ANSI REPORTER

SPECIAL FEATURE

# assessing conformity

a synopsis of current accreditation activities in the product and personnel certification arena

ANSI
American National Standards Institute

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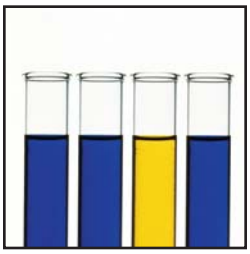

## On the Cover

*assessing conformity*

"Trust, but verify"

Russian proverb ("doveryay, no proveryay")

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Buyers in the global market demand that sellers fulfill their needs. Confidence that these needs can and will be met is built through a variety of means, including the assessment of conformity to standards. Since ANSI promotes and facilitates standards that define requirements, it is logical that the Institute is concerned with and involved in activities that assess conformity.

Conformity assessment is defined as a "demonstration that specified requirements relating to a product, process, system, person or body are fulfilled." There are many of these conformity assessment activities applied in today's marketplace including certification, inspection, registration, supplier's declaration, and testing, but the one dimension that ANSI is directly engaged with is accreditation. The Institute provides accreditation services specifically in areas that recognize the competence of bodies to carry out product or personnel certification in accordance with requirements defined in International Standards. ANSI's accreditation programs are themselves created in accordance with similar international guidelines as verified by government and peer review assessments.

This special editorial feature of the *ANSI Reporter* provides insight and a brief synopsis of some of the activities now underway within the sphere of influence of ANSI's product and personnel certification accreditation programs.

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# ANSI REPORTER

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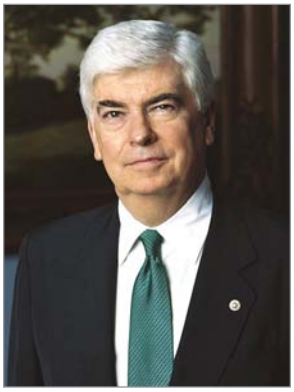

**The Honorable Christopher J. Dodd** is a U.S. senator from the state of Connecticut. Senator Dodd is currently a senior member of the Health, Education, Labor and Pensions Committee and the Foreign Relations Committee. He also serves on the Banking, Housing and Urban Affairs Committee, and is the senior Democrat on its Securities and Investment Subcommittee. Senator Dodd recently authored a law to help local fire departments purchase new equipment and hire additional personnel, and has a shown a firm commitment to a strong national defense and his desire to build a more secure world.

In this special issue, Senator Dodd talks to the *ANSI Reporter* about the responsibility of the federal government to support first responders and the small manufacturing industry, the role of foreign-trained workers in the U.S., and accreditation and certification programs in health care.

**ANSI Reporter (AR):** *Ensuring that first responders have the appropriate skills seems to be critical for minimizing the potential impact of a future attack on the homeland. What role does the federal government have in assuring that first responders are adequately trained and are credentialed as having the required competencies? What types of initiatives are required of Congress or the executive branch to ensure that first responders have the training needed to protect the American people?*

**Senator Dodd:** It is critical for the American people to have confidence in the training of first responders, and it is equally critical that our first responders receive the equipment and resources they need to protect our communities.

For this reason, in 2000, I co-authored the FIRE Act, which established the *Assistance to Firefighters Grant Program*. Thanks to FIRE Grants, local fire departments have received over $2.6 billion in federal funds to purchase new equipment like trucks, HazMat suits, and devices to detect chemical and biological weapons. In 2004, I also co-authored the SAFER Act, which established the first federal grant program to local fire departments for the purpose of hiring new firefighters. I am also a strong supporter of the COPS program, which has put over 100,000 new police officers on our streets.

Since different communities have different needs, the responsibility for training and credentialing is best left primarily in the hands of state and local authorities. Fighting forest fires in California requires different skills and training from fighting a fire in a skyscraper in New York City.

The federal government does, however, have a responsibility to ensure that our nation can respond to emergencies of national significance, such as terrorist attacks. As such, the federal government can and should offer training and guidance and work with local first responders to ensure that they are prepared to respond to such emergencies. One example is the Department of Homeland Security's Office of Domestic Preparedness. This office helps state and local governments prepare for potential acts of terrorism by training first responders and by running comprehensive exercises that simulate natural disasters and terrorist attacks.

**AR:** *Who should be responsible or take the lead to ensure that foreign trained professionals who want to work in the U.S. meet the standards and competencies expected of U.S. trained professionals? Is this a governmental responsibility at either the federal or state level? Or should this be delegated to the private sector—perhaps to be completed by the relevant trade or professional association?*

**Dodd:** There is no one-size-fits-all answer. In many, if not most, industries, there is not a great need for government—particularly the federal government—to get involved in deciding who is competent to work at certain jobs and who is not. For example, government is not about to step in and set standards for foreign-trained computer programmers. These standards can be best developed by trade and professional organizations.

. . . to the extent that workers are moving from state to state like never before, there could be a federal role to play in credentialing.

That said, in some industries—particularly those which serve critical public needs and which impact public health and public safety—there is a need to ensure a certain level of competence through a licensing process.

While I would initially look to state and local governments, as well as the relevant trade associations, to perform this role, to the extent that workers are moving from state to state like never before, there could be a federal role to play in credentialing.

