



April 30, 2012

Submitted Electronically to Docket No. OMB-2012-7602

Mr. Cass Sunstein
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Mr. Sunstein:

Underwriters Laboratories Inc. (UL) appreciates the opportunity to comment on the US Office of Management and Budget's (OMB) Request for Information to inform OMB's consideration of whether and how to supplement and update Circular A-119 (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities).

UL is an independent standards developer and product testing and certification organization dedicated to public safety. Since our founding in 1894, UL's engineers and staff have helped develop safety standards and product-testing protocols, conducted independent product safety testing and certification, and inspected manufacturing facilities around the world. UL is driven by our global safety mission, which promotes safe living and working environments by the application of safety science and hazard-based safety engineering. The application of these principles manifests itself in the evaluation of tens of thousands of products, components, materials, and systems for compliance to specific requirements. Through these activities, UL actively engages the US government in its development and administration of federal regulations and conformity assessment programs at the federal, state, and local levels. Further, UL also participates in many international standards development technical committees as well as international conformity assessment schemes and national certification programs.

UL believes that Circular A-119 should include supplemental principles regarding the use of private sector standards and expand the guidance to cover conformity assessment programs explicitly. In the fourteen years since Circular A-119 was last updated in 1998, UL has seen a positive trend in the federal government's engagement and consideration of private sector standards for rulemaking purposes. New developments during that same period, however, warrant supplemental guidance. Furthermore, the private sector has significantly expanded its expertise, capabilities, and capacity to conduct conformity assessment activities that support not only market-driven needs, but also those regulatory needs of various agencies. While some regulators have engaged the private sector in related conformity programs, the trend has been uneven. Clearer guidance in Circular A-119 for use of private sector conformity assessment programs would clarify expectations and help to shape a corresponding mindset for public-private engagement moving forward.

At the core of UL's responses to the questions posed in the Federal Register Notice are the following principles:

- **Transparency of Process:** While the Administrative Procedures Act provides a general process and level of transparency for agencies in rulemaking, UL believes that the transparency of the mechanisms for engaging the private sector needs to be improved. Of particular interest is transparency with respect to informing and soliciting feedback from standards development organizations, conformity assessment providers, industry, and the public at-large of a particular agency's goals for a specific program or activity, the rationale for use or non-use of private sector standards and conformity assessment capabilities, and periodic reviews of current policy.
- **Consistency in Approach:** While agencies' programs may vary with respect to reliance on the private sector, all federal agencies should follow a consistent process when determining how to incorporate private sector standards and conformity assessment programs into their activities. Variance exists today across agencies, and even within programs housed within the same agency. A common process incorporating appropriate comment periods, formal reporting, respect of intellectual property rights, and public-private partnerships is in line with espoused good regulatory practices, will facilitate more effective use of private sector standards and conformity assessment procedures, and could promote greater alignment of requirements for products subject to multiple agencies' oversight.
- **Government as Coordinator:** Government agencies, particularly the National Institute of Standards and Technology (NIST), should actively coordinate the engagement of stakeholders on emerging issues, convene fora and other information sharing events, facilitate public-private partnerships for the advancement of priority sectors, and provide oversight for the efficacy of government activities involving standards development and conformity assessment. UL respects the general regulatory rights of agencies and believes that this recommended approach preserves those rights, provides an appropriate bridge to the technical excellence of the private sector, and fosters the best outcomes.
- **Government as Champion of Competitive Environment:** Where regulators rely on private sector-based conformity programs, they should ensure and preserve robust competition within the private sector. This means ensuring a level playing field by relying on an accreditation or recognition process that assures appropriate minimum competency levels, that enables all qualified providers to participate, that mitigates unfair competition by government labs, and that explicitly considers reciprocity.
- **Sustained Engagement:** The federal government should prioritize engagement with the public, particularly the standards development and conformity assessment communities, throughout the development and implementation of regulations, programs, or policies that will reference or utilize private sector standards and/or conformity assessment schemes. Such engagement will foster the more efficient exchange of information, reduce duplicative efforts in the public and private sector, and provide a platform for continuous engagement to ensure that programs adapt to changing market dynamics and regulator needs.
- **Avoid Least Common Denominator Safety:** UL respects regulators' rights to choose standards and conformity mechanisms that meet their confidence needs based on a host of relevant factors. Where a regulator determines that independent third party testing or certification is not required to demonstrate compliance with requirements, the recognition of results should include a means of recognizing results and certification marks of third-party organizations when manufacturers prefer

to engage them. This approach promotes competition while preventing disincentives to manufacturers who would otherwise use third-party providers.

- **Continuous Improvement:** To ensure that regulatory programs reflect changing market and regulatory dynamics on an ongoing basis, there should be a process and metrics to drive such an objective assessment. There are two facets to this. First, how do regulators revisit opportunities to rely upon private sector standards and conformity assessment models. UL supports the application of current regulatory look-back initiatives to those regulatory programs relevant to the purview of Circular A-119. We advocate the development of metrics and benchmarking of the effectiveness of such programs on a regular basis. Such tools will help to advance the goals of reducing complexity and redundancies, of relying on the private sector wherever possible, and of protecting and safeguarding the public. Second, the periodic review should provide for an assessment as to whether technological or material changes in an industry pose new risks and warrant a change in the conformity mechanism relied upon.
- **Rational Regulatory Alignment:** To drive innovation and facilitate trade, UL supports agencies' efforts to align requirements within the US and globally. Harmonizing such technical and conformity requirements is ideal. Where harmonization may not be practical, reliance on other alignment tools may be best. In pursuing such alignment, regulators should employ a process that ensures parity of technical requirements, conformity measures, accreditation criteria, and government oversight infrastructure.

