

January 28, 1999

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: NRC PARTICIPATION IN THE DEVELOPMENT AND USE OF CONSENSUS STANDARDS

PURPOSE:

This Commission paper responds to the codes and standards portion of the SRM for SECY-97-303, "The Role of Industry (DSI-13)," and provides the Commission with recommendations on using NRC resources to more effectively and efficiently participate in the development and use of consensus standards. This paper also describes a program consistent with the Commission's direction in COMSECY-96-062.

SUMMARY:

This paper summarizes and analyzes comments received ([Attachments 1 and 2](#)) during stakeholder meetings that addressed NRC participation in the development and use of consensus standards. A program is outlined that would (1) define the agency's policy and objectives and the staff's responsibilities for the development and use of standards, (2) promote the efficient use of NRC resources by focusing staff participation on developing standards to more specifically address defined regulatory needs, (3) address stakeholder comments by implementing defined options that, among other things, would improve communication with standards developing organizations (SDOs) and the timeliness of standards endorsement, (4) implement Federal requirements for agency participation in the development and use of consensus standards, and (5) provide for the monitoring and evaluation of internal performance indicators to ensure program efficiency and effectiveness. The program is provided in the form of a detailed outline for a proposed management directive ([Attachment 3](#)).

BACKGROUND:

In September 1996, the Commission published a series of Direction Setting Issue (DSI) papers as part of the Strategic Assessment and Rebaselining Initiative. One of the papers, DSI-13, "Role of Industry," identified options for placing further reliance on industry activities as an alternative to NRC regulatory activities. A major topic of that paper was the use of voluntary consensus codes, standards, and guides as an option for improving the effectiveness and efficiency of the regulatory process. For simplicity, voluntary consensus codes, standards, and guides will be referred to in this paper as consensus standards. For reference, a consensus standard is the product of an SDO operating with openness, balance of interests, due process, an appeals process, and consensus, which represents general agreement but not necessarily unanimity. It should be recognized that usually only one NRC representative participates on a given committee while the balance of members include the utilities, vendors, consultants, and other participants.

COMSECY-96-062 on DSI-13 provided direction with regard to industry initiatives as an alternative for NRC regulatory activities and NRC use of codes, standards, and guides. The staff's response was provided in SECY-97-303. The SRM for SECY-97-303 specifies that separate papers be prepared for (1) industry initiatives as a substitute for regulatory action and (2) the use of consensus standards in the regulatory process. The use of industry initiatives and consensus standards are related in that both industry initiatives and consensus standards may serve, in specific instances, as substitutes for regulatory actions. However, because of the usually lengthy process required to develop consensus standards, particularly complex ones, their use would likely be limited to initiatives that do not require immediate resolution, while industry initiatives would address initiatives that do. The staff believes that both industry initiatives and consensus standards can serve industry and NRC needs and that the preferred path should depend on the particular situation.

This paper discusses the issues related to the development and use of consensus standards; a separate paper is being prepared to address industry initiatives as a substitute for regulatory action. The SRM to SECY-97-303 approved the staff's recommendation to meet with stakeholders to discuss issues related to NRC endorsement of consensus standards, including the potential for streamlining the process. Further, that SRM directed the staff to (1) provide the Commission with an analysis that includes a review of stakeholder comments, identification of resources required and their associated impacts, and recommendations, (2) obtain feedback from stakeholders on how best to use the approximately 10 FTEs already allotted to codes and standards endorsement, look at methods to set priorities, or investigate more efficient methods for the work being contemplated, and (3) inform the Commission and provide the basis, when the NRC staff proposes to use its own standard in a regulation in lieu of a consensus standard. Interim guidance on this issue was disseminated to the NRC staff⁽¹⁾; a report to the Commission is not required when the staff proposes to use industry developed guidelines in lieu of a consensus standard.

Shortly before the DSI-13 paper was issued, the National Technology and Transfer Act of 1995 (Public Law (P.L.) 104-113) was enacted on March 7, 1996, to promote participation by Federal agencies in the development and use of consensus standards. P.L. 104-113 requires an agency to use a standard developed by a consensus body unless such use is inconsistent with applicable law or is otherwise impractical. The law requires a report from the head of the agency to the Office of Management and Budget (OMB) whenever the agency uses its own standard (i.e., a government-unique standard) in a regulation or procurement, instead of utilizing an existing consensus standard.

OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment," revised on February 19, 1998, provides specific guidance for implementing P.L. 104-113. This guidance includes issuance by the head of the agency of an annual report on the agency's participation in the development of and use of consensus standards. The annual report identifies and provides the basis for instances during the year of the agency's initial use of its own standard in a regulation in lieu of an existing consensus standard. Further, the OMB

circular specifies that each agency must select a senior level manager as the agency's Standards Executive responsible for coordinating the agency's activities to implement P.L. 104-113. The circular further specifies that agency staff participating on standards committees do so as authorized agency representatives who, among other things, are responsible for expressing views that are in the public interest and, as a minimum, do not conflict with the interests and established views of the agency.

The NRC Strategic Plan (FY 1997 - 2002) incorporates the implementation of P.L. 104-113 by specifying that, in the areas of nuclear reactor safety and nuclear materials safety, "We will increase the involvement of licensees and others in our regulatory development process consistent with the provisions of the National Technology and Transfer Act of 1995. We will encourage industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by the industry."

DISCUSSION:

The NRC staff conducted two stakeholder meetings to identify issues and develop options for NRC participation in the development and use of consensus standards. The first meeting, held on July 7, 1998, was with the NRC staff (internal stakeholders) to discuss issues and options related primarily to NRC participation on standards committees. This meeting included staff from the Office of Nuclear Regulatory Research (RES), Office of Nuclear Reactor Regulation (NRR), Office of Nuclear Material Safety and Safeguards (NMSS), Office for Analysis and Evaluation of Operational Data (AEOD), Office of the General Counsel (OGC), and the Advisory Committee on Reactor Safeguards (ACRS). Discussions focused on identifying options for improving the effectiveness and efficiency of NRC staff participation in developing consensus standards. The second meeting, held in Chicago on September 1, 1998, with external stakeholders included three breakout sessions; codes and standards development, endorsement, and use; industry initiatives as substitutes for regulatory action; and reporting requirements for nuclear power plants, transformation to a risk-informed framework, and regulatory effectiveness.

The codes and standards breakout session was conducted to solicit input from external stakeholders on how the NRC could more effectively and efficiently utilize consensus standards, including how and whether the endorsement process could be streamlined. The consensus standards meeting included representatives from individual utilities (reactor licensees), the Nuclear Energy Institute (NEI), SDOs (e.g., the American Society of Mechanical Engineers (ASME), Health Physics Society (HPS), and American Nuclear Society (ANS)), entities in support of the nuclear power industry and nuclear materials industry (e.g. manufacturers, consultants, service organizations), State government, a public interest group, and individual members of the public. A summary of the internal stakeholder meeting is provided in [Attachment 1](#). A summary of the external stakeholder comments, an analysis of those comments and identified options for addressing them are provided in [Attachment 2](#). A transcript of the September 1, 1998, meeting was made available to the public on the NRC external web site shortly after the meeting.

Based on input from the stakeholder meetings and its own experience, the staff has developed a program in the form of an outline for a proposed management directive ([Attachment 3](#)) to improve its participation in the development and use of consensus standards. The major elements of this program and their basis are described in the remainder of this paper.

NRC Participation in the Development of Consensus Standards:

The NRC staff has always participated actively in the development of consensus standards. At present, 145 staff participate on 254 committees of 16 SDOs. These committees cover a broad range of SDO activities, including formulation of standards at the writing committees, voting on provisions of standards at the consensus committees, and establishing technical direction at the supervisory boards. NRC staff typically become involved in a standards activity based upon a request from an SDO to participate in the development of a specific standard. SDOs consider NRC membership on the various levels of committees to be an important factor in achieving future regulatory endorsement of a new or revised standard.

NRC staff are selected to represent the agency on specific committees primarily because of their technical expertise and functional responsibilities, thereby being cognizant of the technical and associated regulatory issues. Once assigned to a standards committee, staff members generally have a long-term relationship with the committee and may become associated with other committees within that SDO. NRC committee members are responsible for coordinating their ballot positions with cognizant members of headquarters and regional staff during the development and approval of new or revised standards. Coordination is important in obtaining sufficient information to present an appropriate staff position along with any applicable regulatory requirements for consideration by the committee. This helps limit or avoid the need for the NRC to place limitations or modifications on the standard when using it in a regulation, regulatory guide, or other regulatory document.

