U.S. NUCLEAR REGULATORY COMMISSION

DIRECTIVE TRANSMITTAL

TN: DT-99-26

To: NRC Management Directives Custodians

Subject: Transmittal of Directive 6.5, "NRC Participation in the

Development and Use of Consensus Standards"

Purpose: Directive and Handbook 6.5 provide direction for

implementing the National Technology Transfer Act of 1995 (Pub. L. 104-113) and OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards." Organizational responsibilities and guidance are provided for (1) staff participation in the development of consensus standards, including identifying and prioritizing needed new and revised technical standards, selecting and nominating staff as authorized agency representatives on standards developing organization (SDO) committees, and coordinating standards activities with SDOs and other stakeholders, and (2) NRC use of consensus standards including identifying and prioritizing standards for endorsement, timely endorsement, annual reporting, exceptions to using a consensus standard, and monitoring and assessing the NRC standards program.

Office and

Division of Origin: Office of Nuclear Regulatory Research

Contact: Gilbert Millman, 415-5843

Date Approved: November 2, 1999

Volume: 6 Internal Management

Directive: 6.5 NRC Participation in the Development and Use of

Consensus Standards

Availability: Rules and Directives Branch

Office of Administration

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NRC Participation in the Development and Use of Consensus Standards

Directive 6.5

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U. S. Nuclear Regulatory Commission

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RES

NRC Participation in the Development and Use of Consensus Standards Directive 6.5

Policy (6.5-01)

It is the policy of the U.S. Nuclear Regulatory Commission to increase the involvement of stakeholders in our regulatory development process and, consistent with the provisions of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113), to encourage NRC staff participation in the development of consensus standards in support of its mission and to encourage industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by the industry.

Objectives (6.5-02)

- Promote the efficient and effective use of NRC resources by focusing staff participation on the development of standards that address a defined current or anticipated regulatory need. (021)
- Implement Pub. L. 104-113 and the Office of Management and Budget (OMB) Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities." (022)

Objectives (6.5-02) (continued)

 Monitor and assess internal performance indicators to ensure efficient and effective staff involvement in the development and use of consensus standards needed in NRC program offices. (023)

Organizational Responsibilities and Delegations of Authority (6.5-03)

Chairman (031)

- Ensures agency compliance with Pub. L. 104-113 and OMB Circular A-119. (a)
- Designates a senior-level official as the NRC Standards Executive who will be responsible for NRC's implementation of Pub. L. 104-113 and OMB Circular A-119 and represent the agency on the Interagency Committee on Standards Policy (ICSP).¹ (b)
- Transmits to NIST no later than December 31 of each year (specific date dependent upon request from NIST) the annual report on NRC participation in the development and use of consensus standards with an explanation of the reason(s) for using Government-unique standards instead of voluntary consensus standards. NIST summarizes the information it receives from Federal agencies and submits it to OMB. (c)

¹The ICSP is comprised of the Standards Executives from Federal agencies. It is chaired by staff from the National Institute of Standards and Technology (NIST) and is responsible for providing the forum in which Federal agencies discuss and coordinate methods for implementing Pub. L. 104-113 and OMB Circular A-119.

Executive Director for Operations (EDO) (032)

Ensures that the annual report on NRC participation in the development and use of consensus standards is prepared and transmitted to the Chairman in a timely manner.

Regional Administrators (033)

- Provide recommendations in a timely manner to the cognizant office director on the need for new or revised consensus standards. (a)
- Identify appropriate regional staff to participate as authorized NRC representatives on committees of standards developing organizations (SDOs) needed to support the NRC mission and regional needs. (b)
- Ensure that regional participation in consensus standards bodies is consistent with the agency mission, authorities, priorities, and budget resources. (c)
- Annually review the basis for continuing the participation of each staff member in the region on an SDO and transmit this basis to the NRC Standards Executive. (d)
- Coordinate standards needs and activities with the cognizant office director. (e)
- Upon request, provide office input on staff participation in the development and use of consensus standards to the NRC Standards Executive for incorporation into the NRC annual report on standards. (f)

