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ENHANCING THE COMPETITIVENESS OF THE AMERICAN STANDARDS SYSTEM BY RENEWING CIRCULAR A-119

RESPONSE TO REQUEST FOR INFORMATION
OMB-2012-0003
Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities

The Office of Management and Budget should supplement A-119, with the following objectives:

(1) OMB should eliminate ambiguity about the requirement of Due Process in the development of standards that are intended or adopted for regulatory use. Consensus standards bodies often provide greater opportunity for genuine public participation that agencies are able to do in formal rulemaking.

(2) As supplemented, A-119 should recognize that the distinction between "mandatory" rules and regulatory guidance, which has never been clear-cut, is not helpful when a regulatory scheme (a) relies on private conformity assessments, (b) attempts to influence management systems (*e.g.*, HACCP), or (c) requires constant adjustment due to technology. OMB should promote the migration of detailed technical standards from the Code of Federal Regulations (CFR) to directives and interpretations (that are equally authoritative, but changeable by notice). Agencies should publish these directives in notices that incorporate private standards by reference. Doing so both informs the public and extends copyright protection. This will require substantial change in the practices of the Federal Register, which currently approves incorporation ***only*** if standards are codified in the CFR.

(3) OMB should require agencies, during the retrospective process set forth in Executive Order 13563, to remove or update obsolete, dysfunctional, and insignificant references to private standards. To the extent standards remain in codified rules, OMB should streamline the process for incorporating new editions.

(4) OMB should discourage agencies from giving private standards primacy over regulations and statutory requirements, as PHMSA has done.

The American model (open development of market-based standards) is ascendant internationally, even in European countries that have relied heavily only on direct government control. American standards development organizations (SDOs) have increasing influence with our trading partners.[1]

But our own process needs reform. American safety standards may once have been broadly regarded as the gold standard, but we cannot expect international recognition when many of them are dated or obsolete. Nor are these archaic standards adequate to protect the American public. For example:

- Between 1962 and 2004, the average American gained 24 pounds. Our children were, on average, 0.7" taller.[2] But all Federal Motor Vehicle Standards assume body weight and dimensions based on survey data from 1960 and 1962. *See* 49 CFR 571.3(b) (95th percentile adult male). Because these data are hidden behind an incorporation by reference (and inadequate publication of revised data), the implausibility of its assumptions has escaped public scrutiny for more than four decades.

- The Coast Guard requires merchant vessels to carry a first aid kit. 46 CFR 160.041-4. This kit must contain 100 tablets of phanacetin compounded with caffeine. Phanacetin can be hard to come by, because it is an internationally recognized carcinogen also associated with renal necrosis. Iboprofen would be a better choice, but it had not been invented in 1941.

- The FDA allows food to be treated with sulfonated coal, but only if the coal meets the grading standards for anthracite. 21 CFR 173.25. ASTM updated this standard in 2005, and also maintains one prior version (1999) for historical purposes. But since the FDA requires reference to the 1938 edition, it has issued a "technical amendment" advising the public to purchase the 74-year old standard from a company once known as "University Microfilms." In fact, the successor entity does not offer the 1938 standard for sale in its database.

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[1] These comments are submitted in my personal capacity. I previously served as Deputy Director for Research and Policy at the Administrative Conference of the United States (ACUS), and as staff counsel to its Committee on Administration and Management. Except as expressly noted, the opinions herein do not reflect official positions of ACUS or any other United States Government agency.

[2] 2004 is the last date for which the government published these statistics. *See* The CDC continues to conduct the survey, but has declined to post the raw data on data.gov. They may be available from the Gates Foundation. . This lack of transparency is all the more remarkable because CDC has studied change increasing body size as a problem in the design of safe truck cabs.

- The NRC recently committed to synchronize its rulemakings to coincide with ASME's biennial revisions of its boiler and pressure vessel code. 76 FR 36233 (June 21, 2011). A single copy of the current edition of this code costs $15,500. ASME sells the two most recent prior versions at similar prices, but earlier editions are hard to find, even in resale markets. Agencies, some of which may have congested regulatory agendas, retain 348 incorporations of 36 different editions of this standard and its predecessor, dating back to 1936. The Departments of Energy and HUD have not updated any references to this code for over 20 years. 24 CFR 3280.704(b)(2) (1992 ed.); 10 CFR 440 Appendix A (also 1992 ed.). The latest version accepted by OSHA and the Federal Railway Administration is more than 40 years old. 29 CFR 1910.261(a)(4)(i) (1969 ed.); 49 CFR 229.51 (1971 ed.).

- The National Rifle Association has publicly posted its 2012 rulebook for high powered rifles. The NRC, which is the only agency to place testing procedures for security guards in the Code of Federal Regulations, cannot use this document, because it has incorporated the 1976 version, which can be viewed at the National Archives. 10 CFR App. B to Part 73, IV C note 2.

These examples are not unique. ***On average***, a standard incorporated by reference in today's Code of Federal Regulations (CFR) is 24 years old. In part, this is a result of the antiquated practices of the Federal Register. But it often reflects an additional reality: ***the benefits of consensus standard-setting are simply not consistent with the traditional cycle of formal rulemaking***.

Today, 403 parts of the CFR contain 6637 citations to 2520 private standards (or portions thereof). These include:

- 11 standards from before 1948;
- the 348 citations to the Boiler & Pressure Vessel Code involve nine agencies citing 32 different annual editions;
- 106 citations by eight agencies to 11 editions of the National Electrical Code (1962-2005);
- seven editions of the Life Safety Code (from 1970);
- The FDA cites to four out-of-print editions of the Food Chemicals Codex (1972-1996). Yet, it does not cite any of the four editions issued in the last 16 years.

About 90 percent of the private standards currently incorporated are owned by SDOs that have congressional charters, are ANSI members, or otherwise appear to be consensus-based. This does not mean that they complied with Due Process

Requirements, because most predate the 1998 version of A-119. But it does suggest that, if updated, new revisions would be consensus standards.

One obstacle to resolving this plethora of inconsistent versions is the Federal Register's failure to implement ACUS 34-year old recommendation on updating standards. Rec. 78-4, 44 FR 1357 (Jan. 5, 1979). ACUS proposed that the Federal Register promulgate a rule establishing a joint rulemaking[3] procedure, which would allow agencies jointly to collect public comments on the advisability of adopting more recent versions of a particular standard.[4] Each agency using a superseded standard could elect to participate. Since agencies may use the same standard in very different ways to address fundamentally different risks, each would retain its ability to make their own specific decisions as to how to use of the standard.