**AR:** *As a strong supporter of the manufacturing Extension Partnership (MEP), you have stressed the importance of ensuring that the U.S. small manufacturing industry be competitive in the global marketplace and that products from outside the U.S. meet certain standards so as not disadvantage U.S. products in the marketplace. What type of legislation could be approved at the federal level to support the U.S.-based small manufacturing industry?*

**Dodd:** Small manufacturers are critical to our economy, particularly in an age when many large companies, like Lockheed and Boeing, now consider themselves "integrators" rather than "manufacturers." Instead of building entire products in-house, large companies are relying more and more on small and medium-sized manufacturers to build critical components.

Outsourcing of jobs overseas, or "offshoring," is one factor that is hurting our small manufacturers. It's estimated that about 3.3 million jobs will go overseas by 2015. I don't believe the federal government should seek to end all offshoring—but at the very least, we should take steps to stop the outsourcing of federal government contracts to overseas companies. American tax dollars should not be used to send American jobs overseas. I have introduced legislation, the *USA Jobs Protection Act*, that would enact this principle into law.

"A national investment in health care information technology is the most critical commitment we can make to improve the quality of care in America today."

We also ought to be taking full advantage of institutions we've set up to help manufacturers. The Manufacturing Extension Partnership (MEP), part of the National Institute of Standards and Technology (NIST), is the principal federal initiative that helps small and medium-sized manufacturers compete. Unfortunately, the Bush Administration has proposed to cut the MEP's funding by 50 percent. In an age of global competition, this kind of cut is simply unacceptable.

We also need to get tough on unfair trading practices by our competitors. China has manipulated its currency, the Yuan, to provide its manufacturers with an unfair advantage by enabling them to sell goods in the United States at artificially low prices. The European Union heavily subsidizes domestic industries to help them bring products to market. And nations in Europe and Asia use arrangements known as "offset contracts" to force American companies to buy their goods and hire their workers in order to do business overseas.

I'm a strong advocate of free trade, but these practices are not free trade—they are cheating the system and are putting American manufacturers who play by the rules at a disadvantage. America's manufacturers need a level playing field if they are to compete in the global marketplace. Unfortunately, I am not optimistic that the current Congress or Administration will take action in this regard.

Finally, we can help small manufacturers by providing incentives for them to engage in research, development, and innovation. After decades of leading the world in science, technology, and innovation, America has begun to fall behind. If the President's budget for the upcoming fiscal year is adopted, in real terms, federal investments in research and development would decline for the first time in a decade. Several of these areas—including physical sciences, mathematics, engineering, and computer science—have had flat or declining federal funding for 15 years.

Small manufacturers are twice as likely as large ones to be involved in high-impact, radical innovation. We ought to encourage them to devote more resources to researching new and innovative technologies.

One example of such an incentive—the Research and Development Tax Credit—accomplishes this goal by providing companies with tax incentives to engage in research and development. I would support permanently extending the R&D Tax Credit. I also believe we should explore expanding it to include other practices, like standards development, which provide small manufacturers with greater flexibility, compatibility, and capacity to meet the needs of large companies and government agencies.

**AR:** *Americans are becoming increasingly concerned not just about the costs of health care, but also about the quality of their care and the overall training and skills of health care professionals who provide treatment. In your view, should a consumer rely on whether a facility is accredited or whether a health care professional has a certain credential when considering their options for health care? How can the credentialing or accreditation process help enhance the overall delivery of quality health care services in the U.S.?*

**Dodd:** There are few industries where the credentialing of professionals and institutions is as important as health care. Credentialing increases consumer confidence in health care providers, professionals, and facilities, and helps ensure that they meet the standards we expect of them.

Third-party accreditation organizations play an important role in this process. In fact, a number of government agencies rely on third-party accreditation organizations. Medicare, for example, only reimburses hospitals which are accredited by JCAHO—the Joint Commission on Accreditation of Health Care Organizations.

A national investment in health care information technology is the most critical commitment we can make to improve the quality of care in America today. To a large extent, America's health care system has not entered the 21st century. Doctors still write down prescriptions on paper. The information technology revolution has not yet reached our hospitals, clinics, and doctors' offices.

It's estimated that improvements in health care information technology could save our nation $100 billion annually in health care costs. They would also increase patient safety substantially by dramatically reducing the number of medical errors, and could also improve the privacy and security of patients' medical records.

(*Continued on page 6)*

According to the World Trade Organization, cross-border trade in services now accounts for more than 22% of all global commerce. Globalization has affected nearly every sector and exposed many professions to new areas of competition. Along the way, it also has escalated the need for equivalency in personnel services across national borders. Dr. Roy Swift, ANSI program director, explains how the American National Standards Institute is breaking new ground with its implementation of an accreditation program for personnel certification bodies.

# global ACCREDITATION

## BUILDING WORLDWIDE CONFIDENCE IN PERSONNEL CERTIFICATION PROGRAMS

Certification and credentialing programs have become widely recognized as effective tools for universally and consistently qualifying and recognizing the competence and proficiency of personnel. In the United States alone, more than 2,000 certifications and 3,000 credentials are offered.

For many years, stakeholders affected by cross-border trade in personnel services discussed the need for a globally accepted benchmark for organizations that certify individuals. The development of an internationally recognized standard was identified as a solution that would help:

- promote public confidence in the competence of people who provide specialized services,
- enable the mobility of service professionals,
- protect the integrity of individual certification programs, and
- create international consistency in areas such as assessment, subsequent surveillance, and periodic reassessment.

In 2003, the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) responded to stakeholder needs by publishing the first-ever internationally recognized standard on personnel certification and credentialing, *General Requirements for Bodies Operating Certification Systems of Persons* (ISO/IEC 17024).

