



Key Issues Impacting Global Standardization and Conformance: Today and Tomorrow

White Paper

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Introduction

The U.S. Department of Commerce reports that standards and conformity assessment impact more than 80% of global commodity trade. From design and manufacturing to distribution and marketing, all traded products and services are affected at some point in the supply chain by standardization.

Today's business climate is global in nature and scope, and the U.S. standardization system has evolved rapidly to keep pace with the demands of the marketplace. In this white paper, the American National Standards Institute (ANSI) offers some perspectives from the U.S. private sector on key issues affecting global standards and conformance – today and tomorrow.

About ANSI

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. Its membership is comprised of businesses, professional societies and trade associations, standards developers, government agencies, and consumer and labor organizations. The Institute represents the diverse interests of more than 125,000 companies and organizations and 3.5 million professionals worldwide. The Institute 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).

Key Issues for the Current System

In the first part of this paper, ANSI presents key issues related to current international standards and conformity assessment activities, which affect the ability of U.S. industry to conduct global trade effectively and efficiently.

1.1 Dynamic nature of global trade impacts domestic industry and economy

Recent decades have seen tremendous growth of the world economy, which has been driven in part by brisk international trade. Trade barrier reduction and trade expansion over the last 50 years have helped to make the last half century the period of the most rapid, sustained growth ever recorded. Increased trade has

benefited the United States by encouraging investment and boosting economic growth; supporting more productive, higher paying jobs; and increasing the standard of living for Americans.

According to World Bank data, more than 95% of the world's consumers live outside of the United States.¹ U.S. firms that do business abroad are exposed to – and typically adopt – internationally accepted standards and conformity assessment practices, which allow them to effectively compete in the global marketplace. Trade has also been shown to help mitigate domestic economic downturns. In general, industries with higher export shares experience larger reductions in the volatility of their total shipments.



One in every five American factory workers owes his or her job to exports

The United States is the world's largest manufacturer, producing almost 18 percent of manufactured products.² One in every five American factory workers owes his or her job to exports, which have long been a source of strength in the U.S. economy. U.S. exports of manufactured goods alone support about 6.8 million jobs. Exports contribute, on average, an additional 18 percent to workers' earnings in the U.S. manufacturing sector. And imports also help fuel domestic production and exports, which further drives economic integration and the globalization of production. From 1998 to 2008, the import content of U.S. exports increased from 9.5 to 13.5 percent.

Rapidly expanding economies around the world continue to provide a wealth of opportunity for trade and investment. Average growth rates in India, China, and Brazil are significantly higher than those in the United States and its more mature trading partners, such as Canada, Mexico, and the European Union. But the issue is not just that emerging economies are growing – it is how they are growing. Innovation's pivotal role in national wealth creation, and a rising standard of living, has prompted many nations to adopt innovation-based growth strategies similar to that of the United States. Governments around the world are boosting public spending on research and development (R&D), building research parks and centers of innovation, and ramping up education efforts to produce the next generation of scientists and engineers.

Another fundamental shift has been in international trade, as multinational companies have evolved into truly global enterprises. Twenty years ago, trade was mostly about goods that moved physically across national borders. But today, the geographic footprint of supply chains is global. For example, U.S. companies increasingly develop products and services and serve customers through foreign affiliates and foreign business ventures. In fact, sales from foreign affiliates of U.S. companies are more than three times greater than U.S. exports of goods and services.³

¹ World Bank, World Development Indicators: <http://data.worldbank.org/data-catalog/world-development-indicators>.

² According to data from the United Nations Conference on Trade and Development (UNCTAD) database (UNCTADStat) http://unctadstat.unctad.org/ReportFolders/reportFolders.aspx?sCS_referer=&sCS_ChosenLang=en.

³ For more information, see <http://www.nam.org/Issues/Official-Policy-Positions/International-Economic-Affairs-Policy/IEAP-02-International-Investment-and-Finance-Policy.aspx>.