UL believes that these principles, together with our more detailed context and recommendations outlined below, demonstrate the need for OMB to address not only standards-related matters but also conformity assessment principles in any subsequent re-write of, or supplemental guidance to, Circular A-119. Doing so recognizes the equal importance of standards and conformity considerations in advancing regulators objectives and in reducing regulatory burdens through greater reliance on the private sector. The existing guidance, together with these supplemental recommendations will help to drive greater efficiencies within government programs, will reduce the complexity and duplication of requirements that manufacturers face, will drive innovation and facilitate trade, will support an industry that brings thousands of high-paying and high-skilled jobs to the United States, and will uphold regulatory agencies' fundamental health, safety, and environmental protection goals.

UL would be pleased to discuss further the content of our submission with you and your team. Please contact me or UL Global Government Affairs Vice President Ann Weeks (ann.weeks@ul.com; 202.296.1435) with any questions. Thank you for your time and consideration.

Sincerely,



Columbus R. Gangemi, Jr.
Senior Vice President
Chief Legal Officer, Chief Ethics & Compliance Officer and Corporate Secretary

cc: Ann Weeks, Vice President, Global Government Affairs

Office of Management and Budget (OMB): Docket No. OMB-2012-7602
UL's Comments on Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities

April 30, 2012

1. Agency Implementation of Circular A-119 in Rulemakings

On the surface, annual reports from OMB to Congress on the efforts of federal agencies to comply with Circular A-119 and the National Technology Transfer and Advancement Act (NTTAA) indicate broad government adoption of private sector standards in rulemaking and procurement activities. Based on our experience, UL has observed that federal agencies are implementing the principles of Circular A-119 in an uneven fashion. While the OMB reports indicate a high level of adherence, the data that comprises those reports appear to be a self-reporting of the agency's efforts with little verification and anecdotal cases, raising questions about the metrics applied and completeness of the analysis. Adding to the perceived unevenness of implementation, the OMB reports provide little insight into how private sector standards are referenced, be they for procurement or rulemaking purposes.

UL's own experience is that there is little consistency across agencies, and even within agencies, on how agencies determine whether there are private sector standards available to meet their needs and the conformity assessment mechanisms they choose to use. In certain cases, some agencies actively engage UL staff, and we suspect other private sector standard development organizations (SDOs), prior to the actual rulemaking process to inquire about the availability of private sector standards that might meet their needs. Other times, UL will learn about an agency's investigation into applicable private sector standards through the issuance of a Notice of Public Rulemaking (NPR), and in more extreme cases, UL will learn about agencies referencing UL standards in rulemaking after the fact. Though it could be improved, the Standards Incorporated by Reference Database has become an important tool for UL to track how the government is incorporating UL standards and tracking UL's intellectual property.

Apart from these challenges of notification, it is generally clear that agencies are using private sector standards in rulemaking activities. What is less apparent is the extent to which private sector standards are being used in procurement efforts. To our knowledge, little data exists to conclusively determine the success of Circular A-119 guidance in this regard. In procurement activities as well as instances where the government is creating, maintaining, or revising voluntary programs that utilize standards, UL is more often than not unaware of the government's interest in utilizing or referencing private sector standards until the program has been developed or changed.

UL Recommendation: A revised Circular A-119 should require greater levels of transparency and engagement with the SDO community in rulemaking efforts, procurement activities, voluntary program development, and the on-going maintenance of government activities and programs. One way to accomplish this would be to require agencies who are undertaking activities (rulemaking, procurement, or otherwise) to issue a public call for information through the Federal Register in advance of any program or rulemaking efforts. Additionally, agencies should disclose which SDOs were engaged as well as the rationale for their use or non-use of private sector standards at the completion of any rulemaking or program development. Lastly, the Circular should require

government agencies to notify the SDO that published a standard of that standard's incorporation by reference. An open and transparent dialogue between government agencies and SDOs at the very outset of government interest in referencing private sector standards will minimize confusion, avoid duplication of efforts, and promote collaboration between government, industry and other interested stakeholders.

2. Standardization Activities

Consensus standards, as well those developed through alternative processes, serve different needs in the market place. To that end, UL believes that the government should not restrict itself to using and referencing only consensus standards, but instead look to the ultimate objective to drive the selection of a standard or standards. This is not uncommon to how accredited SDOs like UL approach standards development. UL uses its technical expertise and knowledge of the market to develop standards that meet a variety of needs.

In practice, consensus standards often result in effective minimum requirements, agreed upon by industry, standards development organizations, regulators, consumer advocates, and other interested stakeholder groups. In safety, security, and health-related scenarios, a consensus standard creates a level playing field, which provides a clear set of expectations for new and current suppliers.

Consensus standards sometimes lag behind market developments. For industries with short development cycles or for rapidly emerging technologies, SDOs may employ different development techniques (such as UL's Outlines of Investigation, OOI) to offer industry and other stakeholders a platform to document preliminary requirements that act in the short term, as a baseline. In such circumstances, UL, for example, can choose to proceed with an OOI that is grounded in science, drives technical consistency in approach to innovative products, and serves as a record of requirements applied during early stages of innovative product deployment in the market. Many industries view this approach to standards development as an important way to facilitate market acceptance of new products. Because of the OOI approach, new technologies can achieve critical mass in the market or mature to the point where consensus can be achieved.