The United States, via ANSI and its U.S. National Committee of the IEC, joined with more than 85 other nations in approval of the ISO/IEC standard. ANSI was the first among the more than 140 ISO and IEC member nations to begin implementation of ISO/IEC 17024 when it launched a U.S. accreditation program for personnel certification bodies based on the standard. ANSI committed itself to providing an assurance of openness, balance, due process, transparency, and consensus throughout the accreditation process.

### Evaluating certification programs

Although the criteria under which a personnel certification program is evaluated are set forth in ISO/IEC 17024, ANSI's actual accreditation process is based on procedures contained within another international standard, *General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies* (ISO/IEC 17011). The components of openness and peer review required by the two standards facilitate an ongoing quality improvement mechanism that contributes to the soundness of the accredited certification program and helps to build the additional levels of quality assurance that are critical for protecting the public's interest and improving the service profession.

ANSI's personnel certification accreditation program features a two-step evaluation process:

- a detailed application in which the applicant documents how it meets each requirement in ISO/IEC 17024; and
- an on-site visit (audit) by trained assessors to validate and confirm the information provided by the certification body. The findings of the assessors are presented to an ANSI oversight body composed of nationally recognized experts in certification and test development and a broad representation of industries and the public.

Nonconformities identified during the application process and audit must be corrected during a predefined time frame. Upon approval, accredited bodies must also engage in an annual reporting process that details any changes to their program; in some cases an additional on-site visit is required.

Six organizations have already been accredited by ANSI under ISO/IEC 17024, including the National Inspection, Testing, and Certification Corporation (NITC), an internationally recognized agency that certifies personnel in the construction industry.

"The ANSI accreditation is an undeniable mark of quality and integrity," says Michael T. Massey, executive vice president of NITC. "We have already witnessed a business volume and profitability benefit. The accreditation process itself improved delivery of our services."

More than 20 additional applicants—representing a wide range of occupational sectors as health care, security, construction, energy and informational technology—are currently engaged at some stage of the accreditation process.

### Contributing to international models of quality assurance

A certification body's decision to embark on the accreditation process is purely voluntary; there are no U.S. laws requiring accreditation under ISO/IEC 17024. Many agencies choose to proceed because of the return on investment derived from benefits and competitive advantages.

"Accreditation allows us—by the way of an independent third party—to prove that we're a quality certification program, within our industry and to our user industries," says Betsy Blazar, senior membership and marketing manager for the American Society for Nondestructive Testing, Columbus, Ohio. "The annual review feature also helps to keep us diligent and cognizant of the process itself. Continuous quality improvement is a strong reinforcement."

A mark of accreditation that has been awarded by a fair, impartial, and globally recognized third party such as ANSI is widely recognized as a valid measurement of the credibility and competency of the certification body. Additionally, accreditation enhances the integrity of the certification process, improves consumer and public confidence in the personnel who hold the credential, and promotes the national and international reciprocity of certified individuals.

"Attaining accreditation from a well-respected independent organization like ANSI sends a very positive message about NBCOT to patients, clients, and other consumers of services provided by the Occupational Therapist OTR and Certified Occupational Therapy Assistant COTA," says Randy Strickland, past president of the National Board for Certification in Occupational Therapy.

By driving a system that recognizes a certification agency against international standards of quality, ISO/IEC 17024 promotes the global exchange of services provided by qualified individuals from around the world. And as a response to globalization, there is no better tool. ■

**Interview: The Honorable Christopher J. Dodd**
(*Continued from page 4*)

**AR:** *What role can Congress play to help the American people maintain confidence in the quality of our health care delivery system?*

**Dodd:** I've introduced legislation to require the President to develop a national strategy on health care information technology. It would establish a new White House Office of Health Information Technology to oversee these activities and lead a public-private partnership to develop health information technology standards. My legislation would also award competitive grants to hospitals, health care providers, states, and communities for the purpose of improving their health care technology systems. Finally, it would provide for the development of a standard set of health care quality measures so we can better understand how our health care system is performing, and where we need to focus our efforts to improve the quality of care. ■

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# DEFENDING THE HOMELAND

## USING CERTIFICATION TO ENSURE THE PROFICIENCY OF TRANSPORTATION SECURITY SCREENERS

*By Elizabeth Kolmstetter, Ph.D., Peter Marcello, and Ann Quigley*
*Transportation Security Administration*
*United States Department of Homeland Security*

The law that created the Transportation Security Administration (TSA) in the aftermath of September 11, 2001, (Aviation and Transportation Security Act (ATSA) Public Law 107-71, approved November 19, 2001) includes a number of unique provisions regarding persons employed as Transportation Security Screeners. In addition to specifying job-related requirements (e.g., sufficient aural and visual acuity), the statute mandates conduct of an "Annual Proficiency Review":

> (5) ANNUAL PROFICIENCY REVIEW: The Under Secretary shall provide that an annual evaluation of each individual assigned screening duties is conducted and documented. An individual employed as a security screener may not continue to be employed in that capacity unless the evaluation demonstrates that the individual:
>
> (A) continues to meet all qualifications and standards required to perform a screening function;
>
> (B) has a satisfactory record of performance and attention to duty based on the standards and requirements in the security program; and
>
> (C) demonstrates the current knowledge and skills necessary to courteously, vigilantly, and effectively perform screening functions.

Congress, then, explicitly recognized the criticality of hiring qualified persons into this important national security job and ensuring that those qualifications are maintained throughout employment. To our knowledge, the TSA screener job is the only one in the federal service that requires passing a rigorous assessment of the full range of job requirements annually to maintain employment.