Office Directors (034)

- Annually identify the current and anticipated needs and associated priorities for development of new or revised standards; convey this information to the NRC Standards Executive for coordination with appropriate SDOs. (a)
- Identify appropriate office staff to participate as authorized NRC representatives on SDO committees needed to support the NRC mission and office needs. (b)
- Ensure that office participation in consensus standards bodies is consistent with agency mission, authorities, priorities, and budget resources. (c)
- Annually review the effectiveness and efficiency of the offices' participation on consensus codes and standards committees, and transmit all changes to this participation to the NRC Standards Executive. (d)
- Develop NRC technical positions in a timely manner for use in the standards development process. (e)
- Coordinate views of paramount importance to the NRC and to the Federal Government with other Federal participants on the SDO committees so that a single unified Federal position may be established, whenever feasible. When this is not possible, establish a mutual recognition of the differences. (f)
- Review rulemakings and procurements to ensure that the OMB Circular A-119 requirement to include requests for comment on the use of consensus standards instead of Government-unique standards is a part of the action. (g)

Office Directors (034) (continued)

- Upon request, provide office input on staff participation in the development and use of consensus standards to the NRC Standards Executive for incorporation into the NRC annual report on standards. (h)
- Establish appropriate communication interfaces with those SDOs whose standards are of primary interest to the office. This communication should be coordinated with the NRC Standards Executive and other cognizant offices to prevent redundant meetings. (i)

Director, Office of Nuclear Regulatory Research (RES) (035)

> In addition to the other responsibilities of an office director, ensures the effective and efficient agencywide implementation of this management directive.

NRC Standards Executive (036)

- Promotes the following goals relative to staff participation in the development and use of consensus standards: (a)
 - Effective and efficient use of NRC resources (i)
 - Development of NRC positions that are in the public interest and are consistent with the agency mission and with implementation of Pub. L. 104-113 and OMB Circular A-119 (ii)

NRC Standards Executive (036) (continued)

- Timely development of NRC technical positions that are coordinated with other Federal participants on the same SDO committee (iii)
- Representation of NRC's interests in Federal agency standardization activities coordinated by the ICSP (iv)
- Coordinates agency participation in consensus standards bodies through the following actions: (b)
 - Ensures that NRC current and anticipated needs and priorities for standards development to support the regulatory program are communicated at least annually to the SDOs. (i)
 - Establishes 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 interest and will express views that are consistent with established agency views. (ii)
 - Ensures that representatives from NRC and other Federal agencies on the same standards committee 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. (iii)
 - Cooperates with NIST representatives in carrying out responsibilities of OMB Circular A-119. (iv)

NRC Standards Executive (036) (continued)

- Consults with NIST representatives, as necessary, in the development and issuance of internal agency procedures and guidance implementing OMB Circular A-119, including developing and implementing an agencywide directory that identifies agency employees who participate on SDO committees and provides the names of those committees. Also, maintains an NRC external web page with this information. (v)
- Prepares an annual report for transmittal by the Chairman to NIST on NRC use of Government-unique standards instead of voluntary consensus standards and on the status of NRC participation in the development and use of consensus standards. (vi)
- Establishes a process for reviewing NRC's use of standards for the purpose of updating existing references. (vii)
- Coordinates with NRC offices and regions to ensure that processes exist for the review of agency participation and support for consensus standards bodies so that agency support and participation will comply with applicable laws and regulations, and will be effective and efficient. (viii)
- Signs and issues nomination letters to SDOs for staff participation on SDO committees as authorized NRC representatives. (ix)
- Reviews lists of needed consensus standards with defined regulatory needs provided by office directors to identify

NRC Standards Executive (036) (continued)

duplicate efforts between offices and, as appropriate, to eliminate such duplication through discussions with the cognizant offices. (x)

 Coordinates periodic meetings with internal stakeholders to coordinate standards development needs and resources and with SDOs and other stakeholders to communicate NRC needs to external stakeholders. (xi)

Applicability (6.5-04)

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

Handbook (6.5-05)

Handbook 6.5 provides guidance on NRC participation in the development and use of consensus standards.

