

MD 6.5

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

DT-16-44

Volume 6: Internal Management

Approved By: Michael Weber, Director
Office of Nuclear Regulatory Research

Date Approved: October 28, 2016

Expiration Date: October 28, 2021

Issuing Office: Office of Nuclear Regulatory Research
Division of Engineering, Regulatory Guidance and Generic Issues Branch

Contact Name: Kurt Cozens

EXECUTIVE SUMMARY

Management Directive (MD) 6.5, "NRC Participation in the Development and Use of Consensus Standards," provides direction for implementing the National Technology Transfer and Advancement Act of 1995 (Public Law 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." This revision—

- Establishes new roles and responsibilities, including the Standards Steering Committee, Technical Forum, Program Manager, and Standards Development Organization (SDO) coordinator.
- Clarifies the roles and responsibilities for and NRC representatives to SDO committees.
- Eliminates the roles and responsibilities for the Chief Information Security Officer.
- References a new guidance document that contains detailed implementation steps, previously contained in the handbook, and cites additional implementation guidance.
- Updates the references cited in MD 6.5.

TABLE OF CONTENTS

I. POLICY	2
II. OBJECTIVES	2
III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY	3
A. Chairman.....	3
B. Executive Director for Operations (EDO)	3
C. General Counsel (GC).....	3
D. Director, Office of Nuclear Regulatory Research (RES).....	4
E. Office Directors and Regional Administrators	4
F. Division Director with Staff Participating on Standards Development Organization (SDO) Committees	4
G. Director, Division of Engineering, Office of Nuclear Regulatory Research	5
H. NRC Standards Executive	5
I. Standards Steering Committee.....	6
J. Technical Forum.....	7
IV. APPLICABILITY	7
V. DIRECTIVE HANDBOOK	7
VI. REFERENCES	7

I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) 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 standards bodies consistent with the provisions of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 104-113). The NRC also takes into account (e.g. evaluates, integrates) standards development through multi-lateral international organizations such as the International Atomic Energy Agency.

II. OBJECTIVES

- Promote the effective and efficient use of NRC resources by focusing staff participation on the development of standards that address a defined current or anticipated regulatory need.

-
- Develop coordinated NRC staff positions in standards.
 - Implement the NTTAA 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.”
 - Evaluate the incorporation by reference (IBR) of standards consistent with the Office of the Federal Register (OFR) IBR handbook.
 - Endorse or reference standards important to the NRC in a timely fashion.
 - Ensure efficient and effective staff involvement in the development and use of consensus standards to support regulatory actions.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Chairman

1. Ensures agency compliance with the NTTAA and OMB Circular No. A-119.
2. Delegates authority to the Executive Director for Operations to designate a senior-level official as the NRC Standards Executive, who is responsible for the implementation of the NTTAA and OMB Circular No. A-119 and represents the agency on the Interagency Committee on Standards Policy (ICSP).

B. Executive Director for Operations (EDO)

1. Designates the Director, Division of Engineering, Office of Nuclear Regulatory Research, as the NRC Standards Executive.
2. Ensures that the annual report on NRC participation in the development and use of consensus standards is transmitted by the NRC Standards Executive to the National Institute of Standards and Technology (NIST) by December 31 of each year.

C. General Counsel (GC)

1. Reviews proposed uses of voluntary consensus standards and Government-unique standards to determine whether they are consistent with the NTTAA, OMB Circular No. A-119, and the OFR IBR handbook.
2. Reviews requests for rulemaking that contain standards for legal sufficiency.
3. Reviews rulemaking that contain standards in accordance with the Office of the General Counsel’s Operating Manual.
4. Reviews rulemakings that contain standards 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, and definitions.

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

1. Ensures the effective and efficient agencywide implementation of this management directive.
2. Supervises the performance of the Standards Executive.

E. Office Directors and Regional Administrators

1. Ensure that the NRC Standards Executive receives appropriate information on NRC's current and anticipated needs and associated priorities for development of new or revised standards.
2. In coordination with the NRC Standards Executive, ensure that appropriate staff participate as NRC representatives on standards development organization (SDO) committees in support of the NRC mission and office needs.
3. Ensure that office participation on SDO committees is consistent with the agency mission, authorities, priorities, and budget resources.
4. Ensure that office input on staff participation in the development and use of consensus standards is provided to the NRC Standards Executive for incorporation into the NRC annual report on standards use.
5. Ensure appropriate communication with SDO committees, whose standards are of primary interest to the office.
6. Ensure that appropriate standards are referenced or endorsed in the NRC regulatory infrastructure (e.g., rules, regulatory guidance documents) in a timely manner.
7. Ensure that both domestic and international standards are considered to be referenced or endorsed in the NRC's regulatory infrastructure, as appropriate.

F. Division Director with Staff Participating on Standards Development Organization (SDO) Committees

1. Approves participation of their staff as members on specific SDO committees.
2. Provides funding for approved staff to participate and travel to SDO committee meetings at which activities important to the NRC are occurring.
3. Participates on the Standards Steering Committee, as appropriate.
4. Provides the NRC Standards Executive appropriate information on NRC's current and anticipated needs and associated priorities for development of new or revised standards.

