US-EU HIGH-LEVEL REGULATORY COOPERATION FORUM

REPORT ON THE USE OF VOLUNTARY STANDARDS[1] IN SUPPORT OF REGULATION IN THE UNITED STATES

(October 2009)

1. PURPOSE OF THIS REPORT

This report responds to a request by the United States-European Union (US-EU) High-Level Regulatory Cooperation Forum to provide information on the use of standards in support of regulation in the United States. The report outlines the U.S. legal and institutional framework regarding the use of standards in support of regulation. The report includes a case study from the Federal Communications Commission (FCC).

2. BACKGROUND

The Administrative Procedures Act (APA), the Trade Agreements Act of 1979 (TAA), Executive Orders and other official guidance provide a framework for regulatory agencies concerning the development and implementation of regulations. As part of this framework, agencies consider cost, enforcement mechanisms, use of voluntary consensus standards and other factors, including the avoidance of unnecessary obstacles to trade.

How these procedures and considerations are applied may also depend on statutes applicable to individual agencies. The laws and policies governing regulations reflect the fact that regulations should achieve their intended objectives, and avoid imposing burdensome or unnecessary costs. Such costs may include harm to the economy and higher prices for goods and services including through the creation of unnecessary trade barriers. The use of standards within a regulation is one aspect of a much larger analysis and decision making process that must be undertaken by a U.S. regulatory agency. Agencies are required to look at many aspects of a proposed regulation, unless directed to do otherwise by the authorizing statute, including but not limited to:

- whether a market failure or other compelling public need exists for a regulation,
- whether regulation at the Federal level is the best approach,
- the use of alternative regulatory approaches,
- how well those approaches meet an agency's regulatory objectives,
- the costs and benefits associated with a proposed regulation,
- the cost-effectiveness of a proposed regulation,
- whether to use specific standards or parts of standards, and

[1]Office of Management and Budget (OMB) Circular A-119 defines the term "standard," or "technical standard" to include all of the following: (1) common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices; and (2) the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength.

- how the requirements contained in the regulation will be enforced.

Agencies review and analyze such issues -- both individually and collectively -- to determine the overall quality and effectiveness of the regulation.

2.1 Overview of the U.S. Regulatory Process

To better understand how the United States uses standards in regulation, it is necessary to first present a basic overview of the U.S. regulatory requirements and processes. Embedded in statutes and other documents guiding rulemaking in the United States are certain key principles, including:

- *Transparency in the making of technical assessments, factual findings, and normative policy choices, and transparent and open opportunities for public participation regarding those matters to ensure effective monitoring, critiquing and reviewing of rulemaking;*
- *Regulatory analyses, based on sound science and data and the consideration of alternative approaches to and stringency of regulation;*
- *Strong support from the government for the use of regulatory best practices; and*
- *Accountability of government agencies within the executive, legislative and judicial branches of the Federal government.*

Compliance with these principles increases the quality and effectiveness of the U.S. rulemaking process in meeting regulatory objectives, while minimizing the burden on industry and the public.

Article I, Section 1, of the Constitution gives the U.S. Congress the sole power to make statutes or laws. However, Congress has passed a number of statutes that delegate certain specified rulemaking authority to Executive Branch regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA). In so doing, Congress generally establishes factors/criteria within the statute to guide and limit how the agency exercises its use of that authority. The degree of specificity in Congress' delegation of authority and guidance varies from statute to statute. Each regulatory agency implements the authority given to it by Congress by developing and establishing regulations or rules to the extent necessary to achieve agency objectives. These regulations or rules, when finalized, have the force and effect of law. Regulations are almost always much more detailed than the statues or laws that authorize the regulation's issuance. The statute or law containing the rulemaking authority granted by Congress to an agency is known as the agency's authorizing or "enabling" statute. An agency may have more than one enabling statute.

Congress may also supplement an agency's enabling statute(s) by later enacting new statutes or laws giving agencies other authorities or directing the regulatory agency to use its existing general rulemaking authority in a specific way to meet legitimate national objectives, such as the preservation of health and safety, animal welfare, protection of the environment, or the protection of consumer choice. In some cases, an agency's appropriation acts may also add to or limit the implementation of an agency's authorities.

All such statutes are first made publicly available in final enacted form as a Public Law. They are then codified in the United States Code, which is also publicly available. In addition, proposed and final regulations are published in the Federal Register, which is publicly available. The regulatory text in final rules is then codified in the Code of Federal Regulations, which is again publicly available.

In addition to enabling and related statutes, there are other requirements that govern the development and issuance of rules or regulations by Federal agencies. These requirements include other statutes, such as the APA, TAA, the National Technology Transfer and Advancement Act (NTAA), as well as Presidential E.O.s and Office of Management and Budget (OMB) Circulars. These requirements impose procedural obligations that are intended to ensure reasoned and fair decision making, and to ensure international trade obligations are met. These other statutes, E.O.s, and Circulars typically require that the agencies adopt regulations only after thoroughly analyzing the potential impact of the proposed regulations and considering alternative regulatory approaches. For all economically significant regulatory actions, this analysis includes an assessment and comparison of the benefits and costs of the regulation, the regulation's cost-effectiveness, an analysis of alternative regulatory approaches, and an analysis of the impact of alternative levels of stringency in the requirements contained in the regulation. These requirements are designed to ensure an open and transparent U.S. rulemaking process that gives all members of the public the opportunity to participate. The process seeks to give the public the information needed to understand what the regulatory agency is proposing to do and the rationale for its actions.

