Z80 Accredited Standards Committee for Ophthalmic Optics

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Comments of ANSI-Accredited Standards Committee Z80 (ASC Z80)

To the Federal Participation in the Development and Use of Voluntary Standards and in Conformity Assessment Activities, Docket No. OMB 2012-7602/2012-003

Introduction to Comment Submitter

American National Standards Institute ("ANSI") - Accredited Standards Committee Z80 ("ASC Z80") oversees the standards writing activity in ophthalmic optics. This includes developing technical standards on prescription and nonprescription consumer medical devices, such as eyeglass frames, prescription lenses, nonprescription sunglasses, over-the-counter reading glasses, and contact lenses. It also includes standards covering diagnostic equipment and other ophthalmic instrumentation used by eye care professionals when treating their patients.

Formed in 1956, ASC Z80 consists of 18 voting organizations and over 100 experts, with participants ranging from optometrists, ophthalmologists, and opticians, to manufacturers of eyeglass frames, lenses, sunglasses or readers, to the U.S. Food and Drug Administration ("FDA"). Its standards are developed as voluntary consensus standards in conformity with ANSI principles of transparency and due process. Also, ASC Z80 experts participate in international standards writing through participation through the ISO.

Principal Concern of Submitter

ASC Z80 is committed to the voluntary consensus standards drafting process and feels that standards developed via that method should always be preferred by federal regulatory agencies over standards developed via non-consensus standards writing. Likewise, ASC Z80 commends the desire of the drafters of the proposed revisions to OMB Circular A-119 to promote greater participation by the public and by government in the voluntary consensus standards writing process.

Toward that goal, however, ASC Z80 respectfully requests that the drafters consider adding language cautioning participating federal agencies against sending as representatives to standards writing meetings officials from the departments that oversee any licensing or approval processes covering the devices that are the subject of the

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standards writing activity. ASC Z80 believes that the potential for a chilling effect exists on non-governmental entities, particular manufacturers, if the person representing the agency in the standards writing process might also be involved in deciding whether a pre-market approval application for a particular product is to be granted. In this situation the private sector representative, who in the standards writing process is working on behalf of a broader interest group or trade association, may feel restrained from advocating a position on behalf of this group if it is inconsistent with the position taken by the government entity, out of concern that such an action could impact the disposition of current or future activity of that representative's specific employer before that agency representative.

ASC Z80 understands that circumstances or resource restrictions can exist that requires the presence of such agency personnel at standard writing sessions. That being said, ASC Z80 respectfully submits that the standards writing process is enhanced when the agency participates in the standards writing session through personnel who do not oversee licensing or approval of other participant's medical devices. Circular A-119 should be revised to establish this point.

Response to Questions Posed by OMB

1. Are Federal agencies generally following the guidance set out in the Circular and providing an adequate explanation of how they considered standards and conformity assessment-related issues in the preambles in rulemaking?

ASC Z80's experience in this regard is limited, but based on its experience believes that the Circular is being followed.

2. OMB A-119 does not establish a preference between consensus and non-consensus standards developed in the private sector. A limited set of foundational attributes of standardization activities are identified in the Circular, focusing on voluntary consensus standard activities. It may be important to recognize the contributions of standardization activities that take place outside of the voluntary consensus process, in particular certain activities in emerging technology areas. What factors should agencies use in evaluating whether to use voluntary non-consensus standards in regulation, procurement solicitation, or other nonregulatory uses?

ASC Z80 believes that OMB A-119 should state a preference for voluntary consensus standards over ones derived via a non-consensus process, and does not see any factors favoring non-consensus standards over consensus ones. As an ANSI accredited standards writing committee, ASC Z80 oversees the voluntary consensus standards writing process

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and sees its benefits first hand. Issues raised at the subcommittee level are worked through by all participants of that subcomittee. As such, the possibility of domination by one or more particular interests is mitigated in favor of collective accord. In those situations were a negative ballot cannot be resolved then the unresolved commentator has a right to appeal. This path to resolution likely does not exist where consensus is not required, so that the possibility that interest group blocs can promote standards writing activity to their commercial benefit and to the detriment of others is very real.

