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VIA ELECTRONIC FILING
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Office of Information and Regulatory Affairs
Records Management Center
Office of Management and Budget
Attn: Mabel Echols, Room 10102
NEOB, 725 17th Street, NW
Washington, DC 20503

**Re: Request for Comments on New Executive Order on "Federal
Regulatory Review," Fed. Reg. Vol. 74, No. 37 (Feb. 26, 2009)**

GTW Associates is an International Standards and Trade Policy consultancy. Standards have direct, significant and material implications for both US and global regulatory policy and for the US and global economy. GTW Associates applauds President Obama's decision to seek ways to improve the existing regulatory framework of our country,¹ and thanks OMB for soliciting public comment. Various US regulatory policy documents have in the past recognized the contributions of standards. Yet the potential of the voluntary standards community to assist in achieving the goals of the new administration deserves increased attention at the highest levels of the new administration. The positive contributions of standards and the significant potential of standards to achieve administration goals deserve recognition in any revisions to President Clinton's Executive Order 12,866, *Regulatory Planning and Review*.

My 40 year career has entailed designing products to meet standards; participating in standards development committees; managing standards committees; promoting and defending the US standards system in global discussions; and providing advice about the strategic role of standards in the competitiveness of businesses, organizations and countries in the global marketplace. GTW Associates is pleased to submit these comments to the Office of Management and Budget (OMB) on a proposed Executive Order on "Federal Regulatory Review."

Executive Order 12866 Regulatory Planning and Review created incentives for federal agencies to take account of private sector initiatives such as standards to

¹ Presidential Memorandum of January 30, 2009, titled "Regulatory Review;" Fed. Reg. Vol. 74, No. 21 (Feb. 3, 2009).

solve problems. Yet the contributions of standards are not specifically mentioned and should be in any revision of the Executive Order.

Executive Order 12866 Regulatory Planning and Review October 1993 is a strategic statement of US Government policy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Voluntary Standards could easily be recognized through such additional text as indicated in red below.

*(a) Agency Responsibilities. (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. Each agency also is directed to explore **private sector voluntary standards solutions** and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.*

The remainder of comments identify existing regulatory policy statements, legislation, and international agreements addressing the role of standards. All of the examples below provide rationale for including a statement on standards at the highest levels of US government regulatory (as well as procurement) policy.

National Technology Transfer and Advancement Act (NTTAA) of 1995 is US legislation that support the addition of a statement on standards

Public Law 104-113, the National Technology Transfer and Advancement Act of 1995, directs federal agencies to use standards developed by voluntary consensus bodies. The law added weight to what had long been government policy codified in the President's Office of Management and Budget (OMB) administrative circular A-119 for US Federal agencies to use consensus standards. OMB has been the guardian of the previous policy and is responsible for the more detailed interpretation of the law in OMB Circular A-119. The Department of Commerce's National Institute of Standards and Technology (NIST) plays a coordinating role in standards and conformity assessment activities between the public and private sectors.

Congress passed and the President signed Public Law 104-113 on March 7, 1996. Section 12 of the "National Technology Transfer and Advancement Act of 1995" addresses standards conformity. Section 12 (a) gives NIST responsibility to compare

private sector standards with Federally-adopted or recognized standards and to coordinate Federal agency use of private sector standards, emphasizing those private sector standards developed by consensus organizations. Section 12(b) gives NIST the role of coordinating Federal, state and local technical standards and conformity assessment activities with private sector activities. Section 12 (d) (See Figure 1) requires federal agencies and departments to use standards that are developed or adopted by voluntary consensus bodies except when that would be inconsistent with applicable law or otherwise impractical. Section 12(d)(4) defines technical standards to include related management system practices.

Figure One Excerpts from the National Technology Transfer and Advancement Act of 1995

SECTION 12 (d) UTILIZATION OF CONSENSUS TECHNICAL STANDARDS BY FEDERAL AGENCIES; REPORTS

(1) IN GENERAL- Except as provided in paragraph (3) of this subsection, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.

(2) CONSULTATION; PARTICIPATION- In carrying out paragraph (1) of this subsection, Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards,

EXCEPTION- If compliance with paragraph (1) of this subsection is inconsistent with applicable law or otherwise impractical, a Federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of each such agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards. Each year, beginning with fiscal year 1997, the Office of Management and Budget shall transmit to Congress and its committees a report summarizing all explanations received in the preceding year under this paragraph.

Even before this legislation it had long been administration policy to substitute private sector standards whenever possible for government development and promulgation of regulatory or procurement standards. Previous to this legislation, some agencies used the relevant OMB Circular A-119 to justify significant support for voluntary standards activities. Other agencies largely ignored the policy with no repercussions. The elevation of the instruction to agencies to use private sector standards from that of an OMB Circular to that of a Public Law increased the attention of regulatory agencies to the valuable role voluntary standards could play in advancing their goals.

Section 12(b) of the NTTAA gives NIST the role of coordinating Federal, state and local technical standards and conformity assessment activities with private sector activities.

Circular OMB A-119 Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities is the OMB circular interpreting to practice the NTTAA legislation and could also be mentioned in a revision of 12866.

