

Dear SEC,

This is in response to your proposed rulemaking “Regulation Systems Compliance and Integrity” as referenced in the *Federal Register*, (FR 78-18083). [17 CFR Parts 242 and 249 Release No. 34-69077; File No. S7-01-13 RIN 3235-AL43]

By way of introduction, the American National Standards Institute<sup>1</sup> (ANSI) is a private, not-for-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. In this role, the Institute oversees the development and use of voluntary consensus standards by accrediting the procedures used by standards developing organizations (SDOs), and approving their finished documents as American National Standards. Internationally, the Institute is the official U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC).

ANSI would like to comment on a sentence on page 215 of the proposed rule, which reads: “Proposed Rule 1000(b)(1)(ii) states that such policies and procedures would be deemed to be reasonably designed if they are consistent with current SCI industry standards, which would be required to be: (A) comprised of information technology practices that are widely **available for free** [emphasis added] to information technology professionals in the financial sector; and (B) issued by an authoritative body that is a U.S. governmental entity or agency, association of U.S. governmental entities or agencies, or widely recognized organization.”

The U.S. standardization system and its consensus-based, public-private partnership are reflected in the *National Technology Transfer and Advancement Act of 1995* (NTTAA), Public Law 104-113. This law directs all federal government agencies to use for regulatory, procurement, and other agency activities, wherever feasible, standards and conformity assessment solutions developed or adopted by voluntary consensus standards bodies in lieu of developing government-unique standards or regulations. The NTTAA also encourages government agencies to participate in standards development processes, where such involvement is in keeping with an agency’s mission and budget priorities.

The U.S. government’s announced policy under OMB Circular A-119 is to “observe and protect” the right of copyright holders when incorporating by reference into law voluntary consensus standards. The very purpose of this policy is to permit the government to benefit from the efficiencies of the voluntary consensus standards development process. When the government references copyrighted works, those works should not lose their copyright, but the responsible government agency should collaborate with the SDOs to ensure that the public does have reasonable access to the referenced documents. The requirement that the subject practices be “available for free” contained in the SEC’s proposed Rulemaking runs counter to the government’s announced copyright policy for voluntary consensus standards and should therefore be rejected, as contrary to the intent of the NTTAA and OMB A-119.

Attached are two documents submitted by ANSI to OMB and NARA that describe in greater detail the concerns of the US standardization community to efforts that undercut long-standing copyright protections.

Best regards,

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## ANSI Response to Request for Comments on Incorporation by Reference

**1 CFR Part 51 [NARA 12-0002]**

National Archives and Records Administration, Office of the Federal Register

Thank you for the opportunity to comment on the petition submitted by Professor Peter Strauss *et al.* to the Office of the Federal Register (OFR), regarding the availability of material incorporated by reference (IBR) in the Code of Federal Regulations (CFR).

The American National Standards Institute<sup>1</sup> (ANSI) respectfully submits the following comments addressing two main issues:

- Why IBR matters to ANSI and the standardization community
- The nine specific questions asked by the OFR in the *Federal Register* notice

### Why Does IBR Matter to ANSI and the Standardization Community?

ANSI is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. In this role, the Institute oversees the development and use of voluntary consensus standards by accrediting the procedures used by standards developing organizations, and approving their finished documents as American National Standards.

Internationally, the Institute is the official U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC).

ANSI's membership is comprised of businesses, government agencies, professional societies and trade associations, standards developing organizations (SDOs), and consumer and labor organizations. The Institute represents the diverse interests of more than 125,000 companies and organizations and 3.5 million professionals worldwide. ANSI works closely with stakeholders from both industry and government to identify consensus-based solutions to national and global priorities – an inclusive, collaborative partnership between the public and private sectors.

### The U.S. Standardization System

Standards are the backbone of trade, the building blocks for innovation, and the basis for quality, safety, and interoperability. Voluntary consensus standards and compliance activities are essential to the U.S. economy. Market driven and highly diversified, standards support technological innovation, build bridges to new markets, and create gateways for businesses in this increasingly complex world of global access. Standardization also helps to assure health, safety, and quality of life for individuals in the United States and around the world.

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<sup>1</sup> <http://www.ansi.org/>

Our national standardization system is a democratic process that thrives on the active participation and engagement of all affected stakeholders. The open, market-driven, and private sector–led nature of our system is critical to achieving the widely shared policy goals of expanded U.S. leadership and innovation on the global stage.

Currently, the U.S. has the most robust standardization system in the world, which gives the nation a competitive advantage. Unlike the standards development systems of many other countries, the U.S. system considers the views of all interested parties in a balanced way. And the openness of the system to new participants means that their needs can be met quickly and through innovative, collaborative solutions.

Decisions made about our national standardization system and our priorities for action reach far beyond our borders, especially when it comes to the continued success of our products, services, and workforce on the global stage. Any decisions or actions that would fundamentally undermine this system will cause the U.S. to lose this competitive advantage to other countries that would be quick to seize the opportunity. Additionally, significant changes to the system would compromise the role that standards play in protecting health, safety, and the environment.

### **Why Does IBR Matter to the Standardization Community?**

ANSI is often asked about why SDOs charge for standards at all.<sup>2</sup> The answer is that every standard is a work of authorship and, under U.S. and international law, is copyright protected<sup>3</sup>, giving the owner certain rights of control and remuneration that cannot be taken away without just compensation.

