U.S. BEST PRACTICES

FOR STANDARDS AND CONFORMANCE

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INTRODUCTION

The development and application of standards, technical regulations, and conformity assessment, hereafter collectively referred to as "Standards and Conformance," has a tremendous impact on global trade and economic development, as well as on protection of the environment, health, and safety. When developed and applied in an effective manner, standards and conformance can bring tremendous economic and societal benefits. However, intentional or unintentional misapplication of standards and conformance in the process of formulating regulations can create significant negative consequences for industry and consumers.

The American National Standards Institute (ANSI) has prepared the following summary of various U.S. best practices in the area of standards and conformance. The intended purpose of this document is to create increased recognition of the importance and impact of standards and conformance and to encourage the exchange of information on national best practices internationally to maximize their benefits.

Please visit www.StandardsPortal.org for additional information provided by ANSI on the U.S. standards and conformity assessment systems, as well as information on the standards, conformity assessment, and technical regulations used in the U.S. As you read through this document, you may also find useful this link to a glossary of standards and conformance terms found on StandardsPortal.

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TRANSPARENCY

Transparency is the process whereby the creation, terms, and application of technical regulations, standards, and conformity assessment procedures are made public, and opportunities are provided for the public to comment on proposed technical regulations, standards, and conformity assessment procedures.

Transparency in the development of standards and conformance procedures provides several benefits – both to industry and to society. First, transparency helps to assure that the best and most effective standards and regulations are leveraged in the protection of the environment, health, and safety. When input from all affected stakeholders – including domestic and foreign companies, government representatives, consumers, and other experts – are heard and considered, the collective expertise of each of these groups can be leveraged to create the best solution. Further, stakeholders benefit tremendously from "early warning" on standards and regulatory developments, are able to contribute their experiences and perspectives into the process, and are better able to make necessary adjustments to business processes in order to assure compliance.

Transparency in Technical Regulations

Transparency in the creation of technical regulations and conformity assessment procedures has been addressed by the World Trade Organization (WTO). The WTO Technical Barriers to Trade (WTO/TBT) Agreement includes language whereby WTO members have agreed to notify the WTO Secretariat of any proposed new technical regulations or conformity assessment procedures, or changes to technical regulations or conformity assessment procedures that are not based on relevant international standards and that may significantly affect trade. Beyond these WTO requirements, many countries take additional measures to ensure transparency, including the publication of all proposed new or changed regulations in a national gazette, and maintaining a centralized repository of all national regulations.

U.S. Approach

The U.S. *Administrative Procedures Act* (APA)[1] calls all U.S. federal regulators to operate in a transparent manner. The main provisions of the APA:

- require agencies to keep the public informed of their organization, procedures, and rules;
- require agencies to provide for public participation in the rulemaking process;
- require agencies to establish uniform standards for the conduct of formal rulemaking and adjudication; and
- defines the scope of judicial review.

Through a process outlined by the APA and coordinated by the Office of Management and Budget (OMB), U.S. regulators provide information about planned regulatory developments in the U.S. *Unified Agenda*[2] (also known as the *Semiannual Regulatory Agenda*), which is published twice a year and summarizes the rules and regulations that each Federal agency expects to issue during the next year. Regulators also provide information about proposed rules and regulations and their final versions in the U.S. *Federal Register*[3] (a daily publication of the U.S. government), gather comments from all interested stakeholders (foreign and domestic) and address these comments, and publish all federal regulations in the U.S. *Code of Federal Regulations* (CFR)[4]. Each of these publications is offered free of charge online to domestic and international stakeholders via the U.S. Government Printing Office (GPO) website: www.gpo.gov/fdsys/.