Comments from stakeholders on NRC participation in the development of consensus standards generally pertained to (1) NRC communication with SDOs and (2) participation of NRC staff on SDO committees. These comments are discussed below. Guidelines for addressing these issues will be provided in the proposed management directive as detailed in [Attachment 3](#) in the proposed Handbook, "Procedures: Part 1 - Participation in the Development of Consensus Standards."

Communication with SDOs. A concern expressed by external stakeholders was that NRC communication with SDOs was generally infrequent and not proactive. The SDOs want to communicate more frequently with the NRC, with other SDOs in attendance, to describe their ongoing activities and to develop a better understanding of NRC needs regarding standards development and use. The staff agrees that communication with SDOs is a primary area for improvement and proposes action to foster a better understanding of NRC needs and resources and the interests of the public, industry, and SDOs by holding periodic coordination meetings with key SDOs and other stakeholders. The NRC already meets periodically with the ASME. These public meetings would provide an opportunity for the NRC to identify (1) specific standards where the NRC could participate in the initial development or revision and (2) the regulatory need and underlying regulatory requirement for the standards activity. These meetings, which are expected to be held annually, would be coordinated by the NRC Standards Executive. Such meetings would help address the NRC Strategic Plan commitment to utilize consensus standards to increase the involvement of licensees and others in its regulatory development process, consistent with the provisions of P.L. 104-113 and OMB Circular A-119.

Participation of NRC Staff on SDO Committees. Recognizing that staff participation on standards committees is a resource issue, as it is for others on the committees, stakeholders were especially concerned that cognizant staff might not continue to be available on writing committees. A desire was expressed by stakeholders for NRC staff to expand its participation on writing committees to ensure that technical and regulatory concerns of the staff are adequately presented and discussed during early phases of standards development. In addition, stakeholders strongly encouraged NRC staff to coordinate standards issues within the NRC as early as possible. Stakeholders believe that having NRC staff involved in endorsement on writing committees will help ensure better technical alignment between the standard issued and the needs of the NRC. The staff agrees with this view, but recognizes that, in order for it to be effective, the SDOs must be in agreement with this philosophical approach.

NRC staff currently participate on a broad range of committees at multiple levels, including many writing committees. Although P.L. 104-113 and OMB Circular A-119 promote Federal agency participation on SDO committees, these government-wide requirements contain the caveat that such participation be, among other things, within agency budget resources. The staff proposes to (1) continue its participation on SDO writing committees when a standard is actively being developed that is tied to a defined NRC need and to ensure early management involvement in decision making, and (2) reduce the level of participation on other writing committees or at other levels. This realignment would occur primarily through annual office reviews of NRC needs for development of new or revised standards and the assessment of needed staff participation on SDO committees by each individual's management. This assessment would take into account ongoing or planned industry actions to address specific issues through the development and use of consensus standards, or other industry voluntary initiatives. The staff expects that these reviews will focus NRC resources on standards most important to the regulatory program and will reduce the amount of staff participation. This reduction in participation may result in increased staff effort to review final versions of consensus standards and may result in the need for NRC limitations or modifications to assure the standard is consistent with regulatory requirements. The overall desired result is to improve the effectiveness and efficiency of NRC resources expended on consensus standards activities. It is expected that the periodic coordination meetings with SDOs and other stakeholders discussed above would supplement the staff's input to and knowledge of ongoing SDO activities.

NRC Use of Consensus Standards

The NRC may use a consensus standard as a mandatory requirement or as a voluntary provision. Mandatory use occurs through incorporation of a consensus standard in a regulation, license condition, order, or technical specification for individual licensees or certificate holders. Regulatory guides, or in the materials area, NUREGs and regulatory guides, that identify an acceptable method for licensees to comply with NRC regulations, are the primary mechanisms for allowing voluntary use of consensus standards by licensees and certificate holders. Currently, there are approximately 20 consensus standards mandated through rulemaking, and hundreds of consensus standards are endorsed for voluntary implementation through regulatory guides and NUREGs.

Topics related to the endorsement of standards that were discussed at the stakeholder meetings include (1) the timeliness of endorsement, (2) NRC limitations and modifications on consensus standards, and (3) the 120-month mandatory update in [10 CFR 50.55a](#). Each of these issues is discussed below. Guidelines to address these issues are provided in the proposed management directive as detailed in the [Attachment 3 Handbook](#), "Procedures: Part 2 - Use of Consensus Standards."

Timeliness of Endorsement. Stakeholders commented that the current NRC process for initially endorsing and updating references to standards in regulatory documents is generally too slow to enable industry to use new or revised standards in a timely manner. In the case of [10 CFR 50.55a](#), which mandates use of the ASME Code for construction and inservice inspection and testing of nuclear power plant components, and the regulatory guides that endorse ASME code cases, that provide alternatives to specific provisions of the ASME Code, nuclear power plant licensees have taken to submitting specific requests for use of later versions of these consensus standards that have not yet been generically endorsed. The use of frequently revised standards in the regulations is problematic in terms of timeliness because attempts to have the regulation reflect the most current version of a standard that is updated annually, for example, would place the regulation in a state of perpetual rulemaking. An example of this is the incorporation by reference of the ASME Boiler and Pressure Vessel Code, which is revised annually, into [10 CFR 50.55a](#). Whether it is advantageous to reference specific standards in the regulations is dependent on the specific case, however the staff considers it inefficient to reference a standard that is revised frequently in a regulation.

To contribute to the early identification, and subsequent timely endorsement, of needed new and updated referenced standards, the NRC staff intends to establish a systematic process for (1) identifying agency needs for standards to address items such as specific technical issues, new technologies, or regulatory processes, and (2) staying abreast of industry standards initiatives and SDO actions through annual and routine ongoing meetings with SDOs, industry, licensees and other stakeholders. Further, this process would implement the provisions of OMB Circular A-119 to review the agency's use of standards for updating as necessary by including a systematic review of existing rules, regulatory guides, and other regulatory documents that reference standards to determine whether there is a need to update or incorporate new standards. Such an ongoing process could initiate the timely reference of new or updated standards.

To endorse standards in a more timely manner, the staff proposes that criteria be established for determining the preferred endorsement method for specific situations. Examples of such methods would be the use of direct final rules, regulatory guides in place of regulations, and NUREG reports as used by the Office of Nuclear Material Safety and Safeguards (NMSS). In the direct final rule option, if no significant adverse public comments are received within a specified time-frame, the rule becomes final. If warranted by comments received within the specified time-frame, the process reverts to a proposed rule in which comments are resolved and a separate final rule is issued. Incorporation by reference of consensus standards in NRC regulations could be appreciably shortened by the direct final rule option when use of the standard is noncontroversial and no NRC limitations or modifications are imposed on the standard. A shortened endorsement process could also be achieved by changing the method of endorsement. Standards incorporated by reference in regulations could alternatively be endorsed for voluntary use in regulatory guides, which generally have a somewhat shorter development period. Under this approach, the regulation could be rewritten to be performance-based.

NMSS has significantly shortened the time to endorse standards by using an integrated approach which consolidates current guidance (e.g., regulatory guides, standard review plans, policy and guidance directives, information notices, and references to acceptable standards) for a specific materials use into a single NUREG report. The NUREG becomes the Standard Review Plan for that use. The reference of standards in the NUREG provides the licensee the option to use the latest referenced consensus standards. Licensees document their intent to use procedures from the NUREG that incorporate selected standards in their radiation protection program (10 CFR Part 20.1101). Under this approach, a licensee's failure to implement a selected standard referenced in its radiation protection program could result in enforcement action. The NUREGs are developed using a multi-team approach with intra-office support that provides for earlier input from cognizant offices thereby avoiding delays that could occur during later office reviews. Some of the benefits of this process are that applicants, licensees, and NRC staff find all the relevant information in one location, and updates to the references, such as standards, occur faster because the staff is focused on updating a single document instead of many. The regulatory guide process could be adapted to elements of this NMSS process as well. The current NMSS schedule shows completion of approximately 22 final NUREGs by December 2000. NRR and RES adopted a similar integrated approach in the development of risk-informed regulatory guides and standard review plans. In all methods described above for adopting consensus standards, the referencing document is noticed in the Federal Register for public comment before it is made effective in final form.

A standard could be endorsed at a significantly earlier date if the endorsement process were started before the SDO issued the final standard. This approach would be resource intensive and the staff would need to be selective in identifying and prioritizing standards to be considered for endorsement. A recommendation was made by an SDO to maximize concurrency of the NRC and SDO public review process. One way to implement that suggestion would be to use the SDO public review period as a "trigger" for initiating NRC action to endorse the standard. Other efficiencies that could complement this process would be to use interoffice, interdisciplinary teams to develop regulatory positions during development of the standards to prevent surprises during the endorsement process, and to reduce paperwork through the elimination of any overlapping internal requirements for documented analyses.