Although many people working on standards development are volunteers, SDOs incur significant expenses in the coordination of these voluntary efforts. From the time a new project is commenced until the final balloting and adoption of a standard, the drafting process draws heavily on an SDO's administrative, technical, and support services. Tens of thousands of staff employed by SDOs across the nation provide direct support for the technical development activities of the volunteers.

SDOs are – for the most part – non-profit organizations. In order to recoup their costs, some SDOs rely heavily on revenue from copyright-protected sales and licensing of the standards. Some organizations receive revenue through membership support including membership fees, project fees, registration fees, and other member-generated income. Still others rely on a combination of these and other revenue-generating activities.

By funding operations at least in part through sales and licensing of standards, SDOs can minimize barriers to qualified participation and maximize independence from entities seeking to influence the outcome for commercial or political reasons. Standards sales also allow non-profit SDOs to recoup basic administrative costs while passing on to implementers all of the benefits of the voluntary and inclusive

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<sup>2</sup> "Why Charge for Standards,"

[http://publicaa.ansi.org/sites/apdl/Documents/ANSI%20Position%20on%20Protection%20of%20Copyright%20for%20Standards%20Referenced%20into%20Public%20Law/Why\\_Charge\\_for\\_Standards.pdf](http://publicaa.ansi.org/sites/apdl/Documents/ANSI%20Position%20on%20Protection%20of%20Copyright%20for%20Standards%20Referenced%20into%20Public%20Law/Why_Charge_for_Standards.pdf)

<sup>3</sup> <http://www.copyright.gov/title17/>

process of standards development, including openness, balance, opportunities to participate, and protection from undue influence.<sup>4</sup>

The U.S. government's announced policy under OMB Circular A-119 is to "observe and protect" the right of copyright holders when incorporating by reference into law voluntary consensus standards. The very purpose of this policy is to permit the government to benefit from the efficiencies of the voluntary consensus standards development process. When the government references copyrighted works, those works should not lose their copyright, but the responsible government agency should collaborate with the SDOs to ensure that the public does have reasonable access to the referenced documents.

In February 2011, ANSI's Intellectual Property Rights Policy Committee<sup>5</sup> developed a white paper on the copyright implications of voluntary consensus standards in regulation. The complete white paper is appended to this response and is also available for download.<sup>6</sup>

### Responses to Questions from the *Federal Register* notice

Given the importance of this issue to the broader U.S. standardization community, ANSI requested input from its membership on the following questions posed in the *Federal Register* notice. The responses below take into account the input received, and represent a consensus response that has been approved by the ANSI Intellectual Property Rights Policy Committee and vetted by ANSI's governance.

1. Does "reasonably available"
  - a) mean that the material should be available
    - i) For free and
    - ii) To anyone online?
  - b) Create a digital divide by excluding people without Internet access?

ANSI believes that the text of standards and associated documents should be available to all interested parties on a reasonable basis, which includes appropriate compensation as determined by the SDO/copyright holder.<sup>7</sup>

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<sup>4</sup> ANSI Essential Requirements, <http://www.ansi.org/essentialrequirements>; World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement Principles for the Development of International Standards, [http://www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm)

<sup>5</sup> IPRPC includes participation from a broad range of stakeholders, including several U.S. government agencies.

<sup>6</sup> "Why Voluntary Consensus Standards Incorporated by Reference into Federal Government Regulations Are Copyright Protected," <http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Critical%20Issues/Copyright%20on%20Standards%20in%20Regulations/Copyright%20on%20Standards%20in%20Regulation.pdf>

<sup>7</sup> This statement is in alignment with the Administrative Conference of the United States (ACUS) recommendations from December 2011, which in turn reference a statement made by the National Science and Technology Council Subcommittee on Standards. <http://www.acus.gov/wp-content/uploads/downloads/2011/12/Recommendation-2011-5-Incorporation-by-Reference.pdf>

“Reasonably available” should not be strictly defined using terms such as “for free” and “to anyone online;” rather, the definition should encompass a broad spectrum of access options. For example, some SDOs make certain standards available online on a read-only basis. And many SDOs make standards available at discounts or without charge to consumers, policymakers, and small businesses.

“Reasonably available” means that the public and private sectors should work together to make standards available on a timely basis and readily accessible – either for free or at reasonable prices – to anyone who wants them. This approach is already working in the marketplace, and ANSI has not been made aware of any instances where access was denied to an individual or organization. While SDOs continue to actively consider further efforts that can be made to make their documents available, this is a dynamic environment with no one-size-fits-all solution.<sup>8</sup>

The internet has certainly expanded the public’s access to information. However, it has not changed the underlying protections of intellectual property, nor has it changed the need and the ability of standards developers to cover the significant costs of creating the documents that are used to further public policy goals in law and rulemaking.

*2. Does “class of persons affected” need to be defined? If so, how should it be defined?*

ANSI does not believe that this term needs to be defined. CFR language states that a document incorporated by reference must be “reasonably available to and usable by the class of persons affected by the publication.” But depending upon the standard being referenced, the “class of persons affected” may vary significantly.

*3. Should agencies bear the cost of making the material available for free online?*

Generally speaking, ANSI would discourage agencies from bearing the cost of making materials available for free online. If agencies subsidize the costs of standards, then budgets will need to be substantially increased in order to pay such costs, either through taxes or additional interest on the national debt.<sup>9</sup>

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<sup>8</sup> For example, any attempt to define “reasonable availability” must take into account the myriad uses of IBR by different agencies. Many standards accepted under IBR have within them normative references to a second, or even third, level of standards. Making each and every standard referenced directly or indirectly through an IBR available free of charge to the public would be challenging and extremely cost-ineffective.