Joint rulemaking has many economies. It facilitates public comments from experts on the standard that might not normally participate in every agency's rulemaking. It allows each agency to learn how others have used or altered the standard, so that they can consider the possible implications for their own regulatory environment. Ultimately, the NRC will probably make different choices about how to update and alter the Boiler & Pressure Vessel Code than the Coast Guard. Still, especially when agencies are undergoing retrospective review of all their rules, this joint rulemaking process could realize great economies and generate ideas on how each agency can consolidate and simplify rules and eliminate obsolete provisions. Joint rulemaking can also identify instances in which some of the participating agencies could reasonably choose to cross-refer regulations. Cross-referred rules are another efficiency that the Federal Register limits unreasonably.[5]

There is another, probably greater obstacle. Since the 1970s, the Federal Register has refused to provide copyright protection to private standards ***unless the agency incorporates them into a formal rule in the CFR.*** Of course, this greatly complicates the most minor revision, resulting in regulatory use of long-superseded standards.[6] And

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[3] Jody Freeman and Jim Rossi have recently analyzed the strengths and weaknesses of joint rulemakings as a tool of interagency coordination. Freeman and Rossi, "Agency Coordination in a Shared Regulatory Space," 125 Harv. L. Rev. ___ (2012) (draft of forthcoming article).

[4] This rule could provide for the participating agencies to agree upon a lead agency other than the Federal Register.

[5] Federal Register. Document Drafting Handbook, 1.15 ("We permit you to cross-reference your own or another agency's rules in limited situations."); 1 CFR 21.21(c).

[6] Both the Federal Register and a consultant to ACUS have repeatedly insisted that private standards need to be codified in the CFR is order to be "enforceable." This contrary to the stated intent of Congress in 1935, 1947, and 1966, as well as actual practice of administrative

more useful standards simply never get on the regulatory agenda, as agencies elect to write their own guidance documents. This reduces the competitiveness of American products, discourages the revision process, and embarrasses our national commitment to open, market-driven consensus standards. Unfortunately, the inability to accommodate frequent change is a particular obstacle to broader implementation of conformity assessment and complex technology standards.

Many technical standards are detailed and revised far more frequently than formal rulemaking requirements can conceivably accommodate. Consistent with Paragraph 6(c) of A-119, detailed, frequently changing "test methods, sampling procedures, and protocols" should be annexed as directives in support of rules that "determin[e] the level of acceptable risk and set the level of protection." Subsequent ***technical*** revisions to specific protocols should be accomplished through administrative action, subject to OMB guidance and judicial review to insure that they do not materially change costs or benefits. Every revision should promptly be published (or incorporated by reference) by notice in the online Federal Register. OMB should allow and encourage agencies to adopt rules that expressly permit the agency to publish (or incorporate by reference) revisions without further rulemaking. But a revision can never be automatically adopted. There must always be an administrative determination of its suitability, for which the head of the agency is accountable.

Because incorporating a standard into a final rule is so difficult, just ten agencies account for 93% of all incorporated standards.[7] In rank order, they are EPA, DOT, Coast Guard, HUD, Labor, FDA, RUS, Energy, Interior, and the NRC. Only 16 more departments or independent agencies incorporate any standards at all.[8]

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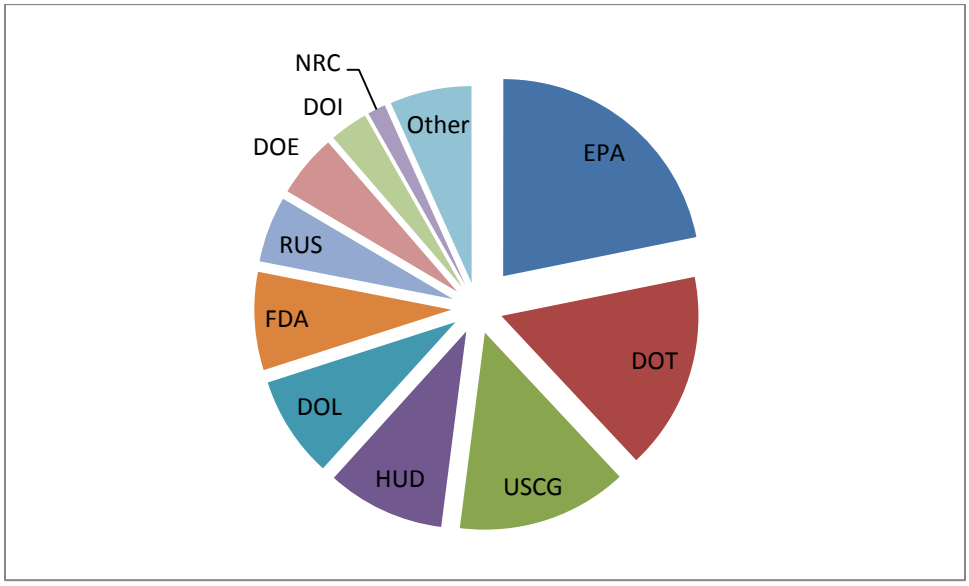
agencies from 1938 until the Federal Register's 1982 ban on revision by notice. The court case that the Federal Register cites was overruled 24 years ago. Federal Register, A Brief History Commemorating the 70th Anniversary at 8 (2006), citing Hotch v. United States, 212 F.2d 280 (9th Cir. 1954), superseded by statute, United States v. Mowat, 582 F.2d 1194 (9th Cir. 1978). Appalachian Power v. EPA, 566 F.2d 451 (D.C. Cir. 1977), cited in the Bremer, "Draft for Committee review, Oct. 19, 2012: Incorporation by Reference in Federal Regulations," (Bremer Report) at 4 & fn.3, does not involve a private standard. The utilities did not have "actual notice [because it was not clear] which materials were intended to be incorporated."

[7] These statistics are all based on NIST's database.

[8] FCC, HHS (other than FDA), Treasury, NARA, CPSC, USDA (other than RUS), ATBCB, FTC, Commerce, Justice, VA, Education, ACE, SEC, NASA, USPS, NSF, SBA.

INCORPORATED STANDARDS BY AGENCY



Based on the vintage of the standards incorporated, the number of standards adopted by agencies appears to have actually ***slowed*** since 1998.