Around the world, there is continuing convergence in national interests that are affected by global economic conditions. Interdependence among nations offers a golden opportunity to move beyond static engagement to dynamic global strategic partnerships that will spur economic growth, development, and job creation. Agreed-upon standards and conformance practices that facilitate trade provide an important underpinning for such partnerships.

1.2 Standards from varying sources are used globally

Standards are technical and strategic documents that are needed by industry and other stakeholders in the private and public sector. For standards to address the needs articulated by their users, their content needs to be sector specific, practical, and market based. The process used to create standards has to be accepted and recognized by standards users, and it must follow principles that incorporate openness, transparency, and inclusiveness of all interested stakeholders.

No one organization or standards developer has a monopoly on knowledge or collective wisdom to translate the needs of standards users into standards. It therefore follows that a wide range of standards developing organizations, consortia, and other groups can and do develop standards that will be implemented. Ultimately, users determine and choose the standards that meet their needs, no matter which group published them or where the standard originated. This can result in duplicative and conflicting standards; however, sectors that find it especially important to achieve a single set of standards that is accepted worldwide have focused their international standards development activities in one or two standards organization(s) that support their common vision.

1.3 Standards and conformity assessment

Harmonized standards facilitate cost effective and expedient conformity assessment for products, services, and personnel. These efficiencies enable manufacturers to export to multiple markets with minimal product changes and reduced needs for duplicative testing for compliance. A product with a single standard offers significant cost reduction to the industry.

However, in reality, users of the same standard from different markets can demand different conformity assessment activities as a demonstration that the requirements in the standard are fulfilled. The broader the use of the standard, the greater the number of users and, potentially, the higher the variability in the types of conformity assessment activities demanded to accommodate national and marketplace differences.

What Are Standards?

Behind the scenes, standards make everyday life work. They establish the size, shape, or capacity of a product or system. They specify performance of products, processes, or personnel. They also define terms so that there is no misunderstanding among those using the standard. With standards in place, our homes, workplaces, and daily lives are safer and more convenient.

What Is Conformity Assessment?

Conformity assessment can verify whether a particular product meets a given level of quality or safety. And it can provide information about the product's characteristics, the consistency of those characteristics, and the performance of the product. Conformance activities include accreditation, certification, inspection, registration, supplier's declaration of conformity, and testing.

Key Issues for the Future

In the second part of this paper, ANSI seeks to present, from a U.S. industry perspective, some thoughts on key issues for a more effective international standardization system.

2.1 Varying uses for global standards

One standard – one test – accepted everywhere . . . while this is the wish of many, the reality of today’s global marketplace does not completely reach that lofty goal. This may be the case because standards are called upon to fulfill myriad purposes, or perhaps because that vision is a bit unrealistic given the complexity of the world economy. Different industries and economies have different entrenched realities related to risk and infrastructure, and may hold different opinions on what level of standardization is acceptable and desired to meet their needs.



One standard – one test – accepted everywhere: an important goal, but not yet an unqualified marketplace reality

Standards are tools to facilitate manufacturing, production, distribution, installation, systems operations, and interoperability. Standards also help to meet requirements for health, safety, and security, and meet the quality expectations of consumers and other users.

Some standards are voluntary and offer alternative solutions to a problem. Other standards, though voluntarily conceived and developed, are adopted or recognized by governments as a means of demonstrating compliance with laws and regulations. While alternate means to demonstrate compliance may be permitted, companies typically must provide documentation to support deviating in some way from the requirements in a recognized standard and evidence that their product otherwise meets or exceeds the standard. This can add significantly to the expense and amount of time it takes for product clearance. Somewhere between

these two extremes are standards that are not part of any regulatory scheme, but are a major factor in customer acceptance of a product. For globally traded goods, there is a direct relationship between where standards fall on the voluntary scale and the level of support by the affected industry for a single system of international standards.