Furthermore, many standards under current IBR rules are International Standards such as those promulgated by ISO and IEC. Any changes to CFR Part 51 would not have any jurisdictional effect on current sales and distribution policies of ISO and IEC.

<sup>9</sup> Requiring that U.S. government agencies pay license fees for access to standards introduces another challenge: it would make the U.S. government the monopoly purchaser of standards, and could compromise balanced influence and representation of all stakeholders within the standards development process. These changes would fundamentally undermine the current market-based standardization system.

Rather, agencies should continue on the path that has already proven successful – working with the individual SDOs whose standards are incorporated by reference in order to determine the best mechanism for making those documents reasonably available.

Consider the following findings of the Federal Energy Regulatory Commission (FERC), published in the *Federal Register* in December 2009<sup>10</sup>:

When the Commission weighed the advantages achieved by the North American Energy Standards Board (NAESB) standards development process against the cost to the Commission and the industry of developing these standards through notice and comment rulemaking, we found, and continue to find, that the benefits of having a well-established, consensus process outweigh whatever costs non-members may incur in having to obtain copies of the standards.

As one of the biggest users of standards, the U.S. government's participation in and support of standards development activities are of the utmost importance. The standardization community highly values the expert input that government employees provide and the reliance that agencies demonstrate by adopting and relying on voluntary consensus standards and compliance programs.

*4. How would this impact agencies budget and infrastructure, for example?*

As indicated above, agency budgets would be significantly impacted by undertaking the responsibility to provide all referenced standards for free online. In addition, new staff and contracting mechanisms would be required to negotiate with SDOs on appropriate compensation for standards development and dissemination. A separate but equally significant issue would be the real or perceived undue influence by a single stakeholder – the U.S. government – in the consensus-based standards development process.

*5. How would OFR review of proposed rules for IBR impact agency rulemaking and policy, given the additional time and possibility of denial of an IBR approval request at the final stage of the rulemaking?*

Both in the development of voluntary consensus standards and the federal rulemaking process, stakeholders have adequate opportunity to review pending standards and regulations and provide feedback. As the national body to facilitate standards development, ANSI has promulgated strict guidance for the standards development process and publishes weekly notices of upcoming development activities and requests for comments. Further, the OFR does not maintain expertise in the subjects agencies have identified for rulemaking. If OFR were to circumvent the development of rules and regulations by agencies with the statutory expertise and obligation, OFR would essentially drive the development of rules and regulations, which is not part of its mission.

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<sup>10</sup> <http://edocket.access.gpo.gov/2009/E9-28619.htm>

6. *Should OFR have the authority to deny IBR approval requests if the material is not available online for free?*

For the many reasons outlined above, OFR should not have the authority to deny IBR approval requests solely on free availability of the referenced document. Requesting such authority would likely place OFR in the midst of a contentious fight involving numerous federal agencies and many private-sector entities over copyright limitations. See the response to question 8 below.

7. *The Administrative Conference of the United States recently issued a Recommendation on IBR. 77 FR 2257 (January 17, 2012). In light of this recommendation, should we update our guidance on this topic instead of amending our regulations?*

ACUS speaks with the authority of the General Counsels of U.S. government departments and independent agencies. It is both an independent federal agency and a federal advisory committee. Updating OFR guidance on IBR based upon the ACUS recommendation, which was passed on a voice vote at the December 2011 ACUS Plenary, makes good sense.

8. *Given that the petition raises policy rather than procedural issues, would the Office of Management and Budget be better placed to determine reasonable availability?*

As described above, the SDO community has already been working in partnership with agencies to make standards available as appropriate. This issue is already the subject of policy in OMB Circular A-119; it is unclear that there is any new need to escalate this issue to a policy level. But if that course of action is pursued, then OMB could be the appropriate office to set the parameters of acceptable agency use of IBR, including recognition of copyright protections.

9. *How would an extended IBR review period at both the proposed and final rule stages impact agencies?*

An extended review period at various stages of rulemaking at agencies would almost certainly further slow this already complex and time-consuming process. This could have a chilling effect on agencies' willingness to refer to voluntary standards in support of regulatory actions, which would undermine the federal policy set forth in OMB Circular A-119.

## **Conclusion**

Standards and conformity assessment activities are inextricably linked to all facets of our national economy and are vital to the continued global competitiveness of U.S. industry and the maintenance of appropriate health, safety, and environmental protection mechanisms. ANSI appreciates this opportunity to share more information about the U.S. standardization system, and welcomes further dialogue on this critical issue.

We thank you for this opportunity to provide comments.



## ANSI Response to Request for Comments

### Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities

#### Office of Management and Budget

Thank you for the opportunity to comment on the *Federal Register* notice submitted by the Office of Management and Budget (OMB) regarding whether and how to supplement OMB Circular A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.”

The American National Standards Institute<sup>1</sup> (ANSI) is a private, not-for-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. In this role, the Institute oversees the development and use of voluntary consensus standards by accrediting the procedures used by standards developing organizations (SDOs), and approving their finished documents as American National Standards. Internationally, the Institute is the official U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC).

