

Greenaway Speaks on Food Safety Modernization Act

On June 6, ACLASS Vice President Keith Greenaway spoke at the Food and Drug Administration (FDA) Food Safety Modernization Act Public Meeting: Focus on Inspections and Compliance. His prepared remarks follow:

The ANSI-ASQ National Accreditation Board is a non-profit, non-governmental organization that provides accreditation services to public- and private-sector organizations in the areas of management systems, laboratories, inspection, reference material producers, proficiency test providers, product certification, and personnel certification. We are jointly owned by the American National Standards Institute and the American Society for Quality.

We operate predominately in the realm of ISO international standards, which are developed, based on consensus, and then adopted globally, and subsequently adopted as American National Standards. Two organizations provide oversight and a recognition infrastructure for accreditation bodies operating inside this global infrastructure. The International Laboratory Accreditation Cooperation (ILAC) was



established to oversee laboratory and inspection body accreditation and the International Accreditation Forum (IAF) was established to oversee management systems and product and personnel certification. Recognized accreditation bodies then accredit conformity assessment bodies (that is, inspection bodies, laboratories, certification bodies, and product certifiers) to specific international standards who then audit and/or test for competence.

This generic third-party conformity assessment (see p. 2) model illustrates the conformity assessment activities that are offered competently and credibly by ILAC and IAF member bodies. We developed the model in conjunction with the National Institute of Justice and the National Institute of Standards and Technology to support a new private-public sector partnership for accredited third-party conformity assessment activities with oversight.

The FDA must embrace a model based on international consensus standards that has already proven to work across international borders and within multiple industries through the existing recognition infrastructure of ILAC and IAF. In today's political environment, uncertainty remains whether funding will even be available for the mandated inspectors under the Food Safety Modernization Act. Given this uncertainty, it is imperative that the FDA work together with the private sector under the existing international infrastructure and rely on accredited private sector conformity assessment bodies to work in coordination with appropriate government inspectors to help fulfill the mission of the FDA under the Food Safety Modernization Act. The food industry is already operating under a realm of uncertainty as they prepare for both private sector

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food safety certification programs and government inspections. This is unnecessary duplication, which increases costs to the consumer and wastes taxpayer money.

The infrastructure that's used globally and by many U.S. regulators will support the role of the FDA in protecting our nation's food supply under the Food Safety Modernization Act, and it will do so without adding unnecessary duplication for private industry and without wasting taxpayer dollars.

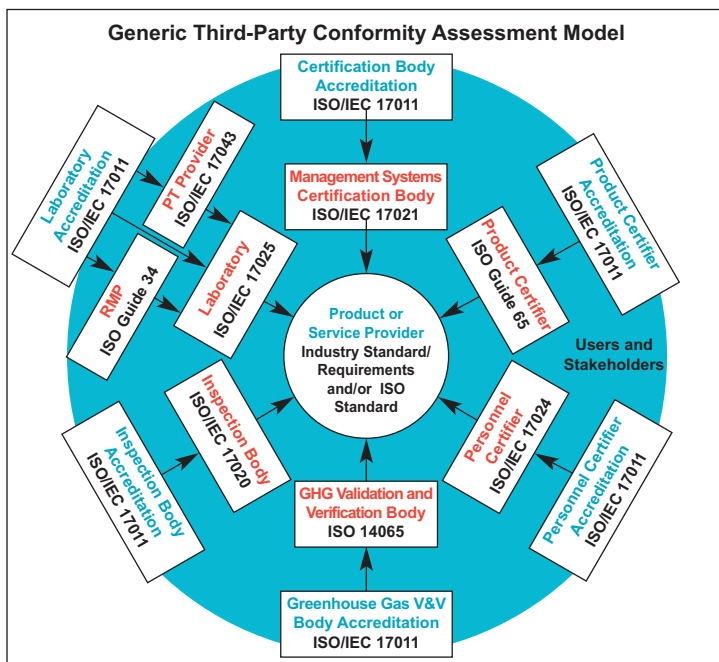
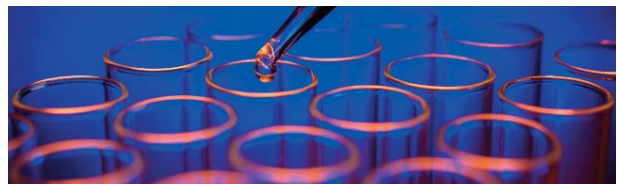
Sica Named Coordinator for Environmental Programs

Matthew Sica will be ACLASS's new program coordinator for environmental programs starting July 1. He will be a contact for technical issues related to the Department of Defense (DoD) Environmental Laboratory Accreditation Program (ELAP) and will assist Geneva Bowman with daily program activities.