It is important to note that, although the staff can create an environment favorable to timely endorsement, whether the standards are developed in a way that would enable timely endorsement will be dependent on the cooperation between the NRC staff and SDO committee participants and on the actions of the SDO that lead to a standard that is consistent with identified regulatory needs.

NRC limitations and modifications on consensus standards. A comment expressed by stakeholders was that they believe it is inappropriate for the NRC to place limitations or modifications on consensus standards because the standards have been developed in an open consensus process. Stakeholders expressed concern that having an NRC representative on standards writing and approval committees did not ensure that a given standard would be endorsed without supplemental limitations or modifications.

The NRC imposes a limitation or modification on a consensus standard when, in its view, the consensus standard does not adequately address a specific regulatory issue, the standard is technically incorrect, or it is inconsistent with current regulations. NRC does not take lightly the limitations and modifications it sometimes imposes on consensus standards. Such exceptions are subject to stakeholder comment as part of the public review period conducted as part of proposed rulemaking or regulatory guide development. In this context, it should be understood that (1) SDOs are responsible for developing standards consistent with the consensus process and NRC representatives constitute only part of that process, and (2) the NRC is responsible for establishing regulatory requirements and may use appropriate consensus standards to complement those requirements, subject to public comment. Since the NRC has specific regulatory responsibilities, and consensus standards are sometimes written with a focus on burden reduction that in the judgement of the NRC staff does not provide an adequate basis for regulatory requirements or guidance, the NRC must reserve the right to limit or modify any consensus standard it uses as part of its regulatory process.

Better understanding of the issues through meetings with SDOs and other stakeholders and closer coordination of staff and SDO participants at writing committees, including the development of better documented justifications by all committee participants for significant actions, may reduce the need for exceptions. In the long-term, this approach should result in standards that better satisfy user needs and result in fewer NRC exceptions.

Mandatory 120-month Update in 10 CFR 50.55a. As proposed in SECY-97-303, the mandatory 120-month update was discussed during the September 1, 1998, meeting with external stakeholders. The 120-month update provision in 10 CFR 50.55a requires licensees to update their inservice inspection (ISI) and inservice testing (IST) programs every 120-months to the edition/addenda of Section XI of the ASME Boiler and Pressure Vessel (BPV) Code referenced in the regulations one year prior to the next 120-month interval. Because recent revisions to Section XI contain few safety-significant provisions, the 50.55a update typically results in licensees revising their programs to implement many nonsafety-significant actions. Past staff practice has been to revise 50.55a without explicitly addressing the provisions of 10 CFR Part 50.109, the backfit rule. Although the staff's position on the backfit rule for the 120-month update requirement remains valid, the staff considers the safety significance of periodic revisions to Section XI to be declining. In view of the burden imposed on licensees by the 120-month update, with little or no safety benefit, the staff is presently reassessing the need for that requirement and will present the results in a separate Commission paper.

Implementing P.L. 104-113 and OMB Circular A-119:

The direction and recommendations in this paper are consistent with P.L. 104-113 and its guidelines for implementation, OMB Circular A-119. There are several aspects of the law and circular that are noteworthy. OMB Circular A-119 specifies that each agency should "... establish a process for ongoing review of its use of standards for the purpose of updating such use." To this end, it is proposed that each applicable NRC office incorporate a review process into future operating plans that would implement an ongoing process for reviewing existing rules, regulatory guides, and other regulatory documents that reference standards, to determine whether there is a need to update or incorporate new standards to address specific technical issues, new technologies, or regulatory processes. In order to minimize the impact on resources, this would be integrated to the extent possible into the responsibilities for staff participation in standards development. The results of the individual office reviews would be coordinated through the NRC Standards Executive to prioritize agency-wide standards needs and to eliminate duplicate efforts. Guidelines for implementation of this process will be included in the proposed management directive described in Attachment 3. NMSS has initiated an effort to implement such a process for each of its

divisions. Standards identified by that review should be prioritized according to need and benefit for subsequent action.

With regard to regulatory and procurement activities, OMB Circular A-119 states "... all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments." An exception is provided in P.L. 104-113 for instances in which compliance would be inconsistent with applicable law or otherwise impractical. One approach to rulemaking, as specified in the previously noted interim guidance, would be to implement a process for each proposed rulemaking whereby, in the Statements-of-Consideration for the rulemaking, comments are requested regarding the proposed use of a consensus or government-unique standard. Procedures for implementing these provisions are outlined in the proposed management directive ([Attachment 3](#)) and the guidelines for requesting information on applicable consensus standards for regulations ([Attachment 4](#)).

Proposed Management Directive:

A management directive is outlined ([Attachment 3](#)), which when completed and implemented, will provide clear expectations to the NRC staff by defining the agency's policy and objectives and the staff's responsibilities for the development and use of consensus standards. The proposed policy is consistent with direction provided in the Strategic Plan for the use of standards. The proposed management directive would:

- Promote the efficient use of NRC resources by focusing staff participation on the development of standards determined to address a defined current or anticipated regulatory need.
- Address stakeholder comments by implementing defined options that, among other things, would improve communication with SDOs and the timeliness of standards endorsement.
- Implement Federal requirements for agency participation in the development and use of consensus standards.
- Provide for the monitoring and evaluation of internal performance indicators to ensure program efficiency and effectiveness.

The management directive would be made available to the SDOs and other stakeholders to foster better understanding of NRC participation in the development and use of consensus standards.

RESOURCES:

The SRM for SECY-97-303 stated that "Because it is unlikely the NRC will be able to budget for an additional 10 FTEs for earlier development of a regulatory position on emerging standards in order to streamline the endorsement process, the staff should obtain feedback from stakeholders on how to best use the approximately 10 FTEs already allotted to codes and standards endorsement. The staff should look at methods to set priorities, or investigate more efficient methods for the work being contemplated." The proposed program discussed above, including better management of staff participation in consensus standards development organizations and coordination meetings with these organizations are expected to result in resource savings and provide information that will be used to make decisions concerning the priority of staff activities related to codes and standards. The resources that will be expended to implement the program will be held to current levels and will be identified as part of the Planning, Budgeting and Performance Management Process. Factors that affect resources related to codes and standards activities are briefly discussed below.

Factors that affect the amount of resources expended include (1) enhanced coordination among NRC staff earlier in the standards development process to define agency positions, (2) enhanced coordination between the NRC staff and SDOs to better communicate NRC needs and priorities, (3) annual review by NRC of its standards needs and participation on SDO committees, and (4) annual coordination meetings with SDOs and other stakeholders. These factors will initially raise the overall resources required. In the initial phase, these resource needs will be accommodated on a case-by-case basis by ensuring that committee participation is focused on those activities that have a clear regulatory need. In the long term, it is expected that some efficiencies to reduce the resources required will be realized by better management of NRC staff participation in SDO activities, especially from a long-term reduction in the number of staff participating on SDO committees.

Other factors that could reduce resource needs in the long term include (1) more timely agency-wide adoption of consensus standards into the regulatory process could reduce the need for case-by-case requests by licensees and certificate holders to use later versions of consensus standards, (2) better coordination among NRC staff and between NRC staff and SDOs could result in the need for fewer exceptions when endorsing standards, which should result in reduced staff resources to endorse the standards, and (3) implementation of the OMB Circular A-119 provisions to review existing agency use of consensus standards to determine whether there is a need to update or incorporate new standards could promote more timely availability of new and revised standards in the regulatory process. The staff will approach the Circular's review of standards usage as a part of staff committee responsibilities, which should reduce the resources necessary because the staff will be more familiar with the subject matter. Certain aspects of the review will not be related to committee activities and that part of the review process may be more resource intensive. Because the OMB Circular does not define a time frame for completing the review, the review is intended to be ongoing at an available resource level.

RECOMMENDATION:

That the Commission note that, unless otherwise directed, it is my intention to affirm that the process outlined above for participating in the development and use of consensus standards should be formalized in a management directive within 6 months from the date of this paper. Staff requests action within 10 days. Action will not be taken until the SRM is received. We consider this action to be within the delegated authority of the EDO.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Chief Information Officer has no objection to this paper.

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Attachments: 1. [Internal Stakeholder Meeting](#)
2. [External Stakeholder Meeting](#)
3. [Outline Proposed Management Directive NRC Participation in the Development and Use of Consensus Standards](#)
4. [Guidelines for Statement of Consideration in Federal Register Notice on Use of Voluntary Consensus or Government-Unique Standards](#)

ATTACHMENT 1

INTERNAL STAKEHOLDER MEETING

- [I. Background](#)
- [II. Summary of Discussion](#)

I. Background

The NRC staff conducted an internal stakeholder (staff) meeting on July 7, 1998, to discuss issues and options related to NRC participation in the development and use of consensus standards. This meeting was, in part, preparatory for an external stakeholder meeting on related issues to be held in Chicago on September 1, 1998.