STANDARDS PER YEAR

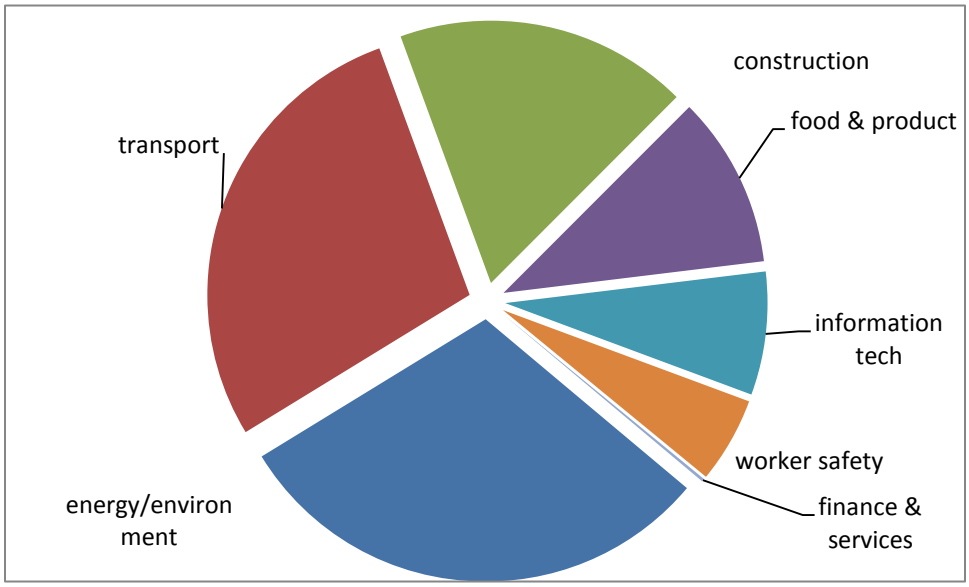
NIST does not record the year in which the incorporation was made. Edition vintage may lag because the SDOs revision cycle may be 2- 5 years.

	-60s	70s	80s	90-94	95-99	last 12 years	no date
energy/environment	1	28	54	121	122	68	89
Transport	5	33	44	103	127	44	162
Construction	8	44	38	41	31	20	74
food & product	1	12	50	19	25	3	95
information tech			23	49	19	10	41
worker safety	6	11	5	4	5	5	73

As a result, we are left with a 20th century mix of standards, despite the vitality of the American standards movement in the emerging areas of conformity assessment, management systems, financial services, and information technology. There is great potential to enhance our security through more effective use of standardized

conformity assessment. Yet, outside the Coast Guard, DHS currently incorporates only six private standards.

INCORPORATED STANDARDS BY SECTOR



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? Please provide specific examples.

Section 552(a) provides for incorporation by reference in the Federal Register, not just in final rules published in the Code of Federal Regulations. Incorporation replaced a practice where notices of proposed rulemaking referred to standards as explanatory exhibits, which the agency filed for public inspection at the Office of Federal Register.[9]

As Congress emphasized when it amended the Administrative Conference Act in 2004, 5 U.S.C. 594(1), "***more*** effective public participation … in rulemaking" is an essential democratic value. In contrast to many state regulators (*e.g.*, CPUC website), federal agencies generally do not fund a public advocate or provide compensation to intervenors in rulemaking

[9] The Federal Register now withholds approval until the final rules is published. At this point, the Director really has no choice, so disapproval is never a credible threat. Disapproving incorporation could substantially delay the promulgation of any effective rule. The approval process is not transparent, and there is no public evidence that the Federal Register has ever rejected a final rule for lack of reasonable availability. The Federal Register acknowledges that there is no inquiry at all, as long as the agency provides one paper or electronic copy for the Office of Federal Register itself.

proceedings.[10] Some state laws also have express requirements for public participation before rules or standards can be adopted. *e.g.*, Cal. Gov. Code 11346.45.

Access to relevant standards is critical during a comment period. Standards are relevant whenever they are essential to understand the policies on which public comment is sought. This is true even when they are not proposed to be included in the text of an actual rule. Incorporation should be sought as soon as the agency recognizes that a standard provides essential context for the requested comments. The agency should publish a Federal Register notice, provide some form of public access, and send an archival copy to the Federal Register. The Federal Register should summarily approve the incorporation and retain the archival copy.

A. REGULATED PARTIES

In its final recommendation, ACUS qualified its concern about facilitated low-cost access by regulated parties. As to ***current*** standards[11], most regulated parties already have actual notice of their contents. The preference for consensus standards reflects that many are (a) already in use for commercial purposes or (b) developed by groups with broad engagement from the regulated parties. Regulated parties are able usually recover regulatory costs through market mechanisms, which is why private standards are more efficient that government-unique standards. Therefore, the agency should consider "the ability of [different groups] to bear the costs of access[]," which generally resolves the need for access by regulated parties. It should not disturb the reliance of many SDOs on funding from the regulated parties, which is long-established in many industries.

The concern for the costs of access by regulated parties may be largely theoretical. ACUS did not identify any case in which a small business was disadvantaged. SDOs may provide discounts as a matter of marketing. ASTM F963 – 11, the toy safety standard, costs only $69, but ACUS's consultant found that ASTM wholesaled copies to the small producers' trade association for $2. By contrast, parents who need to know how the standard protects their children cannot recover $69 through marketplace mechanisms. CPSC may be able to provide parents with a thorough

[10] *See* ACUS Rec. 68-5, 38 FR 19782 (July 23, 1973) (proposing People's Counsel). While Chairman of ACUS, Justice Scalia suggested that the standard-setting authority of the Consumer Product Safety Act would "benefit commercial rather than consumer interests" unless Congress funded a federal consumer advocate. Scalia and Goodman, "Procedural Aspects of the CPSA," 20 UCLA L. Rev. 899, 952 (1973).

[11] Access to archaic standards ***can*** be a substantial cost, even for large companies, which is another reason that updating is beneficial.

description and understanding of the toy safety standard without disclosing the actual text.

B. SMARTGRID

NAESB has been very successful in modernizing standards for electric utility reliability and proposes to set standards for SmartGrid and utility cybersecurity, including consumer privacy.[12] The States of California and Texas submitted comments to NTIA on the need to increase public access to NAESB standards during these proceedings – since ***state*** law prevents adoption of rules without public participation.

