

Standards and Competitiveness— Coordinating for Results

**Removing Standards-Related Trade Barriers
Through Effective Collaboration**

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THE SECRETARY OF COMMERCE
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The international language of commerce is standards. Adherence to agreed upon product or service specifications underpins international commerce, enabling trillions of dollars of goods to flow across borders, regardless of the spoken language of any business parties. The common acceptance of standards is fundamental to the success of robust, fair, and free trade. Without standards, it would be difficult to imagine the tremendous volume and complexity of today's global trade.

In March 2003, I launched the Department of Commerce (DOC) Standards Initiative, an eight-point endeavor to ensure that the Federal Government works effectively to eliminate standards-related market barriers that undermine trade and, as a result, threaten the international competitiveness of U.S. industry. Indeed, these and other technical barriers to trade, such as duplicative testing and certification procedures, are a growing concern among U.S. businesses.

For example, standards pose obstacles to trade when divergent "local" standards, set for seemingly similar purposes, have the potential to disrupt trade -- the result of conflicting specifications that become barriers to market entry. As part of the Standards Initiative, the Department of Commerce organized more than a dozen roundtable discussions, soliciting individual input from hundreds of businesses as well as standards development organizations, advisory bodies, and other groups on the most pressing standards issues and on priority export markets. This report summarizes the various recommendations submitted, and outlines our progress to date in implementing this important Standards Initiative. It further suggests additional steps that the Department, other federal agencies, and the private sector can take to advocate successfully for U.S. interests in the international standards arena and to respond effectively to challenges that threaten to distort the flow of trade.

This report contains more than 50 recommendations, some strategic, others tactical. Some recommendations are internal to the Department and others require public-private collaboration. The public's views remain important to us as we set priorities and determine next steps for the Department. The Standards Initiative is a long-term commitment by the Department of Commerce. Ensuring that standards are fair and responsive to market and technology needs will require continual vigilance and a collaborative effort by the Department and our partners in U.S. industry.

A handwritten signature in black ink, appearing to read "Donald L. Evans".

Donald L. Evans

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Standards and Competitiveness— Coordinating for Results

Removing Standards-Related Trade Barriers Through Effective Collaboration

Introduction

In March 2003, Commerce Secretary Donald Evans announced the Department of Commerce (DOC) Standards Initiative in response to industry concerns that issues relating to standards and conformity assessment to those standards are among the greatest barriers to expanding exports.¹

The Department also launched its Manufacturing Initiative in the same month to help address the significant competitive challenges facing American manufacturing. U.S. manufacturers produce products that require standards, and, therefore, a greater understanding and acceptance of standards used by these manufacturers should increase market access and expand export markets for U.S. companies.

Standards are a critical issue for manufacturing competitiveness in global markets, as they can facilitate international trade, or they may impede access to foreign markets. Many in U.S. industries view standards as the principal non-tariff barriers in markets around the world. DOC estimates that standards issues impact 80 percent of world commodity trade. The Department carries out a wide range of activities in support of the private sector on standards issues, including investigation of company/sector-specific concerns, training, grant funding for qualified private-sector constituents, outreach to industry, technical contributions, and trade negotiations, both multilateral and bilateral (for details see Appendix A).

The purpose of this report is to summarize current DOC standards-related activities and industry input regarding the priority issues that need to be addressed to ensure an environment in which standards do not constitute barriers to trade. Based on this input, the report provides recommendations on where the Department can enhance its activities. Consistent with the Department's Manufacturing Initiative and the findings of the Bush Administration's recently released report on manufacturing in America, the recommendations in this report are intended to improve the environment for manufacturing and enable U.S. manufacturers to compete more effectively in world markets. Effectively coordinated and leveraged, the Department's standards-related programs can make significant contributions to promoting open markets and a level playing field for U.S. manufacturers.

This report also will be used as a basis for the Department to work with other federal agencies to inventory existing government programs and initiatives in order to improve coordination in the management of federal interagency trade-related standards activities.

The report is composed of several sections. First, a summary progress report on the Standards Initiative is provided. Second, background on standards development and conformity assessment is given. Third, the role of individual Commerce agencies with respect to standards-related issues is described. Fourth, input from U.S. industry on the Department's Standards Initiative, the most pressing standards issues, and priority foreign markets is summarized. Fifth, areas in which Commerce may enhance or expand its activities

¹This report will use the term "standards" to include standards, technical regulations, and conformity assessment procedures unless otherwise noted.

on standards-related issues are recommended. Finally, three informational appendices are provided, including a list of DOC standards-related activities, the DOC Standards Questionnaire,² and a list of acronyms used in this report and their meanings.

I. Commerce Standards Initiative Progress Report

On March 19, 2003, Secretary Evans outlined the eight points of the Standards Initiative. Since then, significant progress has been made, including:

1. **Developing a Commerce Standards Activity Assessment:** DOC's Technology Administration, through the National Institute of Standards and Technology (NIST), conducted an assessment of all existing DOC programs and efforts to reduce standards-related barriers in foreign markets. To support this effort, the International Trade Administration (ITA) surveyed its offices, and NIST circulated a questionnaire to other Commerce bureaus soliciting their input on standards-related activities (see Appendix B). This report is a result of and summarizes the activity assessment.
2. **Reinforcing Expertise in Key Markets:** NIST and ITA have developed a new intensive training program for Department of Commerce standards attachés posted abroad.
3. **Devising an Effective Training and Outreach Program:** NIST and ITA, in cooperation with private-sector organizations, are developing a standards training program for all DOC Commercial Service Officers, which also will be made available to other agencies as appropriate, such as the State Department's Foreign Service Officers.
4. **Creating a "Best Practices" Database:** Working with its offices abroad, other government agencies, and industry, DOC is determining how existing DOC databases that compile information on trade issues can be used or expanded upon to facilitate an understanding of "best practices" when addressing standards-related trade issues.
5. **Expanding the Early Warning System:** DOC is strengthening and expanding "Export Alert!"—a free, Web-based service, which currently disseminates World Trade Organization (WTO) notifications of proposed technical regulations to subscribers—to include notifications of potential trade-related standards concerns identified by Department desks and overseas offices.
6. **Partnering with the President's Export Council on Standards Leadership:** DOC is supporting the development of a dialogue on standards within the President's Export Council (PEC).
7. **Reaching out to U.S. Industry:** Between April and November 2003, DOC hosted a series of industry-specific roundtables to gather input on the most pressing standards issues in foreign markets. The Industry Functional Advisory Committee on Standards (IFAC 2) also provided its advice.
8. **Appointing a Standards Liaison at ITA:** A senior official, Heidi Hijikata, was named as ITA's Standards Liaison with U.S. industry to ensure that industry's priorities on standards are promoted through DOC's international policies and programs. She also works closely with other U.S. government agencies.

²As a part of the DOC Assessment, NIST developed a questionnaire and sent it to all DOC bureaus. DOC bureaus completed the questionnaires, and the responses are summarized in this report.

II. Background on Standards Development

The U.S. standards system is highly decentralized and naturally partitioned into industrial sectors that are supported by numerous independent, private-sector standards development organizations (SDOs)—currently more than 450 such organizations, with at least 150 more consortia. Approximately 20 SDOs develop about 80 percent of U.S. standards.³

The U.S. marketplace is demand-driven, as is standards development in the United States. Individual standards typically are developed in response to specific concerns and constituent issues expressed by both industry and government. Public, formal standards development in the United States began more than 100 years ago as a private-sector enterprise, with strong government participation and support. Without any central responsibility, authority, or overly burdensome interference from government, a wide variety of U.S. voluntary standards activities have proceeded very successfully along sector-specific lines for over a century. Although U.S. decisions about standards authority and responsibilities were not made deliberately with a view to providing support for U.S. efforts in international trade, they work well to support the domestic goals of health, safety, and protection of the environment as well as specification of products, processes, and systems.

The American National Standards Institute (ANSI)

ANSI, a private-sector, non-profit organization founded in 1918 by several SDOs and U.S. Government representatives, is composed of more than 700 company members; 30 government agencies; 20 institutions; and 260 professional, technical, trade, labor, and commercial organizations. Unlike the SDOs mentioned above, ANSI itself does not develop standards. Rather, it functions as a central clearinghouse and coordinating body for its member organizations, which in turn develop standards on a decentralized, consensus basis. ANSI also provides procedures for standards bodies to follow in managing the consensus standards development process in a fair and open manner, and it accredits U.S. SDOs that comply with the procedures. It also approves standards submitted by accredited SDOs, designating them as American National Standards, indicating that they have followed the essential due process and consensus criteria defined by ANSI. However, ANSI's accreditation does not apply to standards not submitted to ANSI for adoption, regardless of the accreditation of the SDO. At last count, ANSI had accredited approximately 200 SDOs and listed about 10,000 of their standards as ANS.⁴

ANSI is also the U.S. member body to the International Organization for Standardization (ISO) and, through the U.S. National Committee, to the International Electrotechnical Commission (IEC). ANSI administers the international secretariat to the Joint Technical Committee (JTC-1) of ISO and IEC, which develops standards in information technology and is the U.S. member body to the Pacific Area Standards Congress (PASC) and to the Pan American Standards Commission (COPANT). As the U.S. representative to these bodies, ANSI convenes delegations, approves delegation members, and appoints technical groups with a broad spectrum of experts to represent the United States in deliberations of relevant international policy boards, individual technical committees, and working groups.