If a proposed or final regulation is likely to have a "significant" impact, that is it's impact on the economy exceeding $100 million in any one year-as defined by E.O. 12866, the agency proposing the regulation must generally submit both the proposed and final versions of the rule to the OMB for review before it is published in the Federal Register. There are some limited exceptions to this requirement. OMB reviews each economically significant regulatory proposal to ensure that it is supported by adequate regulatory analyses and is consistent with the statutes enacted by Congress and the President's priorities. Regulatory analyses undertaken by an agency for economically significant rulemakings must include an analysis of a reasonable number of regulatory alternatives. Such analyses must also include an explanation and justification as to why a particular regulatory approach was selected. Congress also requires that regulatory analyses give special attention to the impact of the proposed regulation on small businesses; small, not-for profit organizations; and U.S. State, local, and tribal governments. Certain specific burdens that will be placed on the public as the result of the regulation, such as the time and effort necessary to complete any required paperwork, energy impact, the disproportionate impacts on children, and a number of other issues also have to be considered.

2.2 Process of Rulemaking

In general, the public portion of a rulemaking begins with the publication by the agency of a Notice of Proposed Rulemaking (NPRM)[2] notifying the public that the Agency may adopt a

[2] In some cases, agencies will first issue an Advanced Notice of a Proposed Rulemaking (ANPRM) to solicit public comment and feedback on a regulatory issue to determine the need for further rulemaking. This is a particularly useful tool when an agency is considering undertaking rulemaking in a new area. The ANPRM process can also be useful when an agency wants to test out a proposal or solicit ideas before it drafts its NPRM.

specific regulation in the future and providing an opportunity for the public to comment by submitting written data, views, and arguments. The NPRM must provide sufficient information to enable the public to envision and anticipate the major aspects of the Final Rule. The NPRM typically consists of two parts: a preamble, which is a narrative discussion; and the text of the proposed regulation. The preamble informs the public of the relevant issues and considerations and may include: information on the problem to be addressed by the proposal; an explanation as to why the agency has tentatively concluded that a regulatory response is warranted; the nature of the proposed regulatory approach as well as the details about the requirements, their levels of stringency, any relevant test procedures, and the proposed use of any standards; and a description of the available research studies and empirical data on which the proposed regulation was based.

In addition, the NPRM provides instructions for submitting written comments, either electronic or hard copy, and identifies an agency contact person who can respond to questions. The agency also generally has discretion on whether to supplement the opportunity to submit written comments with an opportunity to make oral presentations at a public meeting or hearing. In some cases, agencies are required to make such an opportunity available. To the extent that the NPRM does not set forth and explain all of the factual assumptions, analyses, and methodologies that underlie the proposal, the agency will place documents addressing those matters in a public docket[3] so that the public has an opportunity to read and comment on them. The agency also places all comments it receives in response to the NPRM in the public docket, with the exception of documents containing confidential business information, including trade secrets. Most Federal agencies also participate in *Regulations.gov*, an internet website that facilitates public participation in the Federal regulatory process by improving the public's ability to locate, review, and provide comment on Federal regulations.

There are *no* restrictions on who may participate in the comment process. The comment process is open to all, including individuals, businesses, and government agencies of other countries and regions. Persons wishing to comment are not subject to any governmentally controlled or sponsored selection process. Businesses and consumers decide for themselves whether to participate and may participate directly (i.e., individually), indirectly through associations and other representatives, or both. Inquiry Point operations in the U.S. Departments of Commerce and Agriculture facilitate access to the comment process by interested parties, including those in other countries.

Comments can include suggestions for the adoption of all or parts of a specific standard within the proposed regulation, as well as comments both for and against any standard or parts of a standard that the agency has proposed to incorporate into the regulation. Comments may also cover many other aspects of the proposed regulation.

The comment process serves a number of purposes, including enabling the public to:

- *Provide the agency with information, including information on standards, to enhance the agency's knowledge;*

[3] A public docket is a repository for rulemaking and supporting documents (e.g., Federal Register notices, supporting analyses, and comments) for public access and comment.

- *Challenge the agency's interpretation and application of data and research, factual assumptions, analytical methodologies, tentative factual, technical, legal, and policy conclusions, practicability assessments, and assessments of the benefits and other impacts of the proposal, including those that are standard-related; and*
- *Suggest alternatives (including standards-related alternatives) to the proposed requirements and test procedures.*

The agency must then consider the data, views, and arguments submitted by the public, including any substantive comments related to the use and content of standards that may be incorporated into the regulation. In issuing any Final Rules (the revised version of a proposed regulation which will be binding on the public when effective), the agency must provide a statement of the rule's basis and purpose and include the agency's discussion of and response to the public comments, which again includes those that are standards-related. Although many of the analytic requirements for rulemakings are established by Executive Order and other Executive Branch guidance, some of the requirements of a final rule have developed from case law, such as the obligation of agencies to adequately respond to significant comments and to provide a reasonable basis for the regulatory approach that the agencies has chosen and therefore may be challenged in court. It should be noted that there are exceptions to this process in cases where emergency rulemaking is necessary.