> State actions are dependent upon [SmartGrid] standards adopted at a national level…. State commissions maintain jurisdiction over the distribution grid and have the ultimate responsibility for adoption and enforcement of rules. [State] staff has been involved in the process to create these standards on behalf of consumers funding this investment. It is important that the NIST-FERC process for adopting Smart Grid standards recognize the [states'] role.
> Traditionally, the development of standards requires a minimum of eight to ten years. NIST is facilitating an accelerated standard development process to create Smart Grid standards… Some of the problems encountered by Staff include the cost of the standards themselves, which often exceed $1,000 per standard, as well as the cost and difficulty to actively participate in the standard development process itself. There are unanswered questions about the ability of the CPUC and other state commissions to fully investigate and eventually adopt, if necessary, standards that are costly to obtain, or whether or not state commissions can include such standards in any final rules or policies.

As FERC observed, NAESB membership is simply a cost of doing business for utilities, which they recover from state ratepayers. 74 FR 63288 , ¶117 (Dec. 3, 2009). But, since full membership costs anyone $26,000 (the same as utilities), regulators have access to NAESB standards in only four states.[13] However, NAESB does derive some

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[12] NAESB's general counsel has written on the groups history and its application of due process . Boswell and Cargas. "NASEB: Legal and Administrative Underpinings of a Consensus Organization." 27 Energy L. J. 147 (2006).

[13] The report of ACUS's consultant observes, "Members get access to standards for free. Membership also benefits the public interest by encouraging broad-based participation in the development of standards." Bremer Report at 33. As of April 1, 2012, the four states with access are Maine, Maryland, Ohio, and Pennsylvania, which belong to each of the four quadrants (wholesale and retail gas and electric). NAESB website. Each quadrant costs $6500 a year. NAESB Membership Application. SmartGrid standards currently involve wholesale and retail electric. No other regulators or consumer organizations have purchased access.

membership and publication revenues from industrial users and the law firms that represent them. Therefore, in fashioning an accommodation, NAESB may reasonably require a certification that the person reviewing the standard is doing so for evaluation as a consumer, representative of consumers, academic, or journalist, with no expectation of distributing material to any energy producer or industrial user. Limiting access in time can be another effective precaution against unauthorized use, provided it permits meaningful participation in each phase of the rulemaking and judicial review.

C. CONFORMITY ASSESSMENT

Lack of meaningful access is a particularly serious barrier to wider use of standardized conformity assessments in federal regulatory program, which could have substantial economic benefits to both the government and the private sector. Agencies can be reluctant to delegate inspection or audit functions if the procedural and operational principles are not openly posted on the internet. They should be. In contrast to the ***substantive*** details of technical standards, standardized management and conformity assessment systems ***do*** affect the regulatory operations and procedures in fundamental ways. When it passed the APA, the 79th Congress viewed information about the procedures and operations of government as "public property," a view it did not take about the substantive standards.[14] Public access needs to be broad and permanent, to provide for an ongoing understanding of how the standardized programs are performing.

Many of these regulatory programs that to benefit from standardized conformity assessment involve global supply chains. To be internationally effective, these rules must conform to ISO standards. USDA has already incorporated Guide 65, for which a

[14] The recent debate on substantive rules inverts the historic priorities of the APA. The central purpose of Section 552 was to disclose the workings of government to the general public, so it focused on disclosing government structure and procedures. The Senate Report wrote: "[A]dministrative operations and procedure are public property which the general public, rather than a few specialists or lobbyists, is entitled to know or have the ready means of knowing…." Indeed, the original bill written by Congressman Celler (who wrote the Federal Register Act), used the phrase "organizational description …. [and], rules and procedures, formal and informal." This term, "substantive rules," was first used in Senator McCarran's section on rulemaking, and then added to the end of what is now Section 552(a)(1). But the Senate Committee still respected that, to the extent substantive rules includes private standards, they were not necessarily "public property." S. Rept. No. 79-752 at 12 (1945). The "provisions … are of the broadest application because, while some functions and some operations may not lend themselves to formal procedure, all administrative operations should as a matter of policy be disclosed to the public except as secrecy may obviously be required. H. Rept. No. 79-1980 at 22 (1946).

single user license costs $60. Many standards can over a hundred dollars each, and typically contain references to other ISO standards. For example, there are 29 active standards on conformity assessment generally (Guide 65 and ISO 17000 series, plus seven more on food management systems (ISO 22000 series). ISO is highly proprietary and makes few accommodations to government. In this country, its standards are only sold as electronic licenses, which do not permit fair use copying or library use.

One possible approach is to have NIST use its expertise, and the input it has received through the workshops, to create documents explaining ISO-compliant principles. One could function as a "layman's guide," providing a basic explanation that could be used in rule preambles whenever an agency proposed a conformity assessment system. NIST created a "roadmap" for regulatory use of standards in the SmartGrid, which interpreted existing copyrighted standards and helped DoE, FERC and state regulators provide public participation and transparency. NIST could also provide authoritative language that would serve as standard text for a rule or directive, which it could customize working with the agency. Regulations based on the NIST template should provide detailed, but comprehensible language that would be compliant with ISO standards to the full extent required to harmonize with international regulation. Even if, for international purposes, it was necessary formally to incorporate ISO standards by reference[15], the authoritative text domestically (even in judicial proceedings) would be the regulation based on the NIST template. As such, limitations on access to the underlying ISO standards would not prejudice the public.

What are the best practices for incorporating standards by reference in regulation while respecting the copyright associated with the standard?

Since accession to the Basel Convention, ***any*** text not written by U.S. Government employees has automatic copyright, but this does not exclude ***all*** unauthorized copying and use. However, a consensus standard is fundamentally an expression and compilation of facts and ideas. Its protection under copyright law is not the same as the rights accorded to an original artistic work or a patented invention.[16]

Currently A-119 provides: "If a voluntary standard is used and published in an agency document, your agency must observe and protect the rights of the copyright holder and any other similar obligations." The preamble rejected "stronger language," concluding that the formula was "just right." This language acknowledges that

[15] When the ACUS Committee discussed the possible need to incorporate international standards, and David Fredericks, an appellate attorney, observed that their language was not often well-suited to judicial review.

