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Mr. Howard Shelanski, Administrator
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Office of Management and Budget

Dear Mr. Shelanski:

I file the following comments on your proposed revision of Circular A-119 on behalf of myself and other administrative law scholars interested in the problem of incorporation by reference from the perspective of its impacts on federal rulemaking and on the public nature of law. I should perhaps note that as my cosigners have not read all the underlying materials as carefully as I have tried to, they support the basic thrust of these comments, but not necessarily all of the points made or the manner in which every point is expressed.

As you may recall, I and others (including many of the undersigned) filed the petition for rulemaking that resulted in the pending Office of the Federal Register proposal to revise Part 51 of its Regulations, on Incorporation by Reference as permitted by 5 U.S.C. §552(a)(1). We subsequently filed comments in that rulemaking and, to avoid simple repetition, we incorporate them by reference herein. They may be found on the Regulation.gov website as OFR-2013-0001-0024.

Because those comments are in a public document freely available to all, starting this way may serve to illustrate a consistent weakness of your proposed guidelines – that they fail to treat the public's need to know its legal obligations and its right to participate in their formulation nearly so seriously as they do the undoubted benefits of using incorporated voluntary standards as elements of federal regulation and in the international marketplace. As just one example, consider the treatment of the preference the guidelines state for use of voluntary consensus standards as against those not developed using a consensus-driven process. Nowhere in the discussion do you call to agencies' attention the failure of the latter processes even to approximate the notice-and-comment procedures of 5 U.S.C. §553, that control the manner in which agencies may themselves create legal obligations. To the extent consensus procedures are used in generating standards, such as those defined by the WTO, ISO and ANSI, one might believe that there *is* such an approximation. The relevant question then becomes, as your proposal in effect counsels (but unfortunately does not require) what steps must be taken to make that approximation an acceptable substitute. While even the use of consensus standards raises important issues, however, one would expect the failure of non-consensus standards to offer such reassurances to be noted as a serious negative – resulting, for example, in an even greater agency obligation in any rulemaking proposing to convert them into legal obligations to assure that the public has a meaningful opportunity for comment.

Before developing our concerns in greater detail, we wish to emphasize that these comments are directed only to the use of standards to create legal obligations binding on the public, by reference to them in agency regulations as mandatory means of accomplishing regulatory ends. As our comments to the OFR suggest (and as it appears you have recognized in your longer document), the use of standards as *guidance* how one may comply with regulatory obligations whose essential elements are independently stated is more readily defended. It better assures a compliant rulemaking process, as the public will have notice of, and a genuine opportunity for comment on, those independently stated obligations. (It has the added advantage of permitting prompt, informal changes that can help regulated entities attain regulatory compliance.) We note, as our prior comments to OFR did, that both relevant congressional discussion *and* OIRA Administrator Katzen's explanation of the final version of the present circular A-119 assume (as does the current practice of the European Union) that standards are *not* to be used as a substitute for regulation, but *only* as a means for establishing compliance with obligations whose essential elements are independently stated – elements thus fully exposed to the §553 process in their creation, and to the public as their legal obligations. Failure to limit the use of standards to such contexts is the weakness in your proposed Circular A-119 that most concerns us.

These comments do not address the use of standards for procurement. Any participant in a market has the right to specify the qualities it desires; and to do so it must itself know the standard and communicate those requirements to its seller. This is 180º away from the use of standards to create regulatory obligations, that limit the conduct of private individuals, not the market participation of the United States, yet may not be known to them. Nor are these comments concerned with compliance issues. Their sole focus is on those uses of standards that in effect substitute for the notice-and-comment rulemakings by which regulatory obligations are ordinarily created.

In our judgment, a more balanced treatment of these issues would invoke, alongside the three executive orders mentioned on p. 3 of your background discussion document, President Obama's administration's forceful commitment to transparency of government actions, the obligations attending notice-and-comment rulemaking under §553, and the public's ordinary and proper expectation that the legal requirements to which they are subject will be widely available in public libraries and on the Internet – that law is not subject to copyright. Standards creation by private bodies can effectively displace statutory rulemaking procedures, as your proposal recognizes in its emphasis on agency officials' participation in the standards generating process – to the extent even of serving on the boards of standard-setting organizations (pp. 35-38). We are persuaded by that aspect of your analysis. But you should then be paying much more careful attention to the displacement of ordinary rulemaking processes that inevitably results. Rather than counseling agencies merely to take account of the openness of the standards setting process to public participation, the desirability of public access to the content of proposed standards during the notice-and-comment process, and the utility of summarizing the standards in terms readily understood by the public in rulemaking preambles, 6p, you should more appropriately be *requiring* the following elements:

