Global Biological Standards Institute®

Advancing Life Science Standards®

May 9, 2014

Comments submitted via: *http://www.regulations.gov*
(Response to Federal Register Document Number 2014-02891)

To: Office of Management and Budget (OMB), Office of Information and Regulatory Affairs

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

The Global Biological Standards Institute (GBSI) is the only organization specifically dedicated to enhancing the quality of biomedical research by advocating best practices and standards to accelerate the translation of research breakthroughs into life-saving therapies. As a non-profit, GBSI provides a global, independent forum for government, industry, academia and other stakeholders to increase awareness and use of best practices and standards throughout the research process. For more information about GBSI, please see www.gbsi.org.

A. Summary of GBSI Comments To Proposed Circular A-119 Revisions

GBSI appreciates the opportunity to comment on OMB's proposed revisions to Circular A-119 (the "Circular"), a principal document guiding the federal executive branch in the use, and participation in the development, of standards. GBSI's comments falls into three categories:

- GBSI requests clarification that "voluntary consensus based bodies," as defined in the Circular, need not be accredited by a third party organization in order for their standards to be recognized as "voluntary consensus based standards";

- GBSI urges OMB to recognize that in certain situations, for example, early stage research in the life sciences industry, standards that require prescriptive design elements can be important and that performance standards, particularly ones lacking such elements, need not be preferred; and,

- GBSI proposes that OMB add to the Circular: (a) that Agency Standards Executives (ASEs) are empowered to and must receive and give consideration to submissions from the interested public proposing the need for particular standards related to their agencies, and give consideration to the merits of non-frivolous proposals; and, (b) that each agency include with

their annual report to NIST the number of proposals received by such agency during the previous fiscal year and the agency's responses thereto.

B. Reasons For GBSI's Proposals

In the following subsections, GBSI explains why OMB should adopt each of GBSI's proposals regarding revisions to the Circular.

1. Circular A-119 Does Not And Should Not Require Accreditation From A Third Party Organization To Meet The Definition Of "Voluntary Consensus Standards Bodies"

GBSI supports OMB's determination that Federal agencies should rely on voluntary consensus standards in lieu of non-consensus standards or developing their own standards. GBSI also agrees that, in general, voluntary consensus standards should be preferred over non-consensus standards. Standards developed by voluntary non-consensus bodies can be useful in certain circumstances, particularly in industries such as the life sciences where the pace of technological innovation may be sufficiently rapid that standards are not yet developed by voluntary consensus standards bodies.

However, GBSI wishes to point out that there is some confusion among federal agencies and the standards community as to whether an entity promulgating a "voluntary consensus standard" must be accredited by a third party organization in order to be viewed as meeting the definition of "voluntary consensus standards bodies," which is an essential element of the "voluntary consensus standard" definition. GBSI therefore recommends that OMB clarify in the Circular that accreditation is not necessary for meeting these definitions.

The definitions of "voluntary consensus standard" and "voluntary consensus bodies" (and related definitions) set forth in the Circular do not include an accreditation requirement. In practice though, there is currently some disagreement as to whether "voluntary consensus standards bodies" must be accredited by a third party organization to obtain acceptance among some federal agencies for the standards they promulgate. In the experience of GBSI, some federal agencies seem to require evidence of accreditation by a third party that an entity is a voluntary consensus standards body, rather than underlying evidence

that a "voluntary consensus standard" has been adopted by a voluntary consensus standards body, before entertaining the standard for use by the federal agency. At a minimum, there is at least confusion as to whether accreditation is required.[1]

Therefore, GBSI requests that OMB add the following clarification at the end of the "voluntary standards consensus bodies" definition at Section 3.f. of the Circular: "So long as the foregoing is satisfied, no entity meeting this definition need be accredited by a third party organization to be recognized by any Federal agency as a voluntary consensus standards body, although accreditation may serve as a means for establishing that an entity meets this definition."

While it is true that third party organizations can perform a useful function verifying that a voluntary consensus standards body has met the Circular requirements, "voluntary consensus standards bodies" themselves should be able to demonstrate to federal agencies that they have met the Circular definitions in order to obtain appropriate consideration for the standards they promulgate as set forth in the Circular. With the above recommended clarification, GBSI believes that the Circular will appropriately guide Federal agencies in determining whether an entity meets the definition of "voluntary consensus standards bodies," either through evidence provided by the entity that it meets the Circular definition or by receiving evidence of accreditation.

[1] This issue is not limited to the life sciences industry. See, e.g., Stuart D. Kaplow, "Why You Care About the Revision to OMB Circular A-119?", Green Building Law Update (website) (posted April 15, 2014), available at http://www.greenbuildinglawupdate.com/2014/04/articles/codes-and-regulations/federal/why-you-care-about-the-revision-to-omb-circular-a119/ ("Within the green building coterie much is made of the fact that the Green Building Initiative is an ANSI accredited Standards Developing Organization and that its Green Globes 2010 rating system for new construction was ANSI approved. The LEED ratings systems do not pursue ANSI approval and the U.S. Green Building Council points to the fact that "The Foundations of LEED" allows for a flexible and faster adoption of each new version of LEED than the ANSI Essential Requirements permit. Additionally, the ANSI process doesn't contemplate nor accommodate the participation of thousands of people in a voting consensus body. USGBC expresses pride in offering all its members the right to participate in and vote for each proposed version of LEED. * * * Given that the federal government is the largest owner of buildings in North America and is also the owner of more certified green buildings than anyone else, it is of critical importance that any revision to Circular A-119 continue to allow agencies to recognize LEED and Green Globes as voluntary consensus standards.") (last viewed April 21, 2014).