[16] For example, U.S. law does not give copyright holders "moral rights" to protect the integrity of a textual work.

agencies may not only "use" (defined to include incorporation by reference), but may also "publish" a voluntary standard to some extent. Presumably, this reflects the various limitations on the exclusive rights conferred by copyright. Wisely, the ACUS recommendation did not take any position on the extent of copyright law. Indeed, the need to protect those consensus SDOs that depend on revenues may indicate ***more*** protection than copyright law.

Uncertainty about legal rights often fosters collaborative solutions. An approach based on collaboration, rather than claims about copyright entitlement, has resolved these issues for decades – and can continue to do so.[17] ***Even if government posting a standard (or excerpt) is a fair use[18] or subject to a privilege[19], it is simply a bad idea if it facilitates subsequent, private use that threatens the business system of the consensus body.*** This is especially true if the infringement is hard to detect or the rights hard to enforce.[20] Still, standards bodies also recognize that the ability of the public to understand a regulation implies some fair use by private parties – especially when it is feasible to restrict no-cost use to ***unregulated*** parties who (1) would be unlikely to purchase the standards and (2) cannot recover any royalties they pay through the marketplace. Preserving the vitality of the standards process, not theoretical arguments about copyright law, has been (and should continue to be) the basis for reaching

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[17] Of course, added caution is now necessarily because posting something on the internet is universal and effectively irreversible.

[18] The joint authors of consensus standards are typically volunteers, who assign rights to the standards body, sometimes as a condition of membership. This may be significant for purposes of fair-use analysis, because it bears on whether the affected market primarily benefits the subsequent owner. *See* Kasunic, "Is that All There Is? Reflections on the Nature of the Second Fair Use Factor," 2008 Colum. J. of Law and the Arts 101, 130. This may distinguish College Entrance Examination Board v. Pataki, 889 F. Supp. 554 (1995), where the court granted a preliminary injunction against a state law that designated exam questions (created by plaintiff's employees) as public records. *See* Bremer Report at 18; *see* also Pamela Samuelson, Questioning Copyrights in Standards, 48 B.C. L. REV. 193, 222 (2007)

[19] Another privilege or limitation to the copyright may apply. *See* H.R. Rep. No. 1476, 94th Cong., 2d Sess., reprinted in 1976 U.S. Code Cong. & Ad. News 5659, 5687 (potential legislative privilege); FOIA Update, v. IV #4 (1983) (pre-internet guidance stating that analysis of Exemption 4 to FOIA is "congruent" with fair use, but also that "substantial adverse impact on rights-holder's potential market" is necessary, which is not an element of copyright infringement). 17 U.S.C. 108 may apply to disclosures to certain libraries.

[20] For example, the birthdate of every author who has registered a work with the Copyright Office is public information, but posting this information ***in bulk*** on the internet would facilitate identity theft.

accommodations. The reality is that SDOs generally want an agency to adopt ***more*** than fair use of their documents.

The current system is not an effective protection either of copyright or of the business system of SDOs. Anyone who would benefit substantially from unauthorized commercial use (or republication) can afford to travel to the Office of Federal Register, which permits copying ***without limitation***. Due to the Privacy Act, the Federal Register will not disclose persons making copies – and has never received a court order to do so. However, travelling to Washington is not a realistic option for most commenters who want to review the standards only for the purpose of evaluating their regulatory use.

Today, the standards movement recognizes that "Everyone should have the right to access standards referenced into law and be able to review such work, at a minimum, at government facilities and libraries on a read-only basis."[21] SDOs and their members benefit from government use in many ways, and are motivated to accommodate some form of increased transparency – especially when it can be targeted to those who would not otherwise purchase their publications and have no interest or ability to make commercial use of them. Where regulatory or commercial use of the standard is restricted to a small group of persons who would not or could not effectively use a bootleg copy (as is the case for many utility or oil drilling standards), the SDO should consent to posting online. This is also true when the SDO does not rely on publication revenues, but on membership fees or usage royalties. But SDOs are unlikely to consent to posting in many of cases and validly claim adverse impacts if distribution is unlimited.

Government facilities are probably a poor option. They are not well distributed geographically. They increasingly restrict public access. Even some "public reading rooms" identified in the CFR are in buildings that are now completely closed to the public.

Library access is an excellent approach, but can probably only be implemented voluntarily under the supervision and sponsorship of ANSI. No library in the United States has ISO food safety standards. Even the Library of Congress cannot afford a

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[21] ANSI White Paper: Why Voluntary Standards … Are Copy-Protected. In the case of standards prepared specifically for government regulations, ANSI has advised its members to (1) reference only those documents that are publicly available, (2) provide proprietary materials as examples only when necessary, (3) place portions not intended to be enforced in an informative annex or other advisory document, and (4) emphasize the openness and credibility of the consensus process, so that the agency administrative process can be eased through access to a clear consensus record. ExSC 4643 (April 19, 1999).

subscription to the standards database, which is very restrictively licensed within universities (usually to persons working on federal grants). Appropriations law probably prevents the Federal Depository Library program from funding the distribution of standards to its members.[22] Voluntarily, SDOs could make available paper versions (subject to a prohibition on lending or copying) or seat licenses to a database, possibly with terminals that address their security concerns. This approach would have the additional benefit of increasing awareness about standards among non-technical students and university faculties.

The voluntary provision of read-only copies has been acceptable to some SDOs and adequate for evaluation of most regulatory standards. But it is a transitional technology that does not provide impermeable protection. Nor can it provide the same access for the blind or language-impaired that posting on a website does. In the future, the restriction on machine-readability may make this format less useful. Some SDOs, including ASTM (which supplies 28% of all regulatory incorporations) have legitimate concerns about read-only access.

However, almost SDOs should accept some limited access using digital rights management (DRM). DRM can provide protection against unlicensed export of certain standards. DRM can not only provide copy protection, but can also restrict the machine, the place, or the duration of access. SDOs should be allowed to administer their own systems of access, and to require a user to register, acknowledge copyright claims, and certify that the material will be used only to evaluate the standard as proposed for adoption by government. Ultimately, the purpose of these restrictions is to prevent infringement, so SDOs may legitimately prosecute users who violate these terms. Due to the Privacy Act, an agency cannot effectively administer such a system.