Definitions

(6.5-06)

Consensus standard. A technical standard developed or adopted by a domestic or international voluntary consensus body. 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

Directive 6.5

Definitions

(6.5-06) (continued)

openness, balance of interest, due process, an appeals process, and consensus (general agreement but not necessarily unanimity). For the purpose of this management directive, a consensus standard is the same as a voluntary consensus standard. (061)

Government-unique standard. A technical standard developed by the Federal Government for its own use. (062)

Technical standard. Standardized conditions or characteristics developed for products or processes. (063)

Use. Incorporation of a standard in whole, in part, or by reference in regulation, or the inclusion of a standard in whole, in part, or by reference for procurement purposes. (064)

References (6.5-07)

"Federal Participation in the Development and Use of Voluntary Standards and in Conformity Assessment Activities," Office of Management and Budget Circular A-119, February 1998.

Management Directive 7.3, "Participation in Outside Professional and Technical Organizations."

National Technology Transfer and Advancement Act of 1995, March 1996, Pub. L. 104-113.

"NRC Participation in the Development and Use of Consensus Standards," SECY-99-029, January 28, 1999.

Staff Requirements, SECY-99-029, February 17, 1999.

"The Role of Industry (DSI-13) and Use of Industry Initiatives," SECY-97-303, December 30, 1997.

NRC Participation in the Development and Use of Consensus Standards

Handbook 6.5

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Handbook NRC Participation in the Development and Use of Consensus Standards

Participation in the Development of Consensus Standards (A)

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that all Federal agencies consult and participate with standards developing organizations (SDOs) to develop technical standards. This participation is to be in the public interest and to be compatible with the agency mission, authorities, priorities, and budget resources. The following guidelines provide a framework for implementing Pub. L. 104-113 as it pertains to NRC staff participation on consensus standards committees. Staff participation in the standards development process has the goal of reducing the need for NRC to develop and maintain its own Government-unique standards.

Identifying and Prioritizing Needed New and Revised Technical Standards (1)

Each office, as applicable, identifies and prioritizes its need for new or revised technical standards. In filling this need, before writing a Government-unique standard to address an office need, each office determines whether an existing, revised, or new consensus standard could be used instead of a Government-unique standard. In determining the practicality of developing a consensus standard, staff should consider the time frame in which the standard is needed and whether there are related ongoing or planned voluntary industry initiatives. Standards development activities that are of sufficient priority should be considered in the operating plan indicating whether the office has representation on the standards developing committee or whether it provides support to other offices or regions that do. (a)

Identifying and Prioritizing Needed New and Revised Technical Standards (1) (continued)

The need for consensus standards may be specifically identified through ongoing reviews conducted by each office, as appropriate, to determine the suitability of— (b)

- Replacing existing Government-unique standards with consensus standards (i)
- Updating or revising references to existing consensus standards
 (ii)

Consistent with Pub. L. 104-113 and the Office of Management and Budget (OMB) Circular A-119, this directive focuses its attention on the use of consensus standards developed by SDOs, but does not imply a preference for consensus standards in lieu of non-consensus standards developed in the private sector. Primary consideration is given to the development of standards that incorporate risk insights to minimize unnecessary burden and to the use of performance standards when such standards may reasonably be used instead of prescriptive standards. (c)

At the beginning of each fiscal year, each office provides its list of needed new consensus standards or major revisions to existing standards with defined regulatory needs to the NRC Standards Executive. The Standards Executive reviews this information to identify potential duplicate efforts between offices and, as appropriate, to eliminate duplication through discussion with staff from the cognizant office(s). (d)

Searching for Suitable Consensus Standards (2)

Before proposing the development of a new consensus or Government-unique standard, cognizant staff perform a search for