ANSI and its affiliated companies<sup>2</sup> also deliver accreditation services for conformity assessment bodies, assessing the competence of organizations that test, certify, validate and/or verify that products, management systems, personnel credentials, and greenhouse gas emissions statements meet recognized standards. These programs are recognized by dozens of government agencies, trade associations, and professional societies. The Institute is a U.S. representative to the International Accreditation Forum (IAF), and signatory to the IAF MLA (Multilateral Recognition Arrangement).

ANSI respectfully submits the following comments:

#### The Public-Private Partnership

One of the great strengths of the U.S. approach to standards and conformance is the “public-private partnership” – a term that stakeholders in government and industry use to describe the long-standing, effective, and cooperative working relationship between the public and private sectors.

The public-private partnership in the United States is strong because it is a true partnership. Neither government nor industry claims or exerts overall authority over the other, and by working together in

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<sup>1</sup> <http://www.ansi.org/>

<sup>2</sup> The ANSI affiliate ANAB (American Society for Quality National Accreditation Board) provides accreditation services under two brands - ACLASS (for testing and calibration laboratories, inspection bodies, and reference material producers) and ANAB (the U.S. accreditation body for management systems certifiers – to ISO 9001, ISO 14001, etc.)

respectful cooperation, we are able to most effectively respond to the strategic needs of the nation. This dynamic makes our standardization system unique in the world.

### **The U.S. Standardization System**

Standards are the backbone of trade, the building blocks for innovation, and the basis for quality, safety, and interoperability. Voluntary consensus standards and compliance activities are essential to the U.S. economy. Market-driven and highly diversified, standards support technological innovation, build bridges to new markets, and create gateways for businesses in this increasingly complex world of global access. Standardization also helps to assure health, safety, and quality of life for individuals in the United States and around the world.

Our national standardization system is a democratic process that thrives on the active participation and engagement of all affected stakeholders. The open, market-driven, and private sector–led nature of our system is critical to achieving the widely shared policy goals of expanded U.S. leadership and innovation on the global stage.

Currently, the U.S. has the most robust standardization system in the world, which gives the nation a competitive advantage. Unlike the standards development systems of many other countries, the U.S. system considers the views of all interested parties in a balanced way. And the openness of the system to all stakeholders – large and small, public and private – means that needs can be met quickly through innovative, collaborative solutions.<sup>3</sup>

### **The NTTAA and OMB Circular A-119**

This standardization system and its consensus-based, public-private partnership are reflected in the *National Technology Transfer and Advancement Act of 1995* (NTTAA), Public Law 104-113. This law directs all federal government agencies to use for regulatory, procurement, and other agency activities, wherever feasible, standards and conformity assessment solutions developed or adopted by voluntary consensus standards bodies in lieu of developing government-unique standards or regulations. The NTTAA also encourages government agencies to participate in standards development processes, where such involvement is in keeping with an agency’s mission and budget priorities.

The NTTAA remains the cornerstone for promoting the use of voluntary consensus standards and conformance in both regulation and procurement at the federal level. OMB Circular A-119 establishes government policy on the use of voluntary consensus standards, including recommendations on how and to what extent federal agencies must support voluntary consensus standards activities. In doing so, the OMB Circular confirms that close interaction and cooperation between the public and private sectors is critical to developing and using standards that serve national needs and support innovation and competitiveness.<sup>4</sup>

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<sup>3</sup> See the *United States Standards Strategy*, <http://www.us-standards-strategy.org>

<sup>4</sup> This government policy has recently been carefully studied and strongly reaffirmed in an October 2011 report issued by the National Science and Technology Council’s Subcommittee on Standards. [http://www.whitehouse.gov/sites/default/files/microsites/ostp/federal\\_engagement\\_in\\_standards\\_activities\\_october12-final.pdf](http://www.whitehouse.gov/sites/default/files/microsites/ostp/federal_engagement_in_standards_activities_october12-final.pdf)

## What Is at Stake?

It is critical to the continued success of our democratic standardization system that the U.S. government continues to promote the system and participate actively to identify and support the technical work that it perceives to be in the national interest.

Any changes to OMB Circular A-119 that would address incorporation by reference and reasonable availability of standards have the potential to significantly alter the way that U.S. SDOs are able to do business, and would fundamentally shift the open, balanced, and consensus-based way that standards are developed in this country. These changes would have consequences that reach far beyond our borders, especially when it comes to the continued success of American products, services, and workforce on the global stage.

Any decisions or actions that would fundamentally alter or undermine this system will cause the U.S. to lose this competitive advantage to other countries that would be quick to seize the opportunity. Additionally, significant changes to the system would compromise the role that standards play in protecting health, safety, and the environment.

## Responses to Questions from the *Federal Register* notice

Given the importance of this issue to the broader U.S. standardization community, ANSI requested input from its membership on the following questions posed in the *Federal Register* notice. The responses below take into account the input received, and represent a consensus response that has been vetted by ANSI's governance.

