



May 12, 2014

Mr. Howard Shelanski  
Administrator  
Office of Information and Regulatory Affairs  
White House Office of Management and Budget  
725 17<sup>th</sup> Street NW  
Washington, DC 20503

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

Dear Mr. Shelanski,

UL (Underwriters Laboratories) appreciates the opportunity to comment on the Office of Management and Budget's (OMB) Proposed Revision to Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (hereinafter "OMB A-119" or "the Circular").

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.

### **General Observations**

In general, UL believes that OMB's proposed revision to the Circular provides significant and meaningful guidance upon which federal agencies can rely when determining how to participate in the development and use of voluntary consensus standards and conformity assessment activities. UL applauds OMB for incorporating several of the suggestions and best practices that standards developing organizations (SDOs) and conformity assessment bodies (CABs) such as UL offered in their responses to the 2012 Request for Information (RFI; OMB-2012-7602).

UL appreciates that OMB has identified "Principles for Federal Engagement in Standards Activities to Address National Priorities" (Section 1). These principles, if properly applied, will provide agencies with additional clarity in participating in standards development and conformity assessment activities. UL cautions, however, that these objectives, particularly (i) through (iii), would be thwarted if copyright protection is not respected for standards incorporated by reference (IBR). Indeed, without copyright protection and means to generate income, even on a cost recovery basis, many SDOs may stop

developing standards altogether or switch to business models that result in less participation from stakeholders, e.g., charging membership fees. Additionally, more standards development would have to shift to the government, requiring officials to build or hire new teams with expertise in standards-making and forcing taxpayers to bear significant additional costs. Similarly, the government's goals in using voluntary consensus standards (Section 2) will not be met without ensuring copyright protection for standards incorporated by reference.

UL's additional comments on the Proposed Revision to OMB A-119 are organized by the five primary elements identified by OMB in its Summary.

## **1. Preference for Voluntary Consensus Standards**

### *Definitions*

UL concurs with the value that OMB continues to place on voluntary consensus standards in lieu of government-unique standards. In its proposal, OMB defines a voluntary consensus standards development process to include several attributes or elements, including openness, balance of representation, due process, appeals process, and consensus. While these elements are similar to the American National Standards Institute (ANSI) *Essential Requirements* that many standard development organizations (SDOs) abide by, they are not identical and, as written, may actually make it difficult for an agency to differentiate between what constitutes a voluntary consensus standard and a voluntary non-consensus standard. For instance, OMB's definition of "balance of representation" differs significantly from the ANSI *Essential Requirements* definition of "balance of interest," which relies on SDOs to conduct outreach to stakeholders.

- Recommendation: Although most SDOs that conduct standards development activities pursuant to the ANSI *Essential Requirements* likely will meet the attributes of voluntary consensus standards outlined in the proposed revision to OMB A-119, UL nevertheless recommends that OMB, in giving guidance to US federal government agencies, consider greater alignment with the ANSI *Essential Requirements*. UL also encourages OMB to give consideration to the WTO Code of Good Practice for the Preparation, Adoption and Application of Standards and the International Organization for Standardization (ISO) definition of "consensus."

### *Preference for Voluntary Consensus Standards*

UL supports OMB's acknowledgement that "in addition to consideration of voluntary consensus standards, it is also important to recognize the contributions of standardization activities that take place outside of the voluntary consensus process, particularly in emerging technology areas." In our comments to the 2012 Request for Information (RFI) on OMB A-119, UL noted that consensus standards sometimes lag behind market developments and that, for industries with short development cycles or rapidly emerging technologies, SDOs may employ different standards development techniques to offer industry and other stakeholders a platform to document preliminary requirements that act as a baseline in the short term.

However, by stressing that other voluntary standards may only be considered after an agency determines that no “suitable” voluntary consensus standard exists to address the need, OMB appears to limit the flexibility of an agency to use whatever voluntary standard best meets the agency’s and public’s 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.

- Recommendation: As recommended in our comments to the 2012 Request for Information on OMB A-119, UL continues to believe that OMB could best serve agencies by giving them the flexibility to use different types of standards that they believe will meet their needs and program goals, insofar as related conformity assessment requirements entrusted to the private sector are based on open competition. In evaluating the type(s) of voluntary standard to reference, agencies 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 issues 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 types of questions will help an agency determine if the type of standard best suited to achieve the goals of a particular agency’s program is a voluntary consensus standard or alternative voluntary standard developed via other means. In a given situation, a non-consensus voluntary standard may specifically address a new technology, environmental or safety concern not covered by existing voluntary consensus standards and therefore the non-consensus voluntary standard should be considered if it supports the objectives of the agency.