Matt has 19 years of experience in the environmental industry. He has served in a variety of positions and roles in private and municipal sector laboratories and as a state government program administrator. Matt has expertise in quality systems assessments, management, laboratory accreditation and certification, technical monitoring and testing issues, proficiency testing issues, and regulatory issues. He held technical and managerial roles at various environmental laboratories for both chemical and microbiological disciplines. He is an experienced assessor for the Maine Laboratory Certification Rules and the NELAC standard.

Matt is a member for The NELAC Institute (TNI) Board of Directors and the Proficiency Testing (PT) Executive Committee of TNI. He serves on the PT Expert Committee of TNI and is chairman for the New England Certification Officers workgroup. Matt is a voting member of the Standard Methods Committee. He has presented more than 20 training sessions on technical issues and quality systems throughout New England. He has been the Program Manager for the Maine Environmental Laboratory Certification Program with the Maine Centers for Disease Control and Prevention in the Department of Health and Human Services for the last six years.

You can reach Matt by e-mail at msica@anab-aclass.org or call him at 207-624-1532.



To have a truly effective food safety system in the United States, we must have a level of oversight that works in partnership and supports the role of the FDA to provide confidence in the entire life cycle of the product. The best way to achieve this type of system is through accredited third-party conformity assessment services with oversight, through which an independent party verifies and provides written assurance of conformance to internationally recognized standards.



ACLASS Participates in APLAC Mid-Year Meeting

APLAC's Multilateral Recognition Arrangement (MRA) Council held its mid-year meetings in Auckland, New Zealand, in May. Among the follow-up issues on the agenda, the Council reviewed the status of all its RMP MRA signatories for implementing the new ISO Guide 34:2009 with their accredited organizations.

All the members, including ACLASS, reported that they were on track to meet the July 1, 2012, deadline for implementation. ACLASS has already implemented all of its eight accredited RMP organizations a year in advance of the APLAC deadline.

Another topic for the Council was ACLASS's application for MRA signatory approval for ISO 17020 inspection body accreditation and ISO 17043 proficiency test (PT) provider accreditation.

The Council approved the ISO 17020 scope expansion review for ACLASS's next four-year evaluation, which should take place in early summer of 2012. APLAC will decide later this year whether ACLASS will also be reviewed for ISO 17043.

Committee members were updated on ACLASS's very active PT provider accreditation program. To date, we have accredited two testing PT programs, two calibration programs, and additional accreditations in progress.

As yet, there is no MRA in place for PT provider accreditation. APLAC needs at least four accreditation bodies to be approved for their programs before an MRA would begin. ACLASS could potentially be the first AB in APLAC to be approved.

Change in DoD ELAP Assessment Tracking

ACLASS has been working to move the accreditation checklist for the Department of Defense (DoD) Environmental Laboratory Accreditation Program (ELAP) into its Enterprise Quality Manager (EQM) electronic database. EQM will allow the assessor to perform the entire assessment, from document review to final review and approval of corrective action, within its database components.

This system will allow clients to instantly access to their assessment records, keep track of where in the process the assessment is, and respond to non-conformances all in one secure location.

The checklist is currently in the final testing stages. We anticipate implementation of the system no later than July 1, 2011. Stay tuned for further instructions.

Contact gbowman@anab-aclass.org with any questions about the change.

ACLASS and ANAB Week of Professional Development

Annual professional development for ACLASS and ANAB assessors took place in April 2011 in San Juan, Puerto Rico. For ACLASS, the week included a gathering of its Accreditation Council and a full week of training at its Annual Forum of assessors.

ACLASS has instituted several new functions of its Enterprise Quality Manager (EQM) database during the past year, so assessors were trained on the enhancements and more simplified steps to use them. Customer laboratories are also using the EQM database for several functions, including most steps in the corrective action process.

Uncertainty, traceability, and proficiency testing continue to be the technical framework underpinning most of the ACLASS accreditation programs. Providing ongoing training on these elements is intended to strengthen each of the programs.



Answers to Your Questions

This is the first in a series of articles that will provide answers to questions we've recently received from labs and assessors. It's our hope that sharing this information will help others who may encounter the same issues.