The Role of the U.S. Government

While the U.S. Government does not operate or finance a U.S. national standards body, individual agencies do participate actively in the development of voluntary consensus standards. Additionally, the

³Statistic provided by ANSI.

⁴ANSI coordinates the development of American National Standards (ANS) by accrediting standards development organizations (SDOs) to develop and publish ANS. ANSI works through its accredited standards development process to avoid overlap and duplication in proposed standards. Accreditation by ANSI signifies that the procedures used by the standards body in connection with the development of ANS meet the Institute's essential requirements for openness, balance, consensus, and due process.

Government also is directly concerned with setting and implementing standards through legislation, regulation, or contractual obligations for sale to government purchasers. In specific cases, agencies develop mandatory standards as part of technical regulations (e.g., automotive, aviation, consumer products). Public Law 104-113, the National Technology Transfer and Advancement Act of 1995, directs Federal agencies to use voluntary consensus standards to carry out policy objectives or activities determined by the agencies and departments, except when impracticable. Office of Management and Budget (OMB) Circular A119 guides agencies in this effort. Agencies also are directed to participate in the activities of voluntary consensus bodies to aid them in carrying out their standards-related activities. Finally, the Act directs NIST to coordinate Federal, State, and local technical standards and conformity assessment activities with those of the private sector in order to reduce duplication and complexity.

From a policy perspective, and in keeping with Article 4.1 of the World Trade Organization's Technical Barriers to Trade (WTO TBT) Agreement, the U.S. Government also must ensure that central government standardizing bodies accept and comply with the Code of Good Practice.⁵

U.S. Interfaces with the International System

Both the U.S. Government and private sector participate in international standards development in a variety of ways: through private, voluntary organizations whose membership is on a national body basis; through treaty organizations (governments are members); through professional and technical organizations whose membership is on an individual or organizational basis, and through consortia, whose membership is typically company and industry-based.

For example, ISO and IEC are non-governmental international organizations consisting of national member bodies. ISO, established in 1947, is made up of the national standards bodies of 94 full-member countries. IEC, founded in 1906, is made up of national committees from more than 50 individual countries. ISO currently has 185 technical committees with a wide variety of scopes; IEC has 88 committees, primarily on electrotechnical issues. ISO and IEC have one joint committee, JTC-1, which focuses on information technology and its application. Standards developed by ISO and IEC do not, however, cover all areas of technology or application.

Standards developed by other standards developing organizations also are used globally. For example, standards developed by organizations such as ASTM International, the American Society of Mechanical Engineers (ASME), the American Petroleum Institute (API), the Society of Automotive Engineers (SAE), and others are used around the globe to meet specific sector needs, including materials standards, boiler and pressure vessel codes, and specifications for piping and fuels.

Other standards, typically for specific sectors, are developed by treaty organizations with national governments as members. These include:

- The International Telecommunications Union (ITU), a specialized agency of the United Nations, develops standards, guidelines, and policy for communications technology.
- Codex Alimentarius (Codex), created in 1963 by the U.N. Food and Agricultural Organization (FAO) and the World Health Organization (WHO), develops food standards, guidelines, and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme, intended to protect the health of consumers, ensure fair trade practices in the food trade, and promote coordination of food standards by international governmental and non-governmental organizations.

⁵ Article 4.1 of the WTO TBT Agreement states that Members shall ensure that their central government standardizing bodies accept and comply with the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 to this Agreement (referred to in this Agreement as the "Code of Good Practice"). They shall take such reasonable measures as may be available to them to ensure that local government and non-governmental standardizing bodies within their territories, as well as regional standardizing bodies of which they or one or more bodies within their territories are members, accept and comply with this Code of Good Practice. In addition, Members shall not take measures, which have the effect of, directly or indirectly, requiring or encouraging such standardizing bodies to act in a manner inconsistent with the Code of Good Practice. The obligations of Members with respect to compliance of standardizing bodies with the provisions of the Code of Good Practice shall apply irrespective of whether or not a standardizing body has accepted the Code of Good Practice.

- The International Civil Aviation Organization (ICAO) establishes international standards, recommended practices, and procedures covering the technical fields of aviation, security, and the safe transport of dangerous goods in the air.
- The International Maritime Organization (IMO) provides inter-governmental cooperation for international shipping and standards for maritime safety, efficiency of navigation, and control of marine pollution from ships.
- The Organization for Economic Co-operation and Development (OECD) provides technical background and policy for a wide variety of international matters. The OECD develops standards for certain agricultural commodities, as well as for agricultural tractors and good laboratory practices in the chemical sector.
- Working groups of the United Nations Economic Commission for Europe (UNECE) set standards in the transport sector (for vehicles, road signs, and signals, etc.), perishable produce, and electronic data exchange.
- The International Bureau of Weights and Measures (BIPM) ensures the worldwide uniformity of measures and their traceability to the International System of Units under the Convention of the Meter. A companion organization, the International Organization of Legal Metrology (OIML), promotes the global harmonization of procedures and guidelines for measuring instruments used in legal metrology.

Conformity Assessment

Conformity assessment procedures provide a means of verifying that the products, services, or systems produced or operated meet relevant requirements. Those requirements are often specified in standards. Typical examples of conformity assessment activities are: sampling, testing, and inspection; software conformance testing, evaluation, verification, and assurance of conformity (supplier's declaration, certification); management system assessment and registration; accreditation and approval as well as their combinations.

DOC encourages the use of a broad range of mechanisms to facilitate the acceptance of conformity, including suppliers' declaration of conformity (SDOC) and first, second, and third party conformity assessment activities.⁶ Further, conformity assessment needs may be served by various means, including: (1) arrangements among certifying bodies mutually accepting the results of certification internationally; (2) utilization of mutual recognition arrangements among accreditation bodies promoting the acceptance of conformity assessment results by users and regulators; (3) designation as foreign conformity assessment bodies by importing regulatory authorities; (4) unilateral recognition and acceptance; and (5) mutual recognition and acceptance agreements and arrangements. The types of mechanisms depend on the level of risk or hazard posed by the product or the system.

U.S. Interfaces with Regional and International Global Conformity Assessment Organizations

U.S. public and private-sector interests participate in a range of private-sector organizations, termed cooperations, whose members are accreditation bodies or, in some cases, certification bodies. These bodies work together to provide peer evaluation of the competence of participating organizations in the areas of laboratory accreditation and accreditation of management system and product certification. Such cooperations may be used to support government-to-government trade agreements. For example, the Asia Pacific Economic Cooperation (APEC) recognizes regional standing bodies in the areas of standards, accreditation

⁶“Conformity assessment activities may be conducted by the supplier (first party) or by the buyer (second party) either directly or by another party on the supplier's or buyer's behalf, or by a body not under the control or influence of either the buyer or the seller (third party).” *Federal Register*: August 10, 2000; Volume 65, Number 155; Page 48894-48902.

of conformity assessment bodies, and measurement. In addition, the APEC⁷ and Inter-American Telecommunication Commission (CITEL) telecommunications government-to-government Mutual Recognition Agreements (MRAs) state that parties may rely on voluntary mutual recognition arrangements among accreditation bodies to “secure and simplify their participation” in government-to-government arrangements to recognize each other’s test reports and product approvals.

Key Accreditation and Certification Cooperations include:

- International Laboratory Accreditation Cooperation (ILAC)⁸—the principal forum for the development of laboratory accreditation practices, the promotion of laboratory accreditation, the assistance of developing accreditation systems, the recognition of competent laboratories; and the maintenance of a multilateral mutual recognition arrangement (MRA) among laboratory accreditation bodies.
- International Accreditation Forum (IAF)—the principal forum for accreditation of certification bodies in the fields of management systems, products, services, and personnel, and the development of multilateral mutual recognition arrangements (MRAs) among accreditation bodies in these fields. ILAC and IAF are also jointly developing a multilateral mutual recognition arrangement for inspection body accreditation.
- IEC System for Conformity Testing and Certification of Electrical Equipment (also known as the IECCE CB Scheme)—qualifies testing laboratories through a peer-to-peer evaluation, as the basis for participating country acceptance of test reports dealing with the safety of electrical and electronic products (electrical equipment, electronic components, and electrical equipment for explosive atmospheres).
- Regional organizations in Europe, Asia-Pacific, the Americas, and Southern Africa.

III. Description of Current DOC Standards-Related Activities

The Department has several bureaus involved in trade-related standards activities, including ITA, NIST, the National Telecommunications and Information Administration (NTIA), the National Oceanic and Atmospheric Administration (NOAA), the Office of General Counsel (OGC), and the Patent and Trademark Office (PTO). Commerce actions include, but are not limited to, the following types of activities: investigating and addressing U.S. private-sector market access and compliance concerns in foreign markets, assisting developing countries in complying with WTO agreements, assisting both U.S. and foreign parties in understanding U.S. standards and regulatory requirements; addressing sector-specific standards practices; providing information on U.S. and foreign standards and technical regulations; providing technical support to standards committees and working groups; and organizing standards workshops and seminars for both U.S. and foreign interested parties. As part of the Secretary’s Initiative, NIST developed and distributed a questionnaire to appropriate Commerce bureaus to collect information on relevant standards-related trade activities (see Appendix B).

