



KYLE PITSOR

Vice President, Government Relations

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Submitted via <http://www.regulations.gov>

The Honorable Howard Shelanski
Administrator, Office of Information and Regulatory Affairs
The Office of Management and Budget
New Executive Office Building,
725 17th Street, NW
Washington, DC 20503

RE: *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*, Proposed Revisions to OMB Circular A-119, 79 Fed.Reg. 8207 (February 11, 2014).

Dear Administrator Shelanski:

The National Electrical Manufacturers Association (NEMA) is pleased to submit these comments in response to OIRA's request for comments to the proposed revision to OMB Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (hereinafter the "Circular" or "Circular A-119"). While we have a few constructive comments that NEMA requests OMB consider before finalizing revisions to the Circular, NEMA largely endorses OMB's proposed revisions or decisions to leave existing policy and text of the Circular intact. NEMA appreciates that the proposed revisions to the Circular are consistent with a number of our April 30, 2012 comments in response to the Request for Information

About NEMA

As you may know, NEMA is the association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Arlington, Virginia. Its 400-plus member companies manufacture a diverse set of products including power transmission and distribution equipment, lighting systems, factory automation and control systems, and medical diagnostic imaging systems. The U.S. electroindustry accounts for more than 7,000 manufacturing facilities, nearly 400,000 workers, and over \$100 billion in total U.S. shipments.

NEMA is a sponsor of domestic and international standardization

NEMA is also an ANSI accredited standards development organization and sponsors the development of over 500 NEMA and ANSI technical standards related to electrical and medical imaging products. NEMA provides support to 49 product group technical committees and 20 ANSI-accredited standards committees, and promotes adoption of NEMA standards as American National Standards. NEMA product groups conduct regularly scheduled, mandatory reviews of all NEMA standards. When the need for a new standard is identified or when an existing standard is being reviewed for revision or

withdrawal, the product group seeks guidance from both users and manufacturers. By incorporating the views of both groups, the association ensures the design of effective and safe products.

NEMA also responds to codes and standards proposals of other organizations in the U.S. and around the world, facilitating the development of international and North American harmonized standards. Within the Council for Harmonization of Electrotechnical Standardization of the Nations of the Americas (CANENA), NEMA sponsors secretariats for over two dozen technical harmonization committees and subcommittees. CANENA has generated more than three dozen multinational standards. NEMA's significant participation in the international standards process acknowledges the increasing impact of international and regional standardization and conformity assessment on NEMA member products. NEMA currently provides the secretariat for five International Electrotechnical Commission (IEC) technical committees and one International Organization for Standardization (ISO) committee, along with administration of 58 parallel U.S. committees. Three quarters of all NEMA product groups are involved in either IEC or ISO standards development. There are more than 300 individuals from NEMA member companies and staff who actively participate directly in IEC activities.

NEMA's interest in OMB Circular A-119

In a number of its standardization activities, NEMA enjoys or has enjoyed the participation of representatives from federal agencies, either as participant or observer and commenter, in the development of NEMA and ANSI standards. By way of example, the widely-recognized ANSI Z-535 series of safety sign standards was first published by NEMA in 1991 with NEMA serving as the secretariat of the committee. That ANSI Z535 accredited standards committee consisted of a diverse group of participants, including several from U.S. agencies including the Department of the Air Force, Federal Highway Administration, National Institute of Standards and Technology (NIST), Rural Electrification Administration, and the U.S. Coast Guard. The original chair of that Z535 committee was from NIST. The committee spent several years reviewing new learning in human factors and safety and updating older standards from the 1960s and 1970s that had been incorporated by the US Occupational Safety & Health Administration (OSHA) in Title 29 CFR. Just recently, OSHA decided to update its reference to some of these standards to include the 2011 version. See 78 Fed.Reg. 35559 (June 13, 2013). NEMA is the publisher of these standards and they are sold by several authorized standards distributors and the royalties received by NEMA support the cost of the standards development program, but those parts that are incorporated by reference in OSHA regulations are also posted on an ANSI web portal in a read-only format for public review. This particular standards program represents a microcosm of the policy issues reflected in Circular A-119.

Another example is NEMA Standard XR 29-2013, *Standard Attributes on CT Equipment Related to Dose Optimization and Management*, which identifies four key features of CT scanners that contribute to or help perform optimization and or management of doses of ionizing radiation while still enabling the system to deliver the diagnostic image quality needed by the physician. On March 28, 2014, Congress incorporated this standard by reference in the *Protecting Access to Medicare Act of 2014*. The 2013 revisions to the standard benefitted from review and comment by the U.S. Food & Drug Administration as well as medical user groups. A handful of other NEMA and ANSI standards have been incorporated by reference into federal regulations, either currently or in the past, relating to electrical products.