### **Agency Implementation of Circular A-119 in Rulemakings:**

*Are federal agencies generally following the guidance set out in the Circular and providing an adequate explanation of how they considered standards and conformity assessment–related issues in the preambles to rulemakings?*

Yes, generally speaking, federal agencies do a good job of implementing the Circular's guidance related to rulemakings. As part of its oversight role of tracking agency use of voluntary consensus standards, the National Institute of Standards and Technology (NIST) reports that since passage of the NTTAA, "there have been 3,071 reported substitutions of VCS [voluntary consensus standards] for government-unique standards across agencies."<sup>5</sup> NIST has also reported that "only one agency, the Department of Labor, promulgated a government-unique standard in lieu of a VCS."<sup>6</sup>

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<sup>5</sup> NISTIR 7718, [http://standards.gov/nttaa/resources/nttaa\\_ar\\_2009.pdf](http://standards.gov/nttaa/resources/nttaa_ar_2009.pdf)

<sup>6</sup> *Ibid.*

### **Standardization Activities:**

*What factors should agencies use in evaluating whether to use voluntary non-consensus standards in regulation, procurement solicitations, or other non-regulatory uses? OMB also invites comments on the respective roles of voluntary consensus standards vs. voluntary non-consensus standards for agency responsibilities in rulemaking, procurement, and other activities.*

ANSI strongly believes in the importance of consensus in the standards development process. The Institute's *Essential Requirements*<sup>7</sup> cite consensus as one of the cardinal principles for the development of American National Standards (ANS), and ANSI-accredited standards developers conduct their work in a manner that is open to public scrutiny and that provides every stakeholder with an opportunity to be heard, without dominance by any party.<sup>8</sup>

Consensus is also a critical component of international standards development. Whether we are talking about work done through ISO and IEC technical committees, or the many SDOs and consortia that operate on the international stage, what matters is that the standards meet marketplace needs and were developed according to the principles of the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement, which are also consistent with ANSI's *Essential Requirements* for standards development. The process must be consensus-based, open, with balanced participation – and include all other elements that are the hallmarks of our standards system in this country.<sup>9</sup>

### **Conformity Assessment:**

*In conjunction with NIST's efforts to update its conformity assessment guidance, should a supplement to Circular A-119 be issued to set out relevant principles on conformity assessment? If so, what issues should be addressed in such a supplement?*

Relevant principles for conformity assessment – such as those published in the *United States Conformity Assessment Principles*<sup>10</sup> by ANSI – would be instrumental in assuring alignment with the WTO TBT principles, understanding conformity assessment terminology, and promoting neutrality in the application of conformity assessment methods.

In addition, guidance from OMB addressing the following issues would be helpful:

- Encourage federal agency reliance on private-sector conformity assessment programs, capacity, and expertise
- Ensure cooperation and coordination among both federal and private-sector conformity assessment executives

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<sup>7</sup> ANSI *Essential Requirements*, <http://www.ansi.org/essentialrequirements>

<sup>8</sup> The Value of the ANS, <http://www.ansi.org/ansvalue>; Overview of the U.S. Standardization System, [http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/U.S.StandardsSystemOverview\\_Third\\_Edition.pdf](http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/U.S.StandardsSystemOverview_Third_Edition.pdf)

<sup>9</sup> World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement Principles for the Development of International Standards, [http://www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm)

<sup>10</sup> *United States Conformity Assessment Principles*, <http://www.ansi.org/uscap>

- Rely upon third-party accreditation of conformity assessment bodies based on principles of national treatment and reciprocity whenever practicable
- Encourage flexibility in the acceptance of “higher confidence” models of conformity assessment to reduce duplicative testing and the burden on manufacturers

ANSI recommends that a supplement on conformity assessment guidance could parallel the standards guidance in OMB Circular A-119, with the same general guiding principle that regulators should look first to the private sector and provide justification where they chose not to do so.

For example, private-sector conformity assessment programs are already working for many government agencies to provide confidence and reduce duplication. Continued reliance on these public-private partnerships (e.g., the OSHA Nationally Recognized Testing Laboratory (NRTL) Program) and accreditation cooperatives operating under the ISO/IEC 17011<sup>11</sup> international standard is recommended.

*Factors agencies should use in selecting the appropriate conformity assessment procedure, including product/sector specific issues and the level of risk of non-fulfillment of legitimate regulatory, procurement, or other mission-related objectives*

The main factor should be preference for private-sector conformity assessment methods and solutions that are based on voluntary consensus standards, including third-party, private-sector accreditation where appropriate, as well as first-party conformance options where safety level and market needs allow.

*Guidance for regulatory agencies on compliance with relevant international obligations pertaining to conformity assessment and accreditation activities*

An OMB supplement on conformity assessment could provide explicit guidance wherever possible to ensure maximum compliance by federal agencies, and especially as they pertain to international trade agreements under WTO. The current lack of explicit, clear guidance serves as a barrier to more comprehensive use and reliance on third parties by federal agencies.

*Factors agencies should consider in determining whether to recognize the results of conformity assessment and accreditation activities conducted by private-sector bodies in support of regulation*

Federal agencies should consider several factors before recognizing conformity assessment bodies and programs, including 1) transparency, impartiality, and disclosure of conflicts of interest; 2) conformity assessment body limits on ability to cooperate or consult with certified entities; and 3) prohibition of discrimination of any kind. Finally, accreditation bodies and certification bodies should have well-

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<sup>11</sup> ISO/IEC 17011:2004, *Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*

established, well-documented systems in place to assure that their clients are competent and compliant with standards.

Supplements to OMB Circular A-119 should also acknowledge international recognition of accredited conformity assessment. These mutual recognitions among the world's accreditation bodies, such as the Multilateral Recognition Arrangement (MLA) coordinated through the International Accreditation Forum (IAF), and the Mutual Recognition Arrangement (MRA) of the International Laboratory Accreditation Cooperation (ILAC), include nearly all the U.S. trading partner states and are based on regular peer evaluations among the accreditors. Accreditations performed by the accepted participants are then recognized as equally reliable.