### A National Screener Re-certification Program

To comply with this statutory mandate and to ensure that TSA maintains a workforce well equipped to maintain aviation security and protect the traveling public, TSA designed a program that goes beyond mere performance appraisal and implemented a national, state-of-the-art, annual screener re-certification program. The objective of the re-certification program is to ensure that screeners demonstrate proficiency in the knowledge, skills, and abilities critical to effective job performance and the provision of world-class security and world-class customer service. In addition, by having a national program that is centrally managed and implemented consistently across more than four hundred of the nation's airports, TSA can maximize use of the data by allocating training resources more effectively based on program results. Finally, by setting up the annual program to meet the rigors and standards of an official "certification," TSA has established a credential for its screener workforce that demonstrates that this job is a profession requiring high standards for knowledge and skills, ongoing training and development, and current skill in the use of various technologies and screening equipment.

Trainees in the Transportation Security Administration Baggage Screening Training Program listen to an instructor during a media tour near Tampa International Airport in Tampa, Florida. The trainees must complete 44 hours of classroom training and 60 hours of on-the-job training.
(Photo by Matt Stroshane/Getty Images)

TSA certified 42,682 screeners with less than 1% of the workforce failing re-certification.

The program consists of three components or modules. The first is job knowledge and is measured by a multiple-choice objective test that covers standard operating procedures and other job-related content.

The second is proficiency at interpreting X-ray images. This is evaluated by a test in which the screener indicates whether or not there is a prohibited (e.g., lighter) or threat item (e.g., gun, knife, bomb) in an X-ray image of a passenger bag. The third module is a practical skills demonstration in which the screener actually performs screener tasks such as screening someone with a portable metal detector or performing a full body pat-down. If screeners fail a module they are given appropriate remediation and an opportunity to re-test. In addition to passing all three modules, screeners must receive a satisfactory performance evaluation to be deemed "re-certified."

The FY 03-04 annual re-certification program ended May 15, 2004. TSA certified 42,682 screeners with less than 1% of the workforce failing re-certification. These results are truly a reflection of the highly knowledgeable and skilled screener workforce that TSA has hired and trained. This success rate is a tribute to the screeners, the training coordinators, training providers, and the management teams. This effort was a partnership between TSA Headquarters, the Federal Security Directors and their staffs, the screeners, and our contractors.

Many, including the Government Accountability Office (GAO), DHS Inspector General (IG), and members of Congress, have scrutinized the TSA re-certification program. Reports have indicated that TSA has implemented a valid, fair, and objective assessment process with the appropriate standards in place to certify that its screener workforce is proficient and capable of providing the security and service expected by the traveling public.

While TSA is proud of these results, continuous improvement is necessary to keep the screener workforce proficient at all times and ensure TSA's ability to maintain national aviation security. With this goal in mind, the Office of Human Resources (OHR) initiated several follow-up activities.

- Key field personnel at the airports completed an online survey providing feedback on how to improve the re-certification program.

- In June 2004, OHR hosted a field 'debrief and input' session. Forty individuals from 32 airports throughout the U.S. volunteered to participate. They included Screeners, Lead and Supervisory Screeners, Screening Managers, Training Coordinators, and a Federal Security Director. The group identified both program strengths and areas for improvement.

- Cross functional working groups comprised of Aviation Programs, Human Resources, Internal Affairs, and Workforce Performance and Training (WPT) personnel were established to analyze the vast amount of re-certification test data and make recommendations to improve efficiency and performance at all airports.

- Teams visited 21 airports to interview or conduct focus groups with FSDs, Screening Managers, Training Coordinators, and Screeners (including Leads and Supervisors). The goal of these visits was to identify best practices in order to replicate them at all airports. Screeners in particular have been pleased with the ability to provide feedback directly to the program office.

### Lessons Learned

What was learned from all the information gathered? First, re-certification is an important security program that must include objective assessments and demonstration of knowledge and skills. Second, screeners must receive ongoing training and feedback to keep their knowledge and skills current and improving. And finally, it is important to ensure screeners have the information to perform their work and pass re-certification tests anytime, not just once a year.

Re-certification 2004-2005 began in September 2004, concluding at the end of June 2005. At the beginning of April, more than 40,000 screeners had started re-certification and approximately 24,000 had recertified. Again, the fail rate is approximately 1%.

In its ongoing efforts to improve the program and ensure that it reflects the state of the art in assessment and certification, TSA hosted an expert roundtable discussion in April 2005. Participants included members of ANSI and ASQ as well as several organizations that certify personnel. The group was briefed on the TSA annual certification program and brainstormed on improvements. It was a highly productive discussion and TSA intends to continue this type of dialogue

TSA has also submitted a letter of intent to ANSI requesting that the TSA program be accredited through ANSI's conformity assessment process. If the re-certification program is accredited, TSA will again make history as the first government agency to have an accredited certification program.

Screeners from the June working group best described in their own words what the annual re-certification program means to them:

> *"It is the measuring tool of how well we are performing our duties and responsibilities in providing national security for the nation; we are proving to the public that we will aspire to surpass expectations for world-class security and customer service; and, we want to be the standard by which all security programs are measured."*

TSA is committed to and very proud of its efforts to serve and protect the American public. Certification is a critical part of our ongoing work to ensure we provide the best possible service and security. ■

# FCC and Conformity Assessment

## a light regulatory approach encourages innovation

*— by Rashmi Doshi and William Hurst, FCC Laboratory Division*

We are at the dawn of a digital communications revolution. Ideas that once resided in the realm of science fiction are now being transformed into the reality of everyday experience. Wireless technologies are one of the major drivers of this revolution. These networks are largely invisible to consumers, yet powerful enough to transform their lives.