NEMA also participates in the development of three standards projects with financial support from government agencies. In each case, the federal financial support has enabled the more rapid

development of standards than would have occurred over the course of a typical standards development lifecycle and thus facilitated an important public policy objective. Additionally, the federal financial support enabled the broader family of standards (within the NTCIP project described below) for different types of roadside traffic management equipment, and for different types of transport protocols over different transmission channels.

The first of these federally-supported standards development projects is the NTCIP¹ suite of intelligent transportation systems standards. With funding from the US Department of Transportation's Research and Innovative Technology Administration (RITA), the NTCIP standards project developed a family of standards that provides both the rules for communicating (called protocols) and the vocabulary (called the data dictionaries) necessary to allow electronic remote control of traffic control equipment from different manufacturers to operate with each other as a system. The NTCIP is the first set of standards for the transportation industry that allows traffic control systems to be built using a "mix and match" approach with equipment from different manufacturers. Therefore, NTCIP standards reduce the need for reliance on specific equipment vendors and customized one-of-a-kind software. To assure both manufacturer and user community support, NTCIP is a joint product of three SDOs: the National Electrical Manufacturers Association (NEMA), the American Association of State Highway and Transportation Officials (AASHTO), and the Institute of Transportation Engineers (ITE). The NTCIP originated as the National Transportation Communications for Intelligent Transportation System (ITS) Protocol (NTCIP).

The second of these federally-supported standards development projects is the Advanced Transportation Controller (ATC). The ATC is a smaller family of hardware, cabinet, and application programming interface (API) standard specifications for programmable industrial process controllers. These controllers are most commonly used at roadside intersections to operate the traffic signal control displays that hand over the traffic lanes.

The third of these federally-supported standards development projects is the DICOS² standard for security scanning addressing the exchange of digital information between security-imaging equipment and other systems. The standard is designed to facilitate government procurement requirements. In collaboration with and with financial support from DHS and TSA (who are also

¹ National Transportation Communications for ITS Protocol (NTCIP). See www.ntcip.org. Importantly, the NTCIP standards provide state and local governments a pathway to show DOT that their projects conform to the National Intelligent Transportation System (ITS) Architecture for ITS interoperability in order to secure matching federal funding. See generally 23 CFR §940.1 *et seq.* and specifically 23 CFR §940.11(e)(5) ("identification of applicable ITS standards"). See also <http://www.iteris.com/itsarch/html/standard/standard.htm>. The U.S. DOT enjoys several benefits from their financial sponsorship of standards development and maintenance. These benefits include another avenue to promote and ensure a more consistent and safe operation of the nation's highways, which are mostly owned and operated by the state and local DOTs. Another benefit of sponsoring standards is the derivation of uniformly-formatted traffic data, which can then be shared among agencies and with RITA's own Bureau of Transportation Statistics.

² Digital Imaging and Communication in Security (DICOS). See U.S. Department of Homeland Security, Science and Technology Directorate, *FY 2011 Year in Review* at i ("In the field of explosives detection, our Digital Imaging and Communication in Security (DICOS) standard allowed software and hardware technologies to be freely integrated, spurring competition and development of more effective detection tools."). <http://www.dhs.gov/xlibrary/assets/st/st-year-in-review-2011.pdf>

significant users of this equipment), NEMA produced and published within one year DICOS v01, a standard that specifies an extensible, interoperable data format enabling the integration of security screening technologies across multiple vendor platforms and facilitating wider participation in the development of improved security screening technologies and algorithms. DICOS v01 specifies the data format for computed tomography (CT) images and x-ray radiographs that result from airport security examination of checked and carry-on baggage. That standard was quickly updated to DICOS v02, which added an additional screening technology, known as Advanced Imaging Technology or AIT, which is used to examine passengers at airports, and a more complete definition of one type of Threat Detection Report (TDR), known as Operator.

NEMA has also been actively involved as a commenter to government agencies on conformity assessment practices in connection with rulemaking and enforcement practices.