While the result is valuable, pursuing consensus standards can be an arduous, expensive and ultimately uncertain endeavor for standards developers and all those participating in the process. Competitors in a particular industry, offering products of varying levels of performance, are inherently unlikely to agree. When a wide range of stakeholders with other interests are added to the mix, a technical standards panel can often become quite contentious. When members of a standards panel have strongly held and diametrically opposed views, it can require significant time and resources to work through the consensus process and complete a standard. In some cases, it has taken three to five years to reach consensus. In some extreme cases, reaching consensus can take decades to achieve, if at all.

Complicating matters further, consensus can mean different things to different organizations. For instance, the American National Standards Institute (ANSI) and the International Electrotechnical Commission (IEC) both define consensus as a two-thirds voting majority. On the other hand, the International Organization for Standardization (ISO) defines consensus as "general agreement characterized by the absence of sustained opposition to substantial issues by any important part of

the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments... it does not require unanimity.”

UL often uses the ANSI process to develop standards. Other times, such as when standards are needed to address a disruptive technology or to demonstrate environmental leadership as opposed to minimum requirements, reaching consensus could reduce the likelihood of a meaningful solution that provides valued order and clarity to the marketplace and for regulators.

In the environmental arena, stakeholders have worked together to create a variety of leadership performance standards. The Global EcoLabelling Network, for example, includes 28 members who have developed leadership standards in more than 20 countries without consensus as a pre-requisite. These standards are designed to highlight achievement, reward leadership, and recognize innovative new ideas that advance sustainability and environmental performance. Superior performance or leadership standards are created to act as a dynamic ceiling, to help identify actors in the marketplace who strive to exceed minimum thresholds. As with consensus standards, it is important that such standards development processes be open, transparent, incorporate due process, and have a forum for appeals and revision that is open to multiple stakeholders to ensure market acceptance and success. In some cases, these standards are developed on a global platform and, therefore, utilize global concepts for consensus and transparency.

As a market transformation tool, standards that are generated without consensus may help markets push toward desired outcomes either by setting requirements higher than those that are developed through a consensus process or by more efficiently raising the requirements. Nimbleness and rigor are the heart of leadership programs and standards.

UL Recommendation: Regulatory decision-makers should evaluate a given standard’s appropriateness by asking the simple question of whether or not its use would best help meet their needs. The decision to use either consensus or another process of standards development should be based on the value that each provides. Consensus standards can be a valuable tool for establishing minimum requirements and a level playing field with broad support. Standards developed with other approaches can be equally valuable when used to support needs such as promoting leadership or applied to areas with rapid innovation or development.

Agencies should have the freedom and flexibility to use different types of standards that they believe will meet their needs and program goals. When choosing the type of standard to reference, an agency should ask the following questions:

- Was the standard developed by an experienced, independent organization?
- Will that organization provide background and support during implementation, and does the process provide for ongoing review and revision?
- Is the standard technically robust and will the use of that standard enable the intended goals to be reached more efficiently?
- Was the standard developed through an open and transparent process?
- Is the government’s intent to set a minimum level of requirements or a leadership performance standard for suppliers to aspire to?
- Is the standard meant for an emerging technology or priority issue where innovation is fast-paced?

- Is the standard addressing a public safety concern that is otherwise not addressed in standards or technical regulations?

The answers to these questions will help an agency determine the type of standard best suited to achieve the goals of a particular agency's program.

3. Conformity Assessment

Essentially, conformity assessment is “a demonstration that specified requirements relating to a product, process, system, person or body are fulfilled”.¹ In the case of government agencies, this demonstration establishes the basis for how a particular object satisfies the requirements of corresponding regulations or voluntary programs.

Factors Influencing Forms of Conformity Assessment

There are a number of factors an agency must consider when looking to develop conformity assessment procedures, programs, or schemes. Primarily, an agency must determine what goal a particular conformity assessment program will achieve balanced against the appropriate level of confidence associated with this determination. Furthermore, the level of confidence for any conformity assessment demonstration must be considered against the risk of non-compliance and its associated consequences. Put another way, agencies must try to minimize the burden on industry while limiting the risk of non-compliance. Moreover, an agency must consider its strategy for compliance and confidence either prior to market entry (fulfilling requirements prior to market access) or once out in the market (surveillance of the market to ensure the object's fulfillment of requirements). This consideration has implications for oversight architecture that may be costly to build and to sustain and that may otherwise be satisfied through existing private sector programs. Other factors that should inform an agency's decision making process include anticipated cost of compliance (to the agency, suppliers, or conformity assessment bodies involved), appropriate level of expertise needed to assess conformance, consistency with other relevant conformity assessment programs both in the United States and internationally, supporting legal and administrative infrastructure, and even the breadth of private industry suppliers impacted by the conformity assessment scheme and that industry's history of compliance.

Given the myriad factors associated with any conformity assessment program, an agency should implement conformity assessment activities that correctly balance the confidence of conformance against the cost of compliance for all stakeholders. There are a number of conformity assessment models that implement a varying array of mechanisms intended to provide added levels of confidence and rigor to the conformance determination while at the same time streamlining costs. As a case in point, many third-party programs have protocols for accepting qualified manufacturer test data that can reduce overall certification costs. It should be noted that technology and industry conditions are constantly changing and what may be a suitable level conformity assessment model at one time may be inadequate as the technology and industry changes, so there is a need for ongoing review of the adequacy of programs.

¹ ISO/IEC 17000:2004, Conformity assessment—Vocabulary and general principles.