The internal stakeholder meeting included staff from the Office of Nuclear Regulatory Research (RES), Office of Nuclear Reactor Regulation (NRR), Office of Nuclear Material Safety and Safeguards (NMSS), Office for Analysis and Evaluation of Operational Data (AEOD), Office of the General Counsel (OGC), and Advisory Committee on Reactor Safeguards (ACRS). The staff discussed aspects of its participation on standards developing organizations (SDOs) and NRC endorsement of consensus standards. Training and background information was provided by RES staff who over viewed activities associated with Direction Setting Issue 13 (DSI-13), "Role of Industry," Public Law (P.L.) 104-113, "National Technology and Transfer Act of 1995," and OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities."

II. Summary of Discussion

The discussion focused on three specific issues: (1) options for staff participation on SDO committees, (2) responsibilities of staff participants on SDO committees, and (3) methods for NRC endorsement of consensus standards. A summary of each issue is provided below.

Options for Staff Participation on SDO Committees. SDO standards committees are generally hierarchal with the standards writing accomplished at the "lower" level, with reviews, consensus, and policy planning performed at successively "higher" committee levels. Currently, NRC staff tend to cover a broad range of committees. Options were considered to conserve resources while taking into account the effect of NRC's presence on the committees. Options identified for participating on SDO committees were to (1) discontinue staff participation at all committee levels, (2) participate only in higher level consensus balloting or supervisory committees as opposed to standards writing working groups, (3) participate only on select committees, and (4) continue current level of participation. The consensus among meeting participants was that the best option was a combination of options (2) and (3). This combined option would maintain NRC presence on high-level SDO committees, in which a range of new and revised standards are balloted and planned, and would focus participation of staff on specific writing committees whose product would satisfy a defined NRC need. More management attention would be needed to review and to eliminate all present committee participation that does not pertain to a specific product needed by the NRC. The combination of options (2) and (3) represents a good balance of resources and promotes review of individual staff participation on SDO committees. Option 1 was deemed to be unrealistic because it would put NRC completely out of touch with all SDO standards development and because it would be generally inconsistent with P.L. 104-113. Option 4 was not selected because it would continue participation of staff on a broad range of committees without consideration of specific NRC needs or resources.

Responsibilities of Staff Participants on SDO Committees. Discussions focused on the OMB Circular A-119 provisions which specify that agency employees who participate in standards activities of voluntary consensus bodies do so as specifically authorized agency representatives, consistent with agency missions, and will to the extent possible ascertain the views of the agency on matters of paramount interest to ensure that, as a minimum, expressed views are not inconsistent with established agency views. These requirements have been incorporated into recent letters nominating staff for participation on standards committees. Discussions also addressed the provision of the circular which requires each agency to select a senior manager as Standards Executive to be responsible for agency-wide coordination of standards activities; this action has been accomplished by the NRC. It was agreed that

agency-wide procedures, in the form of a management directive, are needed to define staff responsibilities, consistent with the circular, for participating on SDO committees and for coordinating these activities with other staff and agencies, as necessary, and that training would be required to familiarize the staff with the new procedures.

NRC Use of Consensus Standards. Methods identified for incorporating consensus standards into the regulatory process include (1) incorporation by reference in the regulations, (2) endorsement in regulatory guides, and (3) endorsement in standard review plans, branch technical positions, technical specifications, NUREG reports, and other such documents. It was noted that while approximately 20 standards are mandated through rulemaking, hundreds of consensus standards are endorsed for voluntary implementation through regulatory guides. It was further noted that the NRC needs to have varied mechanisms available for incorporating consensus standards into the regulatory process to adapt to case-by-case needs. It was recognized, however, that using a standard that is revised frequently in a regulation could result in perpetual rulemaking when the time between revisions of the standard is close to or shorter than the time to amend the regulation. It was agreed that criteria were needed to assist staff on a case-by-case basis in selecting the appropriate method for endorsing a consensus standard.

ATTACHMENT 2

EXTERNAL STAKEHOLDER MEETING

- I Background
- II Summary of Comments
 - NRC communication with SDOs
 - Staff participation on SDO committees
 - Timeliness of endorsements
 - Imposition by NRC of limitations and modifications
 - Implementation of 120-month update in CFR 50.55a
- III Analysis of Comments

I Background

An external stakeholder meeting was held in Chicago on September 1, 1998, to discuss various issues regarding, among other things, streamlining NRC staff participation in the development and use of consensus standards. (Additional parallel sessions discussed industry initiatives as substitutes for regulatory action, and improvements in regulatory effectiveness). The meeting on consensus standards was formatted as a day-long moderated panel session with audience participation. Attendees included representatives from SDOs, individual utilities, the Nuclear Energy Institute (NEI), industry (i.e., entities that serve nuclear power and nuclear materials industry, such as architect-engineers, manufacturers, nuclear steam supply system providers, consultants), state governments, public interest groups, universities, and the public. The morning session covered issues associated with staff participation on SDO committees, while the afternoon session focused on NRC endorsement of consensus standards. The afternoon session provided an opportunity for attendees to specifically discuss implementation of the 120-month update provision in 10 CFR 50.55a. A presentation was made by staff from the National Institute of Standards and Technology (NIST) to provide meeting attendees with an overview of P.L. 104-113 and OMB Circular A-119. [NIST is responsible for coordinating implementation of the law and circular among Federal agencies.]

II Summary of Comments

The discussion covered the topics of staff participation on SDO committees and NRC endorsement of consensus standards. For purpose of subsequent analysis, the comments have been grouped according to major issues that were identified. The 120-month update provision of [10 CFR 50.55a](#) was raised as a specific discussion topic by the panel moderator and related comments are provided for that issue as well. The comment groupings are (1) NRC communication with SDOs, (2) staff participation on SDO committees, (3) timeliness of endorsements, (4) imposition by NRC of limitations and modifications, and (5) implementation of 120-month update in 10 CFR 50.55a. The complete transcript for this meeting was sent to all meeting participants and made available to the public within a week after the meeting on the NRC web site at www.nrc.gov/NRC/STRATEGY/dsi13trans.html/.

Representative comments for each of the issue groupings are provided below. While the indicated comments are generally not exact quotes, the sense of all comments has been retained. Comments have been grouped to include supporting comments or to indicate differences in opinion. The source of the comment is indicated parenthetically following each comment. NRC staff comments have not been included in these groupings.

NRC COMMUNICATION WITH SDOS

1. NRC should be more proactive in communicating with SDOs on technical and planning issues. (SDO); Regular interaction with SDOs is critical to minimizing differences. (SDO)
2. Regulatory burden is a serious issue that requires active dialogue between SDOs and regulators. (SDO)
3. What is a good SDO, and how does a good SDO interact with the NRC? (SDO)
4. Industry needs to better define its needs. (SDO); Industry has to raise initial agenda, we have needs that you don't even know about. (Industry)
5. There should be a periodic meeting to discuss industry and regulator needs. (University)
6. What I would like to see is a more pro-active stance by the NRC staff in terms of direct communication with the SDOs on Code implementation problems, needs, priorities, justifications. And in turn, the SDOs should provide a timely response and update status on their standards activity.

This way we foster a two-way street and instead of the NRC being in the reactive mode, they're in a pro-active mode. (SDO)

7. Communication is probably one of the most important things for all of us to do. (University)
8. I would suggest that we try to break the mold of traditional approaches and look at using the technology we have for communicating, such as e-mail and chat rooms. (NEI); We now have standards development interactive forums on the web in which task groups are meeting in chat rooms. (SDO); SDOs should use new information technologies to improve the efficiency of the development process and reduce burden on volunteers. (Federal)⁽²⁾