In the February 19, 1998 Federal Register, The Office of Management and Budget (OMB) issued their Circular OMB A-119 Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.

The document defines the nature of standards that government agencies are obligated to consider before developing their own procurement or regulatory standards. The policy states:

All federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical. In these circumstances, your agency must submit a report describing the reason(s) for its use of government-unique standards in lieu of voluntary consensus standards to the Office of Management and Budget (OMB) through the National Institute of Standards and Technology (NIST)

A significant new part of the definition for "voluntary consensus standard" contains the requirement that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties.

a. For purposes of this policy, "voluntary consensus standards" are standards developed or adopted by voluntary consensus standards bodies, both domestic and international. These standards include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties. For purposes of this Circular, "technical standards that are developed or adopted by voluntary consensus standard bodies" is an equivalent term.

(1) "Voluntary consensus standards bodies" are domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. For purposes of this Circular, "voluntary, private sector, consensus standards bodies," as cited in Act, is an equivalent term. The Act and the Circular encourage the participation of federal representatives in these bodies to increase the likelihood that the standards they develop will meet both public and private sector needs. A voluntary consensus standards body is defined by the following attributes:

(i) Openness.

(ii) Balance of interest.

(iii) Due process.

(vi) An appeals process.

(v) Consensus, which is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

This definition is generally understood to mean the kind of standards process that can be accredited in the United States under the procedures of the American National Standards Institute (ANSI) Agencies are excused from using voluntary consensus standards when such use would be inconsistent with applicable law or "otherwise impractical." "Impractical" is defined to include circumstances when use of the "voluntary consensus standard" would be "less useful, than the use of another standard." Consider these excerpts from the Congressional debate on the Bill.

Mr. Brown of California: I would assume...a rule of reason would prevail in the implementation of this section and that new bureaucratic procedures would be inconsistent with the intent of this section. Mrs. Morella: That was our intent in beginning the section with the words "To the extent Practical" For instance we would expect Government procurements of off-the-shelf commercial products to be exempted by regulation from any review under the act. We also do not intend through this section to limit the right of the Government to write specifications for what it needs to purchase. Our focus instead is on making sure the Federal government does not reinvent the wheel. We are merely asking Federal agencies to make all reasonable efforts to use voluntary, private sector consensus standards unless there is a significant reason not to do so..."

The 1998 OMB Circular A-119 also recognized the conformity assessment requirements and obligations defined in the NTTAA and the role of the Department of Commerce in this area. The Circular directed the Secretary of Commerce to issue guidance to the agencies to ensure effective coordination of Federal conformity assessment activities. A November 3, 1999 Federal Register document contains that proposed Conformity Assessment guidance. NIST issued final policy guidance on Federal agency use of conformity assessment activities in August 2000 The provisions are solely intended to be used as guidance for agencies in their conformity assessment activities and do not preempt the agencies' authority and responsibility to make regulatory procurement decisions authorized by statute or required to meet programmatic objectives and requirements.

Circular A-4 September 17, 2003 TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS Subject: Regulatory Analysis The Presumption Against Economic Regulation also identifies a positive role for standards and could be referenced in a revision of 12866

Circular A-4 September 17, 2003 TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS Subject: Regulatory Analysis The Presumption Against Economic Regulation contains advice in preparing the regulatory analysis required by the circular and provides the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of the Executive Order 12866, Regulatory Planning and Review

The Circular states: *Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:*

price controls in competitive markets;
production or sales quotas in competitive markets;
mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

The Circular continues:

Performance Standards Rather than Design Standards ***Performance standards*** express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.

The Circular continues:

Informational Measures Rather than Regulation *If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information,*

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informational remedies will often be preferred. Measures to improve the availability of information include **government establishment of a standardized testing and rating system** (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.

The Circular continues:

*Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. **To correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use,** because competing firms that score well according to the system should thereby have an incentive to publicize the fact.*

Several international agreements and the relevant implementing US legislation address the role standards in international trade. These agreements and the standards related text should also gain attention in a revision of 12866. The Agreement on Technical Barriers to Trade (TBT) and the North American Free Trade Agreement (NAFTA) and the Agreement on Government procurement all contain relevant standards provisions. The implementing legislation contains requirements applicable to standards that deserves increased attention

A goal of the Agreement on Technical Barriers to Trade (TBT) (See Figure Two); the Code of good practice for the preparation, adoption and application of standards (See Figure Three) and the Agreement on Government Procurement (AGP) (See Figure Four) is to promote trade through international agreements on rules for how the marketplace should and should not work.

A basic principle running throughout the agreements is that of "National Treatment." "National Treatment" is the concept that governments and markets should treat products and services produced or supplied from other parts of the world no differently than products and services offered to the government or market from local industries.

Standards can be very effective "Non-Tariff Barriers to Trade (TBTs)." Bureaucrats can devise laws or regulations more easily met by local producers than by foreign firms; markets can depend upon "voluntary" standards that are controlled by the local industries; governments can issue procurement specifications that favor individual suppliers. The TBT and the AGP are the international attempts to remove "unfairly discriminatory" standards as a factor in free trade.