Importance of Fundamental Principles for Conformity Assessment

As standards and conformity assessment activities complement each other, the principles outlined above would also apply to conformity assessment efforts undertaken by the government. Currently, there are no fundamental principles of conformity assessment or agreed upon terminology, in either Circular A-119 or the conformity assessment guidance outlined by NIST. As a result, federal agencies form their own perceptions and interpretations of what conformity assessment is and the basic principles that are needed for a program to be effective. This lack of direction creates confusion amongst private sector stakeholders looking to engage and forces stakeholders to evaluate programs on a case-by-case basis.

If the proper principles and guidance drive a particular agency's conformity assessment program, then the demonstration of fulfillment of specified requirements becomes an asset to the supplier of the "object of conformity." The more the supplier uses the demonstration, the more valuable it becomes. The value placed on the demonstration becomes an effective counter-balance to any incentive there might be to avoid the specified requirements. When this occurs, equilibrium is reached between confidence for users of the conformity assessment and the value suppliers receive from the conformance determination. Again, agencies must weigh the various factors surrounding the scheme to determine the proper rigor of conformity assessment that will maintain the value of fulfillment without being overly burdensome to the supplier and creating a disincentive for fulfillment of the specified requirements.

International Obligations

UL continues to support government guidance on conformity assessment that adheres to international trade obligations and promotes harmonization of conformity assessment schemes when appropriate. These principles help eliminate overly burdensome and duplicative conformity assessment schemes in the United States and abroad resulting in better clarity of stakeholders and harmonized approaches. The ISO Conformity Assessment Development Manual II confirms the choice of all countries to determine the conformity assessment mechanism that meets their own purposes. The Manual notes, "Conformity assessment will depend on the situation in each country and reflect the prevailing technical, economic, and social conditions and needs." The World Trade Organization's (WTO) Technical Barriers to Trade (TBT) Agreement also makes clear that protection of public safety, including decisions to mandate conformity assessment for this purpose, is a matter that rises above trade concerns. The TBT agreement recognizes that no country "should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life, or health of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, *subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or are disguised.*"² Furthermore, US agencies should also look to implement reciprocity provisions that require equal access for US conformity assessment bodies in a particular market as are afforded to foreign conformity assessment bodies that may provide services for a US agency's program.

² World Trade Organization, Technical Barriers to Trade Agreement, (Paragraph 4).

Other Conformity Assessment Principles

Other considerations include policies governing more tactical implementation of conformity assessment programs, such as an agency's acceptance of data or conformity assessment determinations made through harmonized conformity assessment schemes, mutual recognition agreements or, in some cases, conformity assessment schemes deemed equivalent by a particular agency. To ensure a common level of competency and promote fair competition amongst conformity assessment bodies, guidance should also include a principle around minimum accreditation requirements. Infrastructure for post-market surveillance and anti-counterfeiting operations provide additional mechanisms to increase the confidence of attestation. While some private sector conformity assessment bodies already integrate these mechanisms into their conformity assessment activities, agencies must consider whether they will leverage private sector models or establish these mechanisms on their own.

In many cases, choosing a particular model of conformity assessment that already implements these mechanisms will save an agency the time and cost associated with establishing and operating duplicative programs. The agency can then focus on providing oversight and balance to ensure a given conformity assessment program is operating smoothly. These mechanisms are fundamentally cost-neutral, as the cost associated with erecting and operating this infrastructure in the market is either assumed by industry or the taxpayer respectively. These characteristics of robust conformity assessment schemes and policies enable more consistent implementation of conformity assessment programs and private sector engagement on a global scale.

UL Recommendation: To minimize the impact of duplicative conformity assessment schemes on industry, UL suggests that agencies coordinate their activities to stipulate common program requirements and to recognize conformity assessment and accreditation results that have similar requirements. While agencies may still need additional technical or accreditation requirements to meet their confidence needs, promoting harmonization amongst federal agencies and international governments will limit costs and time to market for everyone. NIST could serve as the federal convener for such activities, coordinating engagement amongst federal agencies, private sector, and the public at-large. This coordination amongst stakeholders would facilitate transparency, the sharing of best practices, and efficient implementation of private sector standards and conformity assessment procedures into agency programs. NIST could also provide a mechanism for metrics and reporting to measure program performance and implement program enhancements.

Similarly, UL believes that OMB should include guidance for conformity assessment in a supplement to Circular A-119 that would result in greater consistency in agency approach and implementation of conformity assessment schemes. Specifically, the supplement should outline relevant principles of conformity assessment for federal agencies based on the ISO and IEC joint standard "ISO/IEC 17000 – Conformity assessment - Vocabulary and general principles," Annex A. This supplement to Circular A-119 should address some essential principles of conformity assessment, including clear definitions of terms and agreed upon guidance for conformity assessment. In essence, the supplement would mirror the principles that correspond to OMB's guidance for federal agencies to engage and adopt voluntary standards. The following principles provide the basis for any conformity assessment activity:

- The underlying concept that conformity assessment is a demonstration that the specified requirements are fulfilled, driving higher levels of fulfillment of the specified requirements.

- The three pillars to achieving the intended benefits of fulfilling specified requirements: 1) the effectiveness of the requirements themselves; 2) the competence of the conformity assessment body; and 3) the specifics of the conformity assessment scheme.
- The optimal choice for conformity assessment in any given situation is the balance between needed confidence for users of the conformity assessment and value for the suppliers subjected to conformity assessment.
- The need for confidence in a specific situation as a function of the consequences of non-compliance with the specified requirements.
- The adherence to international trade obligations that promote global harmonization, participation, and equal access, particularly with respect to US conformity assessment bodies through the form of reciprocity provisions.