3. POLICY AND LEGAL CONTEXT FOR THE USE OF STANDARDS IN SUPPORT OF REGULATIONS/ PROCUREMENT

3.1 Obligations at the National Level

The U.S. Federal regulatory system, described above, is designed to protect and improve the health, safety, and well being of U.S. citizens and to protect the environment. It seeks to improve the effectiveness of regulation without imposing unacceptable or unreasonable costs on society. U.S. regulatory policies recognize that marketplace forces are generally the best engine for driving economic growth. U.S. regulatory policies emphasize that regulations should be cost-effective, consistent, sensible, and understandable, and that the regulatory process should be open, transparent and fair to all interested parties. Consistent with this philosophy and to codify a long standing practice by Federal agencies, the U.S. Congress enacted *Public Law* 104-113, also known as the *National Technology Transfer and Advancement Act* (NTTAA), in March 1996.[4] The NTTAA and the Trade Agreements Act of 1979, as amended (TAA) [5] are two key pieces of U.S. legislation affecting the regulatory and procurement use of standards. The NTTAA directs federal agencies to use, when practical and not otherwise prohibited by law, standards developed by voluntary consensus standards bodies to achieve public policy and procurement objectives, and the TAA prohibits federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade and requires federal agencies to take into consideration international standards.

[4] A copy of the entire text of the law is available at: http://standards.gov/standards_gov/nttaa.cfm.

[5] The standards-related provisions of the TAA are codified at United States Code, Title 19, Chapter 13, Subchapter II, Technical Barriers to Trade (Standards).

The NTTAA directs U.S. Federal agencies on their use of standards developed by voluntary consensus standards bodies for both regulatory and procurement purposes. It instructs U.S. Federal agencies to use voluntary consensus standards wherever practical, in lieu of creating government-unique standards. In addition, the Act instructs agencies to review their development and promulgation of conformity assessment requirements and measures with the goal of eliminating unnecessary duplication and complexity in such requirements. The Act also charges the National Institute of Standards and Technology (NIST)[6] with coordinating the standards needs of U.S. Federal agencies to achieve greater reliance on voluntary consensus standards.

Further guidance on implementing the NTTAA is contained in the Office of Management and Budget's (OMB) Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*.[7] This Circular instructs agencies to use voluntary consensus standards in lieu of government-unique standards, except where such usage is inconsistent with law or otherwise impractical. It defines "voluntary consensus standards" as standards developed or adopted by a voluntary consensus body. It also defines a "voluntary consensus body" as an organization – whether domiciled in the United States or elsewhere – that has the following attributes: openness, balance of interests, due process, an appeals process, and consensus. The Circular also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. The aim of the Circular is minimize agency reliance on government-unique standards.

The law and the Circular also recognize that participation in voluntary standards development can benefit agencies in a wide range of activities. U.S. agencies and departments, including regulatory agencies, participate in the development of domestic and international standards as one means of helping to achieve specific goals and missions through cooperative efforts in a wide range of health, safety, environmental, technical and other areas. The Circular directs aagencies to consult with voluntary consensus standards bodies, both domestic and international, and to participate with such bodies in the development of voluntary consensus standards when consultation and participation is in the public interest and is compatible with the agencies' missions, authorities, priorities, and budget resources. Such participation also is carried out in accordance with other applicable policies and laws as well as international agreements such as the WTO Agreement on Technical Barriers to Trade (TBT).

The TAA implements U.S. obligations under the TBT Agreement regarding the development, adoption, and application of technical regulations, standards, and conformity assessment procedures. Specifically, the TAA prohibits Federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade. It further directs Federal agencies to ensure non-discriminatory treatment in applying standards–related activities to any imported product. The TAA directs each Federal agency to use performance based requirements, if appropriate; to take into consideration international standards; and, if appropriate, to base technical regulations on international standards. Further, the TAA

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[6] The National Institute of Standards and Technology (NIST) is an agency with the U.S. Department of Commerce.

[7] A copy of the entire text of OMB Circular A-119 is available at: http://standards.gov/standards_gov/a119.cfm.

provides an illustrative list of reasons that it may not be appropriate to base a technical regulation on an international standard.

There are also other policies and statutes that direct agencies to rely on voluntary consensus standards and avoid use of government-unique standards. For example, such policies and statutes include:[8]

- *The Consumer Product Safety Act, which directs the Consumer Product Safety Commission to rely on voluntary consensus consumer product safety standards rather than promulgate its own standards;*
- *The Telecommunications Act of 1996, which contains several provisions that encourage Federal Communications Commission (FCC) reliance on private sector standards;*
- *The Food and Drug Administration (FDA) Modernization Act of 1997, which contains provisions that allow the FDA in some instances to accept attestation to certain standards during the evaluation of premarket submissions for electrical medical devices; and*
- *MILSPEC Reform, which has resulted in the Department of Defense's (DoD's) moving away from unique specifications and standards (MILSPECS) and toward reliance on private sector standards.*

These Acts of Congress and executive branch policies set forth requirements and goals regarding Federal usage of standards.