Searching for Suitable Consensus Standards (2) (continued)

existing consensus standards developed by SDOs that may suitably be used for the identified application. SDOs include the American Society of Mechanical Engineers, Institute for Electrical and Electronic Engineers, American Nuclear Society, American Society for Testing and Materials, and Health Physics Society. Comprehensive databases that could be used to search for suitable standards are at the web sites for the National Standards System Network (NSSN), http://www.nssn.org; American National Standards Institute, http://www.ansi.org; and the National Institute for Standards and Technology (NIST), http://www.nist.gov. OMB Circular A-119 does not establish a preference between domestic and international consensus standards, but in the interests of promoting trade and implementing the provisions of international treaty agreements, international standards, such as those from the International Organization for Standardization and the International Electrotechnical Commission, are considered for agency regulatory and procurement applications. (a)

A decision to use a Government-unique standard instead of a consensus standard must be reported to OMB. The content of this report is discussed in Section (B)(5)(a) of this handbook. (b)

Identifying SDO Committees on Which To Participate (3)

The cognizant office determines which SDO has the scope and technical expertise for developing new or revising existing consensus standards. A list of SDOs and links to their web-sites may be obtained at the NSSN web site identified above. (a)

Discussions with the candidate SDO are an important part of making the decision to use a consensus standard instead of a Government- unique standard. These discussions are initiated by the cognizant office, and the NRC Standards Executive is advised

Identifying SDO Committees on Which To Participate (3) (continued)

of the initiative. Discussion points with the SDO include its interest in developing the standard, the indicated time frame for the work product, previous successes of the SDO and the most effective committee level(s) for staff participation in the development of the standard recognizing that most technical input generally occurs at the writing level. Experience and the ability to enlist participants with such experience in developing risk-informed and performance-based standards are also important attributes for the SDO determined to be the best choice for developing a consensus standard to address a defined NRC need. (b)

Selecting NRC-Authorized Representatives (4)

Agency employees who participate at Government expense in the standards activities of SDOs on behalf of the agency do so as specifically authorized representatives. Individuals are selected by their office management to be the authorized representative to a specific SDO committee for their ability to contribute to the standards development effort on the basis of their technical expertise and NRC functional responsibilities. The number of individual agency participants in a given voluntary standards activity is kept to the minimum required for effective representation of the various program, technical, or other NRC concerns. (a)

The proposed representative is nominated for NRC-authorized participation on the SDO committee in a letter prepared by the cognizant office to the appropriate SDO official. SDO procedures for submitting relevant nominee background information are followed. The nomination letter is signed by the NRC Standards Executive with concurrence through the nominee's office director. A sample format for this nomination letter is provided in Exhibit 1. Nomination of staff for participation on a standards developing

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Selecting NRC-Authorized Representatives (4) (continued)

committee implies commitment by cognizant management of the time associated with staff participation on the committee and management involvement in developing staff positions for ballot actions. All appointments, replacements, and terminations to staff participation on SDOs are made through the respective letter signed by the Standards Executive. (b)

NRC Form 652, "Participation on Standards Committees" (available through Informs) is completed by all staff nominated for the position of NRC-authorized representative. This form accompanies the concurrence package for the nomination letter but is not transmitted with the letter. Its purpose is to provide background information on, among other things, the regulatory need for the standard being developed, and to provide information for an NRC database that identifies agency employees who participate on SDO committees and the names of those committees. This database is available to the public on the NRC web site. (c)

Each office performs an annual review of the efficiency and effectiveness of its participation on consensus standards committees, and transmits all changes in this participation to the NRC Standards Executive. Such reviews are directed toward maintaining or initiating an effective presence in those areas of standards development process where there is a defined regulatory need and reducing the level of participation elsewhere. The review process is the responsibility of each office. Factors that might be considered include: ongoing or planned industry actions to address specific issues through the development and use of consensus or industry standards, or other industry voluntary initiatives; and the needs of other offices that the reviewing office may be supporting by its participation on SDO committees. (d)