Technology Administration/National Institute of Standards and Technology (NIST)

All of the NIST laboratories have standards-related responsibilities in their technical areas of expertise: carrying out research that provides the technical underpinning for standards; providing calibrations, Standard Reference Materials, and critically evaluated data; and participating in standards development activities related to a broad range of technical areas. NIST provides the measurement infrastructure to

⁷ANSI is recognized by the NIST National Voluntary Conformity Assessment System Evaluation (NVCASE) program to accredit U.S. telecommunications bodies to certify telecommunications equipment in accordance with Industry Canada regulations under the phase II of APEC Telecommunications MRA.

⁸Cooperation is part of the full, legal name of the International Laboratory Accreditation Cooperation (ILAC), which is now incorporated in the Netherlands; it is also the term used to describe cooperative arrangements among accrediting bodies (including the incorporated U.S. National Cooperation for Laboratory Accreditation).

advance U.S. interests in international trade, commerce, and regulatory affairs. NIST is responsible for establishing traceability of its measurement results to the International System of Units, which underpins a wide range of tests and measurements conducted to meet regulatory agency and U.S. business needs, both nationally and internationally.

At the most recent count, some 440 NIST scientists participate in 111 standards-developing organizations, 46 of which are international. They attend standards meetings and correspond frequently with their committee colleagues on all kinds of standards-related and trade-related issues. NIST laboratories host periodic workshops on specific technology areas to solicit private-sector and other agency input on research and measurement needs. Recent examples include workshops on in vitro diagnostic devices, information technology (IT) standardization, biomedical products, biometrics, construction site data exchange standards, and homeland security standards. Standards-related concerns may be raised as part of these workshops or within the context of developing documentary standards.

NIST technical staff work in standards committees administered by ASTM International (formerly known as the American Society for Testing and Materials), the American Society of Mechanical Engineers (ASME), the Institute of Electrical and Electronics Engineers (IEEE), the National Electrical Manufacturers Association (NEMA), the InterNational Committee for Information Technology Standards (INCITS), the International Organization for Standardization (ISO), and the International Electrotechnical Commission (IEC), and many others, including committees accredited by ANSI. NIST staff also participate actively in software conformance testing and quality assurance programs under the auspices of the World Wide Web consortium. NIST holds institutional memberships in 70 standards-related organizations and its staff participate actively in standards-developing activities in technologies ranging from building technology, materials, chemistry, optics, electrical and electronics to biometrics, smart card technologies, public key infrastructure, and information technology.

In addition, Congress has given NIST standards-related responsibilities in several areas of critical national interest:

- **Technical standards activities and conformity assessment activities of the U.S. Government.**

These include responsibilities under the National Technology Transfer and Advancement Act of 1995 (NTTAA), which directs NIST to coordinate technical standards and conformity assessment activities of the U.S. Government with the private sector and with state and local governments in order to reduce duplication and complexity.

- **Information technology (IT) security.** Congress originally gave NIST mandates under the Computer Security Act of 1987, and the recently enacted Cyber Security Research and Development Act of 2002 and Federal Information Security Management Act of 2002 (FISMA) reaffirms and expands that mandate, including development of cryptographic standards and applications, as well as guidelines, procedures, and best practices for Federal IT security, such as Federal Information Processing Standards (FIPS) and Information Security Guidelines.

- **Biometrics.** The USA PATRIOT Act (PL 107-56) and the Enhanced Border Security and Visa Entry Reform Act (PL 107-173) require NIST to develop and certify (through an interdepartmental consultative process) technology standards to verify the identity of foreign nationals applying for a visa and to verify identity of persons seeking to enter the United States.

- **Voting.** The Help America Vote Act of 2002 mandates a NIST role in the development of voting system standards and accreditation of laboratories testing voting systems.

■ **Manufacturing.** The Enterprise Integration Act of 2002 authorizes NIST to “accelerate its efforts in helping industry develop standards and enterprise integration processes that are necessary to increase efficiency and lower costs.”

NIST technical programs support global recognition of U.S. standards, where relevant, as well as harmonization of standards to avoid barriers to trade. These programs take advantage of synergies with related Commerce Department trade-related programs and with the private sector, and are critical to U.S. manufacturers’ access to export markets. NIST works closely with other DOC bureaus, particularly ITA, to support the development of Departmental positions on standards-related trade issues. NIST also works in partnership with the Department’s Foreign Commercial Service to sponsor three standards attachés on location in key foreign markets. These experts support Embassy commercial and economic staffs in the identification and resolution of trade issues involving standards-related barriers. NIST also operates the Inquiry Point for the WTO TBT Agreement and disseminates information on proposed foreign technical regulations for comment by U.S. interests. The NIST WTO TBT Inquiry Point coordinates with the Food Safety and Technical Services Division (FSTSD) in the U.S. Department of Agriculture (the U.S. WTO Sanitary and Phytosanitary Notification Authority and Inquiry Point) on all food- and agriculture-related TBT measures.

NIST is actively involved in implementing key strategic goals of the National Standards Strategy, in partnership with ANSI and stakeholders in the U.S. standards system. A major focus of the strategy is on increasing U.S. presence and leverage in international standards activities and working to improve processes internationally to reflect more closely U.S. principles and vision.

NIST is working with other government agencies and with ANSI and its members to target critical activities in ISO, IEC, and other standards organizations to avoid adoption of international product standards that are technical barriers for U.S. exports. NIST staff represents U.S. interests in some 180 international standards committees and international industrial consortia. Focus areas include health care, information technology, building and construction, manufacturing, and telecommunications. NIST also manages U.S. participation in OIML to prevent discrimination against U.S. products and technology and to align national and international legal metrology standards.

NIST conducts a comprehensive workshop and training program for foreign officials, targeted at key U.S. export markets, to show the value of U.S. standards, technology, principles, and practices. Since 1995, NIST has trained more than 1,000 officials from the Americas, Asia, Russia and the Newly Independent States, and the Middle East. Contacts with foreign officials built through these workshops and through Department standards attachés have facilitated acceptance of U.S. products in key markets.

NIST supports the implementation of three major trade agreements—with Europe, Asia, and the Americas—that provide for mutual recognition of tests and product approvals in regulated areas, particularly telecommunications and IT equipment. The U.S.-European Union Mutual Recognition Agreement (MRA) covers some \$40 billion of two-way trade. As part of its laboratory accreditation activities, under the auspices of the National Voluntary Laboratory Accreditation Program, NIST participates in regional and international laboratory accreditation cooperation—the Asia Pacific Laboratory Accreditation Cooperation and the International Laboratory Accreditation Cooperation—as a means of ensuring mutual confidence among accreditation bodies globally and confidence for users in data from laboratories accredited by competent accreditation bodies. Two other U.S. private-sector laboratory accreditation bodies also participate in the mutual recognition arrangements of these regional and international laboratory accreditation cooperations.

International Trade Administration (ITA)

ITA collaborates with the U.S. private sector and foreign governments to minimize standards-related trade barriers. ITA's Standards Liaison helps ensure coordination among ITA units and related offices that address standards issues including: Trade Development (TD), Market Access and Compliance (MAC), U.S. & Foreign Commercial Service (USFCS), and the Office of the General Counsel (OGC).

The ITA's Standards Liaison is a focal point on standards-related issues internally and externally. Internally, the Standards Liaison ensures that Department efforts are coordinated in promoting U.S. standards issues, policies, and concerns through DOC's international policies and programs. The Standards Liaison has established a Standards Working Group, which serves to enhance internal coordination on standards-related policy issues within ITA and other Commerce bureaus, including NIST, NOAA, PTO, and OGC. Externally, the Standards Liaison works closely with the Office of the United States Trade Representative (USTR) and other U.S. Government agencies to address U.S. standards issues, policies, and concerns in U.S. trade policy. This coordination should result in better leveraging of existing DOC resources and help to decrease the likelihood of standards-related trade barriers.

ITA actively seeks information from U.S. exporters, both to improve exporter market access and compliance with trade agreements the U.S. Government has negotiated. ITA maintains the Department's "Trade Complaint Hotline" where U.S. businesses can register their complaints on-line, including standards-related complaints. When a problem is identified, ITA establishes a team of experts including country experts, industry specialists, USFCS officers, and OGC and NIST staff, to develop an action plan to resolve the problem. OGC works with the team to provide advice and analysis on relevant legal issues, including U.S. laws and WTO Agreements. Commerce team efforts may be coordinated with the USTR and other U.S. Government agencies as appropriate.

Standards issues may be addressed by bilateral or multilateral discussions, industry-to-industry or industry-to-government dialogues, or through trade policy negotiation. ITA engages in bilateral discussions on standards-related issues. Technical and policy level discussions may be helpful in resolving trade concerns. A successful example is the U.S.-Japan Regulatory Policy Reform and Competition Policy Initiative, which is a part of the Economic Partnership for Growth agreed to by President Bush and Prime Minister Koizumi in 2001.

Another way ITA addresses standards-related issues is through sector-specific dialogue. Multilateral meetings held during trade shows or other industry events can bring experts together to discuss the issues. A successful example is the APEC Automotive Dialogue. The Auto Dialogue has a working group for member economies to discuss shared issues concerning automotive standards and support standards harmonization.

Standards-related issues also are addressed in multilateral fora where trade policies are discussed. ITA is the Department's lead on U.S. delegations to the WTO TBT and Sanitary and Phytosanitary Measures (SPS) Committees and the North American Free Trade Agreement (NAFTA) Committee on Standards-Related Measures (CSRM), which are led by USTR. ITA also coordinates policy positions on subjects discussed in OECD and UNECE, and participates in interagency delegations to treaty organizations such as Codex and ICAO. Finally, ITA staff participates in private sector-led delegations to ISO and IEC where relevant.

