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SUBMITTED VIA REGULATIONS.GOV

May 12, 2014

Howard Shelanski, Ph.D.  
Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget (OMB)  
725 17<sup>th</sup> Street, NW  
Washington, D.C. 20503

RE: OMB Circular No. A-119 “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”

Dear Dr. Shelanski:

Since 1913, the Compressed Gas Association (CGA) has been dedicated to ever-improving safe, secure, and environmentally responsible manufacture, transportation, storage, transfilling, and disposal of industrial and medical gases and their containers. Over 120 member companies provide technical and advocacy leadership to establish safety standards; provide safety information and warnings about the chemical or physical properties of gases and their containers; and provide technical training and education. CGA is an American National Standards Institute (ANSI) accredited Standards Developing Organization and works directly with Federal, State, and Provincial agencies and fire code officials to promote safe and responsible practices and regulations.

CGA supports several committees of the International Organization for Standardization (ISO) and coordinates member company participation in the development of ISO standards through U.S. and Canadian advisory groups. CGA also works with other industrial gas associations around the world, through the International Harmonization Council (IHC), to harmonize standards to advance safety in the industrial gas industry. Additionally, CGA participates in the United Nations (UN) to develop model regulations that apply to the industrial gas and equipment industry.

CGA appreciates the opportunity to comment on these following proposed revisions to OMB Circular No. A-119.

#### **1. Preference for Voluntary Consensus Standards (VCS)**

Circular A-119 proposes to establish a general preference for using VCS in federal regulation and for other federal agency uses. The development of codes and regulations in the U.S. is widely supported through the use of standards produced by the private industry sector, including many that are not VCS. While the VCS process may have value in terms of gaining broader feedback, the VCS process does not, of itself, assess the technical validity of a standard. This is best achieved through experts working together to develop technically sound standards. CGA develops its standards using the expertise of our membership, relying on internal committee consensus processes to validate the publication content and to

ensure that the resulting standard does not provide an unfair advantage to any one segment of the industry. Moving to a preference for VCS above all other standards will place an unnecessary burden on smaller standards developers who develop quality publications but do not have the financial or staff resources available to transition their publication process to incorporate VCS procedures. CGA believes that federal agencies should be permitted and encouraged to use the standards that most adequately address technical and safety issues, regardless of the type of process used to develop those standards.

**2. Specific guidance for agencies with respect to intellectual property rights (IPR) related considerations with regard to standards.**

CGA strongly believes that the value of intellectual property contained in standards to the copyright holder is significant. Because of the intellectual property supplied by members, standards developing organizations like CGA are able to readily provide high quality standards that are used to support the regulatory activities of the U.S. government. The material in these standards reduces the costs of goods and services; enhances safety, health, and quality of life; and facilitates innovation, trade, and competitiveness. In order to ensure that the current standards development ecosystem remains intact, agencies should consider referencing standards in a manner that allows the standards developer to determine the best mechanism for distributing the information to interested parties (i.e., available for free online, sold at price determined by the standard developer, etc.). Standards developers should not be forced to choose between nullifying the value of their intellectual property or limiting the public safety impact of a standard by not supporting its reference in agency regulations.

**3. Use of the retrospective review provisions of Executive Orders 13563 and 13610 ensuring that referenced standards are updated on a timely basis.**

CGA strongly supports the use of provisions that promote timely updates to referenced publications as they are revised. A more streamlined process would ensure that regulatory references incorporate the most current technology, safety, and best practices relative to industry operations.

In Canada, a regulation-maker may reproduce requirements described in an existing document into a regulation. Alternatively, the regulation-maker can adopt a document by referencing it by title in the regulation. This reference may be “static” (e.g., referencing a specific version of a document) or it may be “ambulatory” (e.g., referencing a document as amended from time to time). This flexibility in incorporating by reference in Canada allows for timely updates with a more streamlined process reducing burdens; protecting public health, welfare, safety, and the environment; and promoting economic growth, innovation, competitiveness, and job creation. The more frequent use of similar processes in the U.S. could reduce burdens on both standards developers and regulatory officials.