More tactical guidance such as minimum accreditation processes, more stringent criteria for establishing the independence of fire-walled proprietary laboratories, mutual recognition of accreditation and demonstration data, and mechanisms to maintain on-going compliance and program integrity such as market surveillance and anti-counterfeiting should be incorporated into any supplemental guidance for conformity assessment that may fall under the NIST guidance for conformity assessment. NIST should also continue to act as a convener to coordinate public-private partnerships and to facilitate accountability and program enhancement.

4. Protection of Copyright Associated with Standards

The OMB Circular A-119 encourages the government to incorporate in whole, in part, or by reference private consensus standards into regulations or for procurement purposes, in order to take advantage of the efficiencies of private standards development. The circular specifically states that any agency referencing voluntary standards should “observe and protect the rights of the copyright holder and any other similar obligations.” Like other original works of authorship (see 17 U.S.C. Sec. 101), standards are protected by copyright, and under US and international law, rights of control and remuneration cannot be taken away without just compensation. When a government agency references a privately developed standard, the standard should not lose its copyright protection, but the agency should collaborate with the SDO to ensure that interested parties have reasonable access to it, which may include appropriate compensation as determined by the SDO.³

SDOs, such as UL, invest significant amounts of time and resources into developing, maintaining and distributing standards. The typical drafting process is heavily reliant on an SDO’s administrative, technical, and support services over the course of the project. Because the process of developing and maintaining a standard is iterative with experience, the costs borne by the SDO are likewise ongoing. One reason the government has encouraged the use of non-government standards is to eliminate the cost to the government (and in turn, the taxpayer) of creating its own standards, especially in cases where private sector standards already exist or where the private sector is well positioned to develop a suitable standard. Many SDOs sell or license their standards to users in order to recoup some of their investments and continue developing and distributing new standards. The

³ This is in alignment with the December 2011 recommendations of the American Conference of the United States (ACUS) with respect to standards that are incorporated by reference into regulation, as well as the recommendations of the White House’s National Science and Technology Council’s Subcommittee on Standards.

exclusive rights conferred under the US Copyright Act, in particular the right to reproduce, distribute, and prepare updated versions of a copyrighted work, are critical to an SDO's ability to perform its mission. For example, without these exclusive rights, any third party could copy and distribute an SDO's standards free of charge, making it difficult for an SDO to find customers willing to pay for those standards. Consequently, SDOs would not recoup their investments and would be discouraged from engaging in future standards development activities. This would, in turn, shift standards development and maintenance costs from the private sector to the federal agencies having jurisdiction over corresponding products or materials. OMB Circular A-119 was issued to eliminate burdens to the government, and in turn, tax payers. Allowing standards to be freely accessible would jeopardize this goal by providing a disincentive for SDOs to continue developing standards.

While the public should have reasonable access to privately developed standards referenced by regulation, this access should not require the loss of copyright protection nor necessarily grant the right for any individual to own a free copy. Government agencies should make clear to public stakeholders that such private standards are protected by copyright and discourage infringement, while at the same time providing for reasonable public access.⁴

As addressed in the Office of the Federal Register's request for information on standards incorporated by reference, the term "reasonably available" should not be defined simply as free or unlimited access to anyone online. Rather, the definition should encompass the many options already in place, and recognize that "reasonable availability" can vary depending on the particular situation. For example, many sections of the Code of Federal Regulation (CFR) currently indicate that pertinent standards are available for viewing at the National Archives and Records Administration (NARA) whose practice is to provide contact information for the applicable SDOs. Some standards incorporated by reference are also available at government libraries and other facilities. In addition to the availability of referenced standards at NARA, UL standards are available for public viewing at UL Technical Reference Centers. Headings and outlines for individual UL standards are also available at no cost at www.ul.com. UL's full standards, though not always free, are available to the public via licenses that may be purchased through Comm 2000, a third-party vendor that distributes both electronic and hard copy versions of UL standards. Other SDOs provide read-only, online access to their standards that are incorporated by reference, an option UL is currently exploring.

The current approach appears to be working from UL's perspective; UL is not aware of any individuals or groups who have been unable to access UL standards referenced by federal regulation. In any event, UL is willing to work with government agencies to provide reasonable access to referenced UL standards as appropriate, on a case-by-case basis and in a manner, that adequately protects the copyrights of the standards.

UL Recommendation: Agencies have relied on SDOs to provide performance and safety standards while absorbing the cost of development and publication of such standards. The copyright in a standard should remain intact to sustain the mutually beneficial relationship between the public and private sectors. Government should make clear to the public that such private standards are

⁴ For additional background, please see the February 2011 white paper by ANSI's Intellectual Property Rights Policy Committee entitled "Why Voluntary Consensus Standards Incorporated by Reference into Federal Government Regulations Are Copyright Protected," available at: <http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Critical%20Issues/Copyright%20on%20Standards%20in%20Regulations/Copyright%20on%20Standards%20in%20Regulation.pdf>

protected by copyright, while at the same time providing for reasonable access to interested parties and discouraging infringement and illicit distribution. The federal agencies referencing privately developed standards should work closely with the SDOs to determine reasonable access that is appropriate under the circumstances, which may include compensation to the SDO. If copyright protection is removed for such privately developed standards, the costly, time-intensive, and expert-driven process of developing these standards could easily shift from the private sector to federal agencies.