Standards-related obligations can be enhanced in Free Trade Agreements (FTAs). ITA is the Department's lead on U.S. delegations to negotiate these agreements. ITA has participated in FTA negotia-

tions with Chile, Singapore, Australia, Central America, South African Customs Union, Morocco, and the Free Trade Agreement of the Americas.

USFCS has excellent in-country resources that can help establish a dialogue with foreign government officials on standards-related concerns. Particularly, the three standards attachés in Brussels, Mexico City, and Brasilia, are dedicated full-time to this activity. Other commercial officers and Foreign Service National employees also take active roles in establishing ongoing dialogue with local standards developers. There are also three trade agreements compliance officers, located in Beijing, Tokyo, and Brussels, who are dedicated to handling trade-related aspects of technical regulations. U.S. Export Assistance Centers provide exporting advice to U.S. companies, including many small and medium-sized enterprises (SMEs). These domestic resources routinely counsel their clients on a variety of export-related issues, including those involving standards in overseas markets.

ITA manages the Market Development Cooperator Program (MDCP), a competitive matching grants program that builds public-private partnerships by providing federal assistance to non-profit industry groups that are particularly effective in reaching SMEs. Three MDCP grants aimed at addressing standards-related issues have been granted in the last two years.

Within ITA, the Industry Consultations Program staff manage the U.S. Industry Sectoral and Functional Advisory Committees (ISACs and IFACs). Through these groups, private-sector representatives directly advise the Secretary and the USTR on trade policy matters. Twenty-one advisory committees exist, each with some interests on standards issues. More specifically, the IFAC on Standards (IFAC 2) provides input to the U.S. Government on standards, technical barriers to trade, existing free trade agreements, and those under negotiation.

National Telecommunications and Information Administration (NTIA)

NTIA provides leadership and technical contributions to international standards development through its Institute for Telecommunications Sciences (ITS). ITS staff participate in international and national telecommunications standards committees, including ITU through close coordination with the Department of State (DOS) and U.S. telecommunications industry organizations. ITS also participates in ANSI Accredited Standards Committee T1, Telecommunications.

ITS staff work proactively to reduce the likelihood of telecommunication standards being used as non-tariff trade barriers by developing and promoting international acceptance of functional and performance-based standards. ITS leads U.S. delegations to ITU meetings and develops U.S. contributions and negotiating consensus positions for submission to the relevant international standards committee.

ITS staff respond primarily to concerns involving the development and/or voting process for a standard. They use standards databases and work closely with DOS and industry organizations to learn more about standards issues. ITS has developed, implemented, patented, and standardized perception-based, objective quality metrics for voice and video communication systems and services and these metrics have been embedded in commercial products.

ITS coordinates its standards activities with NTIA through daily communications and periodic reports. Information is shared through normal standards committee distribution channels, teleconferences and face-to-face meetings, and participation in U.S.-sponsored ITU preparatory committees.

National Oceanic and Atmospheric Administration (NOAA)

Standardization of data acquisition and data management practices is vital to the mission of NOAA. NOAA seeks to establish voluntary standards with selected industrial associations, academia, and national organizations of State and local governments (e.g., the American Association of State Climatologists), as well as through participation in professional societies (e.g., American Meteorological Society). All NOAA line organizations participate in standards-development activities. In general, standards used in many NOAA activities are established in conjunction with other Federal agencies (e.g., the Department of Defense, Federal Aviation Administration, U.S. Department of Agriculture, and the Federal Geographic Data Committee) either through joint participation in international organizations such as the World Meteorological Organization or by means of bilateral and multilateral agreements with other nations. These standardization activities apply to all phases of environmental data acquisition, processing, and distribution.

Office of the General Counsel's Commercial Law Development Program (CLDP)

CLDP's primary activity is to assist developing countries with creating their standards and regulatory infrastructures to meet obligations under the WTO agreements. This assistance takes the form of workshops, U.S. consultations, or advisors. CLDP receives requests for assistance from the USFCS, other government agencies, SDOs, industry or countries currently working with CLDP. Specific issues are handled by consulting with government agencies and industry representatives to obtain more information about the issue and determine the best course of action. SDOs and regulatory agencies are all involved in the program depending on need and expertise. Specific topics of concern include proposed foreign standards or regulations that may affect trade and/or import certificates for agricultural products.

U.S. Patent and Trademark Office (USPTO)

USPTO, working through the auspices of the World Intellectual Property Organization (WIPO), a United Nations organization, and in conjunction with other Intellectual Property Offices (IPOs) throughout the world, develops various standards dealing predominantly with the presentation of, and exchange of, intellectual property information between the various IPOs. This is done with the intention of coordinating industrial property information activities of the IPOs and by doing so, to further promote international exchange of data relating to industrial property documents. These standards are expressed in the form of recommendations and are directed to states and international organizations, in particular to their national or regional industrial property offices, to the International Bureau of WIPO, and to any other national or international institution interested in industrial property documentation and information matters. These standards can be grouped into several categories: standards of a general nature, common to information and documentation relating to an industrial property right (e.g., relating to basic bibliographic data); standards relating to patent documents in general; specific standards applicable to secondary publications such as official gazettes, indexes, and abstracts; specific standards in respect of microforms; specific standards in respect of machine-readable carriers of industrial property information; specific standards relating to trademark information and documentation; and specific standards relating to industrial design information and documentation.

IV. Industry Input to the DOC Standards Initiative

ITA and NIST conducted 13 roundtables to gather private-sector input on the most pressing standards issues and priority foreign markets, including Information and Communications Technology (ICT) Services; ICT Equipment; Energy and Environmental Technology; Consumer Products and Food; Machinery; Aerospace; Autos (Motor Vehicles and Parts); Medical Devices and Instruments and Pharmaceuticals; Textiles and Apparel; Standards; Conformity Assessment; Forest Products and Building Materials; and Chemicals and Allied Products. While the roundtables conducted by the Department in conjunction with the Standards Initiative dealt in much more detail with standards specifically than did the manufacturing roundtables conducted during the same time period, the findings from both sets of roundtables with respect to standards were consistent.

In addition, the following organizations provided comments to a *Federal Register* Notice (FRN) soliciting input on the initiative: ASTM International, Sperry Marine, ASME International, Illinois Tool Works, Inc; the National Food Processors Association; John Deere and Company; American Forest and Paper Association; and the Pharmaceutical Research and Manufacturers of America. Moreover, IFAC-2 (Standards) sent suggestions on the Standards Initiative directly to the Secretary.

General Concerns Raised by Roundtable Participants

This section highlights comments made by industry during the 13 roundtables and seeks to capture the priority issues that industry believes need to be addressed to ensure an environment in which standards and conformity assessment issues are not barriers to trade.

The following concerns were recorded by DOC employees from oral and written comments raised by the participants and respondents to the FRN. Not all participants shared the same concerns; there were also instances where one participant might contradict another participant. Some industries had no standards issues to report and indicated that standards development was not a problem in their sector. Nonetheless, the following section represents the overarching concerns and industry ideas proposed during the DOC outreach.

Standards Issues

Many participants expressed an overriding concern about the presence of multiple standards or standards differing from international norms in other countries. They stated that these could significantly raise costs for manufacturers, especially small and medium-sized businesses, and limit or eliminate their market access. Wide variation among countries' standards makes it expensive and time consuming for companies to deploy products and technology into different markets. Participants urged DOC to better address foreign governments' adoption of standards in technical regulations, lack of transparency in rulemaking, and limited access to and/or minimal participation in standards development, especially in China and Europe.

A second concern was lack of information and understanding about the standards development process in the United States and in other countries. This concern is amplified for testing and certification issues for specific standards. A participant pointed out that *exclusive reliance on prescriptive test methods and standards that lack international recognition raises costs and establishes criteria that favor domestic producers, particularly as these test methods and standards are referenced in national building codes or other regulations* (Consumer Goods Roundtable).

Conformity Assessment Issues

In many of the roundtables, participants raised concerns related to conformity assessment. One participant noted that some governments adopt conformity assessment procedures that do not recognize that test results already performed according to these procedures are, therefore, by definition, repeatable and reproducible. DOC could provide great assistance by helping other nations recognize that successful test results apply to all similarly constructed products, without the need for expensive and duplicative retesting. Ideally, one could lower the cost of conforming to standards by providing a flexible approach to conformity assessment to standards that allows, depending on the product, a variety of ways to achieve that goal. Unclear labeling and excessive certification requirements create additional problems. Finally, participants commented that some countries require that a product be tested only in labs in their own countries and will not accept tests from U.S. labs. This increases costs and can exclude products from markets.

Participants in several different roundtables also commented that while the Chinese Government has committed to change its conformity assessment procedures to accord non-Chinese products “national treatment,” for many electrical products, it also recently made moves to accept goods built only to either Chinese national standards or standards published by the IEC and ISO (which may not cover products built to North American-based requirements). Furthermore, often only domestic Chinese firms can issue the China Compulsory Certification (CCC) mark for products exported to China. This requires that Chinese technicians from Chinese certification bodies inspect U.S. factories. In other cases, countries have revised their conformity assessment requirements without transparency, advance notice, or public participation.