## **2. Guidance on Use of Standards and Participation in Standards Development**

### *Agency Participation in Standards Development Activities*

UL believes that continuing to dedicate government technical experts to SDOs' standards development panels is critical to ensuring that private sector standards not only adapt to current market dynamics and technological advancements, but also continue to meet the needs of the public sector. Voluntary standards benefit from full engagement and participation by government stakeholders. UL appreciates that, in its proposed revision (Section 7), OMB has provided additional guidance to federal agencies on staff participation in private sector standards development activities. This guidance helps clarify that agency representatives participate in voluntary standards development bodies as informed stakeholders, on an "equal basis with other members" (Section 7(c)), having no more or no less standing than any other participant.

## **3. Guidance on Conformity Assessment**

UL applauds OMB for proposing the inclusion of guidance on how federal agencies participate in conformity assessment activities as part of OMB Circular A-119. UL anticipates that such guidance will result in greater consistency in agency approach and implementation of conformity assessment schemes. Since consistency in definition and implementation of conformity assessment activities is critical, UL offers the following recommended revisions.

### *Section 4. What is Conformity Assessment?*

ISO/IEC 17000—*Conformity assessment, Vocabulary and general principles* (Annex A) has been in use internationally as terminology for conformity assessment for ten years and is the basis for nearly every other ISO/IEC 170xx standard for conformity assessment. In our response to the 2012 RFI, UL recommended that OMB outline relevant principles of conformity assessment for federal agencies based on the ISO/IEC 17000 standard.

In its proposed definition of conformity assessment, OMB includes language (e.g., "directly or indirectly") that is confusing and unnecessary, since all conformity assessment is a demonstration that specific requirements are fulfilled. The methodology used to carry out the demonstration is a "conformity assessment scheme" per ISO/IEC 17000. The scheme specifies the details regarding sampling, evaluation, auditing, attestation, what bodies will perform which activities, etc., and these details vary from scheme to scheme. However, virtually all schemes have an "indirect" element to the demonstration (e.g., sampling as opposed to evaluation of every individual item), and therefore it could be misleading to imply differently through the use of "directly or indirectly" in this foundational definition.

- **Recommendation:** UL recommends that OMB modify the definition of conformity assessment definition in Section 4 as follows (*language recommended to be deleted is indicated by strikethrough; language recommended to be added is indicated by underline*):

“Conformity assessment is a demonstration ~~whether directly or indirectly~~, that specified requirements relating to a product, process, system, person, or body are fulfilled. Activities within a conformity assessment can include sampling and testing, inspection, supplier’s declaration of conformity, certification, and management system assessment and registration. # Activities can also include accreditation by a third party of the competence of the bodies performing the above these activities. by a third party and Recognition (usually by a government agency) of an accreditation program’s body’s capability is also a conformity assessment activity if it involves a demonstration of fulfillment of specified requirements related to capability.

#### *Section 8. What is the Policy on Conformity Assessment?*

In proposed Section 8(a), the phrase “international conformity assessment schemes or private sector conformity assessment activities” provides less than optimal direction. First, it omits the “private sector” modifier for international schemes. UL believes the Circular should be clear that it is not providing guidance on the use of governmental/public sector conformity assessment schemes (national, international, or otherwise). Such schemes are usually mandated by legislation, treaty, trade agreement, etc., and are not the subject of Circular A-119. In addition, the phrase implies that only international schemes are worthy of consideration. Even with the continual increase in the number and breadth of international schemes, many private sector schemes continue to focus on meeting demands for conformity assessment at a national level. The Circular should certainly emphasize international schemes, but not ignore the reality of the appropriate national level focus of many existing schemes.

- Recommendation: UL recommends that OMB replace the phrase “international conformity assessment schemes or private sector conformity assessment activities” with “private sector conformity assessment schemes (including international schemes) or activities.”

With respect to Section 8(b)(i) and (ii), UL believes that the Circular should provide guidance to federal agencies in item (i) to consider, before anything else, the role that fulfillment of specified requirements plays in achieving their objectives.

When fulfillment of specified requirements does play a role, then the Circular should point federal agencies to the next consideration in item (ii)—whether a demonstration that specified requirements are fulfilled is justified, taking account of the factors described. More specifically, OMB A-119 should not imply that any conformity assessment (a demonstration that specified requirements are fulfilled) alone drives achievement of objectives. That implication ignores the critical role of the effectiveness and applicability of the specified requirements and their relevance to defined agency objectives. The most highly optimized conformity assessment will contribute little to achieving objectives if the specified requirements are ineffective or inapplicable. The Circular should link conformity assessment to confidence that specified requirements are fulfilled and refrain from implying that conformity assessment can contribute to achieving objectives independently of the specified requirements.