*Non-regulatory uses of standards (including vendor conformity for purposes of response to procurement solicitations)*

The U.S. government should be aware of such systems but should not necessarily advocate for a level of assurance equivalent to regulatory needs.

*Ensuring that agencies consider how to minimize conformity assessment costs and delays for businesses, especially small and medium-sized enterprises, subject to statutory and budgetary constraints and the ability of agencies to fulfill their legitimate regulatory, procurement, or other mission-related objectives*

An OMB supplement should encourage a competitive market in conformity assessment to assure choice and competitive prices from certifiers, while at the same time ensuring that all accredited certifiers are providing credible, reliable certifications. Federal agencies should also be directed in the supplement to advocate for accredited conformity assessment, and to educate on the value of third-party certification to national or international standards as appropriate.

***Protection of Copyright Associated with Standards:***

*Is lack of access to standards incorporated by reference (IBR) in regulation an issue for commenters responding to a request for public comment in rulemaking or for stakeholders that require access to such standards? Please provide specific examples.*

ANSI believes that the text of standards and associated documents that have been incorporated by reference should be available to all interested parties on a reasonable basis, which includes appropriate compensation as determined by the SDO/copyright holder.<sup>12</sup>

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<sup>12</sup> This statement aligns with the Administrative Conference of the United States recommendations from December 2011, which in turn reference a statement made by the National Science and Technology Council Subcommittee on Standards. <http://www.acus.gov/wp-content/uploads/downloads/2011/12/Recommendation-2011-5-Incorporation-by-Reference.pdf>

This approach is already working in the marketplace, and ANSI has not been made aware of any instances where access was denied to an individual or organization. While SDOs continue to actively consider further efforts that can be made to make their documents available, this is a dynamic environment with no one-size-fits-all solution.<sup>13</sup> For example, some SDOs make certain standards available online on a read-only basis. And many SDOs make standards available at discounts or without charge to consumers, policymakers, and small businesses.

*What are the best practices for providing access to standards incorporated by reference in regulation during rulemaking and during the effective period of the regulation while respecting the copyright associated with the standard? What are the best practices for incorporating standards by reference in regulation while respecting the copyright associated with the standard?*

Everyone should have the right to access standards referenced into law and be able to review such work, at a minimum, at government facilities and libraries on a read-only basis. Depending on the nature of the standard and its intended use, many such standards are also electronically available for viewing for free on either a long- or short-term basis.

Reasonable access, however, does not mean that everyone has the right to own a free copy. Copyright protection must be afforded to standards developers for their original works of authorship.

The U.S. government's announced policy under OMB Circular A-119 is to "observe and protect" the right of copyright holders when incorporating by reference into law voluntary consensus standards. The very purpose of this policy is to permit the government to benefit from the efficiencies of the voluntary consensus standards development process. When the government references copyrighted works, those works should not lose their copyright, but the responsible government agency should collaborate with the SDOs to ensure that the public does have reasonable access to the referenced documents.

In February 2011, ANSI's Intellectual Property Rights Policy Committee<sup>14</sup> developed a white paper on the copyright implications of voluntary consensus standards in regulation. The complete white paper is available for download.<sup>15</sup>

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<sup>13</sup> For example, any attempt to define "reasonable availability" must take into account the myriad uses of IBR by different agencies. Many standards accepted under IBR have within them normative references to a second, or even third, level of standards. Making each and every standard referenced directly or indirectly through an IBR available free of charge to the public would be challenging and extremely cost-ineffective.

Furthermore, many standards under current IBR rules are international standards such as those promulgated by ISO and IEC. Any changes to CFR Part 51 would not have any jurisdictional effect on current sales and distribution policies of ISO and IEC.

<sup>14</sup> IPRPC includes participation from a broad range of stakeholders, including several U.S. government agencies.

<sup>15</sup> "Why Voluntary Consensus Standards Incorporated by Reference into Federal Government Regulations Are Copyright Protected," <http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Critical%20Issues/Copyright%20on%20Standards%20in%20Regulations/Copyright%20on%20Standards%20in%20Regulation.pdf>

### ***Voluntary Consensus Standards and Cost-Benefit Analysis:***

*What resources and other costs are involved in the development and revision of voluntary standards?*

Although many people working on standards development are volunteers, SDOs incur significant expenses in the coordination of these voluntary efforts. From the time a new project is commenced until the final balloting and adoption of a standard, the drafting process draws heavily on an SDO's administrative, technical, and support services. Tens of thousands of staff employed by SDOs across the nation provide direct support for the technical development activities of the volunteers.

SDOs are – for the most part – not-for-profit organizations. In order to recoup their costs, some SDOs rely heavily on revenue from copyright-protected sales and licensing of the standards. Some organizations receive revenue through membership support including membership fees, project fees, registration fees, and other member-generated income. Still others rely on a combination of these and other revenue-generating activities.

By funding operations at least in part through sales and licensing of standards, SDOs can minimize barriers to qualified participation<sup>16</sup> and maximize independence from entities seeking to influence the outcome for commercial or political reasons.

Standards sales also allow not-for-profit SDOs to recoup basic administrative costs while passing on to implementers all of the benefits of the voluntary and inclusive process of standards development, including openness, balance, opportunities to participate, and protection from undue influence.