NEMA's COMMENTS ON THE PROPOSED REVISIONS TO CIRCULAR A-119

NEMA identifies four category areas where OMB proposes to amend Circular A-119: (1) describing processes deployed by standards development organizations; (2) addressing intellectual property rights (IPR) --- patent and copyright --- matters that arise in connection with standards development activities; (3) addressing conformity assessment issues; and (4) federal agency-related issues, particularly (a) updating of federal references to voluntary standards and (b) international trade-related matters. We address each of these in turn.

1. Standards Development Processes.

NEMA notes that OMB proposes to introduce a new category of standards to the Circular for use by the government, which OMB labels "voluntary non-consensus standards." (See OMB, pages 5, 24-25).³ OMB proposes to recognize a preferential hierarchy of standards: (1) continuing preference for voluntary consensus standards over government-unique standards, while (2) acknowledging that other types of voluntary standards, including "voluntary non-consensus standards," may be relevant in meeting agency missions, and (3) stating that voluntary non-consensus standards may be used under certain circumstances and establishes a further preference for voluntary consensus standards over "voluntary non-consensus standards."

NEMA recommends OMB reconsider the phrase "voluntary non-consensus standard." It is a misnomer and the phrase "other voluntary consensus standards" should be considered for the Circular in its place. We explain our reasons below.

We also note the three classes of standards processes and the preferential hierarchy proposed by OMB. NEMA agrees with OMB that the hierarchy is not inconsistent with Section 12(d) of the National Technology Transfer and Advancement Act of 1995, P.L. 104-113. NEMA questions, however, whether the preferential hierarchy is meaningful as practical matter in most cases. A preferential hierarchy appears to assume that in deciding whether to choose to participate in a standards development activity or to use a standard that the agency has options to choose from preferentially. While NEMA knows that

³ References to "OMB" in this context are to the document proposing revisions to the Circular incorporated in the Federal Register Notice, 79 Fed.Reg. 8207, and available at <http://www.whitehouse.gov/sites/default/files/omb/inforeg/revisions-to-a-119-for-public-comments.pdf>

this happens, it is extremely rare, in practice, for this to occur in the case of domestic standards. It would seem to defeat the notion of a “standard” that there would be more than one standards group addressing the same subject-matter. NEMA notes DOE’s “exception” language with respect to voluntary consensus standards (OMB at 20):

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. *Therefore, in instances where there are no suitable voluntary consensus standards, agencies should consider, to the extent consistent with law – as an alternative to using a government-unique standard – other voluntary standards that deliver the most generally favorable technical and economic outcomes (such as improved interoperability) and that are widely utilized in the marketplace.*

NEMA believes the exception (“where there are no suitable voluntary consensus standards” as defined by OMB in its proposed revision) is likely to be the exception that eats the rule in most domestic standards cases.⁴ Furthermore, we don’t believe the exception is limited to “emerging technology areas.” There are a variety of reasons why not all standards are developed in accordance with *all of* the five parameters that OMB has identified for a “voluntary consensus standards process.” Speed of standards development is often cited as one reason, but there may be practical reasons why it is too costly or impossible to find balance of interest (or “balance of representation”). While we agree with OMB that agencies should not be shackled to a single standards process, we urge OMB to consider our comments below about the definition of “voluntary consensus standard” in shaping its thinking on the preferential hierarchy (and exactly how meaningful it is).

Understanding the meaning of “voluntary consensus standard” in the Circular derives from the definition of “voluntary consensus standards body” and that definition’s identification of a “voluntary consensus process.” (See OMB, pages 18-19). There are five attributes to a voluntary consensus process as identified by OMB:

- *Openness*: The procedures or processes used are open on a non-discriminatory basis to interested parties, and such parties are provided meaningful opportunities to participate at all stages of standards development. The procedures or processes for participating in standards development and for developing the standard are transparent;
- *Balance of representation*: The standards development process should have a balance of representation. The representation appropriate to the development of consensus in any given standards activity is a function of the nature of the standard being developed and the sector.
- *Due process*: Due process shall include adequate notice of meetings, sufficient time to review drafts and prepare views and objections, full access to the views and objections of other participants, and a fair and impartial process for resolving conflicting views;

⁴ Where it is possible that there can be some overlap in standards is in the international standards arena. There can be similar yet different national standards (*e.g.*, between Canada and the US or China and the US). International harmonization of standards (see discussion of CANENA at top of page 2, *supra*) is an important project for this reason. There can also be a domestic US standard and an international (*e.g.*, IEC or ISO) standard that cover the same subject-matter in different ways. In some of these situations, an agency *may* have options to consider.