- Recommendation: UL recommends that OMB revise proposed Section 8(b) items (i) and (ii) as follows:

“(i) The objective(s) of the underlying regulation, procurement, or program activity and the role that fulfillment of specified requirements plays in achieving the objective(s);

(ii) The level of confidence regarding fulfillment of specified requirements needed to achieve objectives, required by the agency to ensure that the agency objective(s) has/have been achieved, weighing the risk of non-compliance and its associated consequences and the anticipated costs of demonstrating compliance...”

The term “assess conformity” as used in Sections 8(b)(iii) and 8(b)(ix) is inconsistent with ISO/IEC 17000, which does not define this term. Instead, ISO/IEC 17000 employs the term “demonstrate conformity,” on which ISO/IEC 17000 and all other related ISO standards rely. To ensure that the US government is aligned with international concepts and does not unduly create confusion for US exporters or compromise US obligations under international trade agreements, OMB should consider greater alignment with ISO/IEC 17000. Also, ISO/IEC 17000 describes a broader functional approach to conformity assessment, and any demonstration that specified requirements are fulfilled necessitates competencies beyond merely assessing conformity (e.g., effective sampling, thorough and objective review and decisions regarding the adequacy and effectiveness of the steps followed as a demonstration, etc.). The Circular should encourage federal agencies to consider all aspects of a demonstration that specified requirements are fulfilled.

- Recommendation: UL recommends that for further information, OMB consult ISO/IEC 17000 Annex A and consider a specific reference to this standard in the Circular. In addition, UL recommends that Sections 8(b)(iii) and 8(b)(ix) be revised as follows:

*8(b)(iii)*: “...the appropriate level of competence needed to ~~assess conformity~~ demonstrate fulfillment of specified requirements.”

*8(b)(ix)*: “The need to ensure that information requirements for conformity assessment are limited to what is necessary to ~~assess conformity~~ demonstrate fulfillment of specified requirements and determine fees.”

UL believes that OMB A-119 should encourage federal agencies to consider the use of both private sector conformity assessment schemes and activities. It is very possible that private sector conformity assessment activities are undertaken within governmental/public sector schemes. Recognition, acceptance or use of the results of such activities should also be encouraged by the Circular.

- Recommendation: UL recommends that OMB revise Section 8(b)(viii) as follows:

“The appropriateness of recognizing the results of private sector conformity assessment schemes or activities being utilized in State, local, and/or foreign government regulation, consistent with Section 8a.”

#### **4. Enhanced Transparency**

##### *Transparency and Engagement with SDO Community in Activities*

In our 2012 RFI comments, UL also noted that 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 ongoing maintenance of government activities and programs. UL believes that OMB has taken great efforts in the proposed revision to increase agency transparency and engagement in standards and conformity assessment activities. Most notably, UL supports OMB's guidance (Section 10) that agencies report to OMB, through the National Institute of Standards and Technology (NIST), on use of government-unique standards in lieu of voluntary consensus standards, along with explanation of reasons for non-usage, and on participation in the development and use of voluntary consensus standards. UL is pleased that OMB requires that, in their reports to NIST, an agency must identify (1) the number of voluntary consensus bodies in which there is agency participation, as well as the number of employees participating; (2) the number of voluntary consensus standards the agency has used since its last report; (3) identification of voluntary consensus standards that have been substitute for government-unique standards; (4) evaluation of the effectiveness of the policy and recommendations for changes; and (5) similar information for other (non-consensus) voluntary standards in use.

UL also supports the intent of Section 11, which sets out expectations for agencies' use of standards in regulations. This includes a recommendation that agencies include in the regulatory preamble a discussion of how they are implementing A-119. UL agrees with OMB that such information would be helpful and particularly endorses the recommended inclusion of "which bodies or organizations the agency consulted with to determine whether there are relevant voluntary standards in use in the marketplace (or completion of relevant voluntary standards is imminent) or if voluntary standards that are currently incorporated by referenced have been revised" (Section 11(a)(i)). UL further agrees with OMB that such information might include notice of "whether the agency has worked with relevant bodies or organizations to try and ensure that the voluntary standards meet agency needs..." (Section 11(a)(iii)) and "whether the agency has coordinated its positions in technical advisory groups or technical committees of such bodies with (1) other interested agencies that are or should be participating in such work and, (2) where appropriate, foreign regulatory agencies that are participating in such work, where the work is relevant to regulatory cooperation council work plans described in section 3(d) of Executive Order 13609, 'Promoting International Regulatory Cooperation'" (Section 11(a)(iv)). These types of coordination and information-sharing represent best practices that OMB is right to encourage agencies to adopt.