5. Ensures that division input on staff participation in the development and use of consensus standards is provided to the NRC Standards Executive for incorporation into the NRC annual report on standards use.
6. Ensures appropriate communication with SDO committees whose standards are of primary interest to the office.
7. Ensures that appropriate domestic and international standards are referenced or endorsed in the NRC regulatory infrastructure (e.g., rules, regulatory guidance documents) in a timely manner.

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

In accordance with Section III.H of this management directive, serves as the NRC Standards Executive.

H. NRC Standards Executive

1. Assures the following goals and activities relative to staff participation in the development and use of consensus standards:
 - (a) Ensures the effective and efficient use of NRC resources.
 - (b) Develops NRC positions that are in the public interest and consistent with the agency mission and implementation of the NTTAA, OMB Circular No. A-119, and the OFR IBR handbook.
 - (c) Develops NRC technical positions that are coordinated with other Federal participants on the same SDO committee.
 - (d) Represents the NRC in Federal agency standardization activities coordinated by the ICSP.
 - (e) Considers appropriate international standards as a point of reference for U.S. regulations and guidance.
2. Coordinates agency participation on SDO committees through the following actions:
 - (a) Serves as the chair of the Standards Steering Committee.
 - (b) Works with the Standards Steering Committee to ensure that NRC's current and anticipated needs and priorities for standards development supporting the regulatory program are communicated to the SDOs.
 - (c) Establishes guidance for representatives who participate on SDO committees concerning the awareness and adoption of agency views.

-
- (d) Establishes guidance on how NRC staff participating on committees with other Federal agencies are to coordinate views with the other Federal participants on significant issues so that a single, unified U.S. Government position is achieved and, when not feasible, a mutual recognition of differences is understood.
 - (e) Holds meetings with SDOs and external stakeholders on standards, as appropriate, to discuss issues of mutual concern.
 - (f) Consults with NIST representatives, as necessary, in the development and issuance of internal agency procedures and guidance implementing OMB Circular No. A-119.
 - (g) Approves and transmits, by December 31 of each year, to NIST an annual report on the status of NRC participation in the development and use of consensus standards for incorporation into the Government-wide report to OMB. As needed, provides justification for the NRC use of new, Government-unique standards developed by the NRC or other agencies.
 - (h) Signs and issues nomination letters to SDOs for NRC staff participants on SDO committees.
 - (i) In conjunction with the Standards Steering Committee activities, identifies the current and anticipated needs and associated priorities for staff participation in the development of new or revised standards.
 - (j) Assesses the effectiveness and efficiency of the staff who participate on SDO committees. Coordinates changes to staff participation with the affected NRC offices.
3. Issues additional guidance, as needed, on implementation of this management directive.

I. Standards Steering Committee

The membership of the Standards Steering Committee is composed of division directors from offices with a significant interest in the regulatory use of codes and standards. The Standards Steering Committee:

1. Prioritizes the standards-related activities important to the NRC and discusses the availability of resources to support staff involvement.
2. Consistent with Commission decisions on rulemakings, approves the NRC's development of new, Government-unique standards.

J. Technical Forum

The membership of the technical forum is composed of office or regional division directors, deputy division directors, branch chiefs, and senior level advisors as selected by their management, who are responsible or interested in a specific technical area. The Technical Forum is not anticipated to meet as a body, but to meet with only those individuals necessary to address a specific topic.

1. Establishes recommended NRC positions on consensus standards.
2. As needed, individuals of the Technical Forum provide technical advice to the Standards Steering Committee, NRC Standards Executive, program manager, SDO coordinators, and NRC participants on SDO committees regarding formal NRC positions.

IV. APPLICABILITY

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

V. DIRECTIVE HANDBOOK

Handbook 6.5 contains guidelines for the participation in the development and use of consensus standards.

VI. REFERENCES

Code of Federal Regulations

1 CFR Part 51, Incorporation by Reference.

Nuclear Regulatory Commission

“Guidance for NRC Staff Participation on Standards Development Committees,” available on the RES Standards Development SharePoint at <http://fusion.nrc.gov/res/team/de/SDO/default.aspx>.

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 Standards Development Web Site:

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

SECY-99-029, "NRC Participation in the Development and Use of Consensus Standards," January 28, 1999, available at <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1999/secy1999-029/1999-029scy.pdf>.

Staff Requirements Memorandum, "Staff Requirements – SECY-99-029 – NRC Participation in the Development and Use of Consensus Standards," February 17, 1999 ([ML003751820](#)).

SECY-08-0140, "Development and Regulatory Application of Consensus Standards by U.S. Nuclear Regulatory Commission Staff," September 24, 2008 ([ML081260303](#)).

Office of the Federal Register

"Incorporation by Reference (IBR) Handbook," April 2016, available at <https://www.archives.gov/federal-register/write/handbook/ibr.pdf>.

Office of Management and Budget

Office of Management and Budget (OMB) Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Standards and in Conformity Assessment Activities," January 27, 2016, available at https://www.whitehouse.gov/sites/default/files/omb/inforeg/revised_circular_a-119_as_of_1_22.pdf.

United States Code

Administrative Procedure Act (5 U.S.C. 551 et seq.).

National Technology Transfer and Advancement Act of 1995, Public Law 104-113, March 1996.

DH 6.5**NRC PARTICIPATION IN THE
DEVELOPMENT AND USE OF
CONSENSUS STANDARDS****DT-16-44***Volume 6:* Internal Management*Approved By:* Michael Weber, Director