- *Appeals process*; and
- *Consensus*, which may be defined as general agreement, but not necessarily unanimity. During the development of consensus, comments and objections are considered using fair, impartial, open, and transparent processes.

The term “voluntary non-consensus standard” is not defined by OMB in any way, and the natural inference is that it is anything that either a “voluntary consensus standard” or “unique government standard” is not. The term “voluntary non-consensus standard” would seem to suggest that the standard was not derived by “consensus,” and NEMA contends that this is not likely to be the case in most instances. It is likely to be rare. All it takes for a voluntary standard to not be a voluntary consensus standard is the omission of one of the five attributes of a voluntary consensus process as described by OMB above. For example, that one attribute may be in some cases “balance of representation”: the process is open, there is due process, there is an appeals process, and there was general agreement, if not unanimity among the participants on the standard (“consensus”). In other cases, it is possible that perhaps more than one attribute of the voluntary consensus process is not present, but nevertheless the standard was adopted by consensus and it is voluntary. In these cases, NEMA submits that what is essential for this other category of standards is that they are voluntary and they are achieved by consensus. Federal agencies could also preferentially consider, in their discretion, whether the views of persons other than participants can be submitted and considered, and that there is due process and an appeals process in connection with the development of these *other voluntary consensus standards*. But voluntariness and consensus should be the minimum requirements for these other standards that an agency might consider for use.

NEMA also notes that OMB proposes to define for the first time four of the attributes of a voluntary consensus process.

NEMA submits that the definition of “openness” in the American National Standards Institute’s (ANSI) *Essential Requirements*⁵ is a better and more logically correct definition than that proposed by OMB. ANSI’s definition is:

Openness.

Participation shall be open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation. Voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.

In contrast, OMB proposes (See OMB, pages 18-19) this definition:

The procedures or processes used are open on a non-discriminatory basis to interested parties, and such parties are provided meaningful opportunities to participate at all stages of standards development. The procedures or processes for participating in standards development and for developing the standard are transparent;

⁵ A copy of which is available at http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/2014_ANSI_Essential_Requirements.pdf

The OMB's proposed requirement that parties be "provided meaningful opportunities to participate *at all stages of standards development*" risks the interpretation that everyone who is "interested" shall be entitled to be a voting member of the voluntary consensus body. This is not practical, and it can present problems for achieving balance on a consensus body. As a practical matter, balance is often achieved by restricting the total number of members on the consensus body when one set of interests is not able to find a significant number of stakeholders. Notably, the definition of "openness" in the *ANSI Essential Requirements* does not use the phrase "at all stages of standards development." Importantly, NEMA notes that the Negotiated Rulemaking Act, 5 U.S.C. §561 *et seq.*, offers federal agencies the opportunity to develop federal regulations through a balanced consensus process and expressly limits the membership of the "negotiated rulemaking committee to 25 members, unless the agency head determines that a greater number of members is necessary for the functioning of the committee or to achieve balanced membership. Each committee shall include at least one person representing the agency." 5 U.S.C. §565(b). Achievement of balance, however, may require less than 25 members for the consensus body and the agency has discretion to decide. This statutory provision recognizes that at some point too large a consensus body becomes unwieldy and difficult to manage. The definition of "openness" in the *ANSI Essential Requirements* flexibly represents the solution. There is no need to specify a number of participants for the consensus body in Circular A-119. The interplay between openness and balance will yield the right solution.

The OMB also proposes that federal agencies consider, in connection with deciding whether to use a standard, if "the SDO imposes barriers to membership and participation in the SDO process." (See OMB at page 24). NEMA submits that this is irrelevant, unnecessary and perhaps harmful in the end, although we appreciate the spirit in which it is suggested. The agency's concern on this issue is addressed by whether there is a "voluntary consensus standards process," and it is assured if OMB adopts ANSI's definition of "openness." Consideration of this factor may very well undermine any agency using an "other voluntary consensus standard." NEMA urges OMB to delete this statement at page 24. NEMA will use its own circumstance to illustrate its concerns.

As noted above, NEMA is an accredited standards developer that sponsors the development of hundreds of American National Standards (ANS). The ANSI process assures openness and balanced participation in the SDO process. NEMA also develops a large number of NEMA standards, which may or may not become an ANS. NEMA does not seek ANS status for all of its standards, largely because it can prove very difficult in many cases to find non-NEMA member interest in working on a standard. To put it bluntly, stakeholders representing other segments of the public may not care about every standards development project and the time and effort involved in finding others to participate to no avail is not without significant cost. Nevertheless, NEMA does seek out and consider the views of non-NEMA members in connection with the development of its standards. Even ANSI permits accredited standards committees to restrict membership at some size. Without restrictions on membership it could prove difficult to find balance among the group. Finally, it should be noted that many SDOs, like NEMA, are membership organizations who produce excellent standards.