International standards should be the result of broad agreement and collaboration among all interested parties, including private- and public-sector entities, around the world. This is made possible under the procedures and auspices of organizations that respect the principles of openness and transparency, and that have the expertise needed to implement those procedures and shepherd consensus. It is also important that organizations developing international standards have a mechanism for editing, publishing, and maintaining the documents efficiently.

2.2 Globally relevant standards

The World Trade Organization (WTO) Committee on Technical Barriers to Trade (TBT) has issued document G/TBT/1/Rev.10,⁴ which has a section entitled, “Effectiveness and Relevance of the Decision of the Committee on Principles for the Development of International Standards, Guides, and Recommendations.” According to the text of this WTO document, a globally relevant standard should:



- Effectively respond to regulatory and market needs (in the global marketplace);
- Respond to scientific and technical developments in various countries;
- Not distort markets;
- Have no adverse effects on fair competition;
- Not stifle innovation and technological development;
- Not give preference to characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions; and
- Be performance based as opposed to design prescriptive.

In addition, in the event that a globally relevant standard includes an essential patent claim, the standard should be developed under a patent policy that seeks to balance the rights of the patent holder; the interests of competing manufacturers seeking to implement the standard; the consensus of the technical experts from different stakeholder groups on the desired content of the standard; the concerns, resources, and policies of the standards developing organization and the sector it represents; the impact on consumer welfare; and the need to avoid unnecessary strictures that would discourage participation in the standards development process.⁵

The development of international standards in all organizations and fora should embrace these criteria. The development and adoption of an international standard that fails to meet these requirements is open to being challenged as creating a barrier to free trade. Developing an international standard that projects one solution accommodating one market’s needs but not others does not represent a truly international standard, nor will it encourage other markets to evolve and coalesce to that one solution.

⁴ http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm.

⁵ For more information on specific ANSI policies relative to IPR and standards, see <http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/Critical%20Issues/ANSI%20GSC-15%20Contribution%208-12-10.pdf>.

2.3 Effective engagement of relevant stakeholders

The range of relevant stakeholders for an international standards development project will depend on the subject of the standard. Stakeholder categories should be identified at the outset of each project.

Whether international standards development participation is based on a national delegation model, an organizational model, or an individual expert model:

- It is important to engage all relevant stakeholder categories in the standards development process, as this multi-stakeholder approach results in much greater acceptance, adoption, and use of the standard.
- An adequate balance must be achieved between direct users/implementers of the standards (direct stakeholders) and others that may be impacted by the use/implementation of the standards (indirect stakeholders).
- Guidance should be provided regarding the qualifications or desired capabilities of delegates and experts for the specific standards so that, to the degree possible, those parties naming their experts and representatives ensure that the right expertise is at the table. This does not imply that participation should be conditional upon membership in any organization, nor unreasonably restricted for any reason.



A broad and balanced range of stakeholders should be at the standards development table

Increasingly, new standards development challenges (e.g., smart grid, healthcare informatics, energy efficiency, nanotechnology, cybersecurity, etc.) require significant cross-sectoral collaboration, and new models of standards development must evolve to support such collaboration. The challenge for today and into the future is to bring diverse parties from various sectors and organizations together to collaborate and develop the needed deliverables.

2.4 Efficient use of participant resources

An organization or body that develops international standards should be dedicated to the principle of optimizing the cost effectiveness of standardization. Given business and financial dynamics in the global community, the reduction of unnecessary and duplicative expenses to participants, experts, and users of standards – as well as standards developing organizations – is of paramount importance.

Optimizing cost effectiveness will also lead to a body of international standards having greater international acceptance through the focused participation of expert resources.

Especially in relation to participation by delegates and experts, this cost effectiveness can be advanced by:

- Avoiding duplicative efforts and forum shopping via application of resources by stakeholders in the spirit of, and commitment by standards developing organizations to, the WTO/TBT principle of coherence for international standards, as articulated in document G/TBT/1/Rev.10.⁶
- Recognition and respect among developers of globally applicable standards that many organizations have a stake in providing international standards that meet industry needs. A more harmonious and cost-effective international standardization vision will be achieved by establishing worthwhile partnerships, and by standards developers that recognize and defer to the relevant work of others.
- Advancements and optimal implementation of information technology solutions make standards development processes more efficient, support collaborative authoring, and reduce the need for time-consuming and costly physical meetings.