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[1] United States Code, Title 5, Chapter 5 (1946), http://www.archives.gov/federal-register/laws/administrative-procedure/

[2] Regulatory Information Service Center (RISC), http://www.reginfo.gov/public/do/eAgendaMain

[3] Office of the Federal Register National Archives and Records Administration (NARA), http://www.federalregister.gov/

[4] Office of the Federal Register National Archives and Records Administration (NARA), http://www.federalregister.gov/

Transparency for Voluntary Consensus Standards

The WTO/TBT Code of Good Practice for the Preparation, Adoption and Application of Standards[5] is a mandatory requirement for all WTO Members' central government standardizing bodies, and a voluntary agreement for other standards organizations. Standardization organizations that have accepted the Code are required to notify this fact to the ISO/IEC Information Centre. The Code of Good Practice calls for, among other requirements, transparency in the preparation, notification, and adoption of national standards, including publishing a work program for the development of national standards, providing copies of draft standards to interested WTO members upon request, and allowing a minimum 60-day comment period on draft standards before they are adopted. Further, the WTO/TBT Committee identifies transparency as one of the key criteria for the development of international standards[6].

U.S. Approach

The *United States Standards Strategy* (USSS)[7] promotes transparency in the development of all standards used in the U.S., including American National Standards (ANS)[8]. The ANS approval process has several specific requirements for transparency, including the publication of an organization's intent to develop an ANS, notification and invitation for public comment of the final DRAFT ANS, consideration of comments from all stakeholders, and maintenance of written rules and operating procedures for organizations developing ANS. All announcements and updates relating to ANS are made public via ANSI *Standards Action*, a biweekly publication produced by ANSI. *Standards Action* is available at no charge to all domestic and international stakeholders via the ANSI website: www.ansi.org/standardsaction. In addition to ANS, many other standards developed by accredited U.S.-based standards development organizations are developed in an open and transparent manner, according to WTO definitions.

USE OF RELEVANT INTERNATIONAL STANDARDS IN REGULATIONS WHEREVER APPROPRIATE

Basing regulations on relevant international standards wherever appropriate brings benefits both to regulators as well as to industry and consumers. This practice significantly reduces costs for regulators by not using government resources that would otherwise be needed to develop government-unique technical requirements. This practice also provides interested parties and stakeholders with a voice in the development of regulations, and encourages market-relevant regulations which effectively address threats to the environment, health, and safety without unnecessary burdens. Use of relevant international standards as the basis of regulation brings the additional benefit of facilitating increased compatibility of regulations across national borders, lowering transaction costs for trade.

The WTO/TBT encourages the use of relevant international standards as the basis of technical regulations. However, the WTO/TBT Agreement does not designate particular standards developing organizations or specific standards as "international." Instead, the WTO/TBT Committee lays out the following criteria for the development of international standards:

- Transparency
- Openness
- Impartiality and Consensus
- Effectiveness and Relevance
- Coherence
- Development Dimension

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[5] World Trade Organization (1994), "Agreement on Technical Barriers to Trade," Annex 3, http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

[6] World Trade Organization Committee on Technical Barriers to Trade (2000), "Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade," Annex 4 (G/TBT/9), http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

[7] United States Standards Strategy Committee (2010), http://www.ansi.org/usss

[8] American National Standards Institue (2009), "Value of the ANS Designation," http://www.ansi.org/ansvalue

U.S. Approach

In the U.S., two documents provide the framework for the government's use of voluntary consensus standards, the *National Technology Transfer and Advancement Act* (NTTAA)[9] and the White House Office of Management and Budget (OMB) *Circular A-119*[10]. The NTTAA requires U.S. regulators and procurement agencies to use private sector standards wherever possible. Specifically, the NTTAA:

- requires federal agencies to use technical standards developed or adopted by voluntary consensus standards bodies for regulation or procurement if they are available, in lieu of creating proprietary, non-consensus standards;
- encourages federal agency representatives to consult with, and participate in private sector standards developing activities of voluntary, private sector, consensus standards bodies; and
- requires agencies to annually report their use of government-unique standards and provide an explanation to Congress with the reasons for doing so.