*What economic and other factors should agencies take into consideration when determining that the use of a voluntary standard is practical for regulatory or other mission purposes?*

Consider the following findings of the Federal Energy Regulatory Commission (FERC), published in the *Federal Register* in December 2009<sup>17</sup>:

When the Commission weighed the advantages achieved by the North American Energy Standards Board (NAESB) standards development process against the cost to the Commission and the industry of developing these standards through notice and comment rulemaking, we found, and continue to find, that the benefits of having a well-established, consensus process outweigh whatever costs non-members may incur in having to obtain copies of the standards.

As one of the biggest users of standards, the U.S. government's participation in and support of standards development activities are of the utmost importance. The standardization community highly

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<sup>16</sup> For example, some SDOs have programs in place to subsidize the participation of consumers and other technical experts in the standards development process. Without financial support from SDOs, these individuals might not have the means to attend meetings and share their valuable expertise.

<sup>17</sup> <http://edocket.access.gpo.gov/2009/E9-28619.htm>

values the expert input that government employees provide and the reliance that agencies demonstrate by adopting and relying on voluntary consensus standards and compliance programs.

*How often do standards-developing bodies review and subsequently update standards? If standards are already incorporated by reference in regulations, do such bodies have mechanisms in place for alerting the relevant agencies and the public, especially in regard to the significance of the changes in the standards?*

Because voluntary consensus standards are driven by marketplace needs, any organization working to develop standards is motivated to keep their documents up to date. If a standard is outdated or no longer relevant, it tends to organically fall out of use as stakeholders turn to an updated or different solution.

Stakeholders have adequate opportunity to review pending standards and provide feedback. As the national body to facilitate standards development, ANSI has promulgated strict guidance for the standards development process<sup>18</sup> and publishes *Standards Action*,<sup>19</sup> an online publication with weekly notices of upcoming development activities and requests for comments. Stakeholders with concerns about a standard's content are always encouraged to reach out to the SDO responsible for that standard and get involved in its development and/or maintenance.

***Using and Updating Standards in Regulation:***

*Should OMB set out best practices on how to reference/incorporate standards (or the relevant parts) in regulation? If so, what are the best means for doing so? Are the best means of reference/incorporation context-specific? Are there instances where incorporating a standard or part thereof into a regulation is preferable to referencing a standard in regulation (or vice versa)?*

Standards are updated on a constant basis as revisions are created and/or identified that improve the qualities of the standard or better meet the needs of the marketplace. However, federal agencies that reference such standards in rules and regulations may not be able, for procedural or other reasons, to make timely updates to rules that accommodate changes in the referenced standards. This may even be the case when the agency's own analysis supports the use of the updated standard for the purpose of the rule. In other cases, regulated industries, especially small and medium-sized enterprises (SMEs), prefer the older methods because they are unable to update their own equipment to meet the newer standard. This issue is of particular concern when the standards are related to safety and health, or when they were developed to serve a fast-moving, high-technology industry sector.

Currently there does not seem to be enough flexibility to enable agencies to meet the regulatory needs and make use of updated standards without imposing an extraordinary burden on the agency. At times

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<sup>18</sup> When it comes to the development of American National Standards (ANS), the ANSI *Essential Requirements* make provisions for the revision and maintenance of all ANS, and ANSI accredited standards developers are required to undergo an audit at least once every five years.

<sup>19</sup> <http://www.ansi.org/standardsaction>

this situation can create difficulties where an agency continues to reference a particular standard that has been superseded. Such a situation may create confusion and frustration for manufacturers and purchasers. This may also impede an agency's ability to enforce its health and safety mandates and ensure that only the safest and most-improved products are available (i.e., those that reflect the most recent revision of a standard).

Best practices and guidance from OMB on how to incorporate standards by reference would be useful, including the suggestion that agencies should consult with the relevant SDO before incorporating any standard. But it is important to note that an extended IBR-related review period at various stages of rulemaking is certainly not desirable. Any action that would further slow this already complex and time-consuming process could have a chilling effect on agencies' willingness to refer to voluntary standards in support of regulatory actions, which would undermine the federal policy set forth in OMB Circular A-119.

*Should an OMB supplement to the Circular set out best practices for updating standards referenced in regulation as standards are revised? If so, what updating practices have worked well and which ones have not?*

Yes, best practices for updating standards referenced in regulation would be helpful.

Often an agency must follow a laborious rulemaking process to recognize a revision of an accepted standard. ANSI recommends an alternative approach – namely, the adoption of a rule of construction that would give an agency 90 days after the promulgation of a revision of a referenced standard to update the Code of Federal Regulations (CFR). If the agency does not do so within the 90-day period, it will be presumed that the revision of the standard would be accepted as the new standard. An agency could create a due diligence requirement that such a revision has to be noticed in the *Federal Register* for 30, 60, or 90 days. If no significant opposition has been heard, the revision becomes the new standard. A number of agencies have successfully used this approach.

*Is there a role for OMB in providing guidance on how federal agencies can best manage the need for relevant regulations in the face of changing standards?*

Yes, this seems like an appropriate role for OMB; however, such guidance should be developed with significant input from federal agency standards executives.

*How should agencies determine the cost-effectiveness of issuing updated regulations in response to updated standards?*

A number of different approaches could be effective. One idea is to establish a threshold using risk, economics, or some other factor as a trigger that would require updated regulation.