Finally, NEMA notes that OMB is proposing definitions for several other terms that vary from the ANSI definitions of those or similar terms. NEMA's reading of the proposed revision (OMB at 19) of "balance of representation" (in contrast to ANSI's phrase "balance of interest") is that this would be consistent with OMB's prior "balance of interest" requirement and therefore no material change is intended.

2. Intellectual Property Rights

Patents

OMB inquires: “what factors, if any, should an agency consider regarding the interests of intellectual property holders whose intellectual property is incorporated in the standard and the interests of parties seeking to implement that standard?” (See OMB at page 6).

NEMA respectfully submits that, for purposes of Circular A-119, this question is not properly focused. This question, and a related inquiry at page 22 regarding agency "consideration of the economic effect of the intellectual property rights policies of the voluntary consensus standards bodies on standards implementers, such as the extent to which entities practicing the standards may obtain licenses to patented technology incorporated into the standard on a non-discriminatory and royalty-free basis" suggest Circular A-119 would be used to establish national policy to write standards development organization patent policies. While NEMA does not dismiss the importance of SDO patent policies, as evidenced by its own standards patent policy,⁶ NEMA submits that Circular A-119 is too blunt an instrument to address the very complicated, fact-specific issues that can arise at the standards/patent interface, and this is particularly true when it is recognized that the vast majority of standards development activities never present or address a patent issue with their standards.

The current version of Circular A-119 arguably focuses on whether the standards development organization has a patent policy requiring RAND licensing.⁷ It does not focus on the other details of that policy; it does not ask an agency to make political or economic judgments about the details of that policy. NEMA submits that Circular A-119 should remain focused on whether the SDO has a patent policy, and should have only limited interest in the details of that policy. Circular A-119 should not require federal agencies to engage in some vaguely defined, potentially wide-ranging "evaluation . . . of the economic effect of intellectual property rights policies of voluntary consensus bodies on standards implementers." This "evaluation" may or may not be an interesting area of inquiry for the Federal Trade Commission in a specific case where there is a standards/patent problem that presents economic concerns, but as an area of agency inquiry in connection with the more general concerns of Circular A-119, it would be inappropriate, not to mention the very real potential for increased rule making costs in some cases. If an agency has possible concerns with standards and patents, those concerns are independent of SDO patent policies.

⁶ Available at <http://www.nema.org/Standards/Documents/NEMAPatentPolicy.pdf>

⁷ OMB, Circular A-119 at §4a: “For purposes of this policy, ‘voluntary consensus standards’ are standards developed or adopted by voluntary consensus standards bodies, both domestic and international. *These standards include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties.* For purposes of this Circular, ‘technical standards that are developed or adopted by voluntary consensus standard bodies’ is an equivalent term.” (emphasis supplied), available at http://www.whitehouse.gov/omb/circulars_a119. The current definition is awkwardly phrased insofar as it says that “**standards** include provisions requiring owners of relevant intellectual property to make that intellectual property available . . .” Standards themselves do not do this. It is the agreed-upon policies and procedures of the consensus body that require this outcome. NEMA notes that the OMB proposes to revise the definition of “voluntary consensus standards” by deleting the awkward text.

The general policy concerns in Circular A-119 impact three areas of agency activity: (1) agency personnel participation in private standards developmental activity and other forms of agency support for private sector standards development; (2) when deciding whether to use or incorporate by reference a standard into an agency regulation; and (3) government procurement. With respect to the first activity --- participation in private standards development --- the details of an SDO 's patent policy or its economic effects should be entirely irrelevant. With respect to the second area of activity --- incorporating a standard by reference -- the details of a SDO's patent policy and its economic effect should be *largely* irrelevant: the agency's concern at that point is not with the patent policy or its economic effect, but its concern is whether or not there are standard essential patent claims that present any problems for public policy in the proposed regulation under consideration. This issue comes to the agency's attention in the course of the rulemaking and it will likely be independent of the standard proposed for incorporation by reference (See e.g., 71 Fed.Reg. 44356, 44360 ("possible proprietary (patent) issues regarding amorphous material, ties between efficiency improvements and installation costs" considered by agency in determining whether DOE energy conservation standard could be economically justified); 74 Fed.Reg. 16920, 16945 (DOE considers patented proprietary technology in determining whether consumers will have options)). What NEMA is suggesting here is that when patents may present an economic problem for an agency to consider in deciding to promulgate a rule or not, agencies should not be looking to Circular A-119 to address this issue; a different Circular or Executive Order having nothing to do with SDO patent policies may be a better home. With respect to the third area of agency activity --- government procurement --- the details of an SDO's patent policy and its economic effect should be *largely* irrelevant as well, and NEMA's views just stated with respect to incorporating a private standard by reference apply to government procurement specifications as well.

