

U.S. NUCLEAR REGULATORY COMMISSION MANAGEMENT DIRECTIVE (MD)

MD 6.5

**NRC PARTICIPATION IN THE
DEVELOPMENT AND USE OF
CONSENSUS STANDARDS**

DT-11-22

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EXECUTIVE SUMMARY

Directive and Handbook 6.5 provide direction for implementing the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) and the Office of Management and Budget Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities."

Organizational responsibilities and guidance are provided for the following:

- 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
- NRC use of consensus standards including identifying and prioritizing standards, timely endorsement, annual reporting, exceptions to using a consensus standard, and monitoring and assessing the NRC standards program.

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I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission to (i) involve all interested stakeholders in the NRC’s regulatory development processes, (ii) participate in the development of consensus standards that support the NRC’s mission, and (iii) use consensus standards developed by voluntary consensus bodies consistent with the provisions of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104-113).

II. OBJECTIVES

- 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.
- Implement Pub. L. 104-113 and the Office of Management and Budget (OMB) Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities."
- 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.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Chairman

1. Ensures agency compliance with Pub. L. 104-113 and OMB Circular No. A-119.
2. Delegates authority to the Executive Director of Operations to designate 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 No. A-119 and who will represent the agency on the Interagency Committee on Standards Policy (ICSP).¹

B. Executive Director for Operations (EDO)

1. Ensures that the annual report on NRC participation in the development and use of consensus standards is transmitted to the National Institute of Standards and Technology (NIST) each year, including, if applicable, 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.
2. Designates the Director, Division of Engineering, Office of Nuclear Regulatory Research, as the NRC Standards Executive.

C. General Counsel (GC)

Reviews proposed uses of voluntary consensus standards and Government-unique standards, whether in rulemaking or in regulatory guidance documents, to determine whether they are consistent with the NTTAA and OMB Circular No. A-119.

1. Analyzes each request for a rulemaking action for legal sufficiency.
2. Reviews rulemaking actions in accordance with the Office of the General Counsel's Operating Manual.
3. Reviews rulemaking actions to ensure that they are consistent with current rules and other authoritative statements of NRC policy, including, for example, consistency in the use of wording, terminology, definitions, and risk standards.

D. Regional Administrators

1. Provide recommendations in a timely manner to the cognizant office director on the need for new or revised consensus standards.
2. In coordination with the NRC Standards Executive, identify appropriate regional staff to participate as authorized NRC representatives on standards developing organizations (SDOs) needed to support the NRC mission and regional needs.

¹ The ICSP is composed 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 No. A-119.

3. Ensure that authorized NRC representatives on SDO committees, to the extent possible, ascertain the views of the agency on matters of interest, and express views that are consistent with established agency views.
4. Ensure that regional participation in consensus standards bodies is consistent with the agency mission, authorities, priorities, and budget resources.
5. 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.

E. Director, Office of Nuclear Regulatory Research (RES)

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

F. Office Directors

1. Assist the NRC Standards Executive in identifying the current and anticipated needs and associated priorities for development of new or revised standards.
2. In coordination with the NRC Standards Executive, identify appropriate staff to participate as authorized NRC representatives on SDO committees needed to support the NRC mission and office needs.
3. Ensure that office participation in consensus standards bodies is consistent with agency mission, authorities, priorities, and budget resources.
4. In coordination with the NRC Standards Executive, review the effectiveness and efficiency of the offices' participation on consensus codes and standards committees. Coordinate changes to this participation with the NRC Standards Executive.
5. Develop NRC technical positions in a timely manner for use in the standards development process.
6. Ensure that authorized NRC representatives on SDO committees, to the extent possible, ascertain the views of the agency on matters of interest and express views that are consistent with established agency views.
7. 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.
8. 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 use.

9. Establish appropriate communication interfaces with those SDOs whose standards are of primary interest to the office.
10. Ensure that appropriate standards are endorsed in the NRC regulatory structure in a timely manner. Consider both domestic and international standards for endorsement in the NRC regulatory structure as appropriate.

G. Chief Information Security Officer (CISO)

1. Develops and maintains the agencywide computer security program.
2. Assures agencywide compliance with Federal Information Security Management Act, NIST Special Publications and Federal Information Processing Standards, and NRC Security policies and standards through the development and implementation of compliance monitoring and periodic reporting processes.
3. Serves as agency-level liaison with external entities on mutual information technology security interests.