3. OMB also invites comments on the respective roles of voluntary consensus standards vs. voluntary non-consensus standards for agency responsibilities in rulemaking, procurement, and other activities.

Consistent with its comment to question 2, ASC Z80 believes that voluntary consensus standards should be preferred to voluntary non-consensus standards in all applications.

4. In conjunction with NIST's efforts to update its conformity assessment guidance, should a supplement to Circular A-119 be issued to set out relevant principles on conformity assessment? If so, what issues should be addressed in such a supplement?

ASC Z80 supports any action that promotes transparency and due process. Therefore, it would favor the publication of such a supplement setting out the principles on conformity assessment.

5. Is lack of access to standards incorporated by reference in regulation an issue for commenters responding to a request for public comment in rulemaking or for stakeholders that require access to such standards?

The standards developed within ASC Z80 are available through a number of sources, including internet sources, at modest fees. These fees help offset the cost of standards writing, both at a national and at an international level. In addition, the standards are available for review at public sources, such as public and academic libraries. Because our standards are readily available, ASC Z80 does not see lack of access as an issue as it relates to its standards. We believe that standards written by other voluntary consensus standards writing entities are likely similarly available and priced.

6. What are the best practices for providing access to standards incorporated by reference in regulation while respecting the copyright associated with the standard?

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ASC Z80 feels that the current availability of standards for review at public facilities, and access to those standards for purchase at a modest fee via "standards stores" accessible through the internet, provide access to the standards and protect the copyright associated with the standard.

7. What resource and other costs are involved in the development and revision of voluntary standards?

In a typical year, between 20 and 33 percent of ASC Z80's revenue is raised through the sale of its standards. The rest of its revenue is from membership dues.

This revenue is used to fund the ASC Z80's standards writing activities. Its two biggest costs are dues it pays to ANSI and to ISO, and the cost of hosting the meetings where the various standards writing participants gather to work. Other expenses include the costs of insurance, legal counsel and certain travel expenses.

Each participant in the ASC Z80 standards writing process pays its own travel expenses to participate at ASC Z80 meetings or on behalf of ASC Z80 at ISO meetings. These travel expenses can be significant because ISO meetings rotate among different countries, some of which are expensive destinations.

Also, the individual representatives that participate in ASC Z80 are providing their time. They may or may not receive compensation for this from the organization they represent.

8. What economic and other factors should agencies take into consideration when determining that the use of a voluntary standard is practical for regulatory or other mission purposes?

Based on its experience, ASC Z80 does not see the use of voluntary consensus standards by government agencies as creating a burden, economic or otherwise, on those entities required to satisfy a regulation incorporating a standard. That being said, ASC Z80 believes that the possibility exists where economic or other factor could become burdensome. As a safeguard, the agency could do a cost-benefit analysis as a prerequisite to the use of a voluntary standard in a regulation.

9. Is there a role for OMB in providing guidance on how Federal agencies can best manage the need for relevant regulations in the face of changing standards?

ASC Z80 takes no position on this question other than to reiterate its opinion that it supports the updating of Circular A-119 in a manner consistent with its comments set out herein.

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10. Does the significant role played by consortia today in standards development in some technology areas have any bearing (or specific complications for) Federal participation?

As discussed above in our Principle Concern of Submitter section, we see the problem differently. Agency representatives, because of their positions *vis-a-vis* the various non-governmental participants, can find themselves in a position where their ability to influence the outcome of standards writing exists because of their status as government representatives. Again, we respectfully request that the revised Circular caution against this and recommend that those working on standards for agencies when possible not be the same individuals as those involved with pre-market approvals and other areas of licensing.

In addition, on occasion the FDA has modified the application of standards written within ASC Z80 through the publication of Supplemental Information Sheets ("SIS"). These SIS documents change the scope or application of a standard derived via voluntary consensus (which the FDA participated in), often to incorporate new language or remove portions of the standard that had been opposed by the agency. We have been advised that the use of SIS documents has been discontinued, but would still request that the Circular be revised to reflect that changes to a standard desired by the agency be accomplished via the voluntary consensus standard writing process rather than by SIS.

Respectfully Submitted
Accredited Standards Committee Z80

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By: /s/ Jeff Endres
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