Having stated that the details of SDO patent policies are "largely irrelevant" to two government activities that Circular A-119 addresses, and "entirely irrelevant" to the third activity, what aspects of an SDO patent policy may have some nexus to Circular A-119 policy concerns? NEMA submits there are two: (1) whether or not the SDO's patent policy requires disclosure of standard essential patents (both before and after the standard is adopted) that are known to any participant in the standards activity to be essential? and (2) whether there is a process for providing a statement before the standard is adopted that a license will NOT be provided for a standard essential patent if the standard is adopted, as well as a process for providing that an assurance will be provided by holders of patents containing standard essential claims to implementers of the standard that a license to standards essential patent claims will be made available on reasonable and nondiscriminatory terms (RAND). These two points go to the OMB's comment (see OMB at page 30) that there should be rules governing the disclosure and licensing of IPR. Beyond what NEMA has stated two sentences above, Circular A-119 should say nothing more. The Circular should not attempt to address or standardize what is "reasonable and nondiscriminatory" and should not compel the SDO to do so in order to be recognized in Circular A-119 as a voluntary consensus standards body. Nor should the Circular attempt to spell out what patent claims are "essential." This is a subject that is heavily dependent on specific context and is not always amenable to general rules. The procedures for disclosure and licensing assurances should be left to each SDO, and, while it is always preferable that procedures be free from ambiguity,⁸ the agency should not be compelled to study whether those procedures are clear and unambiguous once it is clear that

⁸ See e.g., *Rambus Incorporated v. F.T.C.*, 522 F.3d 456, 468 (D.C. Cir. 2008); *Rambus Inc. v. Infineon Technologies AG*, 318 F.3d 1081, 1102 (Fed.Cir.2003)(patent disclosure policy suffered from "a staggering lack of defining details.").

disclosure is required⁹ and a participant has a means for announcing it is not licensing standard essential patents or, alternatively, providing a RAND or royalty-free assurance.

More importantly for the government agency is a question that has nothing to do with an SDO's patent policy, although the SDO's patent policy might facilitate this inquiry: are there any standard essential patents respecting the standard to be incorporated by reference in a rule or an agency's procurement specification? This question is a filter for any further agency interest in the patent issue under A-119. If the answer to this question is negative, the agency's concerns with patents and patent policies under Circular A-119 are at an end. NEMA submits that a negative response will be by far and away the most common response. Further agency concerns over the details of an SDO's patent policy are irrelevant under Circular A-119 at this point.

In summary, NEMA urges OMB to scrap the idea that Circular A-119 call on agencies to undertake some likely wide-ranging evaluation of the economic effect of SDO patent policies and the interests of patent holders and implementers, and that OMB focus more narrowly on a couple of things that have some nexus to the policy interests within the scope of the Circular.

Copyright

With minor exception, NEMA agrees with the policies that OMB has recited with respect to respecting the copyright of an SDO in a standard that is incorporated by reference in agency regulation provided they are reasonably available. (See OMB, at pages 9-10 and 34-35). NEMA agrees that the "public interest would [not] be well-served by requiring standards incorporated by reference to be made available 'free if charge.'" NEMA takes exception to one of OMB's list of factors to determine whether a standard is reasonably available.

NEMA has considerable concern about OMB listing as a factor "whether an SDO is willing to provide a summary explaining the standard" (see OMB at page 34), which summary some might interpret as a surrogate for the standard itself and result in non-conformity due to misunderstanding the summary. The federal government should not encourage this practice. NEMA does support the other three factors listed for assessing whether a standard is reasonably available, and we concur with OMB's statement that "the absence of one or more of these factors alone should not be used as a basis for an agency decision not to use the standard." (See OMB at page 35).

