

Written Testimony of the American National Standards Institute**submitted to the****Committee on Energy and Commerce
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Statement of

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Introduction

The American National Standards Institute (ANSI) is a private non-profit organization whose mission is to enhance U.S. global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. ANSI's membership is comprised of businesses, professional societies and trade associations, standards developers, government agencies, and consumer and labor organizations. Through this network of members, the Institute represents the diverse interests of more than 125,000 companies and organizations and 3.5 million professionals worldwide.

ANSI is the official U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC), and is a U.S. representative to the International Accreditation Forum (IAF). A memorandum of agreement between ANSI and the Commerce Department's National Institute of Standards and Technology outlines a mutual understanding of the roles of each organization. This includes ANSI's recognition as the official U.S. member of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Since its formation, ANSI has been coordinating the development of standards-based solutions to support accident prevention and improve worker and consumer safety. Today, 10% of the approximately 10,000 approved American National Standards (ANS)

currently available address issues that help to protect the workforce, consumers and the general public.

Protecting the safety of consumers is of paramount importance to ANSI. It is a key element of the Institute's mission. ANSI works hard to ensure that there is consumer participation at all levels of the total federation – from the Board of Directors all the way through the policy and technical activities. Sometimes the participation is by consumers themselves, at other times representation is through a consumer organization. But there is always a need for more consumer involvement in standards and conformity assessment activities.

ANSI's processes give any interested stakeholder the opportunity to engage in the development of a standard or the approval of a compliance program. The Institute's procedures are written to assure that everyone, regardless of ANSI membership status, is able to participate in ANSI activities. If someone is interested in the subject covered by a standard, for example, that individual may participate by applying to become a member of the consensus body or submitting a contribution during public review and comment.

American National Standards (ANS) run the entire spectrum, from the very first ANS on pipe threads to work that is underway today to meet emerging needs in areas ranging from the service sectors to the aging populations and those with disabilities.

Standards are important for everyone because they influence the design, safety, manufacturing and marketing of many products worldwide. Standards are not only developed in response to injuries, hazards or other identified safety risks, but more often in a proactive manner to prevent injuries from known hazards. Some areas that come to mind where voluntary standards have especially made a difference in enhancing consumer safety include:

- the National Electric Code (ANSI/NFPA 70)
- Safety for Ground-Fault Circuit Interrupters (ANSI/UL 943)
- Safety for Gas Water Heaters (ANSI Z21.10.1)
- Safety of Corded Window Covering Products (ANSI/WMCA A100.1)
- Accessible and Usable Buildings and Facilities (ANSI/ICC A117.1)
- Standard Specification for Protective Headgear Used in Bicycling or Roller Skating (ASTM F1447-98 - Approved as an American National Standard)

Voluntary consensus standards and conformity assessment programs are driven by requirements for continuous quality improvement – especially as technology changes and evolves. ANSI and its hundreds of accredited standards developers and conformity assessment bodies are constantly reviewing and updating their systems to stay abreast of current and anticipated needs.

ANSI: Responding to national priorities

ANSI's actions are aligned with the *United States Standards Strategy* (USSS), an overarching framework document that calls for close cooperation between those who develop the nation's standards and conformity assessment programs and those who use them. The USSS (excerpted in Annex B of this testimony) calls for the consistent use by government of voluntary consensus standards. It also calls for the standardization community to show leadership in developing responses to emerging national priorities.

ANSI's standards panels are excellent examples of how the Institute is addressing the critical needs of the nation. Last fall, ANSI partnered with the Council of Better Business Bureaus to tackle identity theft prevention and ID management – an issue that has victimized more than 18 million Americans over the past two years.

The Institute has partnered with the 9-11 Commission and the DHS to address homeland security; and with the President's Office of Science and Technology Policy to help lead global nanotechnology initiatives. ANSI is working with HHS to implement the President's vision for every American to have a secure electronic health record within the next ten years. And the Institute's newest panel is working with a broad spectrum of agencies to support the commoditization of viable alternatives to fossil fuels and the diversification of the global energy infrastructure.

ANSI has a unique ability to bring together in a neutral forum representatives of industry, standards developing organizations, trade associations, professional and technical societies, government, labor and consumer groups.

ANSI believes that a strong public-private partnership is essential to renew consumer confidence in the safety of toys.

ANSI: Acting to improve toy safety

Earlier this year, the Toy Industry Association asked ANSI to help them design a program of testing, inspection and education that could be implemented across the industry's global supply chain.

ANSI responded with a three-point proposal:

First, we would help the toy industry analyze existing standards, technical regulations and conformity assessment programs.

Next, we would form technical working groups and coordinate their efforts to design testing and inspection methodology programs.