STAFF PARTICIPATION ON SDO COMMITTEES

1. Staff participation should be part of a strategic standardization process that supports goals of the agency. (Federal); Decision for whether it's mission and function related should probably rest with the individual's manager. (Federal)
2. Participate on both higher and lower committees. (SDO); Participation should be broad, probably as broad as you can make it. (Federal); Most control is achieved on the writing group. (Federal); For resource reasons, NRC cannot participate on everything; focus on where regulatory leadership is needed and where you have technical expertise, monitor where you can't participate. (NP industry)⁽³⁾; I'd like to support participation at the grass roots level. (NP industry); Broaden participation at two levels, the people who participate in the development and the managers across NRC. (Federal)
3. What is philosophical goal for NRC participation? If it is to make a perfect (ASME) Code we're never going to get there. (Utility); Need to get participants to understand they represent the agency, and to work with others at the agency to establish consensus. (NM industry)⁽⁴⁾; OMB Circular is very clear that when a person goes to a standards meeting at government expense, they represent the agency. (Federal); I think standards bodies have to recognize those folks (NRC staff) have got a different role than a normal volunteer. (NP industry); You have to participate to get what you want in standards. (Federal); NRC representatives bring their best technical expertise and the committee should recognize that they are not espousing an NRC position on an issue or revision. They are bringing informed views that may have been reviewed internally. That should be the extent of it. (SDO); It appears the key is to get the role and responsibilities of the NRC representative clearly spelled out. (NM industry)
4. NRC concerns with standards should be expressed during the development process. (SDO)
5. Are staff participants on committees involved in endorsement process? (NP industry); Agency staff involved with endorsement of standards or licensing changes might be the key people for participation. (SDO); I'd like to see more of the NRC representatives on the committee involved directly in the endorsement process. (NP industry)
6. Need central person who coordinates agency's committee participation. (SDO); An agency needs to have one view of a particular standard, otherwise it frustrates the system. (SDO); May well need to look at something from a Federal point of view and offer like a half a day on how to participate on SDO committees. (Federal)
7. We meet just four times a year, so this is a minor part of activity; needs to be better coordinated back at agency to make better use of time spent. (SDO); Time to pull information together is (immediately) after every working meeting. (NM Industry); Working on agency standards policy which talks about why, what, when you're participating. Can't come back from meeting, leave everything in briefcase, and never think about it again until next meeting. Guidance will include agency policy, guidance, and probably training on what is meant by participation. (Federal)
8. Strategic standardization looks at the broadest goals of the agency and causes lower levels to assess how an individual project supports overall goals of agency. (Federal); NRC may want to look at the extent to which their mission, objectives and goals relate to standards development activities and get an outside entity to help. (NEI); Need NRC management recognition of the consensus standards process. (SDO)
9. To what extent is there public participation involvement in the SDOs? (Public interest); The public should be involved in the development of standards, at least one Federal agency provides a grant to an SDO to provide for public participation. (SDO); I think it's an issue of how do you maintain meaningful public participation if it appears that you are an agency delegating its regulatory standards development to what some people might view as esoteric closed bodies in which they have no input. Do you have people who might be critical of the nuclear industry serving on these committees, or is it just ordinary people and a few people from NRC? (Public interest); It's essential to get the public involved way up at the front end. (Federal); The NRC can post on its web page that an SDO is developing X-number of standards at a certain time and that it is taking a hard look at it from the standpoint of endorsement. That can be communicated to get the word out to the general interested public just to give them a heads up. (NEI)

TIMELINESS OF ENDORSEMENTS

1. NRC endorsement of standards must be timely. (SDO); Timely endorsement, but also timely writing of standards. (Utility); Endorse current version of standard, endorsement strengthens SDO. (SDO)
2. Needs to be consistent follow through between development of standard and what happens when it gets into NRC. (NP industry); It's so important that the individuals that participate then go on and become part of the rest of the regulatory process. (SDO); Timeliness of adoption is related to participation at right levels. (Federal)

3. What criteria are used to determine if a standard is used in a regulation, regulatory guide, branch technical position, or some other regulatory document? (Federal); Standards used through position papers, generic letters, inspection modules, etc, have great impact. How are they justified? (Federal); You develop a good set of performance-based requirements in rulemaking and that opens the door to the use of voluntary consensus standards. Licensees can use parts of standards. (Federal); NRC needs to give some thought to whether endorsement of a product that comes out of the standards community relates to a regulatory action of the form of rulemaking. The standard practice of using regulatory guides is palatable to the regulated industry because it offers an NRC communication that identifies one way NRC thinks is an acceptable way for doing something. I would submit that NRC could use something like an administrative letter to notify licensees that NRC thinks the standard offers some benefit and they endorse it (NEI); Standards need not always be endorsed through rulemaking, should reconsider the need to endorse voluntary standards in regulatory guides. (NEI)
4. May be an opportunity to streamline the endorsement process by categorizing revisions as technical and nontechnical (administrative) changes. (NEI); SDOs should not define what is or is not safety-significant. (NEI); NRC members that participate in the standards development process represent that agency. So once a standard is approved and goes through the consensus balloting, I'm not sure why there's a real need to do anything more than just say, okay, that's the position. Just go with the standards development process, make sure you're involved in the process for those particular technical issues that you're worried about and use the standards development process to be the regulatory development of the standard. (SDO)
5. It would seem to me that we ought to be able to somehow truncate the rulemaking process recognizing that the standards have been developed in an open and balanced way. (Federal); There could be a concurrent SDO and NRC public review. NRC could consider automatic endorsement within one year of issuance unless clarifications or modifications are identified. (SDO); Perhaps we should make rules performance-based and reference standards in regulatory guides. (SDO)
6. Interested in using consensus standards to even out playing field so that my members know what to expect. (SDO); Primary activity is now consideration of burden reduction, and that's very important to utilities. (SDO); If we're going to proceed with something that's a little more streamlined, I think we need to look at how we get information from the relief requests reviews up front where everyone can use it. (NP industry); Would like indication of NRC recognition of International Standards Organization (ISO) standards on material issues. (State)
7. NRC needs a change in goal which should be to accept and endorse standards, rather than we'll participate in the process, but if we don't like what comes out in the end, we'll change it. You need a management attitude from the top down. (Public); NRC should say we're going to use the voluntary standard system to develop our standard and that's how we're going to do it. (SDO)
8. Four issues affect endorsement. They are technical differences with SDO, 2-year administrative process, NRC as guardian of margin, and public opinion. If we can address each of these, we can make some real changes. (NP industry)

IMPOSITION BY NRC OF LIMITATIONS AND MODIFICATIONS

1. Although there may be good rationale for taking exceptions to the use of a standard, when the NRC does that, it fundamentally flies in the face of the consensus process. (NEI)
2. Concerned with NRC's use of standards where they re-interpret the words intended by the authors. (Utility)
3. The consensus standards process should be sufficiently open that all issues ideally would have been resolved during its development so that there should be no surprises for the Commission or anybody else when they go out in rulemaking. That's the theory. (Federal)
4. Negative example is the 50.55a proposed rule making in which there were a lot of surprises and restrictions placed after the fact, which might have been avoided earlier. (SDO)

IMPLEMENTATION OF 120-MONTH UPDATE IN CFR 50.55A

1. Try to determine the intent (of the 120-month update) to see if it's something that is still necessary. (Public interest); In 1971 it was far easier for the NRC (AEC) to just adopt what the ASME did as kind of shorthand for the NRC doing exactly the same thing itself. (NEI)
2. Once you establish a safety basis and keep the facility operating within the bounds of what you determine is adequate safety, that can be it. Other upgrades can be accomplished if they increase operational efficiency, reduce costs. There has to be a cost-effective basis for it. (Federal); (Later editions/addenda have) no significant changes to increase the safety of plants originally baselined to earlier editions and addenda, licensee could apply saved resources to safety-significant issues in other areas. (NP industry); I see no reason why we can't reference the '89 Edition as our base code for our ISI plan and if we wanted to use a more recent edition do a forward thinking relief request. (Utility)
3. Need to test modifications, limitations, exceptions in 10 CFR 50.55a against backfit rule. (NEI)
4. If the Code updates were voluntary, the incentive to make Code rules that would be additional requirements on utilities would be gone and the only rules that would be made are those that would be relaxing existing requirements. (NP industry); If we froze the Code at the '89 edition, there would be no purpose in having further meetings. There would be no further development to do. That would be the message. (SDO); I don't believe, if the Code were voluntary, that committees would lose their participation because the industry itself drives its needs and it will identify the issues that need to be addressed. (NP industry).

5. Training of NRC staff is needed to minimize inconsistent enforcement region to region and within headquarters. (SDO)

III Analysis of Comments

The above comments emphasize external stakeholder feelings regarding (1) the need for improved communication between NRC and SDOs, (2) the overall importance of the agency representative on SDO committees, and the need for such representation on the lower committees where standards writing actually takes place, (3) the need for timely NRC endorsement of consensus standards, (4) the belief that the NRC's imposition of limitations and modifications on consensus standards is contrary to the consensus process, and (5) the belief that the 120-month update provision in [10 CFR 50.55a](#) may no longer serve a useful purpose. Additionally, the stakeholders emphasized the need for NRC to be creative in developing ways to improve its participation in the development and use of consensus standards and to take a more positive approach to its use of standards. The staff recognized the need to look at new approaches consistent with its responsibility to ensure protection of the public health and safety.

The above issues, along with options for their resolution, are discussed below. In all cases, guidance for the options selected for each of the issues and other procedures would be incorporated into a management directive ([Attachment 3](#)) for agency-wide implementation.