> 1) *That, as in the European Union and elsewhere, rulemaking proposals, and any ensuing regulations, state in their operative text the essential requirements being effected by the regulation.* To do so would convert incorporated standards into means of compliance with requirements independently and publicly stated. Many standards,

of course, are not so much regulatory measures, as means of assuring desirable qualities in a product – offering assurance, for example, of compatibility. But a goodly proportion of the American standards that have been converted into legal obligations through incorporation by reference can only be understood as regulations. See, for example, the standards on public hazard warnings respecting pipelines developed by the American Petroleum Institute and then incorporated by reference as legal obligations by the Pipeline and Hazardous Materials Safety Administration. For standards such as these, the displacement of ordinary public rulemaking by private processes was neither foreseen nor blessed by Congress – as Administrator Katzen's explanation of the intended scope of Circular A-119 explicitly accepted. That understanding should now be reiterated. It has regrettably disappeared from the document as you now propose it.

2) *That agency officials' participation in standards formation be* ***conditioned*** *on the existence of procedures that, on analogy to the Regulatory Negotiation processes of 5 U.S.C. §561 et seq., assure openness, balanced representation of the interests likely to be affected, and a drive to consensus.* Simply urging consideration of these matters disrespects the public's rights of participation, permitting government participation in standards-generating processes that do *not* seek voluntary consensus. While this approach might be acceptable in the procurement context, it has no justification where legal obligations are being shaped that ought ordinarily to be achieved through statutory rulemaking. It greatly magnifies the extent to which the promises of §553 rulemaking are being evaded.

3) *That, for rulemaking proposals that will result in regulatory obligations, agencies assure that scientific and technical studies underlying the proposed rule be placed in the public docket for comment, as agencies have for 40 years now understood to be their obligation in notice-and-comment rulemakings*. Just as proposed regulatory texts must openly state the essential requirements being proposed, their publicly available docket must contain the materials that will make the comment process realistic. This has properly been understood to be a necessary step for enhancing transparency and stakeholder participation in the terms of §553 for more than four decades.

Your document's proposed endorsement of the ACUS recommendations is a step in a good direction, but its discussion at pp. 9-10 and subsequently in the body of your proposed guidance document is troubling in several respects.

First, whether standards are "reasonably available" is by statute the responsibility of the Director of the Office of the Federal Register to determine, not for agencies (although of course agencies will wish to accommodate his concerns). 5 U.S.C. §552(a)(1). It is remarkable and troubling that you neither address the OFR Director in this guidance, nor seek to define reasonable availability as the legal obligation the Director must enforce.

Second, in stating OMB's belief that the public interest would not be served by requiring standards incorporated by reference to be made available "free of charge," you caricature the positions urged by the undersigned, by the ABA Section of Administrative Law and Regulatory Practice, and by others, and denigrate the government's legal obligations. Controlled access, which might be on SDO as well as

agency websites, is provided by many standards organizations, and has not had the harmful impact on their economic viability you apparently fear. SDOs are properly adapting their business models to the computer age, while your proposal appears oblivious to the requirements of the Electronic Freedom of Information Act, among others.

Third, That law must be public is not optional, but this proposition would be honored were agencies to use rulemaking to state the essential requirements of regulations independently of incorporated standards.. Under that practice, incorporated standards would be used (as the NTTAA and present Circular A-119 contemplate) only to identify technical means of complying with regulatory requirements, not themselves as regulatory requirements,. If such an approach might not result in full free access to the incorporated standards, it *would* assure the public its necessary opportunity to influence and to understand the basic conduct being required of it, as simple reference to API's standards for public warning of pipeline safety standards in PHMSA's proposal and eventual regulation assuredly did and does not.

Finally, your proposed guidance fails to note the frequent opportunity of making public not the whole of a voluntary consensus standard, but the limited portions that rulemakings often convert into legal obligations. An example of this that was prominent in our discussion of the OFR rulemaking proposal was PHMSA's incorporation by reference of the definition of a disqualifying "dent" in a hazmat tank truck appearing in a voluminous SDO standard. Your comments are properly concerned, as we are, with preserving the economic viability of the standards-generating process. That process unquestionably serves important public values. Yet making public such limited excerpts would not in any way compromise an SDO's income from sale of its standards as a whole.

Now, a few specifics about the text of your draft revision Circular A-119

1) Your list of "goals," item 2, wholly omits such matters as assuring public participation in rulemaking, increasing public knowledge of the law, acting so as to foster (to the extent possible) SDO standard formation through procedures like those of §553, etc. These are all governing norms of public law. Listing only one side of an important balance is distorting.

2) Your definition in 3b of "standard" does not include "basic or essential regulatory requirements" in what "the term 'standard' does not include." Nor does it say that standards should always be used in a manner supplementing, not substituting for, public regulations. Such a statement is made particularly important by your proposal's guidance, as in 6a, when an agency "must" use voluntary consensus standards.

3) 3d neglects to state that, in order to incorporate a standard by reference as a mandatory requirement, an agency must be able to demonstrate to the Director of the Office of the Federal Register that it will be reasonably available.

4) The second paragraph of 6a appropriately is qualified by "to the extent consistent with law," but fails to note that departures from voluntary consensus procedures make the use of non-consensus standards inappropriate in connection with notice-and-comment rulemaking setting regulatory obligations, absent particularly full attention to the completeness of information provided the public during the rulemaking process.

5) 6c should include "stating the essential requirements of regulation" as an element of what regulatory authorities and responsibilities include.

6) 6e(i) should say "are more appropriate than" rather than "warrant less scrutiny by an agency than," and add after "objective" ", and standards must not be used to set essential regulatory requirements."

7) The second paragraph of 6e(ii), third line, should refer to the affected public generally, not only to "standards implementers."

8) 6e(iii)(1) is improperly worded in a manner that invites the use of standards as a substitute for, rather than a supplement to, essential regulation. As we have noted above and in our comments in the OFR rulemaking, NTTAA and prior OIRA discussion of A-119 both properly reflect the latter understanding. Few of the factors listed under (1) are evocative of the definitions of 3(a), which all reasonably suggest regulation-supplementing, not regulation-substitution. For example, this subsection's stated concern that a standard establish performance rather than design criteria where feasible is strongly suggestive of the characteristics of the essential requirements that should only be achieved by regulation. 6k is subject to the same objection.

9) As reflected in the general comments above, 6e(iii)(3) and (4) are insufficiently discouraging of the use of standards for regulatory (as distinct from procurement) purposes when they have not been generated by VCS bodies. 6f(iii) is equally objectionable in this regard, in its failure to direct agencies in such cases to give special attention to the openness and sufficiency of their own §553 processes.

10) 6j and 6l, addressing intellectual property rights, appropriately invoke the non-discriminatory licensing approaches the WTO and other bodies require where standards and patents are intertwined. Less appropriately, they simply require agencies to "observe and protect the rights of the copyright holder," rather than reflecting the important public policy requiring that access to law be provided. Consequently, your guidance should make clear to agencies that, at the very least, their obligation is to work with an SDO to provide the maximum feasible access to incorporated standards imposing legal obligations. As major SDOs are in fact providing read-only access to standards on their websites without apparent harm to their business model, and incorporation will frequently capture only minor elements of an SDO's complete standards, it will often if not always be true that free public access can be provided without compromising important SDO interests. This wording does not invite those efforts, which the important public policy elements of accessibility to law demand.

11) 6n also fails fully to reflect governing law. The "alerting" that occurs – entirely proper to suggest — should include other unmentioned elements:

- assuring public access to the studies and technical data underlying the consideration of standards,
- working with SDOs to maximize access to the standards process by small and medium sized enterprises and public interest organizations that might otherwise face significant financial barriers to participation,
- providing the public with information about the positions taken by the agency in the SDO process,

etc. The provisions of 5 U.S.C. 561 et seq. governing regulatory negotiation provide an appropriate model, and should be invoked here.

12) 6o is a welcome provision in many respects. It could be noted that the use of standards as guidance about means to achieve compliance with regulatory requirements whose essentials are independently stated, the European model for standards use, would permit more efficient updating. If standards are adopted as guidance, and not rules with the force of law, then rulemaking (as such) would less often be required. In this respect, the paragraph beginning "In the interest of transparency" is seriously misleading. An accurate wording might be

> When standards are referenced as guidance about means of achieving compliance with regulatory requirements independently stated, they are not and may not be made formally mandatory. Of course, many entities will find it more convenient to adhere to them than to determine for themselves effective means of regulatory compliance. Nonetheless, they would remain free to adopt other means of compliance. In such cases, the only proper issue on enforcement or other determinations of legality would be whether the regulatory requirements had been met.

13) The objectionable weaknesses of "take into account" in 6p, and of appearing to devolve the determination of "reasonably available" on the agency rather than on the Director of the Office of the Federal Register, as 5 U.S.C. 552(a)(1) provides, have already been addressed.

Thank you for your consideration of these comments.

Respectfully submitted,

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