Finally, we would recommend steps to improve compliance activities throughout the toy industry's global supply chain.

TIA accepted this proposal and I, along with several ANSI colleagues, began working with the association and its members two months ago.

Almost immediately, we agreed that two criteria were necessary for success in the global marketplace: common product requirements and harmonized test methods.

This means the system must be efficient, consistent and sustainable. It must focus on improving how products are evaluated and assessing who is conducting the evaluations.

ANSI is focusing its facilitation efforts on the development and standardization of compliance procedures that can be used industry-wide and throughout the supply chain . . . in the past, these activities have been defined by individual manufacturers and retailers.

The Institute is also turning its attention to harmonization of the current practices used to evaluate the competence of the conformity assessment bodies that are evaluating compliance to requirements . . . regardless of whether those requirements are defined in a voluntary standard or a federal regulation.

For both the requirements and the organizations, we are working to harmonize these practices for use industry-wide.

Our solutions will draw from a toolbox of conformity assessment resources. Not just testing and inspection, but also systems auditing, accredited certification programs, and – of course – education and training. These tools are defined in the *National Conformity Assessment Principles of the United States*, excerpted in Annex C of this testimony.

The program we are developing will be committed to improving product safety, not just reducing the number of recalls. It will be sustainable and forward looking – to anticipate and prevent problems yet unknown. It will be considerate of all types of suppliers – regardless of size or location. And it will support the concept of “One standard . . . One test . . . Accepted everywhere.”

We are making great progress. Three working groups on Process Control, Testing and Reporting, and Design are meeting on a weekly basis. During bi-weekly teleconferences, they report to a Steering Committee comprised of the WG leaders, and representatives of consumers, the U.S. government, and staff from both ANSI and TIA.

Recommendations from the Working Groups and Steering Committee are targeted for broad review and approval – including a public comment period and a formal review and endorsement by TIA – before year-end.

Implementation is expected to begin in early 2008.

In the meantime, a broad spectrum of stakeholders is already taking decisive action to remove unsafe products from distribution. In particular, brands and retailers have shared

with ANSI that they have intensified their conformity assessment efforts to ensure the integrity of the import safety net.

There can be no guarantee unless all the stakeholders are working together. From producer to government regulator to retailer to parent – everyone has a role to play.

Building Consumer Confidence

Just as consumers have the right to expect that the toys they buy for their children will be safe, the same expectation should hold true for the toothpaste they use, the tires they travel on, and the food they eat.

The emergence of the global marketplace has created both consumer benefits and problems. If the public and private sectors work together, practicable solutions can be found to address the emerging issues of consumer health and safety in a global world.

Steps are already being taken. On September 26, ANSI hosted a conference focused on building consumer confidence in the products that enter into our marketplace. Presentations and discussion sessions engaged participants in identifying resources, initiatives, and applicable standards and compliance programs that will create a safer consumer environment.

A follow-up session was held during a joint meeting of the ANSI member forums in mid-October. The Institute is committed to a process that identifies necessary, practicable and immediate actions that can be taken to ensure that only safe products enter into the U.S. marketplace.

Conclusion

ANSI wants to help reassure consumers that the products they find on the shelves of their local retailer have been tested and found to be safe – regardless of country of origin. In order for the Institute to accomplish this objective:

- Standards and conformity assessment resources that are already in place must be used more efficiently.
- Government and industry need to work at a single purpose to identify gaps in the current systems of testing and inspection of products imported to the United States.
- New human and financial resources must be brought to bear to strengthen existing systems and fill any identified gaps.

In some cases, it may be necessary to elevate certain requirements from voluntary to mandatory status. If this happens, the U.S. must also be careful to remain compliant with our obligations in the WTO and existing bi-lateral trade agreements. Any efforts made to improve the safety of imported products should not cause other governments to reciprocate with trade barriers on American exports.

CPSC and the other regulatory bodies that lead oversight and regulation for consumer health and safety issues will not be able to handle the workload alone – even with additional financial resources. Private and public sector resources must be utilized in harmony if consumer confidence in imported goods is to be restored.

ANSI stands ready to coordinate that public/private partnership. The Institute knows how to leverage voluntary consensus standards and the related compliance systems to create solutions that engage and support all stakeholders.

ANSI looks forward to working in partnership with this committee, Congress, and other U.S. public sector representatives to stem the tide of unsafe products imported into our country.

Annex A**Background on the U.S. Standardization and Conformity Assessment System and the Role of the American National Standards Institute (ANSI)**

The U.S. private sector-led, voluntary standardization and conformity assessment system has been in existence for more than 100 years. Highly decentralized, the system is naturally partitioned into industrial sectors that are supported by numerous independent, private sector standards developing organizations (SDOs). Marketplace demand drives the system's activities, with standards and conformity assessment programs typically developed in response to specific concerns and needs expressed by industry, government, and consumers.