NRC communication with SDOs. A concern expressed by external stakeholders was that NRC communication with SDOs was generally infrequent and not proactive. The SDOs want to communicate more frequently with the NRC with other SDOs in attendance to describe their ongoing activities and to develop a better understanding of NRC needs regarding standards development and use. The staff agrees that communication with SDOs is a primary area for improvement.

Options for improving communications with SDOs and other stakeholders with associated benefits and impacts are discussed below.

1. Hold annual meetings with SDOs -- Annual meetings with key SDOs and other stakeholders would promote a better understanding of mutual needs, abilities, and constraints. While such meetings would be helpful for planning purposes, they would not help communications on an ongoing basis.
2. Assign an NRC staff contact to SDOs -- Assignment of an NRC staff contact as a communication conduit with individual SDOs on an ongoing basis would help resolve coordination issues as they occur and would provide a mechanism for more effective ongoing interaction with the SDOs.
3. Enhanced staff involvement on SDO committees -- Guidance should be provided to the staff that clearly identifies the need for an authorized staff representative to present NRC concerns, appropriately documented, at standards writing and consensus level meetings. SDOs should recognize, however, that it may not always be possible to establish an NRC position at an early stage in the standards development process.

Staff participation on SDO committees. Stakeholders would like NRC staff to be involved in as many committees as possible, but they especially would like participation by cognizant staff on the writing level committees. In addition, they recommend closer coordination between staff on standards committees and staff developing the endorsement documents. Because staff participation at standards meetings is a resource concern, consideration should be given to balancing participation in the standards writing process with available budget and human resources. The staff currently participates on a broad range of committee levels on a total of 16 SDOs. Overall agency participation is estimated to be 10 FTEs (145 staff on 254 committees). The options for agency-wide committee participation on standards committees and their associated benefits and impacts are:

1. Discontinue or significantly reduce participation on all committees -- While FTEs and travel costs would be significantly reduced from the levels currently expended, lack of participation is inconsistent with the intent of P.L. 104-113 and OMB Circular A-119 which requires agency participation on standards committees consistent with agency missions and resources. NRC could be made aware of and review and endorse consensus standards based on specific requests from licensees or SDOs.
2. Participate only on higher level committees -- Higher level main committees are responsible for consensus and operate in accordance with American National Standards Institute (ANSI) provisions for consensus which include balance of interest, openness, and due process. Higher level supervisory committees provide policy and technical direction to the consensus and lower level committees. With this option, FTEs and travel costs would be reduced but there would be no participation at the standards writing level where staff participation is deemed to be important by staff and external stakeholders.
3. Participate only on select committees -- Staff would participate on SDO committees selected for participation based upon defined NRC needs. This could result in gaps in overall staff membership in committee hierarchies which could result in reduced influence in the development and approval process. Although SDOs would be receptive to NRC participation, it may not always be possible to join a committee on a case-by-case basis because of structured membership limitations; this is especially true of the higher level consensus and supervisory committees. This option would, however, provide a method for strategically focusing staff participation on writing committees and, thereby, reducing FTEs and associated travel costs.
4. Continue current level of participation -- Currently, staff participate on a broad range of committees (145 staff on 254 committees of 16 SDOs). Participation on many committees is based on continuing long-standing memberships as opposed to reassessing the need based on currently defined NRC needs. With this option, resources would not be reduced, nor would they necessarily be expended in the most efficient or effective manner.

Timeliness of endorsement. Stakeholders noted that the current NRC process for initially endorsing and updating references to standards in regulatory documents is generally too slow to enable industry to use new or revised standards in a timely manner. In the case of [10 CFR 50.55a](#), which

mandates use of the ASME Code, and the regulatory guides that endorse ASME code cases, which provide alternatives to the Code, nuclear power plant licensees have taken to submitting specific requests for use of later versions of these consensus standards which have not yet been generically endorsed.

Options for improving the timeliness of the NRC endorsement process for consensus standards and their associated benefits and impacts are discussed below.

1. Streamline the endorsement process: The present process for endorsing consensus standards in regulations or regulatory guides involves initial demonstration of need in a task initiation document, which, after approval by NRC management, is followed by development of the proposed rule or regulatory guide and supporting regulatory analysis. The package is then reviewed, as needed, by the NRC Committee for Review of Generic Requirements (CRGR), the Advisory Committee on Reactor Safeguards (ACRS) or the Advisory Committee on Nuclear Waste (ACNW), following which the proposed rule or regulatory guide is issued for public comment (approximately 60 days). Subsequently, the public comments are resolved and the rule or regulatory guide is revised to accommodate the resolution. The review process is repeated followed by final issuance of the regulatory document. While this proposed and final rulemaking process can be made incrementally more efficient, it is not likely that such efficiencies would significantly reduce the overall time-frame to endorse a consensus standard from the existing 18 to 24 months measured from task initiation.

One aspect of streamlining that could promote a significantly earlier date at which a standard is endorsed final in a regulation or regulatory guide would be to start the endorsement process before the SDO issues the standard, while at the same time implementing other efficiencies. In order to focus sufficient resources on each approved project, staff could be very selective in identifying and prioritizing standards to be considered for endorsement. A recommendation was made by an SDO to maximize concurrency of the NRC and SDO public review process. One way to implement that suggestion would be to use the SDO public review period as a "trigger" for initiating NRC action to endorse the standard. Other efficiencies that could be considered include the use of interoffice, interdisciplinary teams to develop regulatory positions during development of the standards to prevent surprises during the endorsement process, and the elimination of any overlapping internal requirements for documented analyses. Streamlining could also come about by referencing consensus standards in regulatory guides, instead of regulations which generally have a longer development time, or referencing consensus standards in NUREGs as used by NMSS.

NMSS has significantly shortened the time to endorse standards as a result of a redesign of its materials licensing process and the use of a multi-team approach (including regional and headquarters staff as well as Agreement State representatives) to update and consolidate guidance for various categories of materials licenses. The multi-team approach uses intra-office support that provides early input from cognizant offices thereby avoiding delays that could occur during later office reviews. NMSS uses NUREGs as the medium to consolidate all current guidance (e.g., regulatory guides, standard review plans, policy and guidance directives, information notices, references to acceptable standards) for a specific use. The NUREG becomes the Standard Review Plan for that use and the incorporation of standards thereby allows licensees to be more performance-based in the development of its regulatory program. Revised guidance is being published as a series of volumes of a single NUREG report, with each volume noticed in the Federal Register for a 90-day public comment period. Some of the benefits of this process are that applicants, licensees, and NRC staff find all relevant information in one location, and updates to the references, such as standards, occur faster because the staff is focused on updating a single document instead of many. The current schedule shows completion of approximately 22 final NUREGs by December 2000.

The timely endorsement of new and revised consensus standards by NRC would allow the generic use of updated procedures by licensees without the need for case-by-case requests and associated individual reviews by the staff. The downside is that the staff would have to develop positions in parallel with the standards development process, and be prepared to initiate the endorsement process just before or at the time the standard is issued by the SDO.

2. Automatic endorsement of consensus standards: Stakeholders have suggested that the NRC consider "automatic endorsement" of consensus standards in regulations. Under such an approach, the NRC would promulgate a rule that provides that all future versions of a specific consensus standard would become NRC requirements. A number of problems appear to exist with automatic endorsement. First, such an approach, which constitutes "incorporation by reference" of a consensus standard, would not meet the Office of the Federal Register (OFR) regulations (1 CFR Part 51) for incorporation by reference, which require that (1) the agency obtain OFR approval for each proposed document to be incorporated by reference into the Code of Federal Regulations, and (2) a rule incorporating by reference a publication must "state...the title, date, edition, author, publisher, and identification number of the publication." As a minimum, the date requirements would not be met if the Commission were to adopt an automatic endorsement rule, and the OFR would not likely publish a rule containing a requirement that contemplates ongoing violations of its requirements for incorporation by reference. A second problem with automatic endorsement of a consensus standard is that it would violate the Administrative Procedure Act (APA), 5 USC, which requires that the public be afforded the opportunity to comment on future versions of the consensus standard. Finally, it is not clear whether automatic endorsement of a consensus standard would constitute an unlawful delegation of power to a private entity. Unlike the Federal Aviation Administration (FAA), which has statutory authority to rely upon private entities to conduct certain specified safety oversight activities, the NRC does not have such specific legislative authority in the Atomic Energy Act of 1954, as amended (AEA). Accordingly, it is unclear whether the AEA would permit the NRC to rely upon industry consensus standards without independent NRC review and approval of the standards.

Assuming the legality of automatic endorsement, it would greatly reduce the number of staff needed to keep endorsements in pace with issued standards; however, staff would have to intervene into the process to impose provisions on a standard that the staff felt were necessary to ensure compliance with regulations, or to be technically correct.