H. Director, Division of Engineering, Office of Nuclear Regulatory Research

Serves in accordance with SECY-08-140 as the NRC Standards Executive.

I. NRC Standards Executive

1. Promotes the following goals relative to staff participation in the development and use of consensus standards:
 - (a) Effective and efficient use of NRC resources;
 - (b) 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 No. A-119;
 - (c) Timely development of NRC technical positions that are coordinated with other Federal participants on the same SDO committee;
 - (d) Representation of NRC's interests in Federal agency standardization activities coordinated by the ICSP; and
 - (e) Consideration of appropriate international standards as a point of reference for U.S. regulations and guidance.
2. Coordinates agency participation in consensus standards bodies through the following actions:
 - (a) Ensures that NRC current and anticipated needs and priorities for standards development to support the regulatory program are communicated to the SDOs.
 - (b) Establishes guidelines 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.

- (c) 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.
- (d) Cooperates with NIST representatives in carrying out responsibilities of OMB Circular No. A-119.
- (e) Consults with NIST representatives, as necessary, in the development and issuance of internal agency procedures and guidance implementing OMB Circular No. 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 site with this information at the NRC Standards Development Web site (<http://www.nrc.gov/about-nrc/regulatory/standards-dev.html>).
- (f) Prepares an annual report on the status of NRC participation in the development and use of consensus standards, including, if applicable, an explanation of the reason(s) for the NRC developing a Government-unique standard rather than using a related consensus standard. Transmits the annual report to NIST for compilation into the Government-wide report to OMB.
- (g) 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.
- (h) Signs and issues nomination letters to SDOs for staff participation on SDO committees as authorized NRC representatives.
- (i) Coordinates with office directors to identify the current and anticipated needs and associated priorities for development of new or revised standards.
- (j) 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.

J. NRC-Authorized Representatives

Participate as authorized agency representatives on SDO committees. See Directive Handbook 6.5, Sections II.D and II.E for staff selection criteria and detailed responsibilities. Detailed guidance is not provided in this directive for staff that participate in individual committee meetings for technical support or training purposes, or who participate in standards activities independent of their official NRC duties. If additional information is needed, the NRC Standards Executive should be consulted.

IV. APPLICABILITY

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

V. DIRECTIVE HANDBOOK

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

VI. REFERENCES

Code of Federal Regulations

- 1 CFR Part 51, Incorporation by Reference.
- 10 CFR Part 50, Domestic Licensing of Production and Utilization Facilities.
- 10 CFR Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants.

Nuclear Regulatory Commission Documents

Management Directives—

- 3.52, "Availability, Retention, and Indexing of Codes and Standards."
 - 6.3, "The Rulemaking Process."
 - 7.3, "Participation in Professional Organizations."
 - 10.43, "Time and Labor Reporting."
- NRC Inspection Manual, Chapter 1201, "Conduct of Employees."
- SECY-97-303, "The Role of Industry (DSI-13) and Use of Industry Initiatives," December 30, 1997.
- SECY-99-029, "NRC Participation in the Development and Use of Consensus Standards," January 28, 1999.
- Staff Requirements, SECY-99-029, February 17, 1999.
- SECY-08-0140, "Development and Regulatory Application of Consensus Standards by U.S. Nuclear Regulatory Commission Staff," September 24, 2008.

OMB Documents

"Federal Participation in the Development and Use of Voluntary Standards and in Conformity Assessment Activities," Office of Management and Budget Circular No. A-119, February 10, 1998, available at http://www.whitehouse.gov/omb/circulars_a119.

United States Code

- Administrative Procedure Act (5 U.S.C. 551 et seq.).
- National Technology Transfer and Advancement Act of 1995, March 1996, Pub. L. 104-113.

Web Sites

American National Standards Institute (ANSI):

<http://www.ansi.org>.

National Institute of Standards and Technology (NIST):

<http://www.nist.gov>.

National Standards System Network (NSSN):

<http://www.nssn.org>.

NRC Standards Development Web site:

<http://www.nrc.gov/about-nrc/regulatory/standards-dev.html>.

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Organizational responsibilities and guidance are provided for the following:

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- NRC use of consensus standards including identifying and prioritizing standards, timely endorsement, annual reporting, exceptions to using a consensus standard, and monitoring and assessing the NRC standards program.