Since 1918, this system has been administered and coordinated by the American National Standards Institute (ANSI) with the cooperation of the private sector and the federal, state and local governments. ANSI does not develop standards or conformity assessment programs. Rather, it functions as a central clearinghouse and coordinating body for its member organizations. The Institute is a unique partnership of industry, professional, technical, trade, labor, academic and consumer organizations, as well as government agencies. These members of the ANSI federation actually develop standards and conformity assessment programs, contributing their time and expertise in order to make the system work.

ANSI ensures the integrity of the U.S. standards and conformity assessment system by:

1. establishing a set of due process-based "essential requirements" that SDOs may follow in order to manage the development of consensus standards and conformity assessment programs in a fair and open manner,
2. accrediting SDOs who adhere to these requirements,
3. approving candidate standards from ANSI-accredited SDOs as American National Standards (ANS), and
4. conducting regular audits of the ANS activities of ANSI-accredited SDOs to ensure ongoing compliance with ANSI's essential requirements.

ANSI has accredited hundreds of SDOs across a range of industry sectors. These industries include (but certainly are not limited to) telecommunications, medical devices, heavy equipment, fire protection, information technology, petroleum, banking, and household appliances. There are now approximately 10,000 ANSI-approved ANS that address topics as diverse as dimensions, ratings, terminology and symbols, test methods, interoperability criteria, product specifications, and performance and safety requirements. These standards development efforts serve the public interest and are being applied to new critical areas such as the environment, healthcare, homeland security, and nanotechnology.

The Institute's approval of a candidate standard or conformity assessment program as an ANS verifies that the principles of openness and due process have been followed and that a consensus of all interested parties has been reached. Due process requires that all proposed ANS be circulated to the public at large for comment, that an attempt be made to resolve all comments, and that there is a right of appeal. In addition, ANSI considers any evidence that a proposed ANS is contrary to the public interest, contains unfair provisions or is unsuitable for national use. This basic formula has been the hallmark of the ANS process for decades, and it has garnered worldwide respect and acceptance.

One of the best indicators of confidence in the U.S. voluntary consensus standardization and conformity assessment system (as exemplified by the ANS process) is Congress's 1996 passage of the National Technology Transfer and Advancement Act (NTTAA). This law (P.L. 104-113) requires federal agencies to use voluntary consensus standards and conformity assessment programs for regulatory purposes wherever feasible and to procure equipment and services in accordance with such standards. It also requires agencies to increase their participation in the development process and directs the Commerce Department's National Institute of Standards and Technology (NIST) to coordinate federal, state and local voluntary standards and related conformity assessment activities.

ANSI's success is measured by usage and acceptance. From the government's perspective, there are two examples of confidence in the ANSI process that are worth citing here:

The first is the *Consumer Product Safety Act*. This 1972 legislation mandates that if a voluntary standard exists, CPSC may issue a mandatory standard only when the voluntary standards will not eliminate or adequately reduce the risk of injury or death, or it is unlikely that there will be substantial compliance with the voluntary standard.

The second is Congress' 1996 approval of Public Law 104-113, also known as the *National Technology Transfer and Advancement Act* (NTTAA). This law requires federal agencies to increase their reliance upon and participation in the voluntary consensus standards and conformity assessment systems.

ANSI also promotes the international use of U.S. standards and conformity assessment programs. The Institute serves as the U.S. national body representative in two major, non-treaty international standards organizations: the International Organization for Standardization (ISO) and, through the United States National Committee (USNC), the International Electrotechnical Commission (IEC). ANSI and the USNC play a leadership role in ISO and IEC, respectively, on both policy and technical matters.

Part of ANSI's role as the U.S. member of ISO includes accrediting U.S. Technical Advisory Groups (U.S. TAGs) which develop and transmit, via ANSI, U.S. consensus positions on the activities and ballots of technical committees and subcommittees. Similarly, the USNC approves TAGs for IEC activities. In many instances, voluntary

standards and conformity assessment programs developed by U.S. SDOs are taken forward, through ANSI or the USNC, where they are approved in whole or in part by the ISO and/or IEC as International Standards. ANSI also encourages the adoption of international standards as national standards where they meet the needs of the user community.

In addition, ANSI advocates U.S. positions in various regional standards organizations and regularly meets with representatives from standards bodies in other nations. Thus, ANSI plays an important role in facilitating the development of global standards and related conformity assessment programs that support global commerce and which prevent regions from using local standards that favor local industries as trade barriers.