Responsibilities of NRC-Authorized Representatives (5)

NRC staff who participate as authorized agency representatives on SDOs do so consistent with the following guidelines:

- Participate actively on an equal basis with other committee members with full involvement in discussions and technical debates and, if selected, serve as chairpersons or in other official capacities. (Note: These other official capacities do not include involvement in the day-to-day activities of the SDO [see Management Directive 7.3 for information regarding conflict of interest].) (a)
- As part of committee activities, express views that are consistent with the agency views and strive to reconcile key issues within the staff or between the SDO and agency views on SDO actions. Where there is no agency view on an issue, authorized agency representatives will use their best judgment based on their experience, technical expertise, and discussions with other NRC staff. (Note: Agency participation on SDO committees does not necessarily connote agency agreement with, or endorsement of, decisions reached by such organizations.) When unable to attend a standards development meeting, provide for a designated alternate or otherwise ensure that agency views are adequately represented. (b)
- When NRC participates with other Federal agencies on an SDO committee, coordinate with those representatives to establish a single unified Federal position, whenever feasible. When this is not possible, establish a mutual recognition of the differences. Elevate issues of paramount importance to the NRC and Federal Government to the appropriate office director for coordination. (c)

Responsibilities of NRC-Authorized Representatives (5) (continued)

- Avoid the practice or the appearance of undue influence with regard to agency representation and activities on SDO committees. (d)
- Coordinate standards actions, including preparation of ballots, with cognizant staff from headquarters and the regions during the development and approval of new or revised standards to ensure that key internal issues are identified and conflicts resolved. (e)
- Keep cognizant NRC staff and management informed of the progress of the standard's development through timely written, including email, and verbal reports. (f)
- Record in the agencywide PC/RITs system the time expended on standards development activities, including time for attendance at meetings, including electronic conferencing, travel, and meeting preparation and reporting. (g)
- Individual Performance Elements and Standards for staff participating as authorized NRC representatives on SDO committees reflect this responsibility. (h)

Coordinating with Stakeholders (6)

Coordination meetings are held annually, as a minimum, by the NRC Standards Executive with key SDOs and other stakeholders to enhance communications and thereby foster a better understanding of NRC needs for new or revised consensus standards, priorities, and resources, and the status of SDO standards development projects and interests. Such meetings

Coordinating with Stakeholders (6) (continued)

include participation by cognizant NRC offices and are coordinated by the Standards Executive. (a)

Offices consider assigning staff to interface on an ongoing basis with SDOs whose standards are of primary interest to that office to provide an ongoing communication conduit with each organization. Further communication is achieved with SDOs and other stakeholders through a link on the NRC external web page that provides information regarding NRC staff participation on standards development activities with SDOs. (b)

Training (7)

The NRC Standards Executive coordinates periodic inhouse orientation sessions to familiarize NRC staff with Federal requirements and NRC expectations related to the development and use of consensus standards. This training includes updates to related Federal and NRC requirements and staff experiences on SDO committees.

Participation in the Use of Consensus Standards (B)

Pub. L. 104-113 requires that all Federal agencies use technical standards that are developed or adopted by SDOs as a means to carry out policy objectives or activities determined by the agencies. The law provides an exception when such use is inconsistent with applicable law or otherwise impractical (see Section (B)(6) of this handbook). The following guidelines provide a framework for implementing the law as it pertains to NRC use of consensus standards. Staff use of consensus standards has the

Participation in the Use of Consensus Standards (B) (continued)

objective of reducing agency need for Government-unique standards.

Identifying and Prioritizing Standards for Endorsement (1)

Each office establishes and implements a process to identify and prioritize standards to be endorsed for use in its regulatory process.

