

12th May 2014

U.S. Office of Management and Budget (OMB)

Dear Sir/Madam,

BSI response to Request for Comments on a Proposed Revision of OMB Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities"

BSI (British Standards Institution) welcomes the initiative to bring Circular A-119 to up to date in the light of developments in the area of standards and regulations. BSI has been debating the optimum relationship between standards and regulations for some time. In February 2013, BSI and ISO jointly organized a conference in London on this subject, with delegates from governments, regulatory bodies, industry and consumer representatives and standards developing organizations from all over the world, including USA. There were presentations, open discussions and workshop sessions on the situation in a number of different countries and regions, including Russia, China and Africa as well as Europe and the USA. One output was an agreement by ISO to prepare an updated guide for regulators, which is currently in development before being circulated to ISO member organizations for review and comment.

BSI would like to offer some comments on the relationship between standards and regulations and how Circular A-119 reflects this relationship.

We agree with the general thrust of the Circular: government agencies should use voluntary consensus standards wherever possible to deliver policy objectives and should not create their own standards when standards developed by industry and other interested parties through open, consensus-based processes already exist, are in the process of development or could be developed.

The mandatory use of standards

The precise relationship between a standard and the regulatory text it can support is very important. The WTO TBT Agreement makes a clear separation between standards (voluntary) and technical regulations (mandatory).

Policy is necessarily the prerogative of the regulators and legislators and must be determined by a political process. Regulators establish mandatory requirements that must be met by individuals and organizations in order to comply with the law. This process must ensure that there is proper discussion and informed consent to proposed laws and regulations. Once these have been agreed by the political process it is desirable that they remain stable over time.

However, different considerations apply to the detailed technical means of achieving compliance with these law, which must be must be flexible and subject to continuous review, to reflect innovative solutions and new technical developments. We believe that the formal standards system is best adapted to this task.

Standards developers accredited by ANSI, the international standards organizations, ISO and IEC and their members, and European and other regional standards organizations all have the necessary

processes, organization and stakeholder knowledge and engagement to meet this need. They develop and review standards that reflect commonly agreed best practice and embody the practical experience of all the affected parties.

BSI believes that although the laws are mandatory and exclusive, the means of compliance proposed in standards should be voluntary and non-exclusive. If people or organizations devise better means of compliance, or ones that are simply better suited to their particular circumstances, then these should be as acceptable for regulatory purposes as formal standards.

This principle of mandatory legislation supported by voluntary standards is tried and tested. It has been the guiding principle in the European Union for many years, although it is still commonly designated as the 'New Approach'. It is implicit in the New Approach that standards are referenced by legislation but are not incorporated into it. Incorporation compromises the voluntary nature of the standards and also one of their main advantages.

If it is desirable that regulations are relatively stable, it is equally desirable that standards are flexible and subject to amendment, or even withdrawal, if circumstances change. This is compromised when the content of standards became part of the law itself. We believe it is better for regulations to simply reference standards as a recognized, but not exclusive, means of compliance and, wherever practicable, that reference should be to their latest iteration, rather than a particular dated edition.

We therefore do not agree with the draft revision of Circular A-119 where it permits the use of standards to mean the inclusion, in whole or in part, of standards in regulatory texts. We also do not agree with the explicit possibility in the draft Circular of making reference to older versions of standards (section 6.o, page 34).

The discussion on page 10 of the document containing the draft revised Circular refers to the New Approach-type method of using a standard to provide one means of compliance rather than the only means of compliance. We would be very pleased to discuss this issue further and to provide examples of how the New Approach method has well served both industry and regulators in Europe over 25 years.

Access to standards

As we believe compliance with standards should remain voluntary, BSI is of the opinion that it is appropriate that paying for them should also be voluntary. If an individual or organization believes that using a standard will add value to their business, then that organization should pay to access the standard. Those that don't wish to use the standard should not be required to do so. The willingness of people to buy and use voluntary standards is one of the best indicators of their market relevance.

That is why BSI upholds the right of Standards Developing Organizations to assert their copyright and other IPRs in standards and to sell them to users as one of the most important ways of funding their development and maintenance. This principle seems to be well understood and clearly expressed in the current Circular A-119, and indeed is reflected in the discussion on pages 9-10 of the consultation document, and BSI would not recommend any weakening of it.

However, we do recognize the need for good access to any documents that are instrumental in meeting legal obligations and we support the idea of the ANSI portal which makes standards referenced in US regulation easily available for review online. If the standards are felt to be useful then they are available for purchase.

The international system of standardization

BSI supports the parts of the draft Circular that refer to the WTO TBT Agreement and the requirement to use international standards as a basis for technical regulations. The draft refers to the principles that international standards developing organizations should meet.

We would propose that the definitions at the start of the draft Circular (section 3, pages 17-19) are aligned more closely to the WTO-agreed principles, in particular with regard to coherence, impartiality, effectiveness and relevance.

BSI would suggest that the US Government closely follows developments in ISO and IEC with regard to the international guide on standards and regulations as the best practice this guide will contain should inform the development of the Circular.

Background on BSI

BSI is the UK's National Standards Body, incorporated by Royal Charter and responsible for preparing British Standards and related publications and for coordinating the input of UK experts to European and international standards committees. BSI has 113 years of experience in serving the interest of a wide range of stakeholders including government, business and society.

BSI also presents the UK view on standards in Europe (via the European Standards Organizations CEN and CENELEC) and internationally (via ISO and IEC). BSI has a globally recognized reputation for independence, integrity and innovation ensuring standards are useful, relevant and authoritative.

BSI, as the UK's NSB, is responsible for maintaining the integrity of the national standards-making system not only for the benefit of UK industry and society but also to ensure that standards developed by UK experts meet international expectations of open consultation, stakeholder involvement and market relevance.

A BSI (as well as CEN/CENELEC, ISO/IEC) standard is a document defining best practice, established by consensus. Each standard is kept current through a process of maintenance and review whereby it is updated, revised or withdrawn as necessary.

Standards are designed to set out clear and unambiguous provisions and objectives. Although standards are voluntary and separate from legal and regulatory systems, they can be used to support or complement legislation.

Standards are developed when there is a defined market need through consultation with stakeholders and a rigorous development process. National committee members represent their communities in order to develop standards and related documents. They include representatives from a range of bodies, including government, business, consumers, academic institutions, social interests, regulators and trade unions.

BSI would be pleased to discuss any elements of this response with you.

Yours faithfully,



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