Some participants expressed a desire for more consistent promotion of national treatment for conformity assessment bodies in foreign markets. Certain countries, such as China and Mexico, continue to reject the concept of national treatment as it relates to products, as well as certification processes. National treatment would enable conformity assessment bodies in one country to provide testing and certification to another country’s requirements by being recognized or accredited through the same process used for domestic bodies. Without such treatment, U.S. conformity assessment organizations cannot provide cross-border conformity assessment services in another nation. Still other roundtable participants called for a multifaceted approach to acceptance of conformity assessment results, including non-governmental MRAs, Memoranda of Understanding (MOUs), and private agreements among laboratories, etc.

Regulatory Issues

Participants raised a number of questions about the process for creating technical regulations in foreign countries, noting a strong preference that standards intended for use in regulations be created in an open, balanced process; be technology neutral; and be based on performance. They stated that the European Union (EU) increasingly is establishing regulations that lack technical justification, imposing costs that are disproportionate with the expected consumer or environmental benefits. In particular, the EU procedures for developing regulations may not be transparent or accountable, with particular concerns raised about environmental regulations. Furthermore, the adoption of standards and conformity assessment procedures in foreign regulations, particularly the EU, was seen as a barrier, particularly when the regulation allows only specific marking and/or conformity assessment schemes. A number of participants commented negatively about the EU influence on standards, combined with its preference for detailed, prescriptive regulations and eco-labeling regimes that favor EU producers. Finally, others stated that problems occur when

government regulatory authorities (e.g., Taiwan) require ISO 9000 quality management system certifications, which are intended to be voluntary. Representatives at the automotive roundtable expressed an interest in supporting increased use of U.S. and/or EU regulations in developing countries, instead of the creation of new regulations.

ISO/IEC Concerns

In many of the roundtables, participants expressed a perception that the EU has disproportionate influence in ISO and IEC because each EU national standards body has a separate vote and EU governments have well-funded technical assistance programs to promote their views on standards in developing countries. They felt that one vote-per-country in these organizations instead of representation based on market share allows regional biases to impact trade. One particular example cited by industry was the defeat of an ISO draft standard that would have included listing of ASME boiler and pressure vessel standards and other internationally accepted and used standards because of the alleged EU bloc voting on this standard, one country=one vote system (Energy and Environment Roundtable).

On the other hand, participants noted that U.S.-developed standards used in ISO or other national standards may not be maintained at the same pace as by their originating organization (such as ASTM) and become technically non-equivalent over time. Many in U.S. industry noted difficulties in impacting or effecting timely changes within the ISO system. They also felt that management system standards (e.g., ISO 9000) can be costly to administer and may have limited benefit. In addition, proposed new ISO standards for corporate social responsibility are fraught with potential problems, while other problems have surfaced with a proposed standard for a care label for textile and apparel products that is both trademarked and has a usage fee.

Although participants raised concerns about ISO and IEC (to a lesser extent), they were not clear in suggesting a course of action for DOC. As noted earlier, ANSI, not DOC, is the member body for ISO and IEC (through the U.S. National Committee). It was suggested that closer formal and informal linkages between ANSI and DOC might help to address the concerns raised by industry and ensure the transmission of timely, accurate information.

Funding Issues

Participants raised several issues about funding the standards process, both within the United States and more broadly. They cited increasing costs for standards activities along with time constraints to progress standards more rapidly. One SDO representative expressed concern about the increasingly limited technical resources and personnel (typically drawn from industry) to support standardization activities. *A roundtable participant stated that due to industry consolidation and belt tightening across the board owner-operator participation at standards related meetings is down from 28 percent in 1992 to 12 percent in 2002. Industry associations noted that small organizations put more money and human resources per capita into standards development than do large organizations. These small organizations cannot indefinitely subsidize standards development, especially when the threat exists that copyrights on standards may be revoked* (Environment and Energy Roundtable). Finally, some questioned whether the U.S. Government should consider funding the participation of technical experts in standards development, particularly for critical standards addressing public safety issues. Yet, others, observing that this could be extremely difficult to administer, suggested that the U.S. Government should consider funding structural elements of the current system.

Trade Policy Issues

Participants raised a number of questions about the WTO TBT Agreement, asking that negotiators include stronger disciplines in future U.S. trade agreements, strengthen the required justification of regulations, provide greater flexibility in conformity assessment, and facilitate improvements in transparency.

Roundtable participants noted uneven implementation of the WTO TBT Agreement and regional FTA obligations in terms of failing to allow sufficient time to comment on proposed recommendations and to recognize specific conformity assessment results and asked that DOC continue to press foreign governments to adhere to these agreements.

Industry was particularly concerned that foreign governments misunderstand WTO TBT obligations to adopt international standards. Some countries interpret this to mean only ISO, IEC, and ITU. This misunderstanding furthers the use of European standards, as EU standards may be adopted by ISO under the Vienna Agreement.⁹ Industry asked that, when opportunities arise, U.S. government officials remind foreign governments of the Decision of the TBT Committee of the principles for the development of international standards, guides and recommendations with relation to articles 2, 5, and Annex 3 of the TBT Agreement. They also asked that the U.S. Government use the Trans-Atlantic Business Dialogue (TABD) as a mechanism to resolve regulatory/standards differences between the United States and the EU.

Training and Technical Assistance

In various industry roundtables, strong interest was expressed in continuing and expanding DOC programs for foreign officials such as the Standards in Trade (SIT) workshops, Special American Business Internship Training Program (SABIT), CLDP's technical assistance programs on standards, WTO and FTA implementation and compliance workshops.

Collaboration

Finally, participants repeatedly noted that collaboration between industry and government (particularly U.S. foreign missions) ensures standards-related concerns raised by industry are taken seriously and encouraged DOC to continue its efforts to maximize collaboration.

V. Recommendations

The following recommendations were generated by DOC staff through consultation with DOC bureaus following review of the concerns and recommendations raised during the roundtables and in response to *Federal Register* notices. The recommendations are presented in the order laid out in the Secretarial Initiative Framework, beginning with those that represent direct extensions of ongoing actions under the Initiative Framework, followed by recommendations that represent new or improvement activities for the Department. Secretarial Deliverables are listed for consideration prior to the recommendations.

1. Overarching Recommendations

- a. Explore opportunities to develop a public/private-sector task force to implement a DOC program on early identification and resolution of standards-related barriers to trade. This effort would include extensive collaboration with other agencies, such as USTR, including through the Trade Policy Staff Committee (TPSC) and the existing advisory committee structure.

⁹The Vienna Agreement is an understanding on technical cooperation between ISO and CEN. The agreement went into effect in June 1991, replacing the Lisbon Agreement of 1987. With an aim of providing coordination and harmonization of standards of the member bodies of both ISO and CEN, the goal is to ensure the equivalence, whenever possible, of ISO and European Standards. The Vienna Agreement provides for mutual representation between CEN and ISO Technical Committees, common planning of work, adoption of ISO standards by CEN or European standards by ISO, and the parallel processing and approval of projects developed in ISO and CEN." *ANSI Guide for U.S. Delegates to Meetings of the IEC and ISO*, 2002.

- b. Promote World Standards Week more visibly; invite industry and SDOs to explain the strengths of the U.S. standards approach and their role in it.
- c. Create a National Standards Award to recognize private-sector organizations that have worked successfully to address market access problems relating to standards, conformity assessment, or technical regulations.
- d. Explore how DOC grant authority, specifically ITA's Market Development Cooperator Program authority, might be used for standards-specific projects with the private sector.
- e. Organize a high-level Standards Trade Mission, in which U.S. industry and U.S. domiciled standards developers both have a market interest, probably to China or Europe, focusing on promotion of U.S. approach to standards and strengths of U.S. system for a specific sector. Mission members would include heads of U.S. SDOs and companies, including representatives of the manufacturing and other sectors.

2. Actions to Improve Internal DOC Coordination (Initiative Point 1)

As the Department works to improve the understanding of key information, it will also make it a priority to strengthen internal Department coordination, so that staff with responsibility for standards can be identified readily and better coordination within Commerce and across the U.S. Government can be achieved. To facilitate this coordination, the Department will:

- a. Identify key players in the Department; organize regular meetings to discuss and coordinate standards-related activities; and develop and maintain a master calendar of standards-related activities that is accessible to all Commerce employees.
- b. Use the new ITA Standards Liaison to help ensure coordination on standards-related activities within ITA; interface with other DOC bureaus and U.S. Government agencies.
- c. Prepare guidance for DOC staff on how Commerce will coordinate internally and with the TPSC on standards.
- d. Develop a database of key organizations, contacts, and experts in standards, conformity assessment, and related issues, both in the United States and abroad.
- e. Continue strong DOC agency participation in documentary standards activities, particularly at NIST, NOAA, PTO, and NTIA.
- f. Develop mechanisms for sharing standards concerns and opportunities arising from DOC participants in standards technical committees. Note: DOC has more than 400 participants in technical standards committees; their input could be used as a part of an early warning system. Guidance will be provided to participants on technical committees on how to share and coordinate trade and policy issues that arise from technical committee work.
- g. Develop and promote use of consistent messages within DOC and the U.S. Government on key standards issues to be used publicly and for training purposes. DOC position papers may be a tool used to promote such consistent messages.

