but all requirements of ISO/IEC 17025 must be addressed for the lab.

If you have any questions about these two important functions or the requirements of ISO/IEC 17025 related to them, please contact A2LA.

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Proficiency Testing and Uncertainty

I, Tim Rasinski, recently received the results of a proficiency testing program organized by the [National Association for Proficiency Testing](#) (NAPT) for the calibration of torque wrenches and observed some interesting data reported by the participants that warrants comment. Let me start by saying that I have never calibrated a torque wrench. I have watched the process performed a few times in my visits to labs and own a few beam and click types for working on my vehicles but have never had them calibrated. I hope I do not say anything outrageous and am grateful to Charles Ellis of NAPT and Jeff Gust of [Quametek](#) for spending some time answering my questions about torque wrenches and proficiency testing and for giving me permission to reference their proficiency testing programs. While I intend to focus on the results of torque wrench proficiency testing, the general concepts apply to most proficiency testing performed by calibration labs.

Calibration proficiency testing performance is most often evaluated by calculating E_n , the normalized error, which is more or less a ratio of the error to the uncertainty.

$$E_x = \frac{x - X}{\sqrt{U_{lab}^2 + U_{ref}^2}}$$

where x is the measured value and X is the reference value

If the absolute value of the error is greater than the combined (root sum square) uncertainty of the participating and reference labs, the ratio is greater than one and considered an outlier. The participating laboratory must report two values then, the measured value of the artifact and the uncertainty of the measuring (or calibration) process. Participation is an evaluation of a lab's ability to both perform a measurement and calculate uncertainty. It is the second part of this I would like to focus on since I know more about uncertainty than I do about calibrating torque wrenches.

As part of the NAPT program a reference click torque wrench is sent out to be calibrated. At 30 lbf·ft the reference uncertainty was 0.2535 lbf·ft and at 50 lbf·ft the reference uncertainty was 0.4192 lbf·ft.

Eighteen labs participated in the program and the range of uncertainties reported for the 30 lbf·ft calibration were from 0.037 to 2.05 lbf·ft. At 50 lbf·ft the range of uncertainties were from 0.0409 to 1.703 lbf·ft. In both ranges 10 labs reported uncertainties less than the reference uncertainty.

Range (lbf·ft)	Ref. Uncert. (lbf·ft)	Reported Uncertainty (lbf·ft) (least to greatest, not correlated to participants)					
30	0.2535	0.0379	0.077	0.1	0.1099	0.15	0.1512
		0.18	0.18	0.18	0.2502	0.2567	0.43
		0.4718	0.58	0.625	1.4584	1.484	2.05

Range (lbf·ft)	Ref. Uncert. (lbf·ft)	Reported Uncertainty (lbf·ft) (least to greatest, not correlated to participants)					
50	0.4192	0.0409	0.127	0.18	0.1953	0.25	0.252
		0.3	0.3	0.3	0.4187	0.4197	0.43
		0.58	0.625	0.8582	1.03	1.4616	1.703

The group comparison report issued by NAPT does not reference labs by name, only a code number that is not made public, so I do not know the identity of the reporting labs and am not singling any laboratory out. But the first question that comes to mind is, how can a laboratory calibrate a click torque wrench to an uncertainty of 0.0409 lbf·ft at 50 lbf·ft? This is 0.08 % of the reading. By comparison, Sturtevant Richmond, a manufacturer of torque wrenches with an A2LA accredited calibration lab, has a best uncertainty listed on its Scope of Accreditation of 0.5% of the reading. Four of the participants reported an uncertainty of less than 0.5% and 12 had less than 1% on the 50 lbf·ft artifact. Calibrations of torque to an uncertainty of less than 0.1% are not out of the question, but the effects of the unit under test (UUT) must be negligible. First, the resolution of the UUT would have to be less than 0.1 lbf·ft with no other significant contributing factors. For an uncertainty of 0.5 % the resolution would have to be less than 0.5 lbf·ft. If resolution were not an issue, the repeatability or type A component of the uncertainty would have to be about 0.02 lbf·ft, that is, the standard deviation of a number of repeated calibrations of a click torque wrench to 50 lbf·ft would be 0.02 lbf·ft. For an uncertainty of 0.5 %, the repeatability would be about 0.1 lbf·ft.

I am speculating that a number of the participants in this program did not account for the UUT in determining the uncertainty of the calibration. The uncertainty of the reference standards and calibration equipment used in a calibration is not the uncertainty of the calibration. The process of placing the UUT in the calibration fixture or connecting it to the calibration equipment, manipulating the UUT or equipment, and reading the indication on the UUT all contribute to the uncertainty of the calibration. Consider measuring a 1.000000 inch gage block with an uncertainty of 3 μ m with a wooden ruler incremented in eighths of an inch. The one-inch mark looks like it lines up with the edge of the gage block about as well as it can. Is the uncertainty of the calibration of the ruler 3 μ m?

Section 5.4.6.3 of ISO/IEC 17025:2005 states, "When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis." Note 1 says, "Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and conditions of the item being tested or calibrated, and the operator."

Secondly, as the reference uncertainty approaches and gets larger than the reported uncertainty, the uncertainty reported by the participant becomes less relevant. The smallest uncertainty reported for the

50 lbf-ft artifact is about one tenth of the reference uncertainty. The reported uncertainty might as well be zero. Going back to the denominator of the formula for E_n and putting in the values of 0.4192 for the reference uncertainty and 0.0409 for the lab's uncertainty, the value of the denominator becomes 0.4292. The uncertainty contributed by the laboratory increased the denominator by 2.3%. Assuming that the participating lab's uncertainty calculations are representative of the lab's capabilities, what knowledge is gained about the participant's uncertainty calculations? Essentially, the participating lab is being evaluated at the capability of the reference lab, not its own. Ten of the 18 participants are having the denominator at least doubled by the contributing uncertainty of the reference lab. Again, assuming the reported uncertainties are representative of the participating labs' abilities, what is learned by participating in this program? Realistically, I do not believe the reported uncertainties were accurate in all cases, and I am not advocating that the labs should not have participated in this program.

Laboratories should always make an effort to participate in proficiency testing programs where the uncertainty of the reference laboratory is much smaller, at least 3 to 1. This way the ability of the participant lab to produce an accurate measurement with a reasonable uncertainty can be evaluated with minimal influence from the artifact. A2LA understands there are limits on uncertainty capabilities of the reference laboratory. Technical, physical, and financial realities limit the uncertainty of the reference lab. To be fair to NAPT and the participants in this program, NAPT cannot provide a click torque wrench off the shelf with an uncertainty below a certain value and providing a custom artifact may be cost prohibitive. Some participants will have uncertainties close to 1 to 1. Labs functioning at uncertainty levels very close to the best realized by national labs have a difficult time finding proficiency testing programs, and when they do, they can be pricey.

Jeff Gust of Quametec stated at a recent A2LA Conclave that about 30% of results in his proficiency testing programs are outliers. Statistically the value should be about 5%. Does this mean labs are having difficulty performing calibrations or calculating uncertainties? Uncertainty is just as important in proficiency testing as the calibration. Laboratories should devote just as much effort to getting the uncertainties correct as they do in getting the measurements correct.

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New Applications of ISO/IEC 17025 Requirements

During the first quarter of 2006, the A2LA Criteria Council voted to approve two new applications of ISO/IEC 17025:2005 requirements. These and other explanations may be found on the A2LA website, [Understanding ISO/IEC 17025](#).

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Sections 4.6.1 and 4.6.4 (ISO/IEC 17025:1999) - Should I consider the commercial proficiency testing providers that my laboratory uses to be suppliers of critical services?

Yes. Commercial proficiency testing providers are considered suppliers of critical services and so the requirements of Sections 4.6.1 & 4.6.4 are applicable to the PT providers used by a laboratory. It is important to point out that Section 4.6 of the standard applies to purchased services and supplies. Therefore, a laboratory utilizing internal proficiency programs is not considered to be "purchasing" these services and so Section 4.6 is not applicable.

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Section 5.7 (ISO/IEC 17025:1999) - Does this section apply to my laboratory if we are simply testing a sample taken from a larger, client-supplied sample?

Yes. When a laboratory performs sub-sampling from a larger, client-supplied test item, Section 5.7 applies and the laboratory must have documented procedures for sub-sampling and/or homogenization to ensure that a representative test portion is used for analysis.

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If you have questions about these or any other applications of the ISO/IEC 17025 requirements, please contact A2LA.

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## Pre-Assessment Waivers to the A2LA Traceability Policy?

A2LA acknowledges that there still remain a number of parameters in the laboratory community that are not supported by accredited calibrations. In an effort to assist those laboratories that know they will be receiving a deficiency for such parameters against our [A2LA Policy on Measurement Traceability](#) during their upcoming renewal assessment, A2LA has implemented a means to request a waiver to the traceability policy prior to the assessment – thus eliminating the deficiency.

Beginning with the next batch of renewal assessment paperwork that will be generated this month (laboratories with October 31, 2006 anniversary dates), A2LA will be providing instructions and a form for requesting a waiver to the A2LA traceability policy along with the renewal paperwork submission. The process follows the same instructions that are spelled out in the [Instructions - Responding to the Assessor Deficiency Report](#) form that the assessor leaves with the laboratory staff during the exit briefing.

Laboratories will be instructed to provide the following information for each, individual case for which an exception is requested:

- Equipment name and model;
- Parameter and range of calibration needed;
- Key words used in any website search for an accredited calibration provider;
- List of all sources investigated (e.g., specific accreditation body websites, hardcopy directories, state metrology labs, etc.);
- Objective evidence that the measurement being provided by your present calibration vendor is traceable to the SI (a traceability study verifying the sources of calibration to include a certificate of calibration showing direct calibration by an NMI or by an accredited laboratory). A traceability statement found on the calibration certificate is not adequate objective evidence.

If the request for exception is granted, the lab will be notified by A2LA and the assessor(s) will be instructed not to cite a deficiency (even though traceability to the SI cannot be confirmed through calibration by an NMI or an accredited calibration laboratory) for this piece of equipment.

If the request for exception is incomplete or is not granted, the lab will be notified by A2LA, and the assessor will be instructed to cite a deficiency against the non-accredited calibration provider for that piece of equipment.

If you have any questions of if you require additional information, please contact your laboratory services officer at A2LA.

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