OMB Circular A-119 lays out the federal policy and guidelines on how agencies can implement the NTTAA and benefit from the expertise of the private sector while ensuring the creation of standards that meet their needs. Each federal department or agency ultimately has the responsibility to determine if a voluntary consensus standard is appropriate for any given regulation. The federal policy aims to reduce reliance on government-unique standards, ensuring that whenever possible, and not otherwise prohibited by law, regulations are based on standards already in use by industry – reducing costs and burden both for regulators and for industry.

CASE STUDY: Use of Voluntary Standards in Regulations

Consumer Product Safety Commission (CPSC)

The U.S. Consumer Product Safety Commission (CPSC) works with standards developers, consumers, industry, and other interested parties to develop safety standards for a wide range of consumer products. The *Consumer Product Safety Act* (CPSA)[11] mandates that if a voluntary standard exists, by law, 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. Over the past twenty years, CPSC has worked with industry and others to develop more than 500 voluntary standards.

When mandatory safety standards arise, CPSC generally develops performance standards rather than design standards to give manufacturers the most flexibility in meeting requirements. The Commission may initiate rulemaking based on petitions from outside parties or based on internal staff work. Input is sought from all interested parties, including consumers, industry and other government agencies.

CPSC staff have repeatedly found that voluntary efforts are often faster and less costly to implement than mandatory efforts. Some of the Commission's greatest success stories are in the voluntary standards area.

CPSC and the Gas Appliance Manufacturers Association, now part of the Air-Conditioning Heating and Refrigeration Institute (AHRI), partnered on improvements in gas water heater technology to help prevent incidents that can take the lives of or severely injure children and adults across the country each year. Gas water heater ignition of flammable vapors

[9] U.S. Public Law 104-113 (1995), http://standards.gov/standards_gov/nttaa.cfm

[10] White House Office of Management and Budget (1998), http://www.whitehouse.gov/omb/circulars/a119/a119.html

[11] U.S. Public Law 92-573; 86 Stat. 1207 (1972), http://www.cpsc.gov/businfo/cpsa.html

is involved in nearly 800 residential fires, resulting in an average of five deaths and 130 injuries annually, according to CPSC estimates. The fires typically occur when consumers use flammable liquids, usually gasoline, for cleaning purposes, or when a flammable liquid leaks or is spilled near the water heater. When the vapors come in contact with the appliance's burner or pilot light, the vapors ignite, causing a severe flashback fire.

A voluntary standard developed by industry, in cooperation with CPSC, calls for conventional tank-type gas water heaters manufactured after July 1, 2003, to be equipped with a safety technology, often referred to as a flame arrestor. This safety feature prevents flashback fires by trapping and burning dangerous gas vapors inside the heater while also preventing ignition of the vapors in the room.

The American National Standard ANSI Z21.10.1a was approved in two parts: The first requirement, for flammable vapors-ignition-resistance, was approved in February 2000; the second requirement, for the heater to be resistant to lint, dust and oil accumulation, was approved in November 2002. The final standard, incorporating both parts, became effective on July 1, 2003. All 30, 40, and 50-gallon gas storage type water heaters manufactured after this date are expected to comply with the national safety standard.

The introduction of residential gas storage water heaters that meet this safety standard is an example of the CPSC and manufacturers working in harmony, using the voluntary standards system, to improve the safety and efficiency of a product.

USE OF PRIVATE-SECTOR CONFORMITY ASSESSMENT TO VERIFY COMPLIANCE WITH REGULATIONS

Using private-sector conformity assessment can enable government agencies to effectively verify conformance to regulations and reduce unnecessary burdens to industry. Regulators consider the risk of non-compliance with regulations as a factor when mandating conformity assessment procedures. Leveraging attestations, tests, inspections, or certifications provided by qualified private-sector organizations can help reduce the costs and increase the impact of regulatory programs. For industry, this practice also brings significant benefits by allowing a choice of multiple organizations whose services can be used to verify compliance. Having multiple private-sector options helps to avoid costly bottlenecks which can increase the time required to bring products to market and introduce unpredictability into the business cycle. Further, trade is facilitated if the results of private sector conformity assessment organizations can be recognized in multiple countries, by reducing or eliminating the need for duplicative tests or certifications.