3. Improve/Coordinate Internal Commerce Training Programs (Initiative Points 2 and 3)

To make the Department a better resource for U.S. manufacturers and other industries on standards-related issues, DOC staff needs to receive ongoing and improved training, in addition to feedback received from industry. A NIST-Commercial Service Commercial Officer Standards Awareness Workshop was held on September 29, 2003, to start an ongoing dialogue between the Department and industry on how Commercial Officers (and other ITA staff) can be a better resource for U.S. industry; this dialogue should be continued, expanded, and conducted in coordination with other U.S. Government agencies. To address identified needs, the Department will:

- a. Provide basic training on standards and conformity assessment, including testing, labeling, accreditation, and related issues to Commercial Service domestic and overseas officers, Foreign Service Nationals (FSNs), Market Access and Compliance (MAC) and Trade Development (TD) specialists, and others; and provide basic training on ITA and U.S. trade policy, especially as it concerns standards, to NIST staff. Opportunities for this training also may be extended to State Department's Foreign Service Officers.
- b. Formalize training on standards development, conformity assessment, relevant trade agreements, and interagency process to DOC staff (specifically NIST, NTIA, and ITA).

4. Improve Outreach/Collaboration with industry (Initiative Points 3 and 7)

Since the U.S. voluntary standards system is led by the private sector, industry must take the lead on many critical issues. The industry roundtables clearly indicated that both the government and private sector have a critical stake in standards-related trade issues; therefore, increased and ongoing collaboration between the two is essential. The Department should increase its role in addressing standards-related trade issues and promote increased coordination among relevant U.S. Government agencies.

- a. Build on dialogue recently established by this Initiative and the Manufacturing Initiative through contact with the private sector (including the PEC, ITACs, other) on a regular basis. Ensure that high-level DOC/ U.S. Government officials support dialogue on regulatory cooperation and address standards in Commerce's Trans-Atlantic Business Dialogue (TABD) as it is re-launched.
- b. Determine ways to best utilize existing resources to promote U.S. standards interests in key markets and research possible collaboration/funding sources including the Commercial Law Development Program (CLDP), Middle East Partnership Initiative (MEPI) (State Department) grants, Trade Development Agency (TDA), United States Agency for International Development (USAID), as well as private-sector sources. The Manufacturing Extension Partnership (MEP) may be utilized as a vehicle for outreach to SMEs.
- c. Develop a draft paper for the TPSC on Trade Capacity Building outlining the available standards-related assistance and approaches, which broadly support U.S. objectives in this area. Such a document could be useful to U.S. donor and trade agencies and could be the basis for a more coordinated approach to standards-related technical assistance.
- d. Collaborate with ANSI on the revision of the National Standards Strategy.¹⁰

¹⁰The U.S. National Standards Strategy was developed by ANSI over a two-year period by a diverse group of government and private-sector representatives from industry, government, trade and professional societies, and consumer organizations, and was published in August 2000 as a roadmap to developing reliable, market-driven standards in all sectors. ANSI has announced its intent to revise the National Standards Strategy in 2004-2005.

- e. Consult with interested parties and develop a summary of the U.S. standards system, which captures the relevance of market forces, for use as a marketing and educational tool. Explore ways in which DOC can promote the U.S. standards approach to foreign governments as options for them to consider in their markets. Emphasis would be on SDO use of open, transparent, and consensus-based procedures.
- f. Promote awareness of Export Alert! and provide guidance to exporters on how to provide technical comments on proposed regulations in foreign markets.
- g. Develop and conduct presentations for Members of Congress and Hill staff to raise awareness of standards-related trade issues and their effect on U.S. exports.

5. Improve Public and Internal Access to Information on Standards and Technical Regulations (Initiative Points 4 and 5)

During the industry roundtables, it became clear that both industry and government lack information and have imperfect understanding of standards-related materials and developments. Some resources exist, but they are difficult to locate and understand. The Department will work to improve the flow and understanding of key information by improving its information network and providing a centralized location where information can be stored.

Improve Public Access to Information:

- a. Assemble existing standards-related resources on a single, dedicated Web site with links to key resources such as export.gov, standards.gov, regulations.gov, and private sector (SDO/ANSI, trade associations, etc.) sites. Include ability for interested parties to receive regular e-mail updates.
- b. Establish a plan for an early warning system to provide the private sector and DOC an advanced signal of potential trade-related standards concerns identified in technical committees or other venues.
- c. Evaluate early warning systems used by other U.S. Government agencies, specifically USDA's tiered early warning system.
- d. Support the newly developed pilot Western Hemisphere Regional Program, which was launched in February 2004 and will expand DOC's early warning system. The proposed Standards Regional Program underscores the importance of standards-related issues and work for the Commercial Service. It calls for each Senior Commercial Officer to support the Regional Standards Program by assigning one Commercial Officer and one Commercial Specialist to lead the "standards team" to monitor and report on standards and compliance matters.

Improve Internal DOC Access to Information:

- a. Determine how existing DOC databases which compile information on trade issues can be used or expanded upon to facilitate an understanding of “best practices” when addressing standards-related trade issues. Develop and provide “best practice” guidance to Commerce staff on addressing and resolving standards-related trade problems.

6. Improve Coordination with other U.S. Government Agencies (Point 6)

- a. Addressing the standards-related concerns raised by roundtable participants will require coordination with agencies beyond DOC. In addition, because participants indicated a desire for consistent policies and implementation mechanisms among U.S. Government agencies, the Department will coordinate with other U.S. Government agencies through existing interagency mechanisms, including the Trade Policy Staff Committee Subcommittee on Standards and Technical Barriers to Trade and the Interagency Policy Subcommittee on Standards.
- b. Develop or improve existing interagency contacts to communicate with/cooperate on common standards-related issues (e.g., Codex/ISO coordination).
- c. Provide a common understanding of DOC and other U.S. Government policies on standards and conformity assessment and technical regulations (i.e., national treatment, use of MRAs, U.S. rulemaking process, and other regulatory rules and policies, etc.).
- d. Improve mechanisms for interagency coordination (both DOC and U.S. Government) on trade-related standards issues and policy development, including FTAs.
- e. Continue to work with other public sector organizations to provide technical assistance, possibly including USAID, TDA, and Small Business Administration (SBA).

New/Improvement Initiatives

7. Improve Interactions with China

Input from industry clearly showed significant concern with China and its development and promotion of domestic standards. Industry representatives reported that China’s rulemaking and standards development process lacks transparency. Additionally, a 2004 U.S. General Accounting Office survey of American companies with a presence in China found that standards and certification issues ranked first in importance on a list of specific China WTO implementation commitment areas, above customs procedures, tariffs, and intellectual property rights. The 2004 survey results are notably different from a similar survey done in 2002, where GAO survey respondents ranked standards and certification issues as the 20th important of 30 WTO-related commitment areas. These results suggest a growing awareness in the business community of standards as a key trade issue for U.S. exporters to China. The Department should expand on current programs relating to standards in China, including initiatives announced by the Secretary in Beijing in October 2003.

- a. Support U.S. industry and SDO efforts to partner with the Chinese government and industry on standards development as China modernizes its standardization system to comply with its WTO obligations.
- b. Support and work closely with U.S. industry in their efforts against China's use and promotion of its domestic standards not developed using WTO guidelines.
- c. Continue to monitor China's compliance with its standards obligations contained in its WTO accession package and with the TBT and SPS Agreements.
- d. Expand on current DOC China-specific technical assistance efforts to ensure China is able to implement its WTO obligations in the TBT and SPS areas, including 2004 and 2005 comprehensive workshops as well as increased sector-specific programs and increased technical cooperation with Chinese provincial and local authorities and businesses.
- e. Continue efforts to ensure China's CCC safety mark does not create market access or trade barriers to U.S. manufacturers and exporters to China through continued industry outreach and cooperation with China's conformity assessment authorities.
- f. Explore ways to strengthen current U.S. Embassy Beijing Commercial Service staffing in the standards area.
- g. Continue ongoing DOC CCC Mark seminar series, which provides information on China's new certification and standards requirements, including the CCC safety mark to U.S. exporter audiences.
- h. Expand efforts to encourage U.S. industry and SDOs to utilize WTO mandated comment periods to influence Chinese mandatory standards and promote a better understanding of how to work within China's standards development system.
- i. Periodically assess how Chinese standards development and new standards affect U.S. exports and market access to key industry sectors.

8. Improve Interaction with Other Foreign Governments

Roundtable participants repeatedly noted that the Department should work with USTR and other U.S. Government agencies to increase and improve dialogue with foreign governments on standards-related issues, especially to foster better understanding of U.S. and international standards development and help identify opportunities where U.S. standards may be promoted.

- a. Enhance focus of existing Department workshop programs¹¹ to educate foreign government officials on the U.S. standards and conformity assessment system and to build bridges for future cooperation. Focus programs more on strategic markets and sectors.
- b. Improve coordination of standards and conformity assessment-related programs under DOC's Commercial Law Development Program. Focus programs more on strategic markets and sectors and expand inter-departmental use and coordination of training materials and target audiences.

¹¹These include NIST's SIT Program and the SABIT Standards Program.

- c. Where feasible, facilitate dialogue between U.S. regulators and foreign regulators to engage government authorities on questions of standards, governance, and regulatory discipline. For example, in Europe, work with European Commission (EC) regulators to find solutions for regulatory problems with the EU, and to ensure justification, transparency, and openness in the development of directives, as well as “national treatment” and accountability in their application.
- d. Continue to make sure that existing and new members of the WTO fulfill their obligations.
- e. Continue to support private sector and other interested parties understanding of standards and conformity assessment procedures in key markets. Discuss the U.S. standards system during bilateral, regional, and multilateral meetings or fora.
- f. Create and maintain regular and ongoing information exchange between posts and in-country standards players in key foreign markets.