3.2 Stakeholder Participation in the Regulatory Use of Standards

In accordance with the NTTAA, the TAA, and U.S. international obligations, U.S. regulators (in considering what standards to use in regulations) look to standards that have been developed in accordance with certain principles. These principles include: transparency, openness, impartiality/balance and consensus. Most standards developers within the U.S. standards system endorse the principles of openness, balance, and lack of dominance in the standards development activities.[9] Standards developed in accordance with such principles

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[8] Based on information compiled by the *American National Standards Institute (ANSI), "Significant Federal Laws and Policies,"http://www.ansi.org/government_affairs/laws_policies/laws.aspx?menuid=6*

[9] The American National Standards Institute (ANSI) has established a process to approve standards as "ANS" standards. ANS standards must have been developed in accordance with the following principles:

- *Openness* means that participation in a standards development activity is open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation, and voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.
- *Lack of dominance* means that the standards development process is not to be dominated by any single interest category, individual or organization. This applies to government agencies that choose to participate in a standards development process. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.
- *Balance* means that standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance.

allow any interested party or stakeholder, whether or not based in the United States, to participate as an equal member in the standards development process and to have his or her viewpoint fairly considered. A representative from one or more government agencies may participate and have his or her viewpoint(s) heard, but such viewpoints do not carry more weight than those of other stakeholders in the process. In other words, agency representatives are not to dominate the process.

Thus, during the standards development process, stakeholders have the opportunity to influence the content of any standard developed by bodies that adhere to these principles, including standards that might be used in regulatory applications. During the rulemaking process, stakeholders have a second opportunity to influence the choice of standard or parts of a standard that a regulatory agency may be considering for adoption. As noted above, the U.S. rulemaking process is committed to transparency in the development of technical assessments, factual findings, and normative policy choices. It is also committed to transparency and openness in the public participation process regarding those matters to ensure effective monitoring, critiquing and reviewing of the rulemaking process.

4. IMPLEMENTATION

4.1 Implementation of Legislation and Policies

As mentioned above, OMB Circular A-119 provides support for the implementation of the NTTAA. The Circular contains guidance for Federal agencies and sets forth policies on Federal use of and participation in the development of voluntary consensus standards and on conformity assessment activities. NIST is charged with carrying out the responsibility of the Secretary of Commerce to coordinate, foster and otherwise implement the provisions of the Circular within the Executive Branch of the U.S. government NIST provides administrative guidance and assistance to other Federal agencies, including identifying voluntary consensus standards and conformity assessment bodies that support agencies' missions. The TAA gives the United States Trade Representative (USTR) the lead role within the Federal government on the coordination and development of international trade policy related to implementation of the standards-related provisions of the Act. The TAA also gives USTR the responsibility for coordinating discussions and negotiations with foreign countries for the purpose of establishing mutual arrangements with respect to standards-related activities. Coordination under the NTTAA and the TAA is conducted through two interagency committees.

The Interagency Committee on Standards Policy (ICSP) is charged with providing consistent and effective standards policies across government. The ICSP was authorized by OMB Circular A-119 and is chaired by NIST. The ICSP provides advice and recommendations to the Secretary of Commerce and other Executive Branch agencies on matters related to Federal standards policy. Besides promoting effective and consistent standards policies, the ICSP fosters cooperation between government, industry, and other private organizations involved in

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In addition, public and private sectors joined together under ANSI auspices and published the United States Standards Strategy (USSS) in 2005. The Strategy confirms the U.S. commitment to these and other internationally accepted principles of standardization endorsed by the World Trade Organization (WTO) – transparency, openness, impartiality, effectiveness and relevance, consensus, performance-based, coherence, due process, and technical assistance. A copy of the USSS is available at: http://www.ansi.org/standards_activities/nss/usss.aspx?menuid=3

standards activities. The ICSP also seeks furtherance of U.S. domestic and foreign goals, and, to this end, fosters cooperative participation by the Federal government and U.S. industry and other private organizations in standards activities. This includes the related activities of sampling, inspection and testing; management system registration; certification; and accreditation. The ICSP meets three to four times a year and is composed of Federal agency standards executives or their designated representatives.

To ensure that agencies are following the provisions of the NTTAA and the Circular, Federal agencies must annually report to NIST on: their participation in standards development organizations and conformity assessment activities; their adoption and use of voluntary standards; and on the promulgation of any government-unique standards, along with agencies' rationales for such use. This results in an annual review of the standards activities of the U.S. government. NIST files annual summary reports with the OMB, which are sent to Congress. Individual agency reports and the annual summary reports to OMB and Congress are available at Standards.gov, a NIST-supported web portal for government standards activities.

Meanwhile, USTR oversees an interagency trade policy process that incorporates input from numerous government agencies, including regulatory agencies, in the implementation and coordination of U.S. trade policy.[10] The vast majority of decision-making on standards-related activities takes place at the Trade Policy Staff Committee (TPSC) Subcommittee on Technical Barriers to Trade. In cooperation and coordination with relevant agencies, including regulatory agencies, the USTR monitors U.S. compliance with WTO and any other international obligations related to technical regulations, standards, and conformity assessment procedures, including those associated with the use of international and performance-based standards.