U.S. Approach

The U.S. *National Technology Transfer and Advancement Act* (NTTAA - Section 12b) encourages government agencies to coordinate their conformity assessment activities with the private sector, so as to eliminate unnecessary duplication and complexity in conformity assessment requirements. The *National Conformity Assessment Principles*[12] document further describes U.S. conformity assessment activities based on the language used in the WTO/TBT Agreement. Increasingly, many regulators are choosing to utilize private sector resources – recognizing that this approach can help them achieve regulatory objectives in a more effective and less costly way.

As with using voluntary consensus standards, each U.S. government agency has the autonomy to decide whether and how to use private sector conformity assessment. Individual agency approaches vary based on several factors, including the products being regulated, the consequences of products not meeting the regulations, the mandates of the agency, among other factors. Approaches may include acceptance of Suppliers' Declaration of Conformity (SDoC) or acceptance of testing, inspection, or certification results produced by qualified or accredited private sector conformity assessment bodies.

[12] American National Standards Institute (2007), http://www.ansi.org/ncap

CASE STUDY: Reliance on Quality Private Sector Conformity Assessment
Federal Communications Commission (FCC)

The Federal Communications Commission (FCC) is charged with regulating interstate and international communications by radio, television, wire, satellite, and cable. In order to certify that new telecommunications equipment complies with its requirements, the FCC has four equipment approval programs, all of which involve the use of the private sector to some degree. The type of approval required is specified in the regulation pertaining to a particular piece of equipment. The four equipment approval programs are:

- Verification – Self-approval by the manufacturer
- Declaration of Conformity (DoC) – Self-approval using an accredited laboratory
- Certification – Approval by the FCC or a Telecommunications Certification Body (TCB)
- Telecommunications Certification Body (TCB) – The FCC may designate a TCB to approve equipment under the Certification procedure

Most products require either DoC or Certification, and for some products the manufacturer is given a choice between the two. A TCB is an independent third-party certification body that has been accredited according to relevant ISO/IEC guidelines and is designated by the FCC to approve equipment subject to certification. Laboratories outside of the United States can be recognized as TCBs if they are included under the terms of a Mutual Recognition Agreement (MRA), or if they have been accredited by an organization recognized by the FCC.

In June 2000, the FCC recognized ANSI as a qualified accreditor of product certifiers that approve various telecommunications equipment. By utilizing the private sector for a large portion of its conformity assessment needs, the FCC has been able to streamline its approval process and make more funds available for market surveillance and other key functions. Manufacturers benefit from the increased choice in demonstrating compliance as well as faster product approval.

NON-REGULATORY APPROACHES FOR THE PROTECTION OF THE ENVIRONMENT, HEALTH, AND SAFETY (EHS)

The common objectives of protecting the environment, health, and safety (EHS) are of critical importance and are recognized by various international organizations. While regulation is a very important tool for the protection of EHS, there are also non-regulatory approaches which, in many cases, can help to accomplish these objectives more effectively and efficiently by leveraging the resources of both the public and private sectors. Examples of non-regulatory forces that may be effective in the protection of EHS include incentive programs organized by government agencies, or voluntary standards and conformity assessment that become "market acceptance" requirements. These requirements include the standards or conformity assessment activities which are not enforced by a government but become de facto requirements due to pressure from consumers, retailers, insurers, or other private-sector stakeholders. Non-regulatory approaches can be beneficial either as a complement or an alternative to governmental regulations.

U.S. Approach

Under the U.S. *Administrative Procedures Act* (APA)[13], regulators conduct a risk assessment and impact analysis before issuing new or amended mandatory technical regulations. These practices help to uncover alternatives or complements to regulations that help protect the environment, health, and safety. In the U.S., various non-regulatory factors exist that create incentives for industry to work toward the protection of EHS, and support non-regulatory approaches. First, the U.S. legal system (both tort law and contract law) creates a strong incentive for manufacturers to voluntarily follow standards, and to demonstrate this through private-sector conformity assessment.