*Do agencies consult sufficiently with private-sector standards bodies when considering the update of regulations that incorporate voluntary standards, especially when such standards may be updated on a regular basis?*

Many agencies do a good job of consulting and collaborating with SDOs when considering the update of regulations that incorporate voluntary standards. However, several ANSI-accredited SDOs have observed that some agencies seem to feel constrained in advancing positions or interacting with private-sector organizations. This is a concern not just for standards that have been incorporated by reference, but also for participation by government agencies and government technical experts in the standards development process.

Hearing the government's priorities firsthand helps the standards community be a more effective and proactive partner. And if the private sector does a better job of reaching out to agencies and sharing information about standards development activities already underway – both here in the United States and internationally – then agencies will have a better handle on where greater participation is needed. The public-private partnership should focus on deepening and extending this ongoing dialogue, and should not be limited to one-off events that disband once the immediate objective is accomplished.

***Use of More Than One Standard or Conformity Assessment Procedure in a Regulation or Procurement Solicitation:***

*Should OMB provide guidance to agencies on when it is appropriate to allow the use of more than one standard or more than one conformity assessment procedure to demonstrate conformity with regulatory requirements or solicitation provisions?*

Yes, OMB should consider providing guidance for those instances where it may be appropriate to use more than one standard or conformance procedure; however, such guidance should be developed with significant input from federal agency standards executives. The U.S. standardization system embraces the “multiple path approach,” where multiple standards or conformance systems may achieve global relevance and applicability. If more than one standard or conformity assessment solution could satisfy the need, then these should be considered, so long as they are in compliance with the principles of the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement.

*Where an agency is requested by stakeholders to consider allowing the demonstration of conformity to another country's standard or the use of an alternate conformity assessment procedure as adequate to fulfilling U.S. requirements, should OMB provide guidance to agencies on how to consider such requests?*

Yes, OMB may wish to consider providing such guidance. As described above, the multiple path approach is at the core of the U.S. standardization system, and due consideration should be given to any existing solutions that may meet a need, whatever the source of those solutions. For example, there may be technologies and conformity assessment activities that have been practiced and proven in a foreign market before coming to the United States or being applicable to the U.S. marketplace.

### ***Other Developments:***

*Have there been any developments internationally – including but not limited to U.S. regulatory cooperation initiatives – since the publication of Circular A-119 that OMB should take into account in developing a possible supplement to the Circular?*

ANSI suggests that supplements to OMB A-119 could underscore the critical relationship between a robust, supported domestic standardization infrastructure and continued success in the global marketplace.

As the sole U.S. representative to ISO and, via the U.S. National Committee, the IEC, ANSI enables U.S.-based technologies and experts to have a prominent role in those standards organizations. With the support and backing of U.S. trade associations, SDOs, industry, and government agencies, our experts play leadership roles on nearly all ISO and IEC technical and policy committees to advance U.S. interests and minimize unnecessarily duplicative standards activities.

Developing countries are steadily increasing their participation in international standardization activities, resulting in new and emerging markets for U.S. products, systems, services, and personnel. This is especially true in emerging technology areas, such as nanotechnology, smart grid, information and communication technologies (ICT), cybersecurity, and electric vehicles. But with greater participation comes greater competition, as developing and developed economies alike are playing an increasingly significant role in standardization activities. It is vital for the U.S. to maintain its key role in developing globally relevant, responsive standards – we simply cannot afford not to be at the table where international standards are being set.

As the U.S. member to ISO and IEC, ANSI not only ensures that U.S. experts can participate actively, but also is in the unique position to provide information and intelligence about what our competitors and trade partners around the world are doing. In addition, the Institute can provide a strategic link to those U.S.-domiciled SDOs developing international standards that support global competitiveness.

ANSI suggests that supplements to the circular should encourage U.S. government stakeholders to participate actively in international standardization activities. With respect to standards development work through ISO and IEC, ANSI will facilitate this greater level of engagement by improving access to publicly available information on U.S. Technical Advisory Group (TAG) activities, and will coordinate efforts with federal agencies to ensure that all interested government stakeholders are aware of opportunities for participation.

*Does the significant role played by consortia today in standards development in some technology areas have any bearing on (or specific implications for) federal participation?*

Consortia play a critical role in the standardization landscape, especially in emerging or fast-moving technology areas. As appropriate, the U.S. government should treat participation in a consortium – or reliance on a consortium’s work product – as they would any other SDO, so long as the consortium’s processes comply with the principles of the WTO TBT Agreement.

In fact, U.S. government technical experts already participate actively in a number of consortia, in particular those working on cloud computing and smart grid issues.

## Conclusion

Enhancing the competitiveness of U.S. industry, protecting our environment, and assuring public health and safety are some of the key initiatives advanced by administration leaders – and timely and effective standards and conformance activities are key to making these goals a reality.

Market-driven and sector-specific, our national standards system is fueled by private-sector standards developers that have the technical expertise, speed, and responsiveness needed to find robust, consensus-based solutions to national priorities. By identifying and collaborating with the right private-sector partners – and working alongside ANSI in its coordination role – government agencies can work faster and smarter to meet and exceed their directives and mandates.

As one of the biggest users of standards, the U.S. government's participation in standards development activities is of the utmost importance. In keeping with the tenets of the NTTAA, the standardization community highly values the expert input that government employees provide and the reliance that agencies demonstrate by adopting and relying on voluntary consensus standards and compliance programs.

We thank you for this opportunity to provide comments and welcome further dialogue on this critical issue.