As noted previously, agencies are required to use relevant international standards to the extent provided in Article 2.4 of the WTO TBT Agreement and other trade agreements, as a basis for their technical regulations. However, agencies are not prevented from taking measures at levels the agencies consider necessary for the protection of human, animal, plant life or health, and the environment; or for the prevention of deceptive practices. International standards can be used by regulatory agencies to meet these objectives. The policy of the U.S. government is to use the term "international standard" to refer those standards developed in a manner that is consistent with the World Trade Organization (WTO) Technical Barrier to Trade (TBT) Committee's *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 Agreement*.[11]

All economically significant government regulations require the preparation of a detailed Regulatory Impact Analysis (Presidential Executive Order (E.O.) 12866).[12] According to

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[10] The interagency coordination process among U.S. Federal agencies related to good regulatory practice is described in detail in the Communication from the United States to the WTO Committee on Technical Barriers to Trade, "Good Regulatory Practice: The Role of Strong Central Government Coordination in TBT Agreement Implementation," G/TBT/W/315.

[11] See Annex B of G/TBT/1/Rev.9.

[12] For a copy of E.O. 12866, see http://www.whitehouse.gov/omb/inforeg/eo12866.pdf.

OMB Circular A-4, which provides more detail on how to conduct a proper Regulatory Impact Analysis (RIA), the agency should carefully analyze any concerns that their rulemaking could create a non-tariff barrier. Although Circular A-4 does not specifically require it, many agencies do consider the costs and benefits of using international standards as a part of their analyses. In fact, an OMB-EC joint report on considering the international impacts of regulation recommended that agencies should consider existing international standards or regulatory approaches as an explicit regulatory alternative in an RIA. OMB encourages such analysis of standards under Circular A-4, concluding that such analysis would satisfy an agency's obligation to consider standards under OMB Circular A-119 and the NTTAA. In addition, as noted above, the TAA requires Federal agencies to take into consideration international standards and to base an agency's requirements on international standards where appropriate.

For example, on November 23, 2005, the U.S. Federal Aviation Administration (FAA) published a Notice of Proposed Rulemaking (NPRM) in the Federal Register entitled "Reduction of Fuel Tank Flammability in Transport Category Airplanes." This NPRM was designed to alleviate a risk that had led to several fatal airplane accidents caused by fuel tank explosions, including the Boeing 747 TWA Flight 800 explosion off Long Island, New York in 1996. The FAA proposed new rules that would require operators and manufacturers of all transport-category airplanes in operation in the United States, including airplanes manufactured by Airbus, to take steps to prevent electrical and other systems from igniting flammable vapors in the fuel tank. In its analysis of the impact of the proposal, the FAA specifically noted that the FAA had also considered the interaction of this rulemaking with international standards. Specifically, in keeping with U.S. obligations under the Convention on International Civil Aviation, FAA's policy was to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA determined for purposes of the proposed rulemaking that there were no applicable ICAO Standards and Recommended Practices.

On August 23, 2007, the U.S. Customs and Border Protection (CBP) of the Department of Homeland Security (DHS) published a final rule in the Federal Register entitled "Advance Electronic Transmission of Passenger and Crew Member Manifests for Commercial Aircraft and Vessels." This final rule required electronic manifest transmission to CBP of passenger and crew member information for those onboard international commercial flights and voyages to and from the United States. The rule noted that CBP policies allowed data transmission under this rule to follow the UN/EDIFACT (United Nations/Electrical Data Interchange for Administration, Commerce, and Trade), an international electronic data interchange standard developed under the auspices of the United Nations.

Standards are also a key element of the Coast Guard's strategic plan for maritime regulatory reform. The U.S. Coast Guard has stated that "The Office of Marine Safety, Security, and Environmental Protection is committed to developing nationally and internationally recognized standards as a means to improve maritime safety and marine environmental protection, and to promote an internationally competitive U.S. maritime industry." However, the U.S. Coast Guard also recognizes that safety must be cost-effective. In 1995 the Coast Guard began an effort to look at its regulations, eliminate those that were outdated or inefficient, and adopt international standards where possible. As an example of the Coast Guard's effort, in 1996 the Coast Guard revised its electrical regulations adopting 86 new standards including 32 standards developed by the International Electrotechnical Commission

(IEC). To date, the Coast Guard has adopted approximately 450 industry standards, saving over 25,000 pages of federal regulations and the associated regulation maintenance, while specifying standards already familiar to the regulated industry.

In addition to often examining the possibility of using international standards within a regulation during the analysis of the proposed regulation's impact, agencies ***must*** consider and respond to substantive comments made during the rulemaking process (including comments on the use or non-use of international standards) and justify their final decision in that regard before publishing a final rule.

Some agencies, such as the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA), also participate in a number of international forums. PHMSA is involved in an ongoing process of harmonizing the U.S. Hazardous Materials Regulations (HMR) with international standards and regulations. Participation helps ensure that U.S. interests are communicated and considered in the development of such international standards. PHMSA's objective is to establish and maintain a global regulatory system for hazardous materials transportation that will enhance the safe, secure, and efficient movement of hazardous materials.

In addition, E.O. 12866 specifically addresses the use of performance-based standards, informing agencies that:

"... (P)erformance standards are generally to be preferred to engineering or design standards because performance standards provide the regulated parties the flexibility to achieve the regulatory objective in a more cost-effective way. It is therefore misleading and inappropriate to characterize a standard as a performance standard if it is set so that there is only one feasible way to meet it; as a practical matter, such a standard is a design standard. In general, a performance standard should be preferred wherever that performance can be measured or reasonably imputed. Performance standards should be applied with a scope appropriate to the problem the regulation seeks to address. For example, to create the greatest opportunities for the regulated parties to achieve cost savings while meeting the regulatory objective, compliance with air emission standards can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable air quality outcomes (such as "hot spots" from local pollution concentration)."