5. Voluntary Consensus Standards and Cost-Benefit Analysis⁵

UL allocates millions of dollars (USD) annually and dedicates dozens of staff members for standards development activities while also investing significant amounts of time and resources into the development, and distribution of standards. Additional costs are incurred through the on-going review and continual improvement of standards in order to keep pace with the market and technological developments. 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 standard is convened, 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. 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 standards development outcome for commercial or political reasons. Standards sales or licensing also allow non-profit SDOs the opportunity to recoup basic administrative costs, while passing on to implementers all of the benefits of the voluntary standards development process, including openness, balance, and protection from undue influence.⁶

The principles of the National Technology Transfer and Advancement Act (NTTAA) state that federal agencies should utilize standards developed by private sector, voluntary consensus standards bodies in lieu of developing unique technical regulations. The NTTAA goes on to direct federal agencies to consult with SDOs, including participation in their standards development work. Such consensus standards reflect the interest of diverse stakeholders and serve as the basis for compliance tools. To sustain the private sector SDOs' ability to meet evolving regulator needs, UL believes that all regulators must continue to engage private sector SDOs to enable alignment to federal agency needs. The American National Standards Institute (ANSI), of which UL is a member, explains that "standards developed through a voluntary consensus process have proven effective at meeting both regulatory and market needs in a variety of sectors. As tariff barriers have been reduced, technical standards have become more prominent as potential barriers to market access for products and services. The facilitation of global trade requires that more attention be given to preventing standards and their application from becoming market access barriers and addressing barriers which arise."⁷

⁵ Based on how this question was framed in the Federal Register Notice, our response draws upon UL's experience with consensus standards, but the analysis here also applies to other types of standards as discussed in Section 2.

⁶ 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

⁷ http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/NSSC/USSS_Third_edition/USSS%202010-sm.pdf?&source=whatsnew021411

A review of the annual OMB reports to Congress on the government's use of voluntary consensus standards reveals agency satisfaction with Circular A-119. This sentiment has been acknowledged by many federal agencies. For example, when the Federal Energy Regulatory Commission (FERC) evaluated a private, North American Energy Standards Board (NAESB) standards development process against the cost to the Commission and to the industry of developing these standards through notice-and-comment rulemaking, FERC found that the NAESB process was more efficient. In its report, FERC cited "In choosing to take advantage of the efficiency of the NAESB process, we followed the government regulations that require the use of incorporation by reference. These rules appropriately balance the interest of the standards organization and the expediency of governmental use of privately developed standards."⁸

To this end, one must consider the costs of abstaining from consensus standards. If the federal government were to replace the efforts of private sector SDOs, such as UL, with government standards development bodies, there could be a loss in efficiencies, greater stakeholder diversity, and responsiveness that would undermine the objectives of such government regulations and programs. The government has neither the dedicated resources nor the long-standing expertise to perform the standards development function in an efficient manner. The development of private sector standards is often a more flexible and cost-effective method of developing technical standards than the highly-structured, government rulemaking process. Indeed, the very purpose of Circular OMB A-119 was to allow the government to tap into this efficiency and "eliminate the cost to the Government of developing its own standards."⁹

UL Recommendation: SDOs, such as UL, invest significant amounts of time and resources into developing, maintaining and distributing standards. Government should take into account the significant expenses associated with the standards development process and leverage private sector standards development organizations, especially given their position in the market, expertise, and dedicated resources. Utilizing non-government standards will help to eliminate the cost to the government of creating its own standards, encourage harmonization and promote transparency.

As mentioned previously, when developing new standards or conformity assessment programs there should be a formal mechanism in place for engaging the private sector, as well as an on-going mechanism to develop metrics that will benchmark the effectiveness of related programs established by various agencies. Monitoring and developing such metrics will increase transparency and ensure that the appropriate standard(s) are leveraged with the appropriate conformity assessment scheme.

6. Using and Updating Standards in Regulation

As has been discussed previously, federal agencies implementing Circular A-119 in rulemakings depend on voluntary standards to eliminate costs associated with the government creating its own standards. Many government agencies have referenced UL Standards materials. Some agencies, like the Occupational Safety and Health Administration (OSHA), rely almost exclusively on voluntary consensus standards and consider them "appropriate" for electrical products as well as other product categories under its jurisdiction. Other agencies, like the Food and Drug Administration (FDA), are actively canvassing the private sector for information on privately developed standards that address

⁸ <http://www.gpo.gov/fdsys/pkg/FR-2009-12-03/html/E9-28619.htm>

⁹ Section 1, Office of Management and Budget (OMB) Circular A-119

product categories under their authority, such as medical devices. According to the Standards Incorporated by Reference (SIBR) Database, UL Standards appear 187 times in the Code of Federal Regulations (CFR).

When agencies reference standards, they are incorporating a specific edition of a standard that is current to the date of adoption or revision. Standards are continuously being reviewed and updated. It is also common practice for UL to reference other standards within a UL Standard. In these instances, UL indicates the standard number and notes that the latest version of that standard should be used, when referenced. This reduces the need for updating the UL Standard when the referenced standard is updated. While this is less of an issue in the continuous updating process of voluntary consensus standards development, updating regulations are more cumbersome when a referenced standard is revised.

It is important to adopt and reference the latest edition of a particular standard, as they represent the latest technological advancements available and take into consideration prevailing factors in the marketplace. Updating referenced standards necessitates proactive reliance by federal agencies to monitor standards revisions. Federal agencies should be able to rely on the integrity of the process to update the standard accordingly, given their participation and engagement in the standards development process. The frequency of review of a standard is linked to the needs of the marketplace and is usually driven by 1) technology innovations, 2) product use changes, 3) changes in installation practices, and 4) supply chain changes. In industries or product categories where these factors are repeatedly changing, frequent standards revisions are necessary to keep standards aligned with the marketplace. Specifically, if it is an ANSI-approved standard, then the guidelines require updating at least every five years. While the Regulatory Flexibility Act of 1980 (RFA) requires a review of regulation not more than 10 years from their dates of enactment, standards incorporated by reference may be reviewed and updated multiple times within that same time period. For this reason, UL recommends that when government agencies reference the “most current” version of private sector standards. There are also formal mechanisms and triggers agencies can implement to ensure the most current version of standards are used in regulation. One example is how the Consumer Product Safety Commission (CPSC) references the third edition of UL 325 standard for garage door safety in its regulations. In its regulation, the CPSC included language that requires UL to notify the Commission if there is a revision to that standard. The revised standard will then be incorporated into the consumer product safety rule unless the CPSC determines within 30 days that such a revision does not carry out the purposes of the original regulation.