NEMA would note that it posts standards that are incorporated by reference in federal regulations on a public website in a read-only mode. NEMA would also be willing to allow the agency to do likewise during the notice and comment period. NEMA would also note that its standards are widely

⁹ Having said this, NEMA is mindful that the determination of whether a patent claim is essential, which would naturally be a trigger for disclosure, is complicated and context specific. There has been some suggestion by Justice Department attorneys, see R. Hesse, *Six Small Proposals for SSOs Before Lunch* at 10 (October 10, 2012). <http://www.justice.gov/atr/public/speeches/287855.pdf> (last visited March 19, 2014), that there is some overdisclosure of purportedly "essential" patents, and one reason this may be occurring is the avoidance of subsequent claims of failure to disclose. Furthermore, the evaluation of whether a patent claim is essential also involves some evaluation of whether there are commercially reasonable, non-infringing alternatives to practice the standard. These are not necessarily easy conclusions to arrive at.

available through multiple distributors who charge a price when selling the standard. These are reasonably available.

3. *Conformity Assessment Issues*

NEMA agrees with OMB that “Consistent with this policy guidance, all Federal agencies are encouraged to consider relying on international conformity assessment schemes or private sector conformity assessment activities in conjunction with or, where appropriate, in lieu of governmental conformity assessment, except where such activities are inconsistent with law, unfit for regulatory or other agency purpose, or otherwise impractical.” (See OMB at page 40). NEMA understands the phrase “consistent with this policy guidance,” to refer back to OMB’s discussion of the voluntary consensus process and the preferential hierarchy of voluntary consensus standards (to which NEMA incorporates its comments on that subject at pages 3-5 *supra*). If it does not, then it should be made clear that it does refer to that discussion.

NEMA believes that most important among the ten factors that OMB recommends that agencies consider (see OMB at pages 40-43) are (i) the objectives of the underlying regulation, procurement or program activity, (vi) relevant industry practice and experience and the industry’s history of compliance, and (vii) ensuring consistency, reducing duplication and complexity. If there are existing standards for test procedures, evaluation and conformity assessment that are well understood by the regulated parties that actually facilitates compliance with the substantive law or regulation, then use of those standards ought to be a paramount objective of the agency.

4. *Government Agency Issues*

Agency Support for Standards Development

NEMA observes that OMB is narrowing its discussion in the current version of Circular A-119 of “federal participation in voluntary standards bodies.” NEMA’s reading of the text in the proposed revision is that the “participation” is now essentially limited to the participation of federal personnel (“agency representatives”) in voluntary consensus standards bodies activities. (OMB at 35-38). The current circular is not so limited and we note the discussion at 7c of the current Circular¹⁰ that has been eliminated from the proposed text:

“c. What forms of support may my agency provide?”

“The form of agency support, may include the following:

- (1) Direct financial support; e.g., grants, memberships, and contracts.
- (2) Administrative support; e.g., travel costs, hosting of meetings, and secretarial functions.
- (3) Technical support; e.g., cooperative testing for standards evaluation and participation of agency personnel in the activities of voluntary consensus standards bodies.

¹⁰ http://www.whitehouse.gov/omb/circulars_a119

(4) Joint planning with voluntary consensus standards bodies to promote the identification and development of needed standards.

(5) Participation of agency personnel.”

We can find items (2) – (5) above alluded to elsewhere in the text of the proposed revision, but item (1) (“Direct financial support”) is distinctly absent. Whether this omission is intentional or unintentional, we urge OMB to reconsider this omission and restore item (1). This omission could be interpreted as a change in policy and NEMA submits it is not in the government’s interest. As NEMA points out above at pages 2-4, we have sponsored or co-sponsored three very rapid development standards projects that government agencies were interested in that could not have achieved their objective in a timely way without the federal agency financial support to have subject-matter experts meet frequently in a short period of time, at the expense of time away from their other job responsibilities. This omission seems to eliminate a policy option that could undermine the government’s interest in timely production of standards (see OMB at 15, quoting from Memorandum M-12-08, “Principles for Federal Engagement in Standards Activities to Address National Priorities:”)¹¹

“(i) Production of *timely*, effective standards and efficient conformity assessment approaches that are essential to addressing an identified government need;

“(ii) Achieving cost-efficient, *timely*, and effective solutions to legitimate regulatory, procurement, and policy objectives.”