Figure Two Excerpts from the Agreement on Technical Barriers to Trade

2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

2.5 A Member preparing, adopting or applying a technical regulation which may have a significant effect on trade of other Members shall, upon the request of another Member, explain the justification for that technical regulation... Whenever a technical regulation is prepared, adopted... and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.

2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.

4.1 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... 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... 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 "Code of Good Practice" mentioned in 4.1 above (See Figure 3 below) for standards developers describes rules for openness, notification of work in progress, utilization of international standards and consideration of comments received. **The requirements of the Code of Good practice are nowhere found in US legislation. However ANSI has accepted the Code of Good practice on behalf of all the standards processes accredited by ANSI. The US legislation implementing the TBT and related standards provisions of the North American Free Trade Agreement are found in Figure Five**

Figure Three EXCERPTS FROM THE CODE OF GOOD PRACTICE FOR THE

PREPARATION, ADOPTION AND APPLICATION OF STANDARDS

F. Where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate, for instance, because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems.

G. With a view to harmonizing standards on as wide a basis as possible, the standardizing body shall, in an appropriate way, play a full part, within the limits of its resources, in the preparation by relevant international standardizing bodies of international standards regarding subject matter for which it either has adopted, or expects to adopt, standards. For standardizing bodies within the territory of a Member, participation in a particular international standardization activity shall, whenever possible, take place through one delegation representing all standardizing bodies in the territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardization activity

J. At least once every six months, the standardizing body shall publish a work programme containing its name and address, the standards it is currently preparing and the standards which it has adopted in the preceding period. A standard is under preparation from the moment a decision has been taken to develop a standard until that standard has been adopted. The titles of specific draft standards shall, upon request, be provided in English, French or Spanish. A notice of the existence of the work programme shall be published in a national or, as the case may be, regional publication of standardization activities...The work programme shall for each standard indicate, in accordance with any ISONET rules, the classification relevant to the subject matter, the stage attained in the standard's development, and the references of any international standards taken as a basis.

L. Before adopting a standard, the standardizing body shall allow a period of at least 60 days for the submission of comments on the draft standard by interested parties within the territory of a Member of the WTO. This period may, however, be shortened in cases where urgent problems of safety, health or environment arise or threaten to arise. No later than at the start of the comment period, the standardizing body shall publish a notice announcing the period for commenting in the publication referred to in paragraph J. Such notification shall include, as far as practicable, whether the draft standard deviates from relevant international standards.

N. The standardizing body shall take into account, in the further processing of the standard, the comments received during the period for commenting. Comments received through standardizing bodies that have accepted this Code of Good Practice shall, if so requested, be replied to as promptly as possible. The reply shall include an explanation why a deviation from relevant international standards is necessary.

**FIGURE FOUR EXCERPTS FROM THE REVISION OF THE AGREEMENT ON
GOVERNMENT PROCUREMENT AS AT 8 DECEMBER 2006**

Article X Technical Specifications and Tender Documentation

1. A procuring entity shall not prepare, adopt, or apply any technical specification or prescribe any conformity assessment procedure with the purpose or the effect of creating unnecessary obstacles to international trade.
2. In prescribing the technical specifications for the goods or services being procured, a procuring entity shall, where appropriate:
 - (a) specify the technical specification in terms of performance and functional requirements, rather than design or descriptive characteristics; and
 - (b) base the technical specification on international standards, where such exist; otherwise, on national technical regulations, recognized national standards, or building codes.

Figure Five US Implementation of TBT Standards Provisions

Sec. 2532. Federal standards-related activities

No Federal agency may engage in any standards-related activity that creates unnecessary obstacles to the foreign commerce of the United States, including, but not limited to, standards-related activities that violate any of the following requirements:

(1) Nondiscriminatory treatment

Each Federal agency shall ensure, in applying standards-related activities with respect to any imported product, that such product is treated no less favorably than are like domestic or imported products, including, but not limited to, when applying tests or test methods, no less favorable treatment with respect to--

- (A) the acceptance of the product for testing in comparable situations;
- (B) the administration of the tests in comparable situations;
- (C) the fees charged for tests;
- (D) the release of test results to the exporter, importer, or agents;
- (E) the siting of testing facilities and the selection of samples for testing; and
- (F) the treatment of confidential information pertaining to the product.

(2) Use of international standards

(A) In general

Except as provided in subparagraph (B)(ii), each Federal agency, in developing standards, shall take into consideration international standards and shall, if appropriate, base the standards on international standards.

(B) Application of requirement

For purposes of this paragraph, the following apply:

(ii) International standards not appropriate

The reasons for which the basing of a standard on an international standard may not be appropriate include, but are not limited to, the following:

- (I) National security requirements.
- (II) The prevention of deceptive practices.
- (III) The protection of human health or safety, animal or plant life or health, or the environment.
- (IV) Fundamental climatic or other geographical factors.
- (V) Fundamental technological problems

GTW Associates thanks OMB for soliciting public comments on this matter. I hope these comments assist OMB understand the valuable role of standards in government setting of regulations and procurements. I hope these comments support the addition of statements about this positive role in a revision of 12866.

Sincerely,

George T. Willingmyre

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President, GTW Associates

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