3. Direct final rule: In this option, a proposed rule is issued direct final. If no significant adverse public comments are received in a specified time-

frame, the rule becomes final. If warranted by comments received within the specified time-frame, the process reverts to a proposed rule where comments are resolved and a separate final rule is issued. Applied to the incorporation by reference of consensus standards in NRC regulations, the direct final rule could appreciably shorten the endorsement process. In general, however, agencies have had mixed success with this process as a means of expediting rulemaking. In the case of consensus standards, the direct final rule could be a viable option for incorporation by reference when the reference is noncontroversial and no NRC limitations or modifications are imposed on the standard.

4. Periodically update references to consensus standards: In this option, staff would develop and implement a systematic process for reviewing existing rules, regulatory guides, and other defined regulatory documents that reference consensus standards to determine whether there is a need to update or incorporate new references. NMSS has initiated an effort to have each of its divisions identify the regulatory guides it uses, identify whether there is an existing consensus standard associated with the guide, and if there is none to determine whether a consensus standard exists or should be developed to replace an internal technical standard. Each regulatory guide is prioritized relative to its importance in carrying out the division's functions. The benefit of this option is that the updated and new references to consensus standards would make the latest technology and improved procedures available to licensees. The impact is that the process could be very resource intensive if not closely planned and managed. This option supports the provision of OMB Circular A-119 which requires that agencies have a process for ongoing review of its use of standards for the purpose of updating such use.

NRC limitations and modifications on consensus standards. Before endorsing a consensus standard for voluntary use or mandating the use of a consensus standard, the NRC staff reviews the standard to determine whether it supports and satisfies existing regulatory requirements, and is technically correct. If, in the judgment of the staff, the standard requires the application of limitations or modifications, those provisions would be included in the regulatory document that references the standard. It is not unusual for staff to apply modifying provisions to referenced standards because in the judgement of the staff the standards do not provide an adequate basis for regulatory requirements or guidance. Stakeholders believe that such modifying provisions are inappropriate because the standard was developed under an SDO consensus process which provides for, among other things, balance of interests during the development process and the opportunity for public comment before issuance of the standard. However, because regulations are not always key considerations in standards development and because the staff may consider certain new or revised provisions to be undue relaxations, the staff believes that, under certain circumstances, it may be necessary to impose limitations and modifications to make the standard usable for regulatory purposes.

Options for NRC consideration of limitations and modifications in the endorsement of standards are discussed below.

1. Maintain the existing process: In this option, staff would continue to review standards for use in the regulatory process and take actions as described above. In such cases, the incorporation of limitations and modifications are subject to public review when the rule or regulatory guide is issued for public comment. This option utilizes the standard, with necessary supplemental provisions, consistent with existing regulatory requirements. This process is resource intensive since each consensus standard must be closely reviewed and the necessary limitations and modifications identified, formulated and justified.
2. Accept standards as written and issued by SDO: For this option to be viable, the NRC staff and SDO committees would have to work closely together to define criteria for each standard, including specific regulatory requirements that the standard needs to maintain or achieve, and agree on the technical basis. With such coordination, there would be an increased potential for the resulting standard to be endorsable without limitations or modifications. This option would require special effort by the staff to define the applicable regulatory criteria and to work with the SDO to achieve the defined objective. However, in the staff's view, modifying provisions may still be needed. This option may not necessarily result in reduced staff resources because of the considerable front-end work required.

Mandatory 120-month update in 10 CFR 50.55a. The 120-month update provision in 10 CFR 50.55a requires licensees to (1) implement the nuclear sections (Section III, construction, and Section XI, inservice inspection (ISI) and testing (IST)) of the ASME Boiler and Pressure Vessel (BPV) Code and (2) update their ISI and IST programs every 120 months to the latest referenced edition/addenda of the ASME BPV Code. Because revisions to the ASME BPV Code contain both safety-significant and nonsafety-significant provisions, the 50.55a update generally results in licensees revising their programs to implement many nonsafety-significant actions, and only a few, if any, that are safety-significant. This was not true as the Code was maturing, but with a mature Code, the majority of actions now relate to burden reduction.

Stakeholders generally believe that the 120-month update serves no useful purpose, is burdensome, and uses resources that are better applied to other areas. A separate Commission paper is being prepared by NRR to assess the issues and options associated with this update provision.

ATTACHMENT 3

OUTLINE
PROPOSED MANAGEMENT DIRECTIVE

NRC PARTICIPATION IN THE
DEVELOPMENT AND USE OF CONSENSUS STANDARDS

DIRECTIVE

- Policy
- Objectives
- Organizational Responsibilities and Delegations of Authority

- [Applicability](#)
- [References](#)

POLICY

It is the policy of the NRC to increase the involvement of stakeholders in our regulatory development process consistent with the provisions of the National Technology Transfer and Advancement Act of 1995, and to encourage industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by the industry.

OBJECTIVES

- To promote the efficient use of NRC resources by focusing staff participation on the development of standards determined to address a defined current or anticipated regulatory need.
- To implement Public Law 104-113 and OMB Circular A-119.
- To provide for the monitoring and evaluation of internal performance indicators to ensure program efficiency and effectiveness.

ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

Chairman

- Ensure agency compliance with P.L. 104-113 and OMB Circular A-119.
- Designate a senior-level official as the NRC Standards Executive who will be responsible for NRC's implementation of P.L. 104-113 and Circular A-119, and who will represent the agency at the Interagency Committee on Standards Policy.
- Transmit the annual report on NRC standards participation in the development and use of consensus standards to the Department of Commerce (National Institute for Standards and Technology).

Office Directors/Regional Administrators

- Annually review the current and anticipated need for standards development or revision. Identify these needs to the Standards Executive for coordination of agency needs and priorities with the standards developing organizations (SDOs).
- Develop NRC technical positions that are clearly defined in a timely manner and are appropriately coordinated with other Federal participants.
- Identify appropriate technical headquarters and regional staff to participate as authorized NRC representatives on SDO committees needed to support the NRC mission.
- Annually review the basis for ongoing participation for each staff member and transmit this basis to the NRC Standards Executive.
- Review rulemakings and procurements to ensure that OMB A-119 requirements to include requests for suggestions on use of consensus standards in lieu of government-unique standards is a part of the action.
- Provide office input on staff participation in the development and use of consensus standards to the Standards Executive for incorporation into the NRC annual report on standards.

Standards Executive

- Promote the following goals relative to staff participation in the development and use of consensus standards:
 - 1) Effectively and efficiently using NRC resources.
 - 2) Developing NRC positions that are in the public interest and do not conflict with each other.
 - 3) Developing NRC positions that are consistent with Administration policy.
 - 4) Developing NRC policy positions that are clearly defined and coordinated with all Federal participants on a given committee.
- Coordinate agency participation in consensus standards bodies by:
 - 1) Providing that NRC current and anticipated needs and priorities for standards development to support the regulatory program are effectively communicated to the SDOs to promote acceptance of standards with a minimum of exceptions.
 - 2) Establishing procedures to ensure that NRC authorized representatives who participate in consensus standards bodies will, to the extent possible, ascertain the views of the agency on matters of paramount interest and will, at a minimum, express views that are not inconsistent or in conflict with established agency views.
 - 3) Ensuring that NRC's participation in consensus standards bodies is consistent with agency missions, authorities, priorities, and budget resources.
 - 4) Ensuring, when NRC and another Federal agency participate in a given consensus standards activity, that they coordinate their

views on significant issues so as to present, whenever feasible, a single, unified government position and, where not feasible, a mutual recognition of differences.

- 5) Cooperating with Department of Commerce representatives in carrying out responsibilities of OMB Circular A-119.
- 6) Consulting with staff from Department of Commerce representatives, as necessary, in the development and issuance of internal agency procedures and guidance implementing OMB Circular A-119, including developing and implementing an agency-wide directory that identifies agency employees who participate on SDO committees and the names of those committees.
- 7) Preparing a report on uses of government-unique standards in lieu of voluntary consensus standards, and an annual report on the status of NRC participation in the development and use of consensus standards.
- 8) Establishing a process for reviewing NRC's use of standards for the purpose of updating existing references.
- 9) Coordinating with NRC offices to ensure that processes exist for the review of agency participation and support for consensus standards bodies so that agency support and participation will be both effective and efficient.
- 10) Approving nominations of staff as authorized NRC representatives on SDO committees.
- 11) Coordinating periodic meetings with internal stakeholders to coordinate standards development needs and resources.
- 12) Coordinating annual meetings with SDOs and other stakeholders to communicate NRC needs.

APPLICABILITY

The provisions of this directive and handbook apply to all NRC employees who participate in the development or use of consensus standards.

REFERENCES

- Public Law 104-113, National Technology Transfer and Advancement Act of 1995, March 1996.
- OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Standards and Conformance Assessment, February 1998.
- SECY-97-303, "The Role of Industry (DSI-13)" and Use of Industry Initiatives, December 30, 1997.

PROPOSED MANAGEMENT DIRECTIVE -- HANDBOOK

- [Procedures: Part I -- Participation in the Development of Consensus Standards](#)
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Procedures: Part I -- Participation in the Development of Consensus Standards

OBJECTIVES

Provide guidelines for NRC staff participation on consensus standards committees that provide the opportunity to eliminate the need for NRC to develop or maintain separate Government-unique standards. Such participation is to be consistent with the NRC mission, function, and budgetary resources. These guidelines will address implementation of P.L. 104-113 and OMB Circular A-119.

PROCEDURES

Identification and prioritization of needed new and revised standards

Guidelines for identifying and prioritizing NRC's needs for standards, and documenting that finding.

Identification of standards developing organization (SDOs) committees on which to participate

Guidelines for determining which SDOs to work with on a specific need and for determining the most effective committee levels for participation; should take into account ongoing or planned industry actions to address specific issues through consensus standards development or other industry voluntary initiatives.

Selection of authorized NRC representatives

Guidelines for selecting staff to be authorized NRC representatives on standards writing committees, formally issuing the nomination letter, and annually reviewing the need for continued participation.

Participation on SDO committees

Guidelines for ensuring that NRC staff views expressed as part of committee activities are not inconsistent with agency views, for providing committees with NRC's needs for standards and supporting background on issues, for striving to reconcile key issues, and for ensuring active participation on an equal basis with other members. Includes guidelines for developing and implementing an agency-wide directory that identifies agency employees who participate on SDO committees and the names of those committees. [Attachment 3A](#) provides a proposed form for gathering information on committee assignments.

Coordination

Guidelines for staff representatives interacting with SDO committees, for coordinating standards actions with cognizant staff and management for development and subsequent endorsement (e.g., ensuring that key issues are identified and internal conflicts are resolved), for preparing SDO ballot actions, and for keeping NRC staff and management informed. Additionally, guidelines will be provided for conducting annual planning meetings with SDOs for exchanging ideas on needs and interests in the development of standards, and for assigning NRC staff to interface with individual SDOs to provide an ongoing information conduit to that organization.

Training

Guidelines for initial inhouse training on Federal requirements and NRC expectations for participation in the development and use of consensus standards; refresher training to be conducted periodically to update staff on experiences and new and revised Federal and NRC requirements for standards development and use.

Agency directory of staff membership

Guidelines for maintaining an agency-wide directory of NRC staff serving as authorized NRC representatives on SDO committees.

Monitoring and Assessment

Guidelines for selecting performance indicators to monitor the effectiveness and efficiency of staff participation in the development of consensus standards. Includes guidelines for monitoring the expenditure of staff time in the standards development process.

Procedures: Part II -- Use of Consensus Standards

OBJECTIVES

Provide guidelines to promote NRC use of consensus standards in an effective and efficient manner. These guidelines will address implementation of P.L. 104-113 and OMB Circular A-119.

PROCEDURES

Identification and prioritization of standards for endorsement

Guidelines for identifying and prioritizing standards to be considered for endorsement. Sources include the work products of committees with staff participation, standards available to replace government-unique requirements in existing or proposed regulations, and standards available to replace existing references in regulations, regulatory guides, or other regulatory documents.

Identification of method for endorsement

Guidelines for determining whether a specific consensus standard should be mandated in a regulation, endorsed in a regulatory guide for voluntary use as an acceptable way of satisfying NRC regulations, or be used through some other regulatory mechanism.

Initiation of endorsement process

Guidelines for establishing the point in time to initiate the endorsement process, with the goal of more timely endorsement of selected consensus standards as specified in individual office operating plans.

Endorsement process

Guidelines for endorsing standards through rulemaking, regulatory guide development, or other means, in relation to existing procedures.

Guidelines for ensuring effective coordination between staff that participated in the development of the consensus standard and those responsible for developing the endorsement package, including criteria for establishing and maintaining a database to allow development actions to be reviewed at time of endorsement.

Statements of Consideration (SOC) of Federal Register notice on use of consensus or government-unique standards

Guidelines for incorporating a statement into the SOC of the Federal Register notice of proposed rulemakings to request information on available standards that could affect whether a government-unique or consensus standard is used in the rulemaking action, and for reporting to the Commission whenever a government-unique standard is used in lieu of an existing consensus standard that could require a report to OMB consistent with Circular A-119 ([Attachment 4](#)).

Monitoring and Assessment

Guidelines for monitoring and assessing the overall use of consensus standards, including conducting a review of NRC's use of standards in regulations and procurements to update such use, and guidelines for selecting performance indicators to monitor the effectiveness and efficiency of the endorsement process, including guidelines for monitoring expenditure of resources in the endorsement process.

ATTACHMENT 3A

RECORD OF COMMITTEE ASSIGNMENT

ATTACHMENT 4

**GUIDELINES FOR STATEMENT OF CONSIDERATION IN
FEDERAL REGISTER NOTICE ON
USE OF VOLUNTARY CONSENSUS OR GOVERNMENT-UNIQUE STANDARDS**

1. **Definitions**

"Use" of a standard means incorporation of a standard in whole, in part, or by reference for procurement purposes or for regulations.

A "voluntary consensus standard" is a standard developed or adopted by a voluntary consensus body, either domestic or international. These bodies have agreed to make their standards (intellectual property) available on a nondiscriminatory, royalty-free or reasonable-royalty basis to all interested parties and are further characterized by openness, balance of interest, due process, appeals process, and consensus (general agreement but not necessarily unanimity).

The term "standard" does not include professional standards of personal conduct or institutional codes of ethics.

Government-unique standards are developed by the Government for its own use.

2. **Proposed Rule**

The Statement of Consideration (SOC) shall identify when a voluntary consensus standard is being proposed for use, or when a government-unique standard is proposed for use instead of a voluntary consensus standard. In the latter case, the SOC shall provide a preliminary explanation of why use of the voluntary consensus standard is inconsistent with applicable law or is otherwise impractical. [Note: OMB Circular A-119 defines "impractical" as including circumstance in which use of the consensus standard would fail to serve the agency's program needs; would be infeasible, would be inadequate, ineffectual, inefficient, or inconsistent with the agency's mission; or would impose more burdens, or would be less useful than the use of another standard].

Specifically, the SOC shall invite comment on the intended use of a voluntary consensus standard or Government-unique standard, and shall, as appropriate --

- (1) When proposing to use a voluntary consensus standard, provide a statement which identifies the standard.
- (2) When proposing to use a Government-unique standard instead of a consensus standard --
Provide a statement that identifies the standard and explains the proposed use of the Government-unique standard in lieu of a voluntary consensus standard and why using the voluntary consensus standard would be inconsistent with applicable law or would be otherwise impractical.
- (3) When proposing to use a Government-unique standard and no consensus standard has been identified --
Provide a statement that no voluntary consensus standard has been identified and an invitation to identify any such standard, along with an explanation of why such standard should be used.

3. **Final Rule**

A statement shall be provided in the SOC to explain the agency's final decision on the use of a voluntary consensus standard or a Government-unique standard -

- (1) When using a voluntary consensus standard, provide a statement that identifies the standard and any alternative voluntary consensus standards which have been identified.
- (2) When using a Government-unique standard, instead of a voluntary consensus standard --
Provide a statement that identifies the standard and explains why using the voluntary consensus standard would be inconsistent with applicable law or would be otherwise impractical.
- (3) When using a Government-unique standard and no voluntary consensus standard has been identified --
Provide a statement that no voluntary consensus standard has been identified.

4. **Reporting to OMB**

The staff that prepares the final rulemaking package shall inform the NRC Standards Executive when a Government-unique standard is used in a final rulemaking instead of a standard from a voluntary consensus body.

The NRC Standards Executive shall prepare for transmittal to NIST by the Chairman, or designee, no later than December 31 of each year, a report citing all final rulemakings issued in the previous year that use a Government-unique standard in lieu of a voluntary consensus body's standard. Use of Government-unique standards in situations in which no applicable voluntary consensus standards exist need not be reported.

1. Memorandum to Chairman Jackson et al. from L. Joseph Callan, "Interim Guidance on the Use of Government-Unique Standards," July 31, 1998.

2. Federal: One of the Federal agencies in attendance (i.e., Department of Energy, Department of Defense, Department of Commerce (National Institute of Standards and Technology), not including NRC.

3. NP industry: Nuclear power industry.

4. NM industry: Nuclear materials industry.