##### *Factors for Agencies to Consider When Incorporating Standards by Reference*

With respect to the recommendations outlined in Section 6(p) regarding how an agency can determine whether a voluntary standard is "reasonably available," UL generally agrees with OMB's approach, which is largely consistent with Administrative Conference of the United States (ACUS) Recommendation 2011-

5, *Incorporation by Reference*. UL notes that one of the factors OMB guides agencies to consider is “whether the standards developer is willing to make read-only access to the standard available for free on its website during the comment period” (Section 6(p)(i)). UL believes that this factor should not be limited to posting on an SDO’s website; the American National Standards Institute (ANSI) is hosting an online reading room/portal for SDOs who are financially or technically unable to post such standards themselves.

As an SDO, UL also seeks greater clarity from OMB on what the proposed revision to OMB A-119 means by “freely available” as used throughout Section 6(p). This should not be taken to imply “in the public domain” and/or “not subject to copyright protection.” UL continues to maintain that its IBR standards are protected by copyright, even when made available for free in read-only format on *www.ul.com*. OMB acknowledges the important rights of copyright holders in Section 6(l) when directing “If a voluntary standard is used and published in an agency document, your agency must observe and protect the rights of the copyright holder and meet any other similar obligations...”, but greater clarity is needed in Section 6(p) with respect to what is meant by “freely available.”

- Recommendation: UL recommends that OMB provide greater clarity and definition to what it means by “freely available” material. OMB should direct agencies not to interpret “freely available” as compromising the copyright protection of the standard or violating the intellectual property rights of SDOs.

## 5. **Burden Reduction**

UL generally agrees with OMB’s recommendations outlined in Section 6(o) with respect to how federal agencies should ensure that standards incorporated by reference (IBR) are updated on a timely basis.

- Recommendation: UL does recommend, however, that OMB consider creation of a mechanism, potentially through NIST, by which the government keeps track of SDOs’ revision cycles to allow for more targeted updating. OMB may also want to consider offering guidance to agencies on how they can assess any potential level of controversy associated with updating or substituting a standard. This guidance could help agencies streamline their review and make a determination of whether a standards-specific direct final rule will suffice or whether a standards-specific notice of proposed rulemaking (NPRM) is necessary.

## 6. **International Considerations**

In its proposed revision to Circular A-119, it appears OMB took special care to include guidance to help ensure that federal agencies’ actions are consistent with World Trade Organization (WTO) requirements. WTO and Technical Barriers to Trade (TBT) requirements are addressed throughout the proposal, with recommendations provided as to how compliance can be achieved and maintained. The use of “soft” legal language such as “should” instead of “shall” likely will provide agencies with flexibility in how to apply the Circular.



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UL appreciates the attention provided to the international considerations of A-119. Important considerations include:

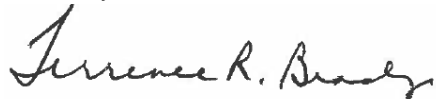
- Reinforcement of WTO principles, including national treatment for standards-related and conformity assessment activities;
- Support of what constitutes an international standard, consistent with the WTO TBT Committee Decision;
- Requirements to consult with appropriate government agencies (for example, USTR and the State Department) to ensure consistency with trade and other international obligations; and
- Support for regulatory collaboration initiatives.

### **Conclusions**

UL applauds the tremendous effort OMB has undertaken to revise OMB Circular A-119 to reflect changes that have taken place in the world of regulation, standards and conformity assessment since the Circular was last revised in 1998. OMB's proposed revision is thoughtful, meaningful and robust, and it is clear that OMB used the information gathered from the stakeholder community during the 2012 RFI to inform its consideration. As OMB evaluates the additional input it will receive during the public comment period on this proposal, UL anticipates that further refinements may be made that will help OMB meet its goal to "provide more detailed guidance to agencies to take into account agency experience under the current Circular..., developments in regulatory policy and international trade, and changes in technology" (FR 8208).

If you have any questions regarding our suggested recommendations or would like to discuss further the content of our submission, please contact me or UL Global Government Affairs Vice President Ann Weeks ([ann.weeks@ul.com](mailto:ann.weeks@ul.com); 202.296.1435) with any questions. Thank you for your time and consideration.

Sincerely,



Terrence R. Brady  
Senior Vice President  
Chief Legal Officer and General Counsel