4.2 Mechanisms and Methods to Make Use of Standards

The U.S. standards system is primarily voluntary, private sector, and marketplace driven with multiple standards developers taking an active role. The U.S. Federal government participates as one of many stakeholders in the standards development process, not as the driver of the process. By comparison, governments in other nations play a more active role; and the process is more centralized.

Although not a driver of the process, as noted above, the U.S. government is committed to reliance on voluntary standards for procurement and regulation, where such usage is consistent with regulatory and procurement objectives. Government regulatory agencies use externally developed standards in a wide variety of ways, including the following:

- *Incorporation by Reference: An agency may adopt a voluntary standard without change by incorporating the standard in an agency's regulation or by listing (or referencing) the standard by title. For example, the Occupational Safety and Health Administration (OSHA) adopted the National Electrical Code (NEC) by incorporating it into its regulations by reference.*
- *Strong Deference: An agency may grant strong deference to standards developed by a particular organization for a specific purpose. The agency will then use the standards in its regulatory program unless someone demonstrates to the agency why it should not.*
- *Basis for Rulemaking: The agency reviews a standard, makes appropriate changes, and then publishes the revision in the Federal Register as a proposed regulation. Substantive comments received from the public during the rulemaking proceeding may result in changes to the proposed rule before it is issued as a final rule.*
- *Regulatory Guidance: An agency may permit adherence to a specific standard as an acceptable, though not compulsory, way of complying with a regulation. The agency provides in the rule text that a regulated entity may comply with the rule set out in the text or may comply with a referenced voluntary standard.*
- *Guidelines: An agency may use standards as guidelines for complying with general requirements. The guidelines are advisory only and therefore compliance with them is not mandatory.*
- *Deference in Lieu of Developing a Mandatory Standard: An agency may decide that it does not need to issue a mandatory regulation because voluntary compliance with either an existing standard or one developed for the purpose will suffice in meeting the needs of the agency.*

A regulatory agency's approach to the use of standards in a particular application is based on the statutes under which the rulemaking is proceeding; the nature of the public comments received; and often the costs, benefits and cost-effectiveness of the various approaches to such usage.

Guidance on the use of voluntary standards in procurement applications may be found in the General Services Administration's Federal Standardization Manual.[13] The manual notes that when a government agency is in the initial stages of developing a Federal Product Description (FPD)[14], the use of voluntary standards are to be given preference over the development of government unique FPDs. The agency is required to do extensive research to determine if a voluntary standard exists that will satisfy its needs and is consistent with applicable laws and regulations. If an existing voluntary standard will satisfy the agency's needs, the agency must adopt the standard by one of the following processes:

- Either the procedure must satisfy the adoption requirement established in OMB Circular A-119, or
- The agency may formally adopt the standard in whole and issue an adoption notice, or

[13] For a copy of this manual, see http://www.dsp.dla.mil/APP_UIL/content/policy/docs/fsman.pdf

[14] Federal Product Descriptions or FPDs consist of Federal specifications and related Federal qualified products lists, Federal standards, and commercial item descriptions (CIDs).

- The agency may reference the voluntary standard in whole or in part in its procurement documents or regulations.

It is also the U.S. Department of Defense's (DoD) policy to make maximum use of non-Government standards and commercial technologies, products, and practices.[15] DoD is committed to the adoption and use of voluntary consensus standards (defined in DoD 4120.24-M as "non-Government standards") where practical, instead of developing new or updating existing government specifications and standards. This policy is consistent with P.L. 104-113, the NTTAA and with OMB Circular A-119.

In addition, the U.S. government, as represented by DoD, is a member of the North Atlantic Treaty Organization (NATO) and endorses the NATO Policy for Standardization that emphasizes the adoption of suitable civil standards (or non-government standards) for use within NATO. The NATO Committee for Standardization (NCS) has issued the NATO Framework Document on Civil Standards, which describes the Alliance's role with respect to relations with Civil Standards Bodies (private sector standards bodies), to make best use of civil standards within the full range of NATO tasks. The document provides that, whenever possible and where advantageous, NATO members use the most appropriate and openly available civil standards, rather than develop military standards. It also stresses that NATO should only develop its own standards when no suitable civil standards exist.

5. MAINTAINING AND UPDATING STANDARDS

5.1 Agency Participation in and Knowledge of Standards Development

Within budgetary constraints, regulatory agencies are encouraged to participate in standards development activities that are consistent with their mission. Such participation is designed to keep agencies aware of standards under development or revision, as well as to contribute to the development of standards that will eliminate the need for government unique standards to be used in regulatory applications.

In the procurement area, the GSA Federal Standardization Manual directs Federal agencies to participate in activities of voluntary standard bodies, where participation has been determined to be beneficial to the agency. The government agency is to participate in a voluntary standard body when participation is in the public interest and is compatible with agency's mission, authorities, priorities and budget limitations. The manual notes that the benefits of such participation include:

- *Allowing agencies to stay abreast of new technologies;*
- *Reducing the cost to the Federal government of developing government unique standards;*
- *Providing agencies with opportunities to learn from both manufacturers and end users; and*

[15] For Information on the U.S. Department of Defense's Standardization policy, see: http://www.dsp.dla.mil/APP_UIL/policy.aspx?action=content&accounttype=displaypolicy&contentid=79#GSA

- *Encouraging reliance on the private sector to supply government's needs for goods and services.*

Agencies also have access to a number of sources for standards-related information, including standards libraries and the services of NIST's National Center for Standards and Certification Information (NCSCI) that can provide agencies with information regarding potential standards that may be of interest in a regulatory or procurement action.