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I. INTRODUCTION

- A.** The National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104-113) requires all Federal agencies to (i) consult with voluntary consensus standards bodies; (ii) participate with voluntary consensus bodies in the development of consensus standards when such participation is in the public interest, compatible with agency missions, authorities, priorities and budget resources; and (iii) use consensus standards as a means to carry out an agency’s policy objectives or activities unless such use is inconsistent with applicable law or is impractical.
- B.** The Office of Management and Budget (OMB) has issued Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," [http://www.whitehouse.gov/omb/circulars_a119], which provides guidance to Federal agencies on compliance with the NTTAA. Although the NRC takes the position that OMB Circular No. A-119 is not binding on the NRC, the NRC voluntarily follows the guidance in OMB Circular No. A-119.
- C.** This handbook provides a framework for NRC implementation of the NTTAA.

II. NRC CONSULTATION AND PARTICIPATION IN THE DEVELOPMENT OF CONSENSUS STANDARDS

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.

A. 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 or revised consensus standard could be used instead of a Government-unique standard. If the staff identifies ongoing or planned standards developing organization (SDO) initiatives to develop a new standard in a relevant technical area, the staff should consider the time frame in which the standard is needed in determining whether to participate in development of a voluntary consensus standard.
2. The need for consensus standards may be specifically identified through ongoing reviews conducted by each office, as appropriate, to determine the suitability of—
 - (a) Replacing existing Government-unique standards with consensus standards, and
 - (b) Updating or revising references to existing consensus standards.
3. Consistent with Pub. L. 104-113 and OMB Circular No. A-119, this directive focuses its attention on the use of consensus standards developed by SDOs, but does not require in all cases the selection of consensus standards in lieu of non-consensus standards developed in the private sector. The standard that best expresses the guidance that otherwise would be stated in a Government-unique standard should be selected for use. 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. International standards that are not consensus standards, such as International Atomic Energy Agency (IAEA) Safety Standards, may be consulted as a useful point of reference for U.S. regulations and guidance, but Pub. L. 104-113 implies no legal obligation to endorse such standards.
4. Each year, each office provides its list of needed new consensus standards or major revisions to existing consensus standards with defined regulatory needs to the NRC Standards Executive. The NRC Standards Executive coordinates this activity, requesting annual input and reviewing the information to identify potential duplicate efforts between offices.

B. Searching for Suitable Consensus Standards

1. Before proposing the development of a new consensus standard or Government-unique standard, cognizant staff performs a search for existing consensus standards developed by SDOs that may suitably be used for the identified application. SDOs include, but are not limited to, the American Society of Mechanical Engineers, the Institute of Electrical and Electronic Engineers, the American Nuclear Society, the American Society for Testing and Materials, and the Health Physics Society. Comprehensive databases that could be used to search for suitable consensus 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 of Standards and Technology (NIST), <http://www.nist.gov>. OMB Circular No. 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 are considered for use in agency regulatory and procurement applications. Examples of international consensus standards include those published by the International Organization for Standardization and the International Electrotechnical Commission. In addition, the search for applicable standards could include appropriate international non-consensus standards which may serve as a useful point of reference for U.S. regulations and guidance.
2. 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 III.E.1 of this handbook.

C. Identifying SDO Committees on Which To Participate

1. 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.
2. Experience and the ability to enlist participants with such experience in developing risk-informed and performance-based consensus 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.
3. Discussions with the candidate SDO are an important part of making the decision to use a consensus standard instead of a Government-unique standard. The cognizant office not only initiates the discussion but also informs the NRC Standards Executive of this initiative. Discussion points with the SDO will include—
 - (a) Its interest in developing or revising the standard,
 - (b) The indicated time frame for the work product,
 - (c) Previous successes of the SDO, and
 - (d) The most effective committee level(s) for staff participation in the development or revision of the consensus standard recognizing that most technical input generally occurs at the writing level.

4. If the staff decides to participate with an SDO in development of a completely new consensus standard (not a revision or compilation of existing consensus standards), the Commission and General Counsel should be consulted.
5. NRC staff may participate in efforts to develop international safety standards that do not meet the definition of consensus standards. The ongoing goal of participation in international SDOs is to share knowledge and experience with international regulators and stakeholders in the development of the international standards. Moreover, if appropriate, NRC may endorse these international safety standards as acceptable means for meeting its regulatory requirements by participating in a process of compliance with the Administrative Procedure Act provisions for notice and comment.