**4. Guidance to agencies on conformity assessment including how to comply with international trade obligations relating to standards and conformity assessments**

CGA generally supports concepts that promote international cooperation and harmonization as these efforts advance public safety through the sharing and utilization of best practices for international operations; reduce confusion through the development of non-conflicting positions; give less developed

areas access to the experience, research, and consensus opinions of industry leading experts; reduce the resource burden of standards development by eliminating duplicate regional efforts; and support standardization, which can lead to reduced operating costs and improved efficiency. CGA supports international harmonization efforts through active participation on ISO committees, UN subcommittees, and the IHC. The IHC consists of four regional gas associations (CGA; Asia Industrial Gases Association (AIGA); European Industrial Gases Association (EIGA); and Japan Industrial and Medical Gases Association (JIMGA)) that work together to harmonize industry standards. While CGA generally recommends the consideration of harmonized positions, it is also critical that regulatory bodies consider the voting requirements of international bodies such as ISO and the UN that can put the U.S. or North American position at a significant disadvantage when compared to other regions with a large number of country votes.

Measures should be taken to allow U.S. businesses to adapt to changing regulatory requirements without unnecessarily obsoleting equipment or practices when doing so results in no substantial safety improvement. Further, CGA supports the use of private sector conformity assessments in conjunction with or in lieu of government conformity assessments. The use of industry conformity assessments further encourages interest groups to self regulate in order to avoid the need for government action or intervention.

#### **5. Increasing transparency and stakeholder participation**

*Specifically, would it be useful to develop additional mechanisms through which an agency would provide advance notice to the public when it is considering use of voluntary standards in regulation, procurement, or programs?*

CGA believes that processes already available through the use of an Advanced Notice of Proposed Rulemaking (ANPRM) and a Notice of Proposed Rulemaking (NPRM) are effective ways to give the public advance notice when an agency is considering use of standards in regulation, procurement, or programs. Any further mechanisms may increase the burden to interested stakeholders without providing any additional benefit.

*Should OMB provide agencies with criteria to consider when determining whether a voluntary standard is “reasonably available”?*

Yes, OMB should provide agencies with specific criteria to determine how a voluntary standard can be made “reasonably available”. CGA believes that the term “reasonably available” should indicate that the material can be accessed by affected or interested persons within a defined time frame, either by electronic means or in hard copy format. These affected or interested persons are those directly impacted by a regulatory requirement.

More importantly, the requirement to make information reasonably available should not impact a standards developers’ ability to protect and maintain the technical and intellectual value of the information produced. Any implication or statement that information should be made widely available

free of charge will challenge CGA's ability to protect our intellectual property, will diminish the value of our product, and will limit our ability to continue production or maintenance of technical standards.

The Administrative Conference of the United States and the National Science and Technology Council has previously indicated that "the text of standards and associated documents should be available to all interested parties on a reasonable basis, which may include monetary compensation where appropriate." As the U.S. government has made clear strategic moves to protect other areas of intellectual property subject to devaluation through online sharing in recent years, this recommendation is aligned with other copyright protection efforts.

Finally, the provision of a non-copyrighted, non-technical, and freely available summary of the standard that adequately explains its content is simply not practicable for many standards developers including CGA, as our standards are highly technical in content and not intended for consumption by the general public. Further, a non-technical summary couldn't, by its very nature, provide sufficient information to allow affected or interested persons to make a fact based judgment on the merits and issues of any proposed standard.

CGA remains committed to developing and providing reasonable access to high quality, technically sound standards and to working with agencies to provide access to these materials in a variety of means, appropriate to the way in which these standards are adopted and used. In order to sustain these activities, a flexible approach is required to ensure that federal agencies have access to the standards that best meet the needs of the public.

Again, thank you for the opportunity to comment on this issue. If any further information is needed, please contact me at 703-788-2737 or mtiller@cganet.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Tiller", with a stylized flourish extending to the right.

Michael Tiller  
President and CEO