Regulatory agencies may also receive information on standards that may be appropriate or inappropriate for regulatory use during the extensive public comment process that most proposed regulations must undergo.

5.2 Maintenance, Updating and Revision of Standards Used in Regulation

The U.S. regulatory process, while very open and transparent, is also resource intensive. Agencies are not only required to involve the public when rules are developed and issued, they are also required to involve the public in amendments, revisions, or repeals of such rules. To ensure that the public is informed, agencies are generally required to publish proposed and final rules in the *Federal Register*. They are also required to publish amendments, revisions or repeals of such rules in the *Federal Register*, including changes to rules that are designed to incorporate a new or revised edition of a standard.

Standards referenced in regulations are generally required to include the title, date, edition, author, publisher, and identification number of the publication. Future amendments or revisions of standards that are incorporated by reference do not automatically amend the requirements of a regulation. Agencies that wish to update a standard that is referenced within a regulation must generally undertake another rulemaking process. Because rulemaking resources are often limited, updating references to standards that have been amended or revised is often not a high priority, particularly if the version currently referenced in the regulation still meets the agency's regulatory objectives.

Many agencies have been actively exploring the use of methods to speed the process of updating references to standards included within regulations, and some creative solutions have been undertaken to speed the rulemaking process in specific cases. For example, some agencies have adopted small, non-controversial revisions to standards through a "direct" final rule. Such a rulemaking stage is not preceded by a proposed rule. However, it includes a public comment period on the implementation of the direct final rule. An agency is obligated to withdraw the direct final rule and proceed with the normal proposed rulemaking process if it receives any adverse comment to the direct final rulemaking process. This is just one example. To date, no one-size-fits-all solution to this issue has been developed.

Currency is less of a problem in the procurement area. The General Services Administration's Federal Standardization Manual[16] requires that agencies not cite the issue date of a standard in the FPD when referencing the voluntary standard, unless a specific issue of the voluntary standard is needed.

[16] For a copy of this manual, see http://www.dsp.dla.mil/APP_UIL/content/policy/docs/fsman.pdf

5.3 Normative References Included in Standards Used in Regulation and Procurement

Currency, as well as applicability, are also issues associated with normative references that are contained in standards that have been incorporated into regulations or included within procurement requirements. A number of private sector, voluntary, consensus standards, including those published by the International Organization for Standardization (ISO), contain a section that lists one or more additional standards that are deemed to be "Normative References." "Normative references" are defined by ISO and the American National Standards Institute (ANSI) as being "indispensable for the application of the document" or standard in which they are listed. Standards referenced in both regulations and in procurement documents may contain a list of "normative references."

CASE STUDY EXAMPLE

CASE STUDY: *Federal Communications Commission*

The U.S. Federal Communications Commission (FCC), a United States government agency established by the Communications Act of 1934, regulates interstate and international communications by radio, television, wire, satellite and cable. The FCC's jurisdiction covers the 50 States, the District of Columbia, and U.S. possessions.

The FCC regulates the private sector communications industry by establishing technical regulations found in Volume 47 of the Code of Federal Regulations (C.F.R.) Parts 0 to 101.[17] These technical regulations aim at minimizing the potential of causing harmful interference to radio services from transmitters and other equipment.

There are a number of ways that the FCC uses standards in support of the technical regulations and conformity assessment procedures. The FCC provides for the use of standards as follows:

- Incorporation by reference;
- Measurement procedures published by national engineering societies;
- Reference to technical limits in a standard; and
- Technical criteria established by standards development organizations.

Incorporation by reference was established by statute and allows Federal agencies to publish regulations in the Federal Register by referring to materials already published elsewhere. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the Federal Register. The FCC has incorporated by reference standards developed by the following standards development organizations:

- Advanced Television Systems Committee (ATSC)
- American Society for Testing Materials (ASTM)
- Consumer Electronics Association (CEA)
- Electronic Industry Association (EIA)
- Federal Aviation Administration (FAA)

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[17] 47 C.F.R. §§ 0 – 101.

- International Electrotechnical Commission (IEC)
- International Maritime Organization (IMO)
- International Radio Consultative Committee (IRC)
- International Organization for Standardization (ISO)
- International Special Committee on Radio Interference (CISPR)
- International Telecommunication Union (ITU)
- International Telegraph and Telephone Consultative Committee (CCITT)
- North American Numbering Council (NANC)
- Radio Technical Commission for Aeronautics (RTCA)
- Radio Technical Commission for Maritime Services (RCTM)
- Society of Cable Telecommunications Engineers (SCTE)
- Telecommunications Industry Association (TIA)

Measurement Procedures – Several measurement procedures have been identified in the FCC regulations by incorporation by reference. In addition to measurement procedures identified by the FCC, the rules provide flexibility to use standards developed by standards development organizations. Those measurement procedures found to be acceptable by the FCC may be used to demonstrate compliance with the technical regulations.