9. Address Concerns about ISO and IEC

Roundtable participants expressed the perception that the EU has disproportionate influence in ISO and IEC because European standards are often adopted as ISO standards and each EU member has a separate vote. However, it was also recognized that many U.S. standards have been adopted as ISO standards as well.

- a. Work with the U.S. private sector to ensure that U.S. interests receive fair treatment in the international standards development process, including ISO and IEC.
- b. Support ANSI’s efforts to develop and disseminate materials on ISO/IEC rules for participation.
- c. Work to develop a plan that would better ensure that the intellectual property of standards developers is protected.
- d. Work with ANSI to track issues raised by U.S. industry and to support ANSI’s efforts to ensure fair consideration of U.S. concerns with ISO and IEC rules, procedures, and actions.

10. Continue to Provide Effective Implementation of U.S. Trade Policy

Representatives of the U.S. private sector would like the U.S. Government to take a more aggressive role in other countries’ implementation and compliance with international trade agreements, including the WTO TBT and SPS Agreements. They also have expressed an interest in the U.S. Government continuing to pursue standards-related trade issues with foreign governments on a bilateral and/or multilateral level, including issues which are not necessarily direct violations of existing WTO Agreements. These recommendations go beyond areas under the direct control of the Department and will need to be vetted inter-agency. Specifically, U.S. Government representatives must continue to:

- a. Ensure that countries adhere to the WTO Agreements, including the SPS and TBT Agreements; use science-based risk assessment where appropriate; encourage foreign governments to permit open participation in the standards setting process and ensure that the process is transparent.

- b. Continue to make suggestions for improvement during relevant WTO Committee reviews, including reviews of the TBT and SPS Agreements.
- c. Consult with industry on opportunities to enhance standards-related obligations in our FTAs; work to ensure consistency across FTAs. (PEC—again emphasize importance of standards provisions in FTAs.)
- d. Provide USTR support in providing technical assistance to FTA partners, so that these countries can meet their obligations under the WTO and the FTAs in a timely manner.
- e. Collaborate with USTR more actively through the TPSC process.

11. Long-Term Strategies

- a. Partner with colleges/universities on R&D aspects of new technologies and influence standards at earliest stages of development of new technologies
- b. Expand inclusion of standards curricula in engineering and business schools, through partnerships with organizations such as the Accreditation Board for Engineering and Technology (ABET), ANSI, National Science Foundation, engineering societies, and trade associations.

Appendix A - DOC Standards-Related Activities and Recent Accomplishments

Company/Sector-Specific

DOC has helped to resolve numerous U.S. private-sector standards-related trade issues and has made positive progress on others.

DOC acts to ensure that foreign governments maintain compliance to their trade obligations. For example, in 2003, Commerce significantly contributed to U.S. Government efforts to ensure that Mexico upheld the 1996 U.S.-Mexico Tire Certification Agreement. Mexico had stopped accepting the test results because of slight changes to standards listed in its technical regulations. U.S. Government and Congressional advocacy resulted in Mexico reaffirming its commitment to the 1996 Agreement. Tire exports that may have been affected were valued at approximately \$500 million.

Commerce also helps interested parties in the United States understand and take advantage of the benefits resulting from WTO Agreements. Several industries expressed concerns to DOC about the EC's proposed regulation concerning the Registration, Evaluation, and Authorization of Chemicals (REACH). Commerce and other agencies, such as EPA, provided significant outreach to industry to inform them of the pending regulations and the process by which to comment and input into the EU's regulatory process. As a result, many U.S. technical comments were provided on this extensive regulatory proposal, which contributed to the more than 6,000 total comments received by the EC.

Commerce collaborates with industry to help other countries understand and consider adopting standards used in the U.S. market. Recently, DOC encouraged Latin American countries to consider the adoption of U.S. standards such as the Advanced Television Systems Committee (ATSC) standard. This resulted in a non-binding Inter-American Telecommunication Commission (CITEL) resolution, which recommends that there be a common regional standard for digital TV broadcasting. In addition, Argentina has adopted and Mexico has agreed to adopt the standard and the resolution.

Additionally, Commerce staff facilitated meetings and communications between the Australian Government and U.S. private sector when Australia was considering switching standards for medical device bar coding. Australia's initial proposal was to accept only the European bar-coding standard, and U.S. manufacturers would have been faced with lost sales or been forced to re-label their products after they were shipped to Australia. In the end, the Australian health industry for medical devices decided to accept both voluntary private sector and European standards.

Commerce also engages countries bilaterally to help them understand how acceptance of products meeting U.S. regulatory requirements can satisfy their market needs. Recently, DOC engaged Taiwan authorities in discussion on emission standards for motorcycles. Taiwan authorities agreed, as an initial measure, that Taiwan would allow the importation of motorcycles that met California's emissions standards.

Training

Commerce provides and facilitates training on standards-related issues in several ways.

Commerce can partner with private-sector companies or trade associations on standards training in a specific sector. DOC recently collaborated with the American Chamber of Commerce and the Government of Russia on two medical device and pharmaceutical regulatory training programs in Moscow to encourage Russian officials to adopt international standards and to modify their regulatory system to comply

with international practices. Specifically, the goals of the International Committee for Harmonization for pharmaceuticals and the Global Harmonization Task Force for medical devices were discussed, and Russian participation in these international organizations was encouraged.

Commerce provides sector-specific technical assistance programs on standards-related issues for a particular country. China has received standards-specific training on medical devices, environmental technology, pressure equipment, elevator and telecom standards, and risk assessment methods for fertilizer. Also, DOC co-sponsored a comprehensive standards workshop with China's Ministry of Science and Technology in 2003. DOC has reached an agreement with the Chinese Government on a series of "U.S.-China Standards Workshops" with China's primary standards body, the Administration of Quality Supervision, Inspection, and Quarantine, to be held in 2004 and 2005.

Commerce also provides informational materials on important standards-related information that assists exporters in accessing foreign markets. Staff authored manuals for the EU's CE Mark, which lays out guidance on how to comply with the three most frequently requested CE Mark directives—machinery, electromagnetic capability, and low voltage.

Commerce increases opportunities for U.S. private-sector representatives to discuss standards development with developing countries. Commerce notifies the private sector of opportunities to participate in conferences and workshops, encourages standards training, and information exchange with colleagues based in many developing countries, including Africa, the Middle East, Latin America, and South East Asia.

Commerce works through regional organizations to provide training opportunities. Commerce is organizing a series of educational workshops for automotive technical regulation and safety experts in five Association of Southeast Asian Nations (ASEAN) countries (Philippines, Thailand, Malaysia, Indonesia, and Vietnam), to be held in 2004, under the Asia Pacific Economic Cooperation (APEC) Automotive Dialogue.

Funding

Commerce's Market Development Cooperator Program (MDCP) provides grant funding for the private sector, including several recent grants for projects with standards-specific objectives in mind. IPC, an Illinois-based association of the electronic interconnection industry, used its MDCP grant to facilitate adoption of its standards in China by opening an office in Shanghai, promoting a Web site, translating standards, hosting educational seminars, developing technical certification programs, establishing a trade show in China, and organizing three trade missions to China.

Additionally, Washington-based Advanced Television Systems Committee (ATSC) Forum, a group of digital television manufacturers & service firms, used its MDCP grant to promote the use of U.S. standards, such as the (ATSC) DTV standard. Focusing on critical Latin American markets such as Brazil, Mexico, and Chile, ATSC Forum provided technical briefings and exhibited U.S. industry technologies to public and private interests, and participated in government bilateral and multilateral discussions on standards to these countries.

Finally, NEMA used its MDCP award to help U.S. firms increase exports to China, provide direct participation in standards committees in China; and publish standards that cover products of U.S. industry firms. NEMA will open a Beijing office headed by a local industry expert who will prepare NEMA literature in Chinese, coach U.S. executives, lead trade missions, organize technical seminars, participate in

standards committees, and publish standards that cover products of U.S. industry firms. This model is based on similar offices they have launched in Brazil and Mexico with MDCP assistance.

Commerce also partnered with Duquesne University's Chrysler Corporation Small Business Development Center (SBDC) over a three-year period to help educate U.S. companies on European trade regulations and the CE Mark, which now affects over 50 percent of U.S. exports to the EU. This successful partnership was the direct result of a Market Development Cooperator Program (MDCP) Award to Duquesne University's SBDC.

Outreach

Commerce conducts various outreach events to industry, where standards-related issues are discussed. These activities include numerous national and foreign outreach trips promoting compliance and market access services. These presentations have resulted in Commerce engagement of many private-sector standards-related trade concerns. Additionally, Commerce has supported 52 different domestic standards events, focusing on the CE Mark, EU standards training, and the CCC Mark for China. DOC has also promoted the Export Alert! Service, which allows U.S. interested parties to receive information on recently proposed foreign technical regulations. Since the launch of the Web site in October 2001, 1,876 subscribers have signed up for Export Alert! Most recently, Commerce has assisted U.S.-based SDOs and other organizations start to establish a private-sector-led Consortium for Standards and Conformity Assessment in China.