Funding for standards development can and should come from multiple sources within government and industry

Given the diversity of organizations which develop standards for the global market and the differing needs of their stakeholders, it remains in the stakeholders' interests to support a pluralistic approach to the ways in which standardization is funded. Most private-sector standards developing organizations are unable to cover their costs through the sale of documents alone. Some standardization systems are established specifically to meet public-sector as well as private-sector needs and as such depend on all the users of the system to provide necessary funding. Even where a standards system is geared mainly to meeting industry and other private-sector needs, the public sector often utilizes these systems for technical solutions that may be adopted or otherwise used for regulation or policy.

Overall, the vitality and longevity of the system and of research that supports standards depends on funding from both the public and private sectors. As users of standards, industry and governments alike are responsible for supporting standards development through the participation of experts, sharing in the administrative costs associated with standards development through dues and other mechanisms, and the sharing of information useful in defining and setting standards requirements.

Copyrights and trademarks are critical to standards developers, both in terms of maintaining the credibility of their standards and defraying the costs associated with standards development. Governments and corporations worldwide are responsible for advancing and respecting policies that ensure the continued ownership and control of copyrights and trademarks of standards developers in all situations. This is especially true when voluntary standards are incorporated into laws and regulations, or adopted into corporate policies and operations.

⁶ http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm.

2.5 Value and justification of national deviations

Whether standards and conformity assessment activities are national, regional, or international, minimizing duplicative or conflicting requirements reduces cost and time to market, which benefits industry and consumers alike.

National and regional deviations can be especially problematic for regulated industries doing business in a global marketplace. While there are many standards that are truly voluntary, most regulatory bodies around the world utilize private-sector standards in one way or another, making some standards less voluntary than others. In broad terms, standards help to fill the gaps (if any) between what is stated in a regulation and what benchmarks – in detailed technical terms – regulators require industry to meet in order to demonstrate compliance with the regulation.

The relationship between standards and regulations varies by country or region, and by industry sector and regulatory agency within each country or region.⁷ Despite these differences, there is one common thread: if standards are accepted by regulators either formally or informally to demonstrate regulatory compliance, then manufacturers must commit significant resources not only to keep track of how regulations vary from one place to the other, but also to understand which standards requirements are identical and which are different, and to keep all of this information current and up-to-date.

Knowledge of which standards must be met in each intended market is essential for industry to decide how best to design a product for acceptance in the greatest number of places. As burdensome as the cost may be to track multiple standards, it pales in comparison to the cost of designing and testing different products for different markets. Therefore, for industry sectors that use international standards as a way of leveling the global playing field, there are strong financial incentives to eliminate or minimize national deviations as much as possible.

However, there are valid reasons for occasionally deviating from international norms, including national codes or regulations, extreme climatic conditions, infrastructural differences, or strongly entrenched local practices that could lead to serious injury if abruptly changed.

For industry sectors that are interested in achieving “one standard – one test – accepted everywhere,” the first step is to ensure effective participation at the international level so that there are as few points of contention as possible between the international consensus standard and its national adoption.



Manufacturers can spend a lot of time and money trying to manage the full spectrum of standards, conformance, and regulatory requirements across all markets

⁷ A detailed review of these differences is beyond the scope of this paper. For an overview, see: “Using and Referencing ISO and IEC Standards for Technical Regulations.” ISO/IEC, Geneva. September 2007 (http://www.iso.org/iso/standards_for_technical_regulations.pdf). Delaney, Helen. “Choosing Standards Based on Merit – Liberalizing Regulation, Trade and Development.” 2010. (http://www.astm.org/ABOUT/images/Choosing_Standards.pdf).