> ***What resource and other costs are involved in the development and revision of voluntary standards? 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?***

Consensus SDOs have a great variety of business systems. Almost all rely on volunteer authors, so maintaining incentives for them to recruit and motivate these volunteers is essential. The ability of SDOs to accommodate transparency depends upon their specific business system, particular the extent to which revenues from publications are essential to its maintenance. Most are non-profit organizations with

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[22] *See* 44 U.S.C. 1903 (exclusion of "cooperative publications"); *see* also GAO File B-114829 (1975) (deposit possible for certain cooperative documents of general interest). Maryland deposits photocopies of its standards with depository libraries, marking them as copyrighted. 79 OAG 322 (Md. Att. Gen., 1994).

commitments to the interests of the public and their memberships. They are not profit-maximizing institutions. The development process requires financial support, which may come from membership dues, seminars, or publications, or a mixture of these. In negotiating with SDOs, agencies should consider the financial benefits they derive from incorporation, netted against any adverse effect on publication revenues.

Publication (or broad availability) of regulatory materials is a critical government function. If the rights owner cannot commit to allowing the standard to be "reasonably available," and its ideas are the best regulatory approach, OMB should encourage the agency to restate the essential facts and ideas to the full extent permitted by copyright law. Where the copyrighted standard is used commercially, the agency alternative should seek to produce a government standard that will operate as harmoniously as possible.

Should an OMB supplement to the Circular set out best practices for updating standards referenced in regulation as standards are revised? If so, what updating practices have worked well and which ones have not?

One practice has a demonstrated record of success over many decades. It is the practice demonstrated in the 1938 edition of the Federal Register, approved by the drafters of the Administrative Procedure Act in 1947, and practiced by many agencies until the 1970s. It is ***keeping the most detailed standards out of the Code of Federal Regulations***. This does not reduce the authority of the standard. Codified rules can and should guide or limit the discretion of the agency to accept new versions. The non-codified standards will qualify for the copyright protection (and exemption from FOIA) once the Federal Register allows agencies to incorporate them by reference in Federal Register notices, which are used to publish directive, interpretations, and other forms of guidance.

In the first editions of the CFR, private technical standards and administrative "safety releases" were listed next to the rule. Agencies sometimes filed these materials with the Federal Register as "exhibits" to a notice in the daily edition. This practice assured centralized custody (and another option for public review) at the Federal Register. Alternatively, the identified cited one standard, but provided that its use was not exclusive, expressly asserting the agency's discretion to consider earlier or later versions.[23] Sometimes, the regulated party was allowed to propose "[an]other recog-

[23] *e.g.*, 30 CFR 13.16(d) (1938) (Bureau reserves right to modify safety test to provide substantially the same information or degree of safety); 14 CFR 405.12 (1949) (stating that detailed safety releases are available, but not published); 7 CFR 1443.64(d)(1970) (pricing standards "in effect on the date of tender"); 14 CFR 2.17-75 (1970) (Commandant of Coast Guard may authorize use of earlier or later edition when circumstances warrant).

nized standard."[24] None of pre-1966 formulas involved automatic revision or dynamic incorporation; each required an official determination for which the agency was accountable and subject to judicial review.

In all of the pre-1966 cases so far identified, agencies allowed inspection of each supplemental or replacement standard pursuant to Section 552(a)(2). This reflected the reality that many test procedures and other highly detailed or changeable standards were ***not*** "substantive rules" requiring codification, but reasonably classified as staff manuals, policies, and interpretative materials.

After the Freedom of Information Act formalized "incorporation by reference" in 1966, the Administrative Committee for the Federal Register provided even greater flexibility at the urging of the Administrative Law Section of the ABA. Under the 1967 rule, the agency did not even file any officially adopted revisions with the Federal Register; it could simply make "available [directly to the public] an official, historic record of changes."[25]

The practice of incorporating (or revising) a standard by filing a Federal Register notice (as opposed to codified a rule) became more difficult in 1972 – and all but impossible in 1982. In 1972, only eight CFR parts had incorporations by reference, and only two involved private standards. Still, the Director was concerned that "overuse" would "emasculate" the CFR. 37 FR 6817 (Apr. 4, 1972).

The 1972 rule appropriately required that a specific edition be identified, but did not exclude subsequent revisions without further rulemaking procedures or Federal Register approval:

> Future amendments or revisions of material incorporated by reference are not included. ***They may be added as they become available, or at any later time***, by the issuance of an amendatory document. Separate approval of the Director of the incorporation of each amendment whose original incorporation was approved need ***not*** be obtained.[26]

The 1982 rule eliminated this section, as well as any copyright protection for subsequent versions of standards. Even when the agency adopts them formally, it cannot file a notice that effects an incorporation by reference. The Federal Register may legitimately require agencies to file materials, but should not interfere with an agency's

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[24] *e.g.,* 14 CFR 12.303, 14.201, 15.0500 (1938); 30 CFR 211.35 (1938) (flexibility to use any "standard design commercially recognized as safe").

[25] 1 CFR 20.12(c)(1972).

[26] 1 CFR 51.8(c)(1973), added by 37 FR 6817 (1972).

decision to use language in a rule that explicitly provides for future administrative adoption of alternate standards.[27] OMB should encourage rules that allow future ***informal*** procedures to adopt revised standards that have no significant adverse cost and safety impacts.

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?

Yes. OMB should not allow agencies to subordinate their regulations to standards or to delegate statutory duties to SDOs. It should also ensure that agencies analyze revised standards for potential impacts on small business, before they accept the new editions.

A. AVOIDING REGULATORY SUBORDINATION

Even before its amendment earlier this year, 49 U.S.C. 60102 required the Secretary of Transportation (through PHMSA) to "prescribe ***minimum*** safety standards" after a 90-day consultation with TPSSC, a federal advisory committee. Part 192 regulation of propane is ***not*** the minimum standard. This because PHMSA subordinated its own regulations to NPFA 58/59 in 1992, ***knowing*** that these private standards would be less stringent in some respects.[28] In these conflicts, NPFA (not PHMSA) sets the minimum standard, because compliance with its less stringent provisions automatically disables any conflicting regulatory text.

In 2010, even before the gas explosions that have drawn congressional attention[29], PHMSA came to regret the reverse priority clause, concluding:

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[27] Strauss and Sunstein, "The Role of the President and OMB in Informal Rulemaking," 38 Admin. L. Rev. 180, 191 (1986) (Congress has placed ultimate authority to make decisions in agencies).