The annual update of the list of standards to be developed (see Section (A)(1) of this handbook) is a resource for information from which to establish the list of standards to be endorsed. Standards on the development list that have been issued by SDOs are primary candidates for endorsement. Additionally, the list of standards to be endorsed identifies existing consensus standards that have been selected, in order of priority, to replace existing Government-unique standards or to update or revise existing references to consensus standards. (a)

NRC offices implement an ongoing review to determine whether there is a need to update or incorporate new standards to address specific technical issues, new technologies, or regulatory processes. To minimize the impact on resources, this review is integrated to the extent practical into the responsibilities for staff participation in standards development. The results of the individual office reviews are coordinated through the NRC Standards Executive to prioritize agencywide standards needs and to eliminate duplicate efforts. (b)

Methods for Endorsing Consensus Standards (2)

NRC adopts consensus standards through incorporation by reference in regulations and through reference in such documents as regulatory guides, NUREG reports, standard review plans, technical specifications, branch technical positions, and

Participation in the Use of Consensus Standards (B) (continued)

Methods for Endorsing Consensus Standards (2) (continued)

procurement specifications. Each office determines the manner in which a specific consensus standard is incorporated into its regulatory process. In the case of a new standard, it is preferable to determine how the standard is to be used before the standard is written. Additionally, reference to frequently revised standards in regulations is considered to be problematic because attempts to have the regulation reflect the most current version of that standard could place the regulation in a state of perpetual rulemaking. It is recognized that it is in the NRC's best interest to incorporate consensus standards quickly in the NRC process and stakeholder products.

Timeliness of Endorsement (3)

Standards are endorsed in a timely manner to enable NRC, licensees, and others to expeditiously use new or revised standards. To accomplish this, staff consider initiating the endorsement process for selective standards before the SDO issues the standard in its final form, consistent with budget and office priorities. Staff may consider the SDO public review period as an initiator for NRC action to endorse the standard. The use of interoffice interdisciplinary teams is encouraged for selected projects to develop regulatory positions during development of the standard to prevent conflicts during the endorsement process.

NRC Limitations and Modifications on Consensus Standards (4)

The NRC reserves the right to apply limitations or modifications on the use of consensus standards that it uses in its regulatory process 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.

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Participation in the Use of Consensus Standards (B) (continued)

NRC Limitations and Modifications on Consensus Standards (4) (continued)

The need to impose limitations and modifications may, however, be reduced by a better understanding of the issues through meetings with SDOs and other stakeholders and closer coordination of staff and SDO participants at writing committees. Better coordination between the NRC representatives on standards writing, consensus, and supervisory committees and NRC staff developing the endorsement document also could lead to a reduced need for limitations and modifications. Such exceptions are subject to stakeholder comment as part of the public review period conducted as part of proposed rulemaking, regulatory guide, or other regulatory document development.

Reporting (5)

Annual Report to OMB (a)

Each office submits to the NRC Standards Executive by October 1 of each year the following information, which is consolidated into an annual report that is submitted no later than December 31 of each year by the NRC Chairman to NIST. NIST summarizes the information it receives from Federal agencies and submits it to OMB.

- Decisions in the previous fiscal year to use Government-unique standards instead of consensus standards (An explanation is included as to why use of the voluntary consensus standard would be inconsistent with applicable law or otherwise impractical.) (i)
- The number of SDOs and standards committees in which there
 is office participation, as well as the number of office
 employees participating (ii)

Participation in the Use of Consensus Standards (B) (continued)

Reporting (5) (continued)

- The number of new or revised consensus standards the office has used since the last report (iii)
- Identification of consensus standards that have been substituted for Government-unique standards as a result of an agency review (iv)

Agency Use of Standards in Rulemaking (b)

Statements are included in the preamble for proposed and final rulemakings to, respectively, request comment and report on the final resolution of comments on the use or non-use of consensus standards. Exhibit 2 provides guidance for developing the appropriate statements in both proposed and final rulemakings. Using a Government-unique standard instead of a consensus standard requires a report to OMB through NIST from the Chairman (see Section (B)(6) of this handbook).