D. Selecting NRC-Authorized Representatives

1. Agency employees who participate at Government expense in the consensus 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 consensus standards development effort on the basis of their technical expertise and NRC functional responsibilities. The number of individual agency participants in a given voluntary consensus standards activity is kept to the minimum required for effective representation of the various program, technical, or other NRC concerns. Staff who participate in international SDOs follow procedures, which are defined at the office level, that differ from those described in this handbook.
2. 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 or designee. A sample format for this nomination letter is provided in Exhibit 1. Nomination of staff for participation on a consensus standards developing 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 voluntary consensus SDOs are made through the respective letter signed by the NRC Standards Executive.
3. NRC Form 652, "Record of Standards Committee Assignments," 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 consensus standard being developed, and to provide information for an NRC list of agency employees who participate on SDO committees and the names of those committees. This list is available to the public on the NRC external Web site at the NRC Standards Development Web site (<http://www.nrc.gov/about-nrc/regulatory/standards-dev.html>).

4. Each office performs an assessment, on an as-needed basis, of the efficiency and effectiveness of its participation on consensus standards committees, and coordinates changes in participation with the NRC Standards Executive. Such reviews are directed toward maintaining or initiating an effective presence in those areas of the consensus standards development process where there is a defined regulatory need and reducing the level of participation elsewhere. 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. This review is typically performed in conjunction with the NRC Standards Executive's request for input to the NRC's annual report to NIST on standards use.

E. Responsibilities of NRC-Authorized Representatives

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

1. 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). Staff also should follow standards of professional ethics in accordance with Agency guidance, such as the annual online ethics training. For additional guidance, see NRC Inspection Manual Chapter 1201.]
2. 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. Standards are not approved for use within the NRC regulatory framework until they have been endorsed (see Section III.B of this handbook).] When unable to attend a consensus standards development meeting, provide for a designated alternate or otherwise ensure that agency views are adequately represented.
3. 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 the Federal Government to the appropriate office director for coordination.
4. Avoid the practice or the appearance of undue influence with regard to agency representation and activities on SDO committees.
5. Keep cognizant NRC staff and management informed of the progress of the consensus standard's development through timely written, including e-mail, and verbal reports.

6. Coordinate consensus standards actions, including preparation of ballots, with cognizant staff from headquarters and the regions during the development and approval of new or revised consensus standards to ensure that key internal issues are identified and conflicts are resolved.
7. Present technical and regulatory issues to the relevant SDO for consideration during development or revision of consensus standards. Attempt to resolve these issues before the consensus standard comes to a final vote.
8. Record in the agencywide timekeeping system the time expended on consensus standards development activities, including time for attendance at meetings, including electronic conferencing, travel, and meeting preparation and reporting.
9. Detailed guidance is not provided in this handbook for staff members who participate in individual committee meetings for technical support or training purposes, or who participate in consensus standards activities independent of their official NRC duties. If additional information is needed, the NRC Standards Executive should be consulted.

F. Coordinating with Stakeholders

1. Periodic coordination meetings are held 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, NRC priorities and resources, and the status of SDO consensus standards development projects and plans. Such meetings include participation by cognizant NRC offices and are coordinated by the NRC Standards Executive.
2. Offices consider assigning staff to interface on an ongoing basis with SDOs whose consensus 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 at the NRC Consensus Standards Development Web site at <http://www.nrc.gov/about-nrc/regulatory/standards-dev.html> that provides information regarding NRC staff participation on consensus standards development activities with SDOs.

G. Training

The NRC Standards Executive coordinates periodic in-house 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.

III. NRC PARTICIPATION IN THE USE OF CONSENSUS STANDARDS

Pub. L. 104-113 requires that all Federal agencies search for voluntary consensus standards that may be used as a means to carry out agencies' policy objectives or activities, unless such use is inconsistent with applicable law or otherwise impractical (see Section III.F of this handbook). The following guidelines provide a framework for implementing the law as it pertains to NRC use of consensus standards.