A mechanism for regulators to rely on the most current edition of a standard is important for compliance purposes as well. Clarity around the application of the most current edition of a standard helps to ensure that similar products in the marketplace are evaluated against the same technical requirements. Many representations are made about a product having been “tested to” that standard. But unfortunately, it is not always clear whether the product actually meets the requirements of the standard. Because there are SDOs that also serve as third-party testing organizations, reference to the standard is often misconstrued as having been tested and certified by the certification arm of the SDO.

UL Recommendation: In order to ensure the most current standards are referenced in agency regulations and programs, the OMB should recommend that federal agencies reference standards by

name and number, rather than by incorporating text into the regulation or other procurement document. Similarly, OMB should recommend including provisions in regulations to refer to the most current version of a standard rather than a specific edition of the standard or date of a standard, and UL would further recommend out-of-cycle mechanisms to ensure that rules remain aligned with changing market dynamics. Where conformity is entrusted to the private sector, regulators should require that product labels reference both the standard to which it was evaluated and the qualified organization who performed the assessment.

As OMB considers the appropriate process and criteria for reviewing existing federal agency regulations under direction of Executive Orders 13563 and 13579, UL encourages agencies to think about how on-going dialogues with SDOs can further support efforts to develop, review, and modify regulations. Although a useful tool, the Standards Incorporated by Reference (SIBR) Database is not updated regularly. Keeping with the principles set out in this document, in order to increase transparency and efficiency, federal agencies should communicate to the public, specifically the relevant SDO, when regulations referencing standards are being contemplated, updated, or reviewed. A mechanism where government agencies would be required to contact a registered SDO agent or representative during one of the previously stated circumstances, would allow both parties to better identify where standards are incorporated by reference in all government documents and open a dialogue on which version of the referenced standard is most recent. Continuing to dedicate government technical experts to SDOs' standards development panels is also critical to ensuring that private sector consensus standards not only adapt to current market dynamics and technological advancements, but continue to meet the needs of the public sector. Because SDOs, including UL, also participate in the alignment of standards internationally, they are uniquely positioned to provide counsel to agencies on requirements that foster global regulatory alignment globally. This alignment helps to reduce the economic burdens to government agencies and the private sector in administering and participating in compliance programs.

7. Use of More than One Standard or Conformity Assessment Procedure in a Regulation or Procurement Solicitation

The goals of individual federal programs or regulations should ultimately dictate whether more than one standard or conformity assessment procedure should be used to fulfill the program or regulation requirements. Based on the objective, the regulator should define the baseline parameters that standards and conformity assessment programs must meet and then either engage the private sector to establish them, wherever practicable, or set them directly. Industry can demonstrate their compliance to the requirements by meeting the requirements directly, or by meeting more stringent requirements established in the marketplace. In establishing the requirements, if there is a best practice outside the United States, the marketplace may choose to align with those requirements, so long as they meet the minimum requirements of the regulator and they have been approved and deemed suitable for the US market by the appropriate US regulator. This process should be open and transparent, with a balance of interest groups, and should not be confused with the term "harmonization" or "international" standards per WTO definition.

For instance, with regard to environmental standards, it is important for federal agencies to have the option to reference multiple standards since the sustainability movement is still relatively young and constantly evolving. In this case, allowing for the use of multiple environmental standards ensures that the marketplace is open to new ideas and innovation, which help foster competition in this rapidly

growing sector. However, if a federal agency decides to use more than one standard, it is imperative for them to conduct an equivalency analysis to ensure that all of the standards referenced fulfill the same goals that the agency program or regulation seeks to achieve. In instances where one standard is appropriate, federal agencies should have discretion to select the standard that most adequately fulfills their requirements. Federal agencies should also have the discretion to consider using multi-attribute standards that address more than one aspect of a product, such as safety and performance attributes, to meet the requirements of their programs or regulations, including instances where the program or regulation is only seeking to address a single attribute of a product.

With regard to the use of multiple conformity assessment procedures, it may actually be less burdensome on industry to use a conformity assessment procedure of a higher confidence than what a federal agency specifies. This is especially true when industry is already using the higher confidence building conformity assessment for other purposes. For example, if a federal agency requires only accredited testing, but industry is already using product certification schemes that include accredited testing, then the federal agency should allow such product certification to fulfill regulatory requirements if the accreditations are equivalent.

In addition, there are occasions where multiple agencies have overlapping jurisdiction of the same product categories. In these cases, differing compliance documentation requirements between federal agencies can add redundant testing and administration to the compliance process for suppliers. For example, CPSC currently requires the issuance of a separate paper certificate of conformity (CoC) for compliance with CPSC requirements for certain products that are under the jurisdiction of both the Occupational Safety and Health Administration (OSHA) Nationally Recognized Testing Laboratory (NRTL) Program and the Consumer Product Safety Improvement Act (CPSIA) requirements, even though comparable certification data is accessible through an accredited NRTL's certification mark.