[28] 49 CFR 192.11(c). PHMSA proposed this provision when it incorporated the 1992 version of these standards because "NFPA rules are updated regularly to include state of the art technology and should be given priority." 57 FR 39573 (Aug. 31, 1992). Four years later, PHMSA included the priority provision in its final rule (over the dissent of four TPSSC members), explaining that the NFPA standards should prevail "even if Part 192 is more stringent" because they "reflect current [propane] technology." 61 FR 28773 (June 6, 1996). NFPA 58/59 are revised every three years, but PHMSA rulemakings to update standards occur infrequently and can take several years, leading to a substantial lag. 69 FR 32886, 32894 (June 14, 2004) (update to 1998 edition); 71 FR 33403, 33404 (June 9, 2006) (update to 2004).

[29] There were propane explosions in Mexico City (1984, 500-600 deaths), Toronto (2008), and Washington State (2012).

- Propane distribution posed "greater potential hazard to the public than LNG [liquefied natural gas]," so it is "inappropriate to impose weaker standards on propane distribution facilities than natural gas facilities."
- NFPA 58/59 was then "significantly less stringent," in part because it was developed to govern design and installation, not the operation of pipelines. Without primacy over NFPA 58/59, PHMSA's operations and maintenance rules "would actually decrease safety."
- NFPA 58/59 "fail[ed] sufficiently to address damage prevention…, leak surveys, emergency plans, failure investigations, [and] public awareness."
- Newer editions of NFPA 58/59 had expanded the "scope of covered facilities, creating more conflicts." 75 FR 48595 (Aug. 11, 2010).

NFPA strongly opposed restoring priority to the regulation. PHMSA refused to update from the 2004 to 2008 edition and promised to "address the subject of primacy in a separate rulemaking." *id*. That rulemaking has not yet commenced. (NFPA has been a pioneer in making ***all*** its standards available on a read-only basis, but it provides the current version.)

No one disputes that even the 2004 version of NFPA 58/59 relaxes clear provisions of Part 192 as they apply to propane. While no explosion has been attributed to these "significantly less stringent" provisions, PHMSA should be required to permit a risk that it has identified. NFPA 58/59's increasing divergence from Part 192 may not be intentional, since they function as global standards for propane storage that apply broadly to stationary tanks. In other cases, granting reverse priority could lead to strategic behavior, such as hiding escape clauses in materials expected to be incorporated or writing regulations that appear to be highly protective but are actually meaningless. It prevents an agency from supplemented or excepting from a standard in any way, which is an essential tool. PHMSA found that the unusual provision even confused utilities, some misinterpreting it to mean that NFPA 58/59 compliance eliminated any application of Part 192.

The Bremer Report cites the provision giving primacy to private standards with apparent approval, stating that it provides "regulated parties with concrete guidance when faced with an unforeseeable conflict." In general, and in this case, agency language will be the more "concrete guidance" when conflicts emerge with standards designed broadly for non-regulatory purposes.[30] The Bremer Report defends the legality of subordinating regulations to private standards, arguing that "a static incor-

poration will always be constitutional."[31] But it fails to analyze whether there is any affirmative showing that Congress intended to authorize PHMSA (or any other agency) to reverse the normal priority of official rules over the private norms that they incorporate.[32] Congress seems unlikely to intend that any regulator make a subdelegation to a private entity that subordinates the agency's own authority to implement its statutory mandate.[33] Until PHMSA succeeds at eliminating the reverse-priority provision, it has tied itself to the mast. No matter how acute the emergency, PHMSA will be unable to impose regulations inconsistent with an eight-year old version of NFPA 58/59.

The hierarchy of statutory law, regulation, and incorporated standard is well-understood, essential to respect statutory mandates, and important to preserve. OMB should discourage agencies from purporting to give priority to private standards.[34]

B. MAINTAINING REGULATORY POLICIES

Agencies should not have an entirely blank check to adopt versions of standards that have significant cost impacts or reduce the level of safety. OMB Memo 07-07 provides direction as to significant guidance documents. The agency is always responsible for considering impacts on small business of any change.

However, where the agency (subject to OMB guidance) concludes that changes in a standard are ***not*** significantly less protective or more costly, it should be able to

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[31] Bremer Report (at 36 & nn. 205-07), citing Siegel, "Use of Legislative History in a System of Separated Powers," 53 Vand. L. Rev. 1457, 1482 (2000); but *see* Verkuil, "Public Law Limitations on Privatization of Government Functions," 84 N.C. L. REV. 397, 422 (2005)(explaining Carter v. Carter Coal, 298 U.S. 238, 311 (1936)) and Metzger, "Privatization as Delegation," 103 COLUM. L. REV. 1367, 1439 (2003) (constitution prohibits on uncontrolled private delegations, but acknowledging that Carter "all but dead in practice").

[32] *See* USTA v. FCC, 359 F.3d 554, 565 (D.C. Cir. 2004) ("subdelegations to outside parties are assumed to be improper absent an affirmative showing of congressional authorization")(citing numerous cases).

[33] For example, P.L. 112-28, which was otherwise designed to limit the authority of CPSC, expanded the exclusion of from the incorporated toy safety standard of material that restates regulations of CPSC and FDA. The purpose was to avoid embedding prior regulations, and so preserve the authority of CPSC and FDA to revise their own rules. 15 USC § 2056B(b).

[34] To my knowledge, the ACUS committee was not aware of any of the history detailed in fn. 28, supra or PHMSA's proposal to restore the priority of its regulations. It did revise the consultant's draft recommendation to suggest that agencies "avoid or resolve" any conflict "when drafting [the] regulation." This may have assumed that any conflicts between the rule and the two NFPA standards could be identified and addressed in advance. All three documents are over 100 pages.

effect those changes administratively. This is most easily accomplished if the standard is in ***not*** in the CFR. Ideally, the rule to which the standard applies should state guidelines for determining that a new version is usable and to authorize the agency to effect these revisions without rulemaking procedures.[35] In order to increase stakeholder acceptance of these determinations, the agency head may choose to consult with a broad-based advisory committee.

Should OMB provide guidance to agencies on when it is appropriate to allow the use of more than one standard or more than one conformity assessment procedure to demonstrate conformity with regulatory requirements or solicitation provisions?

Yes. There are at least three situations where multiple standards are appropriate.