A. Identifying and Prioritizing Consensus Standards for Endorsement

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

1. The annual update of the list of consensus standards to be developed (see Section II.A of this handbook) is a resource for information from which to establish the list of consensus standards to be endorsed. Consensus standards on the development list that have been issued by SDOs are primary candidates for endorsement. Additionally, the list of consensus 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.
2. NRC offices conduct an ongoing review to determine whether there is a need to update or incorporate new consensus standards to address specific technical issues, new technologies, or regulatory processes. The staff should identify and evaluate additional consensus standards that also may be endorsed as alternatives to existing regulatory requirements or guidance. The bases for selection of one (or more) consensus standard(s) over others must be documented. To minimize the impact on resources, this review is integrated to the extent practical into the responsibilities for staff participation in consensus standards development. The results of the individual office reviews are coordinated through the NRC Standards Executive to prioritize agencywide consensus standards endorsements and to eliminate duplicate efforts.

B. Methods for Endorsing Consensus Standards

NRC endorses consensus standards through incorporation by reference in regulations and through reference in such documents as regulatory guides, NUREG reports, and standard review plans. Each office determines the manner in which a specific consensus standard is incorporated into its regulatory process. In the case of a new consensus standard, it is preferable to determine how the consensus standard is to be used before the consensus standard is written. NRC encourages harmonization of technical requirements and subsequent endorsement, if appropriate. In those cases in which a widely recognized international safety standard constitutes a useful point of reference, but is not sufficiently detailed for endorsement in NRC regulatory documents, such a standard may be referenced for technical guidance, in accordance with the appropriate NRC process, even though it is not a consensus standard.

C. Timeliness of Endorsement

Standards applicable to the NRC's regulatory process should be endorsed in a timely manner to enable NRC, licensees, and others to use new or revised consensus standards expeditiously. To accomplish this, staff should consider initiating the endorsement process for selected consensus 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 consensus standard. Such positions should be communicated to SDOs for possible resolution and may help to prevent conflicts during the NRC endorsement process.

D. NRC Conditions on Consensus Standards

1. The NRC reserves the right to apply conditions 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 not sufficiently supported by relevant technical information (e.g., data), or it is inconsistent with current regulations or policy.
2. The need to impose conditions may, however, be reduced by attempts to resolve outstanding issues through meetings with SDOs and other stakeholders and closer coordination between staff and SDO participants at writing committees. Better coordination between the NRC representatives on standards writing, consensus, and supervisory committees and the NRC staff developing the endorsement document also could lead to a reduced need for conditions. 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.

E. Reporting

1. Annual Report to OMB

The NRC Standards Executive consolidates information submitted by each office, outlined below, into an annual report that is submitted each year on behalf of the agency to NIST. NIST then summarizes the information it receives from Federal agencies and submits it to OMB. For that reason, each office submits, when requested—

- (a) 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);
- (b) The number of SDOs and standards committees in which there is office participation, as well as the number of office employees participating;
- (c) The number of new or revised consensus standards the office has used since the last report; and
- (d) Identification of consensus standards that have been substituted for Government-unique standards as a result of an agency review.

2. Agency Use of Consensus Standards in Rulemaking

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 agency (see Section III.F of this handbook).

3. Agency Use of Government-Unique Standards in Solicitations

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 NIST from the agency (see Section III.F 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.

F. Exception To Using a Consensus Standard

1. 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 agency transmits to OMB through NIST an explanation of the reasons for using such standards.
2. The explanation for each such occurrence must be included in the *Federal Register* notice, in the case of rulemaking, or documented in the concurrence package, in the case of other NRC guidance documents. This explanation is also transmitted as part of the NRC annual report (see Section III.E.1 of this handbook) on its participation in the development of and use of standards.
3. 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. OMB transmits to Congress and its committees a report summarizing all such explanations received in the preceding year.

G. Monitoring and Assessment

Offices assess the effectiveness and efficiency of staff participation in the development and use of consensus standards. This assessment should be coordinated with the NRC Standards Executive, on an as-needed basis.

IV. DEFINITIONS

Consensus Standard

Voluntary *consensus standards*, or *consensus standards*, are standards developed or adopted by voluntary *consensus standards* bodies, both domestic and international. These standards include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties. "Technical standards that are developed or adopted by voluntary consensus standard bodies" is an equivalent term.

Consensus Standards Body

Consensus standards bodies are domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. A voluntary *consensus standards body* is defined by the following attributes:

1. Openness,
2. Balance of interest,
3. Due process,
4. An appeals process, and
5. Consensus, which is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

Government-Unique Standard

A *Government-unique standard* is a technical standard developed by the Federal Government for its own use.