There has been a significant increase in the proliferation of radio frequency (RF) devices. Such devices are increasingly relied upon for many everyday functions in consumers' lives. Examples of such devices include cordless phones, computers, baby monitors, and garage door openers. Many millions of wireless devices operate today without any significant interference problems.

This has not always been the case. During the 1920s, radio communication was a veritable free-for-all; anyone possessing radio equipment was allowed to broadcast signals over the air. The result was chaos. By the early 1930s, radio sales and usage plummeted, and the market failure created by this chaos predestined today's regulatory environment. Accordingly, with the passage of the Communications Act of 1934, Congress created the Federal Communication Commission (FCC) to regulate radio communications in the United States, the District of Columbia, and all U.S. possessions. The FCC has historically controlled access to radio spectrum by allocating specific frequency bands for use by licensed service providers. The FCC grants licenses to operators permitting them to broadcast at a particular power level, at a specified location, and in an assigned frequency band. The amount of protection granted to licensees varies from service to service.

In 1938, the FCC first allowed unlicensed devices. Conditions were set to ensure that the devices would not generate emissions or field strength levels greater than a specified maximum. At that time, typical qualifying devices included wireless record players, carrier current communication systems, and control devices. In contrast to licensed devices, unlicensed devices have no exclusivity even in the bands within which they are authorized to operate. The technical standards contained in the FCC rules are designed to ensure that there is a low probability that these unlicensed devices will cause harmful interference to other users of the radio spectrum. In exchange for operating on an interference sufferance basis, unlicensed devices are free from the burden of the normal delays associated with the spectrum licensing process. In general, all the devices that emit RF energy must be tested for compliance with the technical standards.

### Rules and Regulations for Compliance

The FCC uses three different equipment authorization procedures depending on the type of equipment and as specified in the rules. The procedure to which a device is subject depends on the risk of interference that the equipment poses to licensed radio services. The three equipment authorization procedures are as follows:

- *Verification* is a self-approval procedure whereby the responsible party makes measurements or takes the necessary steps to insure that the equipment complies with the appropriate technical standards. Devices subject to verification include business Class A computer equipment, TV and FM receivers, and non-consumer industrial, scientific and medical (ISM) equipment.

- *Declaration of Conformity* (DoC) is a manufacturer's self-approval procedure where the responsible party, who could be the manufacturer, the grantee or the importer of the equipment, makes measurements at a recognized accredited test laboratory to ensure that the equipment complies with the appropriate technical standards. A test lab must be accredited by the National Voluntary Laboratory Accreditation Program (NVLAP); the American Association of Laboratory Accreditation (A2LA); or a designated accredited laboratory under the terms of a negotiated Mutual Recognition

Agreement (MRA). Devices subject to DoC must be properly labeled in accordance with FCC Rules. Examples of devices subject to DoC include certain personal computers and peripherals; CB receivers; super-regenerative receivers; TV interface devices; and consumer ISM equipment.

- *Certification* is an equipment authorization issued by the Commission or its designated entities based on representations and test data submitted by the applicant. The FCC is notified when products are certified. A complete copy of the application for certification is maintained in the FCC database. Examples of devices subject to Certification include: high power transmitters operating in Licensed Radio Services; low power transmitters such as cordless telephones; garage door opener controls; radio control toys; security alarm systems; and scanning receivers. Personal computers and peripherals; super-regenerative receivers; and TV interface devices such as VCRs may show compliance with the FCC rules by using either certification or DoC equipment authorization procedures.

## Conformity Assessment

In the early days of certification programs, all applications for approval were submitted to the FCC. The large growth in the number of devices requiring certification, the need for a speedier approval process and the increasing changes in international trade, led to the adoption of new rules for allowing third party conformity assessment programs in 1998. The two aspects of the program are the development of Mutual Recognition Agreements (MRAs) and the designation of Telecommunications Certification Bodies (TCBs).

Mutual Recognition Agreements (or arrangements) are government-to-government trade facilitating measures aimed at a global approach to conformity assessment. These agreements may be multi-sector, as in the case of the United States/European Union MRA, covering more than one group of products and may also be multi-lateral, as in the case of the Asia-Pacific Economic Cooperation (APEC) Telecom MRA, which provides a guideline for all member economies (countries) to follow. A third MRA exists for the Inter-American Telecommunications Committee (CITEL) of the Organization of American States.

In each of the agreements, participating countries agree to accept the test results and/or product approvals performed by the Conformity Assessment Bodies of the other country based on the use of a set of internationally accepted procedures. The present MRAs only address the issue of harmonizing conformity assessment procedures and do not attempt to harmonize regulatory standards or technical standards.

Within the text of the MRAs the term Conformity Assessment Body (CAB) refers specifically to the organizations performing conformity assessment. A Conformity Assessment Body may be a third party, a supplier's testing laboratory, or a certification body that is designated to perform conformity assessment to an importing Party's Technical Regulations under this Arrangement.

Under the FCC's Equipment Authoriza-tion Program there are two types of Conform-ity Assessment Bodies:

The technical standards contained in the FCC rules are designed to ensure that there is a low probability that unlicensed devices will cause harmful interference to other users of the radio spectrum.