As far as allowing the demonstration of conformity to another country's standards, federal agencies should recognize that standards in any country are developed to address specific national safety issues as well as other cultural norms. Although many national, regional, and international standards and conformity assessment schemes around the world share the common goals of facilitating product safety and performance, and harmonization efforts continue, there is not a single system in place today to assure compliance with all relevant standards, regulations, and schemes. The term "global standards" is used frequently by organizations today; however, few standards truly have global application. Some standards are more accurately described as "internationally harmonized" rather than global standards. While internationally harmonized standards include many common requirements, they also include requirements that are unique and specific to the safety considerations and infrastructure of individual countries. Specifically, the US versions of internationally harmonized electrical standards consistently include national differences in order to address safety norms and other matters unique to the United States. These differences include compatibility with model codes, the uniqueness of our electricity distribution systems, infrastructure needs, and regulatory and legal issues. These infrastructure differences must be taken into account when identifying and adopting product safety standards that meet the needs of US regulators.

Regulatory cooperation dialogues are a useful tool to help minimize the economic impact of meeting duplicative or conflicting requirements in multiple markets for manufacturers, in so far as there is a

meaningful and robust and sustained mechanism for private sector engagement. Because private sector SDOs and conformity organizations play an important role in helping to set appropriate technical requirements and in helping to demonstrate conformance to them, a regulator dialogue that precludes a meaningful role for the private sector could result in changes that are counter-productive to US regulator and the public's interest. UL recognizes that the need for global harmonization must be weighed carefully against the need for national differences between the United States and foreign regulatory regimes given infrastructure, risk tolerance, and other relevant safety factors specific to the US market.

In the end, the best way to address redundant requirements in markets beyond the US, and where third party testing or certification is required, is through consistent national treatment for certification organizations across all markets. This is especially true when harmonization is not technically or politically feasible, or is a long way off. National treatment for product certification organizations means that, where regulators around the world accredit entities to test and certify products sold in their countries, they should accredit foreign entities on terms no less favorable than domestic ones. National treatment enables certifiers to streamline a manufacturer's certification needs across all markets of interest, while satisfying the confidence needs of regulators.

UL Recommendation: OMB should give federal agencies the option to reference more than one standard when it helps to fulfill the needs of their respective programs or regulations, especially for emerging industries, where multiple standards can foster innovation and competitiveness in the industry. However, agencies should engage SDOs to determine when equivalency exists between multiple standards to ensure each standard meets their purposes. OMB should also provide detailed guidance to federal agencies for instances where industry faces multiple demands for conformity assessment. One way for federal agencies to alleviate or minimize redundant conformity assessment schemes is to look at similar efforts of other federal agencies that have equivalent or more stringent safety rules, standards, or regulations. In addition, UL supports the goals of meaningful standards harmonization and regulatory convergence across countries over allowing the demonstration of conformity to another country's standard. For instances where harmonization or regulatory convergence is not technically or politically feasible, consistent national treatment for certification organizations across all markets should be leveraged.

8. Other Developments

UL believes that US agencies accrediting or accepting accreditation of foreign conformity assessment bodies without regard to whether those foreign governments provide reciprocal accreditation put US conformity assessment bodies at a competitive disadvantage. Trade officials typically do not tolerate opening market access for manufactured goods without some market access on a reciprocal basis for similar domestically produced goods. UL believes the same fair competition principles should hold true for service providers as well. Allowing foreign conformity assessment bodies to provide services under a federal program or regulation without regard to whether their host governments provide market access on a reciprocal basis disadvantages US manufacturers and service providers in the global marketplace. Over time, this lack of national treatment for US conformity assessment bodies has a negative impact on high-paying engineering jobs in the United States and on US exports. In addition, US manufacturers benefit from reciprocity provisions by having local access to conformity assessment for foreign regulations. Reciprocity provisions also allow conformity assessment bodies to streamline requirements across markets and bundle services for manufacturers to eliminate

duplicative testing. Reciprocity provisions, like those utilized by OSHA in its accreditation criteria for the NRTL Program and the Federal Communications Commission's (FCC) accreditation criteria for Telecommunications Certification Bodies, are designed to ensure a level playing field for US-based conformity assessment bodies with respect to foreign competition. In addressing reciprocity, regulators should ensure that US subsidiaries outside of the United States are considered part of the US parent body and not treated as a national body in the country in which they are located.

On some occasions, when the government identifies an initiative to be of critical interest to the nation, federal agencies should act as a convener for the standards and conformity assessment communities and refrain from developing separate standards that create duplications and inconsistencies in product requirements for the marketplace. In many cases, the standards and conformity assessment communities already have standards or practices that can meet identified government objectives. For example, when NIST identified Smart Grid as an area of critical interest to the nation, it mobilized experts from the standards and conformity assessment communities to form the Smart Grid Interoperability Panel (SGIP) to provide technical guidance to facilitate development of standards for a secure, interoperable Smart Grid. In many instances, the SGIP was able to identify existing standards to meet the interoperability, communication and security needs of the nascent Smart Grid – it was just a matter of identifying those touch points and coming to consensus as an industry as to which would be adopted.

UL Recommendation: When federal agencies are drafting accreditation protocols for conformity assessment services in the United States, OMB should encourage US government officials through a supplement to Circular A-119 to adopt language outlining reciprocal accreditation of US-based conformity assessment bodies. To support federal participation in consensus-based standards development, federal agencies should advocate for increased government participation in the standards process and ensure the appropriate resources are made available for government personnel to participate in consensus-based standards development activities. On occasions when the government identifies an initiative of critical interest to the United States, federal agencies should facilitate the identification or development of standards by engaging the standards and conformity assessment communities with dedicated technical resources and high level of expertise.