2. OMB Should Clarify At Section 6.k. Of The Circular That For Certain Industries, Such As The Life Sciences, Performance Standards, Particularly Ones Without Necessary Design Elements, Do Not Need To Be Preferred

GBSI recognizes that in many instances, performance standards make good sense and should be preferred. However, for certain industries or activities, performance standards may not be effective nor reasonable, two of the criteria set forth at Section 6.k. of the Circular that dictate when performance based standards should be employed by federal agencies. As explained in greater detail below, in conducting life sciences research, performance standards, particularly without prescriptive design elements, generally are not preferable, because performance standards without such elements can contribute to the very significant problem of irreproducibility.[2] OMB should include a statement in Section 6.k. that if an agency is aware of or receives substantial information that performance standards alone are not appropriate within a certain industry or issue area within the purview of the agency, the agency may apply such information to approve prescriptive standards or at least ones containing prescriptive design elements.

In a recent report published by GBSI, "The Case for Standards in Life Sciences Research: Seizing Opportunities in a Critical Time of Need" (hereinafter, "The Case for Standards"), which is available at http://www.gbsi.org/sites/default/files/uploads/pdf/the_case_for_standards.pdf, GBSI points out that irreproducibility is a central problem facing the life sciences industry, costing enormous sums in terms of wasted time and money. Irreproducibility means the inability of researchers to reproduce results reported to have been achieved. Irreproducibility is a "pervasive, systemic problem" in life sciences research that fundamentally "stems from undefined variance in" practices and testing across laboratories. The Case for Standards at page 4.[3]

[2] The federal government plays a substantial role in funding life sciences research. In fiscal year 2011, the federal government funded $30.2 billion worth of life sciences research. National Science Board, Science and Engineering Indicators 2014, available at http://www.nsf.gov/statistics/seind14/index.cfm/chapter-4/c4s6.htm#s1.

[3] A copy of the "Case for Standards" has been attached as an appendix for the convenience of reviewers of these Comments.

GBSI is far from the only organization that has taken note of the irreproducibility problem in life sciences research. At page 17 of The Case for Standards, GBSI notes that there are several highly publicized articles and scientific studies that have documented the problem. Through extensive interviews of multiple stakeholder groups within the life sciences research community GBSI found that "all stakeholder groups interviewed . . . agree that there is a need for additional standards in life science research." Id. at 7. In life sciences research, the kinds of standards thought to be helpful are ones that provide base reference materials or measurements from which tests or procedures can be conducted (which many in the life sciences industry call materials standards) and methodologies and procedures for performing life sciences research activities (which many in the life sciences industry call documents standards).

Neither of these are performance standards because they do not specify outcomes. Rather, they prescribe how research should be performed. In The Case for Standards, GBSI has compiled concrete examples as to how material and document standards increase accuracy and decrease the irreproducibility problem. For example, at pages 36-37, GBSI explains that there has been improved accuracy in a key test for detecting how well blood sugar is controlled in patients with diabetes, because two separate consensus-based bodies promulgated standards, one allowing for accuracy in base measurement and the other in providing a method for verifying results obtained through the test.

In sum, there are situations in which federal government agencies will work with industries or on issues for which performance standards by themselves are not the correct approach. GBSI urges that with respect to the strong preference for performance based standards set forth in the Circular, OMB should clarify in Section 6.k. that, if an agency is aware of or receives substantial information that performance standards are not appropriate within a certain industry or issue area within the purview of the agency, the agency may apply such information to approve prescriptive design standards, or at least prescriptive design elements with performance standards.

3. The Circular Should Provide That Agencies Will Receive and Review Outside Proposals For Adoption of Standards

The Circular includes helpful detail on periodic review of standards already adopted by agencies, but it does not provide guidance to agencies where no standards currently exist. The Circular is silent on whether agencies should accept and review information provided by non-government actors that a standard is needed. As explained earlier, GBSI has taken a keen interest in the adoption of standards within the life sciences industry, because there is a noticeable lack of standards, which is contributing to an industry-wide problem that must be addressed. Given the federal government's very substantial role in funding life sciences research, the federal government can play an important role in helping to address the problem. GBSI therefore suggests that at Section 15.d., which empowers ASEs to take on certain tasks, the following should subsection should be added: "(iv) accept for agency review proposals by non-government actors that a standard should be adopted." Through their ASEs, agencies can be apprised of the view of interested members of the public regarding needs for standards in areas under their purview.

This suggested addition furthers transparency and stakeholder participation in standards development, two issues on which OMB asked for comment. See http://www.whitehouse.gov/sites/default/files/omb/inforeg/revisions-to-a-119-for-public-comments.pdf at page 8. A number of OMB's improvements to the Circular relate to greater notification to the public as to when an agency is participating in the standards development process or considering use of a standard, which are helpful, but, as set forth in Executive Order 13563, the public should be encouraged to *participate* in the regulatory process, not merely to receive notice of agency-initiated events. An affirmative statement in the Circular that Agency Standards Executives should receive and have reviewed serious proposals for standards adoption will promote interaction between agencies and relevant private sector actors.

To add accountability that serious proposals for adoption of standards are treated as such by agencies, GBSI further recommends that at Section 10.C. of the Circular, OMB should add that agencies

must report to NIST: "(iv) the number of proposals for standards received by the agency during the previous year and their disposition by the agency." (and subsection (iv) currently set forth in the Circular should become (v)). This suggested addition to the Circular should promote agency accountability in reviewing public requests.

C. Conclusion

So that Circular A-119 can better guide federal agencies in their use of standards, GBSI urges OMB to adopt the recommendations set forth in this letter. GBSI would be happy to further discuss its recommendations with OMB if such would be helpful.

Respectfully submitted,

GLOBAL BIOLOGICAL STANDARDS INSTITUTE

By: _____
Leonard Freedman, Ph. D., President