Technical Contributions

Several Department of Commerce bureaus participate directly in standards development and related activities, helping to ensure the technical efficacy of standards at both the national and international levels. These contributions include participating as measurement experts in the development of test methods; product, system, and process specifications; and other types of standards; participating in data collection efforts in support of the development of test methods; and providing measurement standards needed to calibrate instruments used in test methods. Activities at the international level support the consideration of U.S. technology in standards used globally. Examples include international standards for the exchange of product model data, for IT security evaluation and for broadband wireless access. NIST efforts under two MRAs with international counterparts—through the International Committee on Weights and Measures and ILAC—contribute to the acceptance of U.S. products abroad, facilitate global U.S. company operations, and support other federal agencies.

The video quality metric (VQM) developed by NTIA's ITS was the top performing metric for digital video quality measurement systems in independent tests performed in 2003 by the International Telecommunication Union Video Quality Experts' Group. The new standardized VQM measurement tools will enable companies and public entities to determine, through objective technical means, the quality of digital video pictures for new telecommunication services such as direct broadcast satellites, digital and high definition television, video teleconferencing, telemedicine, and e-commerce. These innovative techniques to measure the quality of digital video pictures will significantly enhance the competitiveness of U.S. companies and lead to higher quality products for consumers.

¹²Decisions and Recommendations adopted by the WTO TBT Committee since January 1995, G/TBT/1/Rev. 8, 23 May 2002, Section IX (Decision of the Committee on Principles for the Development of International Standards, Guides, and Recommendations with relation to Articles 2, 5, and Annex 3 of the TBT Agreement issued by the WTO TBT Committee.

Trade Negotiations

Commerce assists the USTR in standards-related trade negotiations. DOC has worked to include industry positions on standards and conformity assessment into recent FTAs. Specifically, the FTAs included provisions to apply the Decision of the TBT Committee on Principles for the Development of International Standards, Guides, and Recommendations.¹² The Committee adopted this decision containing a set of principles it considered important for international standards development. The dissemination of such principles by Members and standardizing bodies in their territories would encourage the various international bodies to clarify and strengthen their rules and procedures on standards development, thus further contributing to the advancement of the objectives of the Agreement. The inclusion of this decision in FTA is a result of broad private-sector support for this decision and how it supports a broad view of international standards. Commerce also supported USTR in preparing for negotiations on non-tariff barriers in the WTO's Negotiating Group on Market Access.

Multilateral

Commerce undertakes several activities in multilateral organizations to address standards-related issues. DOC supported USTR in addressing countries' compliance with the WTO Agreements, including the TBT Agreement. For example, the U.S. Government raised concerns in the WTO for Gulf Cooperation Council implementation of its proposed International Conformity Certification Program, which the U.S. Government believed was inconsistent with WTO obligations, including the TBT Agreement. As a result, several GCC countries have either determined not to implement or delayed making a decision about implementation of this program.

Commerce participates on U.S. delegations to international standardization organizations. In cooperation with the ANSI and other private-sector interests, Commerce monitors ISO to ensure that CODEX food safety standards are not duplicated. DOC also assists in educating U.S. regulatory agencies about the trade policy issues in international SDOs.

Commerce works with interagency groups on other trade agreements as well. Commerce has significantly contributed to U.S. Government efforts to negotiate the World Wine Trade Group Mutual Acceptance Accord. The United States and six other major wine producing countries have agreed to accept each others oenological (wine-making) practices, thus opening up the wine markets to increased trade and investment. The signatory countries are: the United States, Argentina, Australia, Canada, Chile, New Zealand, and South Africa. Agreement also has been reached by the same parties on issues related to the labeling of wine products.

Bilateral

Commerce takes part in bilateral efforts to address standards issues. Two examples include recent Protocol Agreements on standards and technical cooperation with two of China's primary standards-related government agencies and efforts to continue to meet with the Korean Government on a regular basis to discuss outstanding standards issues. A key example of a success of the U.S. Government effort in Korea is the 1998 U.S.-Korea Memorandum of Understanding on Automotive Trade. Frequent consultation with the Korean government resulted in the smooth implementation of a self-certification system for Korea's automotive safety regulations.

Appendix B—Coordination of Standards Efforts within DOC Questionnaire (July 2003)

General Questions

1. Does your agency handle trade-related standards issues and concerns? If yes, please continue. If not, no further action is necessary.
2. What groups and programs within your agency are responsible for standards-related activities? Please list areas of responsibility and contact points (name, phone number and email).
3. How does your agency, or individuals within it, learn of standards related concerns?
4. What steps are taken when a concern arises?
5. How do you capture and share this information?
6. Which standards bodies and organizations does your agency normally interact with?
7. What sorts of concerns about standards does your agency typically encounter? Do you have specific examples?
 - a. Requests for information about a particular standard, including how to obtain copies?
 - b. Information about proposed foreign standards and/or regulations that may affect trade?
 - c. Information about which specific standards or regulations might apply to a product?
 - d. Information about specific procedures required for product acceptance (i.e., testing, inspection, certification, etc.)?
 - e. Concerns arising during the development of and/or voting process for a standard?
 - f. Request for action to remove a specific trade barrier resulting from a standard and/or conformity assessment procedures?
8. Do you have examples of cases where either the technical requirements or the assessment process associated with a product or products resulted in market entry problems?
9. What resources, in both government and private sector, does your agency use to learn more about standards-related concerns? To assist in resolving a standards concern?
10. Do you have examples of a standards concern where your agency or the federal government has effectively resolved the issues?
11. What sorts of coordination mechanisms currently exist for sharing information within your agency about standards-related concerns?

12. What steps are taken when a concern arises?
13. How do you capture and share this information?
14. What improvements might be made? What actions would you recommend the Department under take following this inventory assessment?
15. What sorts of tools would be helpful? Electronic resources, databases, contacts, etc?

Appendix C

Acronyms

ABET	Accreditation Board for Engineering and Technology
ASME	American Society of Mechanical Engineers
ANS	American National Standards
ANSI	American National Standards Institute
APEC	Asia-Pacific Economic Cooperation
API	American Petroleum Institute
ASEAN	Association of Southeast Asian Nations
ATSC	Advanced Television Systems Committee
BIPM	International Bureau of Weights and Measures
CB Scheme	IEC System for Conformity Testing and Certification of Electrical Equipment
CCC	China Compulsory Certification
CEN	European Committee for Standardization
CITEL	Inter-American Telecommunication Commission
CLDP	Commercial Law Development Program
Codex	Codex Alimentarius
COPANT	Pan American Standards Commission
CSRM	Committee on Standards Related Measures
DOC	Department of Commerce
DOD	Department of Defense
DOS	Department of State
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organization
FIPS	Federal Information Processing Standards
FISMA	Federal Information Security Management Act
FRN	Federal Register Notice
FSTSD	Food Safety and Technical Services Division
FSN	Foreign Service National
FTA	Free Trade Agreement
IAF	International Accreditation Forum
ICT	Information and Communications Technologies
ICAO	International Civil Aviation Organization
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IFAC	Industry Functional Advisory Committee
IFAC 2	Industry Functional Advisory Committee on Standards
ILAC	International Laboratory Accreditation Cooperation
IMO	International Maritime Organization
INCITS	InterNational Committee for Information Technology Standards

ISAC	Industry Sectoral Advisory Committee
ISO	International Organization for Standardization
ITU	International Telecommunication Union
ITA	International Trade Administration
ITAC	Industry Trade Advisory Committee
ITS	Institute for Telecommunication Sciences
IPO	Intellectual Property Offices
JTC-1	Joint Technical Committee of ISO and IEC
MAC	Market Access and Compliance
MDCP	Market Development Cooperator Program
MRA	Mutual Recognition Agreement or Arrangement <i>(“Agreement” is used for government-to-government MRAs. “Arrangement” is used for non-governmental MRAs.</i>
MOU	Memorandum of Understanding
NAFTA	North American Free Trade Agreement
NIST	National Institute of Standards and Technology
NEMA	National Electrical Manufacturers Association
NOAA	National Oceanic and Atmospheric Administration
NTIA	National Telecommunications and Information Administration
NTTAA	National Technology Transfer and Advancement Act
NVCASE	National Voluntary Conformity Assessment System Evaluation
OECD	Organization for Economic Co-operation and Development
OGC	Office of General Counsel
OIML	International Organization of Legal Metrology
OMB	Office of Management and Budget
PASC	Pacific Area Standards Congress
PEC	President’s Export Council
PTO	Patent and Trademark Office
REACH	Registration, Evaluation, and Authorization of Chemicals
SAE	Society of Automotive Engineers
SBA	Small Business Administration
SBDC	Small Business Development Center
SDO	Standards Development Organization
SDOC	Suppliers’ Declaration of Conformity
SIT	Standards in Trade
SABIT	Special American Business Internship Training Program
SME	Small and Medium-Sized Enterprises
SPS	Sanitary and Phytosanitary Measures
TABD	Trans-Atlantic Business Dialogue
TBT	Technical Barriers to Trade
TD	Trade Development
TPSC	Trade Policy Staff Committee

TRM	Trade Review Mechanism
TDA	Trade Development Agency
UNECE	United Nations Economic Commission for Europe
USAID	United States Agency for International Development
USFCS	U.S. & Foreign Commercial Service
USTR	Office of the United States Trade Representative
VQM	Video Quality Metric
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization