

August 16, 2002

Belinda L. Collins, Ph.D.
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Dear Dr. Collins:

At the last meeting of the Interagency Committee on Standards Policy (ICSP), you requested Federal agency comments on a proposal by the National Issues Committee (NIC) of the American National Standards Institute (ANSI) to revise Public Law (P.L.) 104-113, the "National Technology Transfer Advancement Act." The proposed revision is described in a draft letter, dated March 26, 2002, from ANSI to The Honorable Vernon J. Ehlers, Chairman of the Subcommittee on Environment, Technology, and Standards, Committee on Science of the House of Representatives. The proposal reads as follows:

"The current version of any voluntary consensus standard shall be deemed to satisfy any reference in law or regulation to any earlier version of the same standard, provided that within 6 months of promulgation of the new standard, or within 1 year of the adoption of this section, whichever is later, the agency using that standard has not made a declaration disavowing its further use."

The U.S. Nuclear Regulatory Commission (NRC) appreciates the opportunity to comment on this draft proposal. While the proposal may have advantages for some Federal agencies, it raises several legal and technical concerns for the NRC, which, by law, performs regulatory functions in the field of nuclear energy. The remainder of this letter summarizes our concerns; more detailed comments are set forth in the enclosure to this letter.

First, regulatory agencies, such as the NRC, have their missions clearly defined in law. The NRC's primary mission is to regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of the public health and safety, to promote the common defense and security, and to protect the environment. This is inherently a governmental function. The NRC does endorse many consensus standards to support its decision making processes. However, many of the consensus standards are not specifically developed with an eye to the NRC's regulatory mission and may require clarification or limitation to support the NRC's needs. Unlike the statute under which the Federal Aviation Administration (FAA) acts, the Atomic Energy Act (AEA) of 1954, as amended, does not give the NRC specific statutory authority to rely upon private entities to conduct certain specified

safety oversight activities. Thus, the NRC does not believe that the AEA would permit the NRC to rely upon industry consensus standards without independent NRC review and approval of those standards.

Second, we believe that the proposal would adversely affect the public's perception of, and confidence in, the NRC's regulatory functions. Currently, the Administrative Procedure Act (APA), 5 U.S.C. 551 et seq., requires the NRC to publish in the *Federal Register* a statement of the bases for adopting each rule and regulation. The ANSI proposal would presumably supersede this requirement, and would require the agency to publish a "declaration" only when the agency chooses to "disavow" use of the latest version of the standard. Thus, under the ANSI proposal, the public would no longer have an opportunity to comment on new standards before they are adopted or endorsed by the NRC. Indeed, the public would not be able to review the agency's bases for adopting or endorsing the latest version of the standard, as they currently can under the existing provisions of the APA and the Commission's notice-and-comment rulemaking procedures. Although we recognize that an agency could, as a matter of discretion, voluntarily publish a *Federal Register* notice setting forth the reasons for not objecting to the use of an updated voluntary consensus standard, as a practical matter this would be unlikely to occur given the agency's budgetary limitations and the extremely short time (6 months) that the ANSI proposal allows for an agency to declare its disavowal of the use of the updated standard.

Third, we believe that implementation of the proposal would require the NRC to increase significantly the resources that the agency devotes to voluntary consensus code activities. The NRC would be required to devote considerable new dedicated resources to reviewing voluntary consensus standards revisions to enable the agency to issue a statement disavowing the use of certain provisions of a revised standard within the required 6-month period, if such a statement were deemed necessary upon completion of the agency's expedited review. In this regard, we also note that the ANSI proposal is not clear as to whether it covers something that is not a "law" or "regulation" containing a "reference" to a voluntary consensus standard. The NRC endorses the use of voluntary consensus standards through regulations codified in Title 10 of the *Code of Federal Regulations* (10 CFR) and in many other ways, including regulatory guides, information notices, and office letters. If the ANSI proposal is interpreted to apply to the informal NRC endorsement of voluntary consensus standards, the NRC would have to increase dramatically the resources that the agency devotes to reviewing voluntary consensus standards so as to ensure proper oversight and review within the 6-month period for disavowal.

For these reasons, we believe that the ANSI proposal in its current form will have the effect of *discouraging* future NRC endorsement of voluntary consensus standards – an outcome which is not in the interests of the NRC or its stakeholders. We recognize that the ANSI proposal appears to address an issue raised by many standards developing organizations (SDOs), namely, the lack of timeliness in endorsing voluntary consensus standards revised by the SDOs. The ANSI proposal may also facilitate the use of the latest voluntary consensus standards (e.g., in Federal acquisition and procurement regulations in a manner that is acceptable to other Federal agencies that do not have a regulatory function). Therefore, we recommend that ANSI revise the proposal to address the matters identified in this letter and its enclosure. Moreover, in order to recognize the unique functions and responsibilities of regulatory agencies, we recommend that ANSI revise the proposal to allow agencies to choose

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either the notice-and-comment provisions that the current APA embodies for adopting new versions of voluntary consensus standards, or a modified version of the ANSI proposal which addresses the issues raised in the enclosure to this letter.

Again, the NRC appreciates the opportunity to comment on the ANSI proposal.

Sincerely,

/RA/

Richard A. Meserve

Enclosure: As stated

**NRC DETAILED COMMENTS ON ANSI PROPOSAL TO REVISE PUBLIC
LAW 014-113,NATIONAL TECHNOLOGY TRANSFER ADVANCEMENT ACT”**

1. NRC believes that the ANSI proposal to revise P.L. 014-113 may be, or is, inconsistent with the current provisions of the Administrative Procedure Act (APA). Consequently, the NRC strongly recommends that ANSI revise the proposal to specify the applicability (or lack thereof) of the notice-and-comment rulemaking provisions in 5 U.S.C. 553.
2. The NRC manifests its *generic* endorsement of specifically identified voluntary consensus standards in a variety of documents other than rules and regulations codified in the Code of Federal Regulations (CFR). Among others, these documents include Commission policy statements, regulatory guides, standard review plans, agency reports, and information notices. The NRC also endorses on an *individual, case-specific* basis the use of specifically identified voluntary consensus standards in various documents, such as safety evaluations of stakeholder-submitted topical reports. Moreover, the NRC includes in legally binding documents (such as license conditions and technical specifications) references to specifically identified industry consensus standards. It is unclear whether the ANSI proposal would cover the reference to voluntary consensus standards in all, some, or none of these situations, inasmuch as the ANSI proposal refers to “law or regulation.”¹
3. The NRC also notes that the ANSI proposal would appear to extend to voluntary consensus standards that are referenced in Federal statutes, inasmuch as the term, “law,” at minimum, embraces a Federal statute. However the ANSI proposal would also appear to extend to references to voluntary consensus standards in State laws and regulations. We question whether this is the intent of ANSI, and recommend that ANSI should clarify the language of the proposal to refer to “Federal” law and regulations.
4. Currently, an agency that wishes to ‘incorporate by reference’ a voluntary consensus standard into the agency’s regulations, must meet the current Office of the Federal Register (OFR) regulations for incorporation by reference (1 CFR Part 51), which require that (i) the agency must obtain OFR approval for each proposed document to be incorporated by reference into the *Code of Federal Regulations* (CFR), and (ii) the rule incorporating a publication by reference must “state...the title, date, edition, author, publisher, and identification number of the publication.” The ANSI proposal would render meaningless the current OFR requirements and would result in CFR references that do not, in fact, reflect the current regulatory requirements with respect to identifying the current voluntary consensus standards which, by virtue of the ANSI proposal, have legal force and effect as binding regulatory requirements.

¹We note that 5 U.S.C. 553(b)(A) excludes “interpretive rules” from the notice-and-comment provisions of that section. The NRC has taken the position that agency guidance documents, such as Commission policy statements and regulatory guides, constitute “interpretive rules” to which the notice-and-comment provisions of 5 U.S.C. 553 are not applicable.

5. The ANSI proposal refers to an agency's "declaration disavowing [a voluntary consensus standard's] further use." The proposed language does not make clear whether the agency may "disavow" one or more individual provisions within a voluntary consensus standard, or whether the agency may only object to the entire standard.
6. The ANSI proposal also states that the "agency using that standard" may make the declaration disavowing the standard. The term, "using that standard," is unclear, inasmuch as there may be more than one agency using the voluntary consensus standard in the same area of regulation. This could result in a situation where the agency originally promulgating the rule adopting the voluntary consensus standard has no objection to the updated/revised standard, but another agency "using" the standard objects to the update/revision and issues a declaration disavowing the use of the updated/revised standard. The ANSI proposal is unclear as to whether the second agency's action has any effect on the originally promulgating agency's use of the updated or revised standard.
7. The ANSI proposal states that the declaration would disavow "further use" of a voluntary consensus standard. Does this refer to use of the standard after the agency issues its disavowal? What is the status of a regulated entity that adopts the use of an updated or revised voluntary consensus standard in the 6-month period after the standards developing organization (SDO) finalizes and approves the standard, but before the agency issues its disavowal?
8. The nature and content of the "declaration" of disavowal is unclear. For example, would the declaration simply declare the agency's "disavowal" of (disagreement with) the voluntary consensus standard, or would the agency be required to provide a statement of bases for its disagreement?
9. The ANSI proposal also does not address the manner in which the declaration is made known to the public and affected regulatory entities; would the declaration (and any necessary statement of bases for the declaration) be required to be published in the *Federal Register*? Would the agency be required to publish the proposed declaration for public comment before finalizing the declaration, and if so, what would be the effect on the interim use of the new standard?
10. What would be the effect, or legal applicability, of other statutory requirements that currently affect agency rulemaking, such as the Paperwork Reduction Act, Small Business Regulatory Enforcement Fairness Act, etc.? For example, would the revised paperwork burdens stemming from an updated or revised voluntary consensus standard have to be reported to the Office of Management and Budget (OMB) and on what schedule?