- Accredited testing laboratories are used to perform testing of equipment subject to requirements that permit the use of a Declaration of Conformity to demonstrate compliance.

- A Telecommunication Certification Body (TCB) is used to perform third-party certification of equipment subject to the FCC requirements that require the product to be certified.

Under the rules adopted by the FCC, a TCB has the authority to review and grant an application for Certification for the FCC. The new rules also establish procedures for foreign TCBs under the terms of a government-to-government MRA. Currently in the U.S., TCBs are required to be accredited by the National Institute of Standards and Technology (NIST), or NIST may allow, in accordance with its procedures, other appropriate qualified accrediting bodies to accredit TCBs. NIST has recognized the American National Standards Institute (ANSI) accreditation program.

TCBs are accredited in accordance with ISO/IEC Guide 65 (1996), *General Requirements for Bodies Operating Product Certification Systems,* and the appropriate FCC Rules. The FCC has worked closely with NIST, ANSI, equipment manufacturers and test laboratories to develop an accreditation process that is consistent with the requirements the various rules. Accreditation is available for several different scopes of equipment subject to certification. TCBs may choose to obtain accreditation for any or all of the available scopes, depending on their needs.

## Conclusions

The rapid growth of devices which use radio frequency spectrum requires that a very large number of them have to comply with regulatory and technical standards established by the FCC and other regulatory agencies. At the same time the consumer demand for constant innovation and fast introduction of new capabilities have led to short product introduction times. This requires that product approval times have to be measured in days rather than months. The FCC approach of a balance between specific technical standards and allowing appropriately qualified Conformity Assessment Bodies has led to a successful model. From an early introduction of the program in 1999, today the TCBs in several countries worldwide, grant almost 93% of authorizations. At the same time the total number of authorizations has also been on rise! ■

*by Lawrence J. Lynch, CAE, President*
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# accreditation and food safety

## PROTECTION FOR THE CONSUMER

While research is showing a decline in some foodborne diseases, the need for continued vigilance among food professionals, regulators and consumers is clear. Unlike many diseases, most foodborne illnesses can be controlled through effective food control, cooking, handling and sanitation methods. They are methods that can be taught and their knowledge validated.

The Centers for Disease Control (CDC) estimate that 76 million cases of foodborne disease occur each year in the United States. The great majority of these cases are mild and cause symptoms for only a day or two. Some cases are more serious, and CDC estimates that there are 325,000 hospitalizations and 5,000 deaths related to foodborne diseases each year. The most severe cases tend to occur in the very old, the very young, those who have an illness already that reduces their immune system function, and in healthy people exposed to a very high dose of an organism.

An April 2005 report released by the CDC in collaboration with the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) showed important declines in foodborne infections due to common bacterial pathogens in 2004. For the first time, cases of E. coli O157 infections, one of the most severe foodborne diseases, are below the national Healthy People 2010 health goal. From 1996-2004, the incidence of E. coli O157 infections decreased 42 percent. Campylobacter infections decreased 31 percent, Cryptosporidium dropped 40 percent, and Yersinia decreased 45 percent.

Anecdotally we can make a correlation between the drop in these incidents with a better educated consumer and better trained food professional. What role, then, does accreditation play in helping to ensure public safety in the food chain? It starts with training.

The Food and Drug Administration's Food Code is developed by scientists with input from a wide range of constituencies and is based on the latest scientific data. The Food Code covers topics including management and personnel; food; equipment, utensils and linens; water, plumbing and waste; physical facilities; poisonous or toxic materials and compliance and enforcement.

The challenge is in determining where to concentrate training when we consider that we are training adults. Studies continue to show that our ability to learn becomes more complex as we age.

We know that adults learn best when they are working to address a current, real-world problem; are highly vested in solving the current problem; actually apply new materials and information; and exchange ongoing feedback around their experiences. In addition, adults often learn best from experience, rather than from extensive note taking and memorization. It stands to reason that effective training is essential in combating foodborne illness but, by itself, is insufficient to proof of knowledge.

Training organizations are hampered by the composition of food-related organizations. Typically retail establishments are low margin businesses. While investment in training is key to the development of their employees and, in the case of foodborne illness, to the safety of the public, it is often weighed against the cost of lost productivity. Training organizations must find the most effective training method(s) to deliver the most compelling messages in the shortest period of time.

The thought, then, may be "why not standardize training?" At face value the idea might seem to have merit. But when again comparing the various components of adult learning theory you realize that trying to standardize training for hundreds of thousands of people in varying work environments is a pointless task.

Instead you take advantage of the scientific development of a high-stakes examination that evaluates both the candidates understanding of the information and the effectiveness of the training.

### What makes this different?

It comes down to the both the complex nature of designing an exam as well as the active participants (subject matter experts) who bring the content to life.

An effective job task analysis (JTA) is the first step in ensuring the effectiveness of the exam by developing important information about the job roles and tasks. These roles and tasks are judged important by stakeholders who are also practitioners and recognized experts in the food industry.

## New National Accreditation Body Ensures Confidence in the U.S. and Worldwide

The ANSI-ASQ National Accreditation Board (ANAB) is the new U.S. accreditation body for management systems. The ANAB accredits certification bodies (CBs) for ISO 9001 quality management systems (QMS) and ISO 14001 environmental management systems (EMS), as well as a number of industry-specific requirements.