When a national committee does determine that some deviations to an international standard are necessary to achieve national consensus, negative consequences can be minimized by:

- Making the minimum technical changes necessary to achieve national acceptance.
- Including a section that lists the specific differences between the international and national standard with a detailed rationale for each of the national deviations.
- Disallowing (rejecting) editorial modifications, including comments suggesting changes to the organization of the standard or copyediting of text to improve grammar or clarify intent. Both types of editorial changes make it that much more time-consuming and difficult to determine technical equivalence between the international and national standard.

If outright errors are found in text that is identical to the international standard and an errata sheet is issued at the national level, inform the secretary of the responsible international committee so that similar corrections can be issued to the international standard.

Of course, it is incumbent upon the entity making deviations to be sure to respect intellectual property rights when adopting international standards or incorporating national deviations based on the work of others.

A hallmark of all respected standards developing organizations is that their process includes the periodic review and revision of their standards. If participants in the standards development process are active in the process when deviations and related rationale are submitted during review, subsequent revisions can bring affected stakeholders closer to a global standard.

2.6 Standards and conformity assessment

The details of conformity assessment activities – what are the specific actions, who carries them out, what is the output, how is that output delivered/controlled – are collectively referred to as a “conformity assessment scheme.”⁸

In many instances, it would be preferable to create one or a very limited number of conformity assessment (CA) schemes that all users of the standard would accept. This is only realistic when a mechanism exists for the various users (or at least all the major users) of the standard to communicate and come to consensus. While developing a standard to record the specifics of the scheme can be a very effective way for all users to reach consensus, it is true that achieving consensus from all users – especially regulatory bodies – can often be the greatest obstacle in developing a globally relevant CA scheme. However, there are examples of globally recognized CA schemes currently in use, such as the IEC CB Systems used by the eletrotechnology sector.⁹ Where one or a limited number of conformity assessment schemes is not realistic, stakeholders should work to

⁸ [ISO/IEC 17000:2004](http://www.iso.org/iso/iec_17000_2004), *Conformity assessment - Vocabulary and general principles*.

⁹ Visit <http://www.iecee.org> for more information.

remove obstacles that prevent a conformity assessment body from providing all the various conformity assessment schemes being demanded. Requirements that limit manufacturers' choice of conformity assessment bodies and/or require the use of only domestic or governmental CA providers increase costs and time to market.

In particular, one action that would benefit global industry would be the acceptance of non-domestic conformity assessment providers using the same criteria as required of domestic conformity assessment providers. This includes open and transparent accreditation and acceptance criteria that both domestic and global CA providers are required to meet. The acceptance of non-domestic CA providers would result in an overall reduction of CA costs, allowing manufacturers to effectively enter multiple markets. It would also reduce the duplicative and time-consuming processes imposed through the requirements of using only domestic and government CA in each individual market.

Conclusion

The expansion of global trade is increasingly important to the growth of the U.S. economy, to productivity and innovation, and to the continued revitalization of the American workforce. But without integration into the international standardization landscape, U.S. products, services, and personnel cannot hope to be competitive in the global marketplace.

This is especially true in emerging and cross-sectoral technology areas, where developing and developed economies alike are playing an increasingly significant role in standardization activities. It is vital for the U.S. to maintain its key role in developing globally relevant, responsive standards – the nation simply cannot afford not to be at the various tables where international standards are being set.

The U.S. standards system acknowledges that there are multiple paths to global relevance. Many standards developing organizations and consortia operate on the international stage – what matters is that the standards were developed according to the principles of the WTO TBT Agreement, which are also consistent with the *ANSI Essential Requirements*¹⁰ for standards development. The process must be consensus based, open, with balanced participation – and include all other elements that are the hallmarks of the strongest and most effective standards and conformance solutions.



Without integration into the international standardization landscape, U.S. products, services, and personnel cannot hope to be competitive in the global marketplace

¹⁰ Visit www.ansi.org/essentialrequirements to read the *Essential Requirements*.