Conformity assessment is the term used to describe steps taken by both manufacturers and independent third-parties to determine fulfillment of standards requirements. ANSI's role in the conformity assessment arena includes accreditation of organizations that certify that products and personnel meet recognized standards. The ANSI-American Society for Quality National Accreditation Board (ANAB) serves as the U.S. accreditation body for management systems certification, primarily in areas such as quality (ISO 9000 family of standards) and/or the environment (ISO 14000 family of standards). ANSI also is involved in several international and regional organizations to promote multilateral recognition of conformity assessments across borders to preclude redundant and costly barriers to trade.

In summary, through its various roles and responsibilities, ANSI advances its mission to “enhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and safeguarding their integrity.”

Annex B**Excerpt from the *United States Standards Strategy*****PRINCIPLES**

It is well established in the community of nations that standards should meet societal and market needs and should not be developed to act as barriers to trade. In approving the World Trade Organization Technical Barriers to Trade Agreement, WTO members recognized that goal and established globally accepted principles as a framework to promote cooperation and discourage the use of standards as trade barriers. The U.S. standards and conformity assessment system is based on the following set of globally accepted principles for standards development.

- **Transparency**
Essential information regarding standardization and conformity assessment activities is accessible to all interested parties.
- **Openness**
Participation is open to all affected interests.
- **Impartiality**
No one interest dominates the process or is favored over another.
- **Effectiveness and relevance**
Standards and related conformity assessment programs are relevant and effectively respond to regulatory and market needs, as well as scientific and technological developments.
- **Consensus**
Decisions are reached through consensus among those affected.
- **Performance-based**
Standards are performance-based, specifying essential characteristics rather than detailed designs where possible.
- **Coherence**
The process encourages coherence to avoid overlapping and conflicting standards and conformity assessment programs.
- **Due Process**
Standards development accords with due process so that all views are considered and appeals are possible.
- **Technical Assistance**
Assistance is offered to developing countries in the formulation and application of standards and related conformity assessment programs.

In addition, U.S. interests strongly agree that the process should be:

- **Flexible**, allowing the use of different methodologies to meet the needs of different technology and product sectors;
- **Timely**, so that purely administrative matters do not slow down the work, but meet market expectations; and
- **Balanced** among competing interests.

Annex C**Excerpt from the *National Conformity Assessment Principles of the United States***

The *National Conformity Assessment Principles for the United States* document articulates the principles for U.S. conformity assessment activities that will allow consumers, buyers, sellers, regulators and other interested parties to have confidence in the processes of providing conformity assessment, while avoiding the creation of unnecessary barriers to trade.

Conformity assessment includes sampling and testing, inspection, supplier's declaration of conformity, certification, and management system assessment and registration. It also includes accreditation of the competence of those activities by a third party and recognition (usually by a government agency) of an accreditation program's capability.

While each of these activities is a distinct operation, they are closely interrelated. The choice of the most appropriate assessment processes, as well as the quality with which any one of them is performed, can have a significant effect on the confidence in and reliance that can be placed on the results of the entire conformity assessment.

The definitions included in the *National Conformity Assessment Principles* document are based on ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*. Some variances, noted in italics, occur where the term is not in ISO/IEC 17000 or has another specific meaning in the United States. Definitions are included in this document to preclude confusion and to make it more understandable. In different contexts, the same term can signify different types of activities.

- **Accreditation**
Third party attestation related to a conformity assessment body conveying a formal demonstration of its competence to carry out specific conformity assessment tasks. (*These tasks include sampling and testing, inspection, certification and registration.*)
- **Certification**
Third party attestation related to products, processes, or persons *that conveys assurance that specified requirements have been demonstrated.*
- **Conformity Assessment**
Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (*This may include any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.*)
- **First, Second and Third Party**
The first party is generally the person or organization that provides the object, such as the supplier. The second party is usually a person or

organization that has a user interest in the product, such as the customer. The third party is a person or body that is recognized as being independent of the person or organization that provides the object, as well as the user or customer of the object.

- **Inspection**

Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.

- **Recognition**

Procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include accreditation of testing laboratories and inspection, certification and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

- **Registration**

Third party attestation related to systems that convey assurance that specified requirements have been demonstrated. Such systems include those established for the management of product, process or service quality and environmental performance.

- **Sampling**

Provision of a sample of the object of conformity assessment according to a procedure.

- **Supplier's Declaration**

Procedure by which a first party or supplier conveys assurance that the object of conformity fulfills specified requirements.

- **Test**

Technical operation that consists of the determination of one or more characteristics of a given product, material, equipment, organism, person's qualification, physical phenomenon, process or service according to a specified technical procedure (test method).

- **Testing**

Determination of one or more characteristics of an object of conformity according to a *specified technical procedure (test method)*. Action of carrying out one or more tests.

- **Test Method**

Specified technical procedure for performing a test.