The American National Standards Institute (ANSI) and the American Society for Quality (ASQ) formed the ANAB – which replaced the ANSI-RAB National Accreditation Program (ANSI-RAB NAP) as of January 1, 2005 – in response to the adoption of ISO/IEC 17011, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*. ISO/IEC 17011 requires that a national accreditation body be a legal entity; the ANSI-RAB NAP as formerly structured did not meet that requirement. ANAB is now also divorced from RAB's personnel certification programs, as ISO/IEC 17011 prohibits a body from engaging in both accreditation and certification activities.

Certification/registration bodies (CRBs) accredited by the ANSI-RAB NAP automatically converted to ANAB accreditation as of January 1, 2005. ANSI-RAB NAP-accredited CRBs will receive the new ANAB accreditation mark for use with their registered clients. New certifications issued by accredited CRBs after January 1, 2005, should carry the ANAB mark. Existing certificates will be revised on the clients' existing recertification schedules.

ANAB is a member of the International Accreditation Forum and a signatory of the IAF multilateral cooperative arrangements (MLAs) for QMS and EMS. Through the IAF MLAs and the Multilateral Cooperative Accreditation Arrangement, ANAB cooperates with other accreditation bodies around the world to provide value to its accredited CBs and their clients, ensuring that accredited certificates are recognized nationally and internationally. The global conformity assessment system ensures confidence and reduces risk for customers engaging in trade worldwide.

ANAB, headquartered in Milwaukee, WI, is a not-for-profit organization that is financially self-supported and governed by a board of directors representing stakeholders. Policy is established by the ANAB board of directors. ANAB exists to serve the conformity assessment needs of business and industry.

### Additional Information

For additional information, please see www.ansi.org/ca or contact Lane Hallenbeck, vice president of accreditation services, (tel: 202.331.312; e-mail: lhallenbeck@ansi.org). ■

## Accreditation and Food Safety

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The value of the JTA for the tests is quite compelling. It provides the basic information for evaluating the job skill and tasks, weighting them so the proper number of questions can be written. Most importantly, it describes the skills and knowledge in such detail as to make the authoring of questions straightforward.

> the test process . . . provides assurance that the candidate, through experience and training, is competent.

Again industry experts assemble, this time using the vast understanding of roles and responsibilities in the industry, to create valid test questions in the creation of the test item bank.

Once the JTA is complete, a validation survey is done, blueprint developed and exam questions created, the certification agency is in a position to administer examinations.

Here, the test process again provides assurance that the candidate, through experience and training, is competent.

Unlike the training environment, the strict security and process surrounding the administration of the examination ensures that you are evaluating the candidate's knowledge. There is no book to review; there are no notes on the desk; no one is standing nearby who can share the correct answer with you. Done properly, the examination is the standard by which the individual will either succeed or fail. It is the true test of their ability to assure the public that their food experience will be a safe one.

States and public jurisdictions throughout the United States recognize the importance of this process in protecting the public. A consortium of interests under the auspices of the Conference for Food Protection (CFP) meets regularly to review the elements of the food code as well as the accreditation process. In conjunction with the American National Standards Institute (ANSI) guidelines have been created that regulate the testing process and accredit those organizations who demonstrate that their testing process is of the highest integrity.

That process of ensuring integrity and building comfort in the exam process has motivated many states and jurisdictions to include the ANSI/CFP accreditation in their statutes, regulations or rules as a critical measure of the acceptability of the certification exam. In these states and jurisdictions, the ANSI/CFP accreditation alone is enough for the regulatory agency to approve use of that exam. The comfort level is there when one equates the use of a valid examination with performance.

Only time will tell, but the continued reduction in certain food-borne illnesses seems to point to a valid correlation between effective accreditation and a protective environment for the dining public. ■

# Let It Flow

## Certifying Drinking Water Treatment Units

*By Greta Houlahan, NSF communications manager*

In the late 1960s, NSF International, a well-known standards developer and third-party certification body, was asked by state drinking water administrators and by the U.S. Environmental Protection Agency (EPA) to help develop consensus standards for the residential point-of-use and point-of-entry drinking water treatment unit (DWTU) industry. At that time, no governmental agency had standards to ensure the effectiveness of these devices.

NSF worked with industry through the Water Quality Improvement Standards and Certification Council, the EPA, state regulators and other agencies to develop the first NSF DWTU standards. NSF/ANSI Standard 42, *Drinking Water Treatment Units-Aesthetic Effects*, was the first to be developed, followed years later by a comparable NSF standard for health effects, NSF/ANSI Standard 53: *Drinking Water Treatment Units-Health Effects*.

As the industry grew to encompass more extensive treatment technologies and claims, NSF International worked with its stakeholders to develop additional standards, such as NSF Standard 58, *Reverse Osmosis Drinking Water Treatment Systems*, and NSF Standard 44, *Residential Cation Exchange Water Softeners*, which were adopted in the early to mid 1980s. Using the same consensus-based standards development process that is used today, the next two standards, NSF Standard 62, *Drinking Water Distillation Systems*, and NSF Standard 55, *Ultraviolet Microbiological Water Treatment Systems*, were officially adopted in 1989 and 1991, respectively.

The NSF Joint Committee on Drinking Water Treatment Units, which is comprised of a balanced number of public health regulators, industry members, and user groups, is the key driver of the development process. This group meets regularly to review the content of these standards and update as needed, considering the development of new technologies, regulatory requirements and the emergence of new contaminants in the world's drinking water supply.

At the same time NSF was meeting the needs of the domestic market with the development of new American National Standards, NSF was also expanding its global outreach. In 1996, NSF became a World Health Organization (WHO) Collaborating Center for Food and Water Safety, and Indoor Environment. This positioned NSF standards and products certified by NSF International at the forefront of the industry and around the world.