For example, under U.S. tort law, consumers and other affected parties who suffer injury, loss of productivity, or other legal damages have the right to bring lawsuits against a company, organization, or individual that is legally responsible, or "liable," for those injuries. This creates a tremendous incentive for manufacturers and companies to ensure that their products meet relevant voluntary standards, and that they do not cause harm to the environment, or to human health and safety. Second, U.S. companies invest heavily in brand-name recognition and recognize that meeting and exceeding environment, health, safety, and quality standards is a key mechanism to maintain a positive brand image. If it becomes publicly known that the company's products or services are faulty or, worse, harmful to consumers, sales will decrease and the company's brand will suffer. Related to brand-name recognition is the free and open press in the U.S., which motivates companies to maintain compliance with standards to avoid negative coverage of product failures in the press. Third, retailers in the U.S. often require that products meet or exceed standards for environment, health, safety, and quality before they agree to sell the products in their stores.

Finally, the standards and conformance infrastructure in the U.S. provides diverse and strong support to help build on the private-sector incentive measures described above. The system encourages manufacturers to follow the standards set by the market through measures such as post-market surveillance and private-sector conformity assessment.

[13] United States Code, Title 5, Chapter 5 (1946), http://www.archives.gov/federal-register/laws/administrative-procedure/

CASE STUDY: Non-Regulatory Approaches

ENERGY STAR

ENERGY STAR is a joint program of the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Energy (DOE) designed to help reduce energy costs and protect the environment through energy efficient products and practices.

In 1992, the EPA introduced ENERGY STAR as a voluntary labeling program designed to identify and promote energy-efficient products to reduce greenhouse gas emissions. Computers and monitors were the first labeled products. Through 1995, EPA expanded the label to additional office equipment products and residential heating and cooling equipment. In 1996, EPA partnered with DOE for particular product categories. The ENERGY STAR label is now on major appliances, office equipment, lighting, home electronics, and more. EPA has also extended the label to cover new homes and commercial and industrial buildings.

Through its partnerships with more than 12,000 private- and public-sector organizations, ENERGY STAR delivers the technical information and tools that organizations and consumers need to choose energy-efficient solutions and best management practices. ENERGY STAR has successfully delivered energy and cost savings across the country, saving businesses, organizations, and consumers about $16 billion in 2007 alone. Over the past decade, ENERGY STAR has been a driving force behind the more widespread use of such technological innovations as efficient fluorescent lighting, power management systems for office equipment, and low-standby energy use.

In 2010, ANSI launched an accreditation program for certification bodies that seek recognition from the EPA to certify products under the ENERGY STAR program. The EPA relies upon ANSI for independent, third-party accreditation of product certification bodies that evaluate and certify the activities of energy-efficient product manufacturers.

With the recent concern over rising energy prices, ENERGY STAR provides a trustworthy label on over 50 product categories (and thousands of models) that deliver the same or better performance as comparable models while using less energy and saving money. ENERGY STAR also provides easy-to-use home and building assessment tools so that homeowners and building managers can start down the path to greater efficiency and cost savings.

CONCLUSION

The concepts outlined above provide examples of how internationally recognized principles for developing standards and conformity assessment procedures are applied in the United States:

- Transparency
- Use of Relevant International Standards in Regulations Wherever Appropriate
- Use of Private-Sector Conformity Assessment to Verify Compliance with Regulations
- Non-Regulatory Approaches for the Protection of the Environment, Health, and Safety

These practices can maximize social welfare in two ways. First, they can help regulators better leverage limited government resources to more effectively meet their mandates for the protection of environment, health, and safety. Second, they can promote economic development by reducing barriers to trade and fostering investment both domestically and internationally.