International Safety Standard

An *international safety standard* is a technical standard developed by an intergovernmental body that provides harmonized approaches to safety, promotes consistency, and facilitates international technical cooperation, commerce, and trade. However, it does not necessarily meet the requirements of a consensus standard.

Standard

The term *standard*, or *technical standard*, includes all of the following:

6. Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices.
7. The definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength.

Use

Use means the incorporation of a standard in whole, in part, or by reference in regulation or associated guidance, or the inclusion of a standard in whole, in part, or by reference for procurement purposes. *Use* also may include endorsement of a standard as an acceptable means for meeting a regulatory requirement.

Exhibits

Exhibit 1 Sample Nomination Letter

[Name, title of standards developing organization official]

[Name of committee]

[Name of standards developing organization]

[Street address]

[City, State, ZIP]

Dear (Dr./Mr./Ms.) _____:

I would like to nominate (Dr./Mr./Ms.) _____ as the authorized NRC representative on the **[name of society, level and name of committee]**. (Dr./Mr./Ms.) _____ is **[position within organization]** and is responsible for **[function as it relates to standards committee]**. (Dr./Mr./Ms.) _____ is replacing (Dr./Mr./Ms.) _____, who [has retired, has taken on other duties within the NRC, etc.].

In accordance with the Office of Management and Budget Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," February 10, 1998, the participation on a committee of an NRC-authorized representative does not connote agency agreement with, or endorsement of, decisions reached by the committee, or of standards approved and published as a result of the committee's efforts. Agency representatives participating on consensus standards developing groups 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.

Correspondence should be addressed to:

U.S. Nuclear Regulatory Commission

ATTN: (Dr./Mr./Ms.) _____

M/S: _____

Washington, D.C. 20555

Telephone: _____

Fax: _____

E-mail: _____

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

Sincerely,

[Name], NRC Standards Executive
Office of Nuclear Regulatory Research

cc: **[Name of Secretary for applicable committee]**

**Exhibit 2 *Federal Register* Notice of Rulemaking: Statement on Use of Voluntary
Consensus Standards**

Proposed Rule

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

- **If the rule proposes using a voluntary consensus standard, then the SOC must contain a statement that identifies the voluntary consensus standard.**
- **If the rule proposes using a Government-unique standard instead of a voluntary consensus standard, then the SOC must contain a statement that identifies the voluntary consensus 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, then the SOC must contain a statement to that effect and an invitation to identify any voluntary consensus standard and to explain why the standard should be used.**

If additional guidance on the application of one of these three cases is needed, the staff should consult with the Office of the General Counsel. The following statement is used to address the use of voluntary consensus standards in each proposed rule or interim final rule:

Voluntary Consensus Standards

The National Technology Transfer and Advancement 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 requests comment on the applicability and use of other voluntary consensus standards." Commenters proposing other voluntary consensus standards should explain why these alternatives should be adopted instead of the standard which the NRC proposes to be endorsed or incorporated by reference in this rulemaking.

Option 2. "The NRC proposes using the Government-unique standard in this proposed rule, instead of the following voluntary consensus standard(s): **[identify the standard(s) 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."] The NRC requests comment on whether the Government-unique standard should be used instead of the identified voluntary consensus standard(s)."

Option 3. "The NRC proposes using the Government-unique standard in this proposed rule. 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. The NRC requests public comment on whether there is a voluntary consensus standard that could be used by the NRC instead of the Government-unique standard in this proposed rule. 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" because **[describe the basis (rationale) for the conclusion that the proposed action does not constitute the establishment of a Government-unique standard]**. The NRC requests public comment on this determination." Commenters suggesting that the NRC action constitutes establishment of a Government-unique standard should set forth the rationale for their position.

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 and Advancement 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 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 consensus 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. In preparing the summary of comments, the staff should review comments received from external stakeholders with the Office of the General Counsel, in order to develop comment responses, as well as any necessary language addressing the specific circumstances of the rulemaking.

- **If a voluntary consensus standard is being used, then the SOC must identify 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, then the SOC must identify the standard and explain 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, then the SOC must state 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 and Advancement 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 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 nor a voluntary consensus standard, the following statement is used:

Voluntary Consensus Standards

*The National Technology Transfer and Advancement 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.*