Continuing to develop needed standards for the drinking water industry, NSF, in 2004, developed the first consensus standard for shower filters, addressing the market need for demonstrating product performance and safety. This standard, NSF/ANSI 177: *Shower Filtration Systems: Aesthetic Effects*, was officially adopted in September 2004.

Today seven American National Standards and a microbiological testing protocol establish design, structural integrity, material safety and contaminant reduction requirements for a wide array of filtration and other residential drinking water treatment technologies. Consumers rely on NSF testing, certification, and standards (NSF/ANSI 42, 44, 53, 55, 58 and 177) to evaluate products available in the marketplace. A thorough evaluation of these products is critical as the interest in home water treatment products has grown tremendously in the last decade.

**NSF International** provides consumers with useful information on how to choose the proper drinking water treatment units, learn about contaminants in drinking water and protect available drinking water supplies.
www.nsf.org/consumer/newsroom/kit_water.asp?program=WaterTre

Accredited by ANSI in accordance with ISO/IEC Guide 65 requirements, NSF International has certified over 5000 DWTU products for over 170 companies. Today, NSF is the single largest testing and certification organization in the world for these products, and the organization responsible for maintaining the American National Standards to which these products are tested and certified.

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## New Certification Guide

To meet the needs of domestic and foreign companies that require additional information about the certification process, NSF has developed a new *Certification Guide for Drinking Water Treatment Systems and Components*. The guide provides a simple understanding of the overall process and saves manufacturers time and money in the certification process, a process if successfully completed allows manufactures to earn the right to bear the NSF Mark on their products and demonstrate their commitment to excellence.

"The guide provides a complete overview of the NSF certification process, from detailed steps required to achieve specific certifications to the many options available in achieving certification," said Tom Bruursema, general manager of NSF's DWTU Program, "The guide simplifies the process for treatment system and component manufacturers, and advises them on ways to get the most from their investment."

This new certification guide highlights NSF's role in managing many of the details that allow the process to move quickly and efficiently. In essence, it is a reference guide to help understand key steps in the program along with best practices based on 33 years of experience in testing drinking water treatment units. The guide contains sections on the process flow, frequently asked questions, standards requirements, listing options, a glossary and even a section that includes information on how to work with your suppliers.

Both certified and non-certified companies will find the guide to be a useful resource. NSF Certified companies familiar with the process can use this as a training and reference tool for those in their organization who may not be as familiar with the process. These clients may also find information they were not aware of.

Non-certified companies will find it very useful in understanding their many options before beginning the process, from options that allow them to streamline the process and save time to understanding the co-marketing opportunities they have once they achieve certification.

"This guide is a reflection of the experience we have developed in this area over many years, and the many ways in which we strive to deliver excellence in customer service and value in the NSF Mark," said Bruursema. "NSF has worked closely with several hundred clients and thousands of projects. This experience is captured in this reference guide that provides a clear understanding of the overall process to help clients make the process work to their advantage."

## A Look Ahead

The DWTU program continues to develop and is currently in the process of adding requirements for claims of Arsenic III reduction to NSF/ANSI 53. Arsenic III will complement the requirements for Arsenic V reduction, already in Standard 53. This will allow a more general claim for arsenic reduction when products can reduce both Arsenic III and V.

Perchlorate reduction is already addressed for reverse osmosis technologies under Standard 58, but it will soon be added to Standard 53, addressing anion exchange resins, a technology that is widely used for perchlorate reduction.

A new standard for supplemental mechanical reduction of bacteria and virus — NSF 244 — is also in the works, and we anticipate its adoption by the end of 2005. With new standards under development and new technologies in place, the months ahead will be an exciting time for NSF International's DWTU Program. ■

To obtain a free copy of the NSF Certification Guide, visit www.nsf.org or contact Cynthia Slusher at 1-800-NSF-MARK ext. 6858, 734-827-6858 or slusher@nsf.org.

# management systems

*in cooperation with Excel Partnership*

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## TRAINING SCHEDULE 2005-2006

www.ansi.org/education
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THE ANSI/EXCEL PARTNERSHIP MANAGEMENT SYSTEM TRAINING PROGRAM IS BASED UPON THE FOLLOWING STANDARDS

### ISO 14001:2004

Environmental management systems — Requirements with guidance for use

This standard specifies requirements for an environmental management system to enable an organization to develop and implement a policy and objectives which take into account legal requirements and other requirements to which the organization subscribes, and information about significant environmental aspects.

### ISO/IEC 17024:2003

Conformity assessment — General requirements for bodies operating certification of persons

This standard specifies requirements for a body certifying persons against specific requirements, including the development and maintenance of a certification scheme for personnel.

### ISO/IEC 17799:2005

Information technology — Security techniques — Code of practice for information security management

This standard establishes guidelines and general principles for initiating, implementing, maintaining, and improving information security management in an organization.

### ISO 13485:2003

Quality Management Systems — Medical Devices — System Requirements for Regulatory Purposes

Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices that consistently meet customer requirements and regulatory requirements applicable to medical devices.

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■ The Institute is a founder and member of the International Accreditation Forum (IAF) and serves as the official U.S. representative to the Inter-national Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). ANSI also participates in regional bodies such as the Pacific Accreditation Cooperation and the Inter-American Accreditation Cooperation.

■ The Institute represents the interests of its company, organization, government agency, institutional and international members through its office in New York City and its headquarters in Washington, D.C.