Items manufactured before the revision of the standard may still be in use. Especially in the case of design standards, these items may not comply with the new standards. Even if they do, the costs of removing them from commerce may be substantial costs when compared to the benefits. The old standard, if it is still available, should remain a "safe harbor" for previously manufactured items.

Where the agency has authority to find that a new edition of a standard is equivalent, or to authorize its use as an exception, the existing standard should ordinarily remain in effect until there has been an appropriate process to amend the rule. There may be express or implied authority to discontinue use of the existing standard on an emergency basis where it is found to be seriously defective in preventing a safety risk.

Multiple standards may also be appropriate to promote fair trade. Recognition of our standard by other countries may require reciprocity. Even in the absence of reciprocity, the agency (with the Trade Representative) may determine that the foreign regulatory system provides equivalent protection, making further evaluation unnecessary. In this case, OMB should permit use of the foreign standard, but require that it be published or incorporated by reference.

Where an agency is requested by stakeholders to consider allowing the demonstration of conformity to another country's standard or the use of an alternate conformity assessment procedure as adequate to fulfilling U.S. requirements, should OMB provide guidance to agencies on how to consider such requests?

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[35] 29 CFR 1911.5 construes the OSHA Act "as permitting the making of minor rules or amendments in which the public is not particularly interested," but has had limited application.

Consistent with Executive Order No. 13609 (May 1, 2012), executive agencies "should reduce, eliminate, or prevent unnecessary differences" to avoid unnecessary burdens on the private sector and to maximize consumer choice. At least where there is expectation of reciprocal treatment, and provided that it would not place domestic producers at an artificial disadvantage, the agency should accept foreign regulatory certifications that are at least as protective as the standard used by the agency. In many cases, the standard will differ in nature, rather than in easily compared parameters, *e.g.*, a risk management standard as opposed to a performance or design standard. Risk management standards may be difficult to compare. The Executive Order provides for a consensus interagency working group and supplements requirements for agency Regulatory Plans and Unified Agenda submissions. OMB should assist agencies in interpreting those requirements.

Have there been any developments internationally-- including but not limited to U.S. regulatory cooperation initiatives-- since the publication of Circular A-119 that OMB should take into account in developing a possible supplement to the Circular?

Yes. The *Due Process Requirements* have been an extraordinarily successful U.S. export. To cite just one recent example, GFSI, formerly an exclusive consortium of European food retailers, has reformed its governance to conform to the consensus model of A-119. More typically, American SDOs (sometimes dropping the word "National" or "American" from their names) because they have become a pre-eminent international body in their field.

The Due Process Requirements are one of ACUS's most important legacies.[36] OMB should reinforce the importance of complying with those requirements. They are essential to this very successful social contract. SDOs provide balance, openness, public participation, and appeal rights ***within the development process***, entitling the results they produce to a substantial presumption of official respect. As Chairman Verkuil has emphasized, this formula even has a constitutional dimension. Carter v. Carter Coal,

[36] In 1979, draft OMB Circulars were not necessarily subject to public comment. Two weeks after ACUS adopted Rec. 78-6, Hon. John Dingell wrote to OMB Director Miller: [ACUS] considers the adequacy of the procedures used by the voluntary standard-setting organization and the fairness of those procedures a key factor in determining whether or not an agency should adopt and - use a standard . As we have noted above, the OMB obviously does not agree, because the Circular flatly states that such adoption and use is not contingent on being developed in accordance with such procedures. *We* again believe that the Conference approach is sound and more consistent with the public interest. … Balanced membership and open decisionmaking should apply. Dingell to Miller, Jan. 17, 1979, at 5. As OIRA Administrator, former ACUS Chair Sally Katzen restored the Due Process Requirements in 1998.

298 U.S. 238 (1936) requires agencies to maintain effective oversight and control over delegations to private entities.

> The message of Carter Coal, that delegation to private bodies can be accepted, indeed even encouraged, so long as there is some public check on their exercise, is implicit in OMB's due process formula. Whether that formula works in practice to adequately preserve the public interest is not easy to determine, however. Verkuil, "Public Law Limitations," 84 N.C. L. REV. at 434-36.

Congress has also emphasized that A-119 "***require[s]*** openness, balance, transparency, consensus, and due process" in consensus organizations. SDO Advancement Act, P.L. 108-237, §102(5). OMB should amplify the importance of due process and clarify any ambiguity created by paragraph 6(g), which states: "This policy does not establish a preference among standards developed in the private sector."[37] It should direct agencies to encourage SDOs (through federal participation and use of standards) to promote balance and openness. Membership fee structures should provide for affordable participation by some representatives of consumer, environmental, and other non-commercial public interests. SDOs should avoid fees, sometimes as much as $200, for a non-member merely to comment on a draft standard in development.

> ***Does the significant role played by consortia today in standards development in some technology areas have any bearing on (or specific implications for) Federal participation?***

Consortia have emerged in high technology fields to respond to the perceived slowness of consensus bodies in maintaining standards that require very frequent revision. This model has many variations, is frequently international, and may operate independently of the ANSI/ISO process. It may provide for participation by both the promoters and adopters of technology. Rapidly moving markets may require flexibility, but the Center for Regulatory Effectiveness has written a white paper identifying some drawbacks of non-consensus standards, which includes many of those developed by "consortia."

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[37] The final rule preamble reads: "The intent of the Circular ***over the years*** has been to discourage the government's reliance on government-unique standards and to encourage agencies to instead rely on voluntary consensus standards. It is has not been the intent of the Circular to create the basis for discrimination among standa*rds developed in the private sector, whether consensus-based or, alternatively, industry-based or company-based." This is somewhat unhelpful, because the Due Process Requirements were only in effect for 1981-82. See 47 FR 16919 (April 20, 1982); DAO 216-14 (Feb. 1983), attaching 47 FR 49496 (Nov. 1, 1982).

There are often alternatives to consortium standards. X12 has contributed many of the Health IT standards so far incorporated into regulations. It operates on consensus principles and belongs to ANSI, but provides for guidance and interpretive documents to address issues that arise between standards revisions. At least one consortium consisting of some of the largest members of X12 has emerged, but has not yet contributed a standard. In general, government should be cautious about substantial participation in consortia that are exclusive of some competitors.

DHS, which is the lead agency for the NIEM initiative in data interoperability, concluded that consensus development was too slow. It developed a "core" set of definitions on a government-unique basis, which it has opened to extension by industry.

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Thank you for the opportunity to comment on these important issues.