Agency Use of Government-Unique Standards in Solicitations (c)

If a Government-unique standard is referenced in a solicitation, an opportunity is provided for offerors to suggest consensus standards that could be used instead of referenced Government-unique standards to meet the agency's requirement. When the project officer submits the request for procurement action with an accompanying statement of work, he or she identifies any Government-unique standard relating to the procurement to the contract specialist. The solicitation will include language that invites offerors to suggest consensus standards that could be used instead of referencing Government-unique standards, if appropriate. Using a Government-unique standard instead of a consensus standard requires a report to OMB through

Participation in the Use of Consensus Standards (B) (continued)

Reporting (5) (continued)

NIST from the Chairman (see Section (B)(6) of this handbook). The requirements of this section do not apply to solicitations that are for commercial off-the-shelf products, products or services that rely on consensus standards or non-consensus standards developed in the private sector, or products that otherwise do not rely on Government-unique standards.

Exception To Using a Consensus Standard (6)

If using a consensus standard is inconsistent with applicable law or otherwise impractical, NRC may elect to use technical standards that are not developed or adopted by SDOs if the Chairman transmits to OMB through NIST an explanation of the reasons for using such standards. The explanation for each such occurrence is transmitted as part of the NRC annual report (see Section (B)(5)(a) of this handbook) on its participation in the development of and use of standards. This information, along with similar information from other Federal agencies, will be submitted in summary form by NIST to OMB. No report is required on the use of Government-unique standards if no applicable consensus standard exists or on the use of other standards. OMB transmits to Congress and its committees a report summarizing all such explanations received in the preceding year.

Monitoring and Assessment (7)

Offices assess the effectiveness and efficiency of staff participation in the development and use of consensus standards.

Exhibit 1 Sample Nomination Letter

[Name, title of SDO official] [Name of committee] [Name of standards developing organization] [Street address] [City, State, ZIP]				
Dear (Dr./Mr./Ms.):				
representative on the [Name of	/Ms.) as the authorized NRC society, level and name of committee] on within organization] and is responsible for committee].			
Participation in the Development and Conformity Assessment Activities," Feb of an NRC-authorized representative endorsement of, decisions reached by published as a result of the committee's standards developing groups will, to the committee of	agement and Budget Circular A-119, "Federa Use of Voluntary Consensus Standards and in bruary 19, 1998, the participation on a committee does not connote agency agreement with, or the committee, or of standards approved and sefforts. Agency representatives participating or the extent possible, ascertain the views of the express views that are consistent with established			
Correspondence should be addressed	to:			
U.S. Nuclear Regulatory Commission ATTN: (Dr./Mr./Ms.)M/S:	-			
Washington, DC 20555				
Voice message:				
Email:				

Exhibit 1 (continued)

Thank you very much for providing NRC with the opportunity to participate in the work of your committee.

Sincerely,

[Name of Standards Executive]

NRC Standards Executive
Office of Nuclear Regulatory Research

cc: [Name of Secretary for applicable committee]

Exhibit 2

Statement in *Federal Register* Notice for Rulemakings Use of Voluntary Consensus Standards

Proposed Rule

The statement of consideration (SOC) for each proposed rule or interim final rule contains a request for comment and appropriate information concerning the use of a voluntary standard.

- [If the rule proposes using a voluntary consensus standard, it contains a statement that identifies the standard.]
- [If the rule proposes using a Government-unique standard instead of a voluntary consensus standard, it contains a statement that identifies the standard and provides a preliminary explanation for the proposed use of a Government-unique standard instead of a voluntary consensus standard.]
- [If the rule proposes using a Government-unique standard and no voluntary consensus standard has been identified, it contains a statement to that effect and an invitation to identify any voluntary standard and to explain why the standard should be used.]

The following statement is used to address the use of voluntary standards in each proposed rule or interim final rule:

Voluntary Consensus Standards

The National Technology Transfer Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, [insert one of the following options].

Option 1. "The NRC proposes using the following voluntary consensus standard: [identify the standard by name, developing organization, and date issued]. The NRC invites comment on the applicability and use of other standards."