General Questions

Q. A lab asked if ACLASS is recognized by the European Cooperation for Accreditation (EA) because a customer of the lab has several special gages that have to be calibrated in a European class.

A. EA is a regional cooperation within the International Laboratory Accreditation Cooperation (ILAC) community. All ILAC signatories, such as ACLASS, and including EA members, have agreed to recognize the calibration certificates and test reports of labs accredited by all other ILAC signatory accreditation bodies.

AClass policy is that all accredited laboratories must have participated in one or more proficiency test programs prior to accreditation. A major finding is written during the initial assessment if no PT participation has occurred and no data has yet been generated.

Q. An assessor asked, "If Lab A sends one of its standards to Lab B to be calibrated and Lab B sends the standard to a subcontractor (Lab C), does Lab C need to be on Lab A's approved vendor list?"

A. Assuming all three labs have been accredited by ILAC signatory accreditation bodies, the answer is no. Lab B assumes responsibility for Lab C's product. It is Lab B's responsibility to verify that its subcontractors are competent (accredited), so Lab C would be on their approved vendor list. However, because Lab B is required to notify Lab A of subcontracting, it would be good practice for Lab A to verify Lab C's competency.



Q. Another assessor asked, "How soon after a scope expansion should the proficiency test for that parameter should be scheduled, or should it be done before we look at the expansion parameter?"

A. There's no specific requirement for either. If it's a sub-area the lab didn't previously have, it has to be added to the four-year plan.

Q. A lab applying for accreditation asked, "Do we have to have a completed proficiency test (PT) before we can be accredited?"

A. ACLASS policy is that all accredited laboratories must have participated in one or more PT programs prior to accreditation. A major finding is written during the initial assessment if no PT participation has occurred and no data has yet been generated. After data is generated and submitted to the PT provider, and assuming no report is yet in hand to give the lab feedback on its success, the lab will receive only a minor finding for PT. In this case, the data generated is acceptable as a short-term corrective action and the longer-term resolution requires a report with the PT feedback within six months of accreditation.

Q. A lab indicated it was adding some parameters to its scope of accreditation during its next visit and wanted to know if ACLASS or the assessor is responsible for adding the information to the scope.

A. The lab is in the best position to do this. After notifying ACLASS about the scope expansion using the Scope Expansion Form (form 28), we'll provide a copy of your scope (in Microsoft Word format) for you to use for this purpose. During the scope expansion, the assessor will witness the parameter and verify the information is correct. ACLASS staff will ensure the information is stated correctly and format the scope during the assessment review.

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Q. An applicant lab asked, “Where can I find definitions of the different types of assessments you do, such as reassessments?”

A. ACLASS policy documents 3 through 8, available on our website at <http://www.aiclasscorp.com/documents/aiclass-documents.aspx>, describe the different types of assessments.

Q. Another applicant lab that had finished its initial accreditation assessment and submitted corrective actions asked, “What happens next?”

A. The first step is a review by your lead assessor of the submitted corrective actions. After any corrective actions are accepted by the assessor, we have a review process that must be followed. This includes sending the report, draft scope of accreditation, and supporting documentation to an Accreditation Review Panel composed of qualified assessors who were not involved in the assessment. The purpose of the review is to verify that ACLASS policies were followed in the assessment. ACLASS requires that assessors review CARs within five workdays of submittal of the CARs, although the review may not take the full five days. If the assessor rejects a CAR or asks for more information, the process may take longer. The five-day requirement also applies to members of the Accreditation Review Panel.

EQM-Specific Questionss

It's not unusual for ACLASS to receive questions about the Enterprise Quality Manager (EQM) database. Here are some questions submitted by labs.

Q. I submitted my corrective actions from the reassessment but they still show “Issued” in EQM. Shouldn't they indicate “Submitted”?



A. Yes. If the NCRs are still listed as “Issued” you should go back into EQM and click “Save” so that the status will change and your assessor can see the corrective actions for review.

Q. Why can't I open a document I just attached?

A. EQM doesn't recognize non-alphanumeric symbols such as “&” or “%”. If you change the name of the document to eliminate any non-alphanumeric symbols and replace the old document with the revised one, you should be able to open it.