Reference to technical limits in a standard – For example, the technical requirements for digital devices found in §15.107 have harmonized the conducted emission requirements with the international standards found in CISPR 22.[18] In §15.109, the FCC rules allow equipment to comply with the radiated emission limits in CISPR 22, third edition, as an alternative to the limits given in FCC Part 15.[19]

Technical Criteria established by standards development organizations – For example, the FCC created the Administrative Council for Terminal Attachment (ACTA), which is sponsored by the Telecommunications Industry Association (TIA) and the Alliance for Telecommunications Industry Solutions (ATIS).[20] Standards development organizations (SDO) accredited by ANSI may establish technical criteria for terminal equipment pursuant to ANSI consensus decision making procedures and submit such criteria to ACTA.

Conformity Assessment Procedures

The FCC administers an authorization program to ensure that equipment reaching the market complies with the technical requirements in the rules. The FCC uses three different equipment authorization procedures, depending on the type of equipment, as specified in the rules. The procedure applicable to a particular device depends on the risk of interference that the device poses to licensed radio services. The three equipment authorization procedures are as follows:[21]

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[18] *See Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement, International Electrotechnical Commission (IEC),* International Special Committee on Radio Interference (CISPR), Publication 22.

[19] 47 C.F.R. § 15.109.

[20] 47 C.F.R. § 68.602.

[21] 47 C.F.R. § 2.907.

Verification is a self-approval procedure whereby the responsible party makes measurements or takes the necessary steps to ensure that the equipment complies with the appropriate technical standards.[22] Examples of devices subject to Verification include business Class A computer equipment, Television (TV) and Frequency Modulated (FM) receivers, and non-consumer Industrial, Scientific and Medical (ISM) equipment.

Declaration of Conformity (DoC) is a manufacturer's self-approval procedure where the responsible party (who could be the manufacturer, the grantee or the importer of the equipment) makes measurements at a recognized accredited test laboratory to ensure that the equipment complies with the appropriate technical standards. A test lab must be accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) or the American Association of Laboratory Accreditation (A2LA); or be a designated accredited laboratory under the terms of a negotiated Mutual Recognition Agreement (MRA).[23] The testing laboratory is required to be accredited to the international standard ISO/IEC Guide 17025.[24] Devices subject to DoC must be properly labelled in accordance with FCC Rules.[25] Examples of devices subject to DoC include: certain personal computers and peripherals; Citizen Band (CB) receivers; super-regenerative receivers; TV interface devices; and consumer ISM equipment.

Certification is an equipment authorization issued by the FCC or its designated entities based on representations and test data submitted by the applicant. Third party certification bodies, accredited to ISO/IEC Guide 65, may be recognized by the FCC to perform the certification of equipment.[26] The FCC is notified when products are certified. A complete copy of the application for certification is maintained in the FCC database. Examples of devices subject to certification include: high power transmitters operating in Licensed Radio Services; low power transmitters, such as cordless telephones; garage door opener controllers; radio control toys; security alarm systems; and scanning receivers. Personal computers and peripherals; super-regenerative receivers; and TV interface devices, such as video cassette recorders (VCR), may show compliance with the FCC rules by using either certification or DoC equipment authorization procedures.

Requirements for Digital Devices

The use of digital technologies has become very common in the design of electronic equipment. Such equipment is known as digital devices and is classified by the FCC as unintentional radiators.[27] Digital devices have the potential for causing interference with

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22 47 C.F.R. § 2.909.

23 47 C.F.R. §§ 2.1071 - 2.1077.

24 *See General Requirements for the Competence of Testing and Calibration Laboratories*, International Standards Organization (ISO) International Electrotechnical Commission (IEC), ISO/IEC 17025:2005.

25 47 C.F.R. § 15.19.

26 *See General Requirements for Bodies Operating Product Certification Systems*, ISO/IEC 65:1996.

27 An unintentional radiator is defined in the FCC rules as a device that intentionally generates radio frequency energy for use within the device, or that sends radio frequency signals by conduction to associated equipment via connecting wiring, but which is not intended to emit RF energy by radiation or induction. *See* 47 C.F.R. § 15.3(z).

licensed radio services and are subject to the technical regulations in FCC Part 15. Examples of such devices include: personal computers, calculators, digital cameras, telephones and similar electronic devices.

Technical requirements – For digital devices, there are two major requirements: conducted and radiated emissions. The FCC has harmonized the conducted emission requirements with the international standards found in CISPR 22. For radiated emissions, the FCC rules allow equipment to comply with the radiated emission limits in CISPR 22, third edition, as an alternative to the limits given in FCC Part 15.[28] Since CISPR 22 does not provide limits for radiated emissions above 6 GHz, it is necessary for a digital device to also comply with the FCC limits at these frequencies.

Measurement procedures – Measurement procedures for digital devices have been developed by the ANSI Accredited Standards Committee, C63®. Digital devices are required to be tested to the measurement procedures found in C63.4-2003.[29] This standard is specified in the FCC rules by incorporation by reference.[30]

Conformity Assessment – A digital device such as a personal computer is required to demonstrate compliance with the FCC rules by use of the Declaration of Conformity procedures. Testing is to be performed by a recognized testing laboratory that has been accredited to ISO/IEC Guide 17025.[31]

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[28] 47 C.F.R. § 15.109.

[29] See *American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz*, IEEE C63.4-2003.

[30] 47 C.F.R. § 15.31.

[31] 47 C.F.R. § 2.948.