Exhibit 2 (continued)

Option 2. "The NRC proposes using the following Government-unique standard: [identify the standard by name, developing organization, and date issued] instead of the following voluntary consensus standard: [identify the standard by name, developing organization, and date issued]. The NRC has determined that using a Government-unique standard is justified because [provide a preliminary explanation such as "using the voluntary consensus standard would be impractical or inconsistent with applicable law."]

Option 3. "The NRC proposes using the following Government-unique standard: **[identify the standard by name, developing organization, and date issued]**. The NRC is not aware of any voluntary consensus standard that could be used instead of the proposed Government- unique standard. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain how the voluntary consensus standard is comparable to and why it should be used instead of the proposed Government-unique standard."

Option 4. "The NRC is **[describe the action being taken in the final rule]**. This action does not constitute the establishment of a standard that contains generally applicable requirements."

If the proposed rule concerns the NRC's approval of a standard design certification, which is neither a Government-unique standard or a voluntary consensus standard, the following statement is used:

Voluntary Consensus Standards

The National Technology Transfer Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC proposes to approve the [name] standard plant design for use in nuclear power plant licensing under 10 CFR Parts 50 and 52. Design certifications are not generic rulemakings establishing a generally applicable standard with which all Parts 50 and 52 nuclear power plant licensees must comply. Design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certifications

Exhibit 2 (continued)

are initiated by an applicant for rulemaking, rather than initiated by the NRC. For these reasons, the NRC concludes that the Act does not apply to this proposed rule.

Final Rule

The SOC for each final rule repeats the statement concerning the use of voluntary standards that appeared in the proposed rule or interim final rule. Further, it acknowledges, summarizes, and responds to comments received, and explains the NRC's final decision.

- [If a voluntary consensus standard is being used, the SOC identifies the standard and any alternative voluntary consensus standards that were identified.]
- [If a Government-unique standard is being used instead of an existing voluntary consensus standard, the SOC identifies the standard and explains why using the voluntary consensus standard would be inconsistent with applicable law or otherwise impractical.]
- [If a Government-unique standard is being used and no voluntary consensus standard has been identified, the SOC states that no applicable voluntary consensus standard has been identified.]

The following statement is used to address the use of voluntary standards in each final rule:

Voluntary Consensus Standards

The National Technology Transfer Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, [insert one of the following options].

Option 1. "The NRC is using the following voluntary consensus standard: [identify the standard by name, developing organization, and date issued]. The following alternative voluntary consensus standards were identified but are not used in this final

Exhibit 2 (continued)

rule: [identify the standard(s) by name, developing organization(s), and date(s) issued]."

Option 2. "The NRC is using the following Government-unique standard: [identify the standard by name, developing organization, and date issued] instead of the following voluntary consensus standard: [identify the standard by name, developing organization, and date adopted]. The NRC has determined that using a Government-unique standard is justified because [provide a preliminary explanation such as "using the voluntary consensus standard would be impractical or inconsistent with applicable law]."

Option 3. "The NRC is using the following Government-unique standard: **[identify the standard by name, developing organization, and date issued]**. No voluntary consensus standard has been identified that could be used instead of the Government-unique standard."

Option 4. "The NRC is **[describe the action being taken in the final rule]**. This action does not constitute the establishment of a standard that contains generally applicable requirements."

If the final rule concerns the NRC's approval of a standard design certification, which is neither a Government-unique standard or a voluntary consensus standard, the following statement is used:

Voluntary Consensus Standards

The National Technology Transfer Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is approving the [name] standard plant design for use in nuclear power plant licensing under 10 CFR Parts 50 and 52. Design certifications are not generic rulemakings establishing a generally applicable standard with which all Parts 50 and 52 nuclear power plant licensees must comply. Design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certifications are initiated by an applicant for rulemaking, rather than initiated by the NRC. For these reasons, the NRC concludes that the Act does not apply to this final rule.