Q. What do the different statuses in my assessment in EQM mean?

A. When you see “Waiting for CAR,” it means we're waiting for you to submit your corrective actions. This status will not change until *all* CARs have been received, at which point the status will change to “Pending CAR Approval.” After your lead assessor has accepted all CARs, the status goes to “Ready for ARP,” indicating the assessment is ready for our review process to begin. When your accreditation manager begins the review and (in some cases) sends the documents to a panel of assessors for review, the status will be changed to “At ARP Review.” Upon return of the panel's review, the status goes to “Final PM Review/ARP” for the accreditation manager's final review. The final part of the review process occurs when the status changes to “Accreditation Decision.” You'll know everything is done when the status shows “Accreditation Granted.”

Names You Trust, Accreditation Services You Need



ANSI Snapshots Show Voluntary Standards Cover the Spectrum

To communicate the vital role standards play in daily life, the American National Standards Institute (ANSI) is publishing snapshots of the diverse standards initiatives undertaken globally and nationally, many of which are performed by ANSI members and ANSI-accredited standards developers. Two of the latest selections follow.

Bank Deposit Tickets

According to the Federal Deposit Insurance Corporation, the 8,500 U.S. financial institutions handled more than 9.6 billion check deposit transactions in 2010. A recently revised standard from Accredited Standards Committee X9 (ASC X9) helps financial institutions accurately process these deposits by providing specifications for deposit ticket design.

X9.100-120-2010, Bank Deposit Tickets, specifies design parameters for personal and commercial deposit tickets. While X9.100-120-2010 does not establish a specific design, orientation, and layout, it does provide specifications for a range within which key design elements shall be placed. The standard is intended to increase uniformity in several aspects of deposit ticket design to improve handling of deposit tickets throughout the entire check processing system.

An ANSI organizational member and accredited standards developer, ASC X9 seeks to develop, establish, maintain, and promote standards for the financial services industry. ASC X9 standards are used throughout the industry and by the federal government to facilitate delivery of financial services and products to users, and to promote global commerce.

Fire Protection Systems

According to the National Fire Protection Association (NFPA), an ANSI member and audited designator, sprinkler systems can reduce the average property loss by 71% in the event of a fire. But proper care and maintenance is critical to ensuring a system's continued effectiveness. *NFPA 25-2011, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, helps maintenance professionals, inspectors, and building owners keep fire protection systems ready to respond.

NFPA 25-2011 establishes minimum requirements for the periodic inspection, testing, and maintenance of water-based fire protection systems, including land-based and marine applications. NFPA 25 is subject to renewal every three years, and the 2011 version takes into account the latest inspection, testing, and maintenance records and other consideration that could have an impact on the adequacy of the fire protection systems.

To Err Is Human: Changing the Paradigm

by Joe Fortuna, Chair, ASQ Healthcare Division

Several years ago, two reports ("To Err Is Human" and "Crossing the Quality Chasm") were issued by the Institute of Medicine decrying the terrible toll in lives and the costs that each year result from errors in medical care. Around the same time, some 18 Centers of Excellence in Patient Safety were funded to the tune of \$3-5 million each. In 2005, the IOM partnered with the National Academy of Engineers in issuing the report "Building a Better Delivery System" in which the answers to the questions raised in their two earlier reports were carefully detailed.

Despite all of this effort, the title of a report published just last month in the well-respected journal *Health Affairs* screamed "Global Trigger Tool Shows That Adverse Events in Hospitals May Be Ten Times Greater Than Previously Measured." The study reported that on average one in three patients admitted to a hospital suffers a medical error or adverse event—nearly 10 times greater than previously believed.

What is wrong with this picture? More importantly, what can be done about it? And what role(s) can ASQ and its members play in helping to fix it? The answers to these questions are not as complicated as they may seem.

ASQ and its members are trained and skilled in problem analysis, sustainable problem solving, and
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change management. Most healthcare workers are not trained in these areas, and even fewer have the experience in these activities that ASQ members have.

Instead, clinicians are trained in how to prevent, accurately diagnose, and effectively treat illness and injury. That is how it should be! That said, I do think that healthcare leaders should be aware of process improvement tools, quality management systems, and culture change so the operational aspects of healthcare are just as error-free as clinical medical care.

I believe that these leaders owe it to their customers (patients) to consult with, employ, or otherwise have access to quality professionals who are every bit as well-trained and experienced in what they do as are the highly skilled and well-trained physicians, nurses, and other clinicians who work in their organizations.

Because there is currently somewhat of a bias in healthcare organizations against quality professionals without clinical backgrounds, we in the Healthcare Division are working hard to change that perception and to equip our members to function in the healthcare institutions of the future where there will be a universal culture of continuous improvement.

At our recent Quality Institute for Healthcare, we provided many workshops and presentations that showcased what quality professionals are doing to improve quality, efficiency, safety, cost-effectiveness, and culture in healthcare. In addition, we're partnering with select ASQ sections on a pilot basis to provide a few medical practices and dialysis centers with access to volunteer quality professionals to help them begin their quality, safety, and process improvement journeys. Our hope is that once they have been successful in such settings that these quality professionals will find it easier to find positions in healthcare.

Finally, in keeping with the federal Partnership for Patients initiative, a public-private partnership to improve the affordability, safety, and efficacy of healthcare for all citizens (with the potential of saving up to \$30 billion in health costs and 60,000 lives within three years), the Healthcare Division is going to partner with other ASQ divisions to provide access to the vast

reservoir of ASQ member intellectual capital to those at the state and federal levels who are struggling every day to make healthcare safer, more effective, and less costly. We feel that by doing this, we may positively impact the grim healthcare safety statistics that were cited earlier in this article.

ANAB Gears Up for Transition to ISO/IEC 17021:2011

Following the publication on February 1 of the 2011 revision of ISO/IEC 17021 and a joint IAF-ISO communiqué announcing a two-year transition period, ANAB is primed for the transition from ISO/IEC 17021:2006 by all of its accredited certification bodies (CBs) in advance of the 2013 deadline.

ANAB's experience with the transition to the 2006 version of the standard was less than satisfactory, with most CBs delaying the transition to the final months of the transition period. This caused scheduling challenges and put a serious strain on assessment resources. As a result, this time around ANAB has been proactive in announcing clear requirements and the corresponding sanctions that will be imposed on CBs that fail to meet deadlines.

ANAB detailed transition requirements in Accreditation Rule 41, available at www.anab.org. CBs can apply for the transition at no charge. Each CB is required to document on an ISO/IEC 17021:2011 Requirement Matrix how its certification system conforms with the standard, with a focus on meeting requirements that have changed from the 2006 version.

ANAB will conduct a document review focusing on the changes for conforming with new requirements. The fee for the review will be on an hourly basis to keep costs low and benefit CBs that implemented changes in anticipation of the new requirements.

CBs must complete the checklist by October 31, 2011, to provide plenty of time to conduct the document reviews and office assessments needed to confirm conformance to the new requirements during late 2011 and through 2012, ensuring a smooth transition without additional cost.



Entrepreneur Award for President of Brylen Technologies

Barbara Tzur, president of Brylen Technologies, Inc., has received The Spirit of Entrepreneur Award in the field of Science and Technology from the National Association of Women Business Owners.

The award program was started at the Santa Barbara Community College in conjunction with the National Association of Women Business Owners - Santa Barbara Chapter (NAWBO-SB).

NAWBO-SB is a foundation that provides monetary grants to high school and college students who start small businesses and mentors them through the process.

Brylen Technologies, Inc., has been accredited by ACLASS since 2005. The company is accredited to ISO/IEC 17025, ANSI/NCSS Z540-1, and ANSI/NCSS Z540.3,

USA and Mexico Sign Telecommunications MRA

On May 26, the United States and Mexico signed a telecommunications MRA that will ease the burden on U.S. manufacturers seeking to export telecommunications products to Mexico. Under the MRA (the Agreement between the Government of the United States and the Government of the United Mexican States for Conformity Assessment of Telecommunications Equipment), Mexican regulatory authorities will accept tests performed by recognized U.S. laboratories to determine the conformity of telecommunications equipment with Mexican technical requirements, rather than requiring additional testing before the American products can be sold in Mexico.

This agreement will permit recognized U.S. laboratories to test telecommunications products for conformity with Mexican technical requirements and Mexican labs to test products for conformity with U.S. requirements. This will save manufacturers the time and expense of additional product testing and should lower prices for consumers. The agreement covers equipment subject to telecommunications regulation, including wire and wireless equipment and terrestrial and satellite equipment. Under the agreement, both countries have made a commitment to undertake confidence-building measures during an 18-month transition period, which will include joint meetings and training opportunities for government officials involved in designating and recognizing testing laboratories and reviewing test reports.

The MRA fully preserves the authority of the Federal Communications Commission (FCC) to determine the level of safety protection it considers appropriate and in no way lowers current U.S. safety requirements

For more information and to view the full text of the MRA, go to http://www.ustr.gov/webfm_send/2879.



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