Timely Updating of Voluntary Consensus Standards

NEMA agrees with OMB that “agencies should update standards that have been incorporated by reference on a regular basis, and that each agency should undertake a standards-specific review of such incorporated standards every 3-5 years, or when stakeholders otherwise provide adequate information that a standards-specific review is necessary due to matters of health or safety, or the need to remain current with technological changes or other compelling reasons.” (See OMB at page 32).

NEMA cites its petition to OSHA to update its rules regarding workplace safety signs that we referenced at page 2 *supra*. Until October 2013, the Occupational Safety and Health Administration’s (OSHA) regulations required workplace signage and tags to meet standards published in 1967 and 1968, which themselves were based on sign formats from the 1940s; this despite various updated revisions to the corresponding standard, the most recent of which occurred in 2011.

Workplace dynamics have clearly evolved significantly over the last several decades and today’s worker faces hazards unimagined in the 1960’s and, therefore, unaccounted for in the safety sign standards of that era. To accurately and comprehensively communicate these hazards to workers, many American companies had long since replaced safety signage compliant with outdated standards and had already implemented signs and tags compliant with the current standard even though, technically speaking, doing so was a violation of the OSHA regulation (which only referenced the earlier standard).

¹¹ (http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08_1.pdf) (January 17, 2012).

To the agency's credit, in October 2013 OSHA issued a final rule referencing the most current standard in the regulation for safety signs. Yet, without a change in policy that instructs OSHA (and other federal agencies) how and when to update standards, history is bound to repeat itself.¹²

NEMA supports the specific factors that OMB asks agencies to consider in connection with deciding whether or not to update a specific reference to a standard, including whether updating a reference is likely to be controversial. (See OMB at pages 32-33).

International Trade

In general, OMB is to be commended for including in the proposed revised Guidance extensive discussion on federal agencies' approach and considerations with respect to regulations, standards and conformity assessment and to U.S. obligations to the rules-based international trading system administered by the World Trade Organization (WTO) and its 159 member states. NEMA strongly endorses and encourages U.S. and all trading partners' adherence to the terms of the WTO Agreement on Technical Barriers to Trade (TBT).

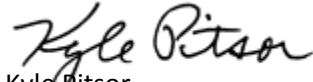
Specifically, NEMA agrees with the guidance that agencies should "pay close attention" to Decisions by the TBT Committee of the WTO. Moreover, OMB's proposed guidance on the potential overlap between a voluntary consensus standard and an international standard (as defined by the WTO TBT Committee) is well-defined on the basis of principles for standards development set out by the Committee: transparency, openness, impartiality and consensus, effectiveness, relevance, coherence and levels of economic development.

Accordingly, NEMA finds that OMB is correct to direct federal regulatory agencies to consult with the Office of the U.S. Trade Representative (USTR) on how to comply with U.S. international trade obligations related to standards and/or conformity assessment.

¹² In some, but not most instances, Congress mandates the agency incorporate the most current standard. NEMA points to the Consumer Product Safety Commission (CPSC) which frequently relies on voluntary consensus standards to ensure the safety of consumer products. In early 2007 the CPSC sought to revise its existing regulation for garage door openers, which incorporated the standard developed by Underwriters Laboratory (UL) – UL 325, third edition, for Door, Drapery, Louver and Window Operators and Systems. The CPSC revision was, of course, in response to a revision made by UL to the standard. The Federal Register notice that published the revision cites the original legislative act (Public Law 101-608) as requiring "...the Commission to incorporate into [the standard] *any revisions that UL proposed to the...requirements of UL 325* [emphasis added], unless the Commission notified UL that the revision does not carry out the purpose of Public Law 101-608." Congress also recognized and incorporated this policy, again with regard to the CPSC, in passing the Consumer Product Safety Improvement Act (CPSIA) of 2008 (Public Law 110-314). Section 102 of CPSIA established the requirements for third party conformity assessment of certain consumer products and authorizes the CPSC to accredit independent bodies accordingly. Part (c) mandates that, in doing so, CPSC "...ensure that the protocols, standards, and requirements prescribed [to accredit third party conformity assessment bodies] incorporate, as the standard for accreditation, *the most current scientific and technological standards and techniques available* [emphasis added]."

Thank you for giving NEMA the opportunity to comment on the proposed revisions to OMB A-119. If you have any further questions, please feel free to contact the undersigned at (703) 841-3274 or by email at Kyle.Pitsor@nema.org.

Sincerely,

A handwritten signature in black ink that reads "Kyle Pitsor". The signature is written in a cursive, flowing style.

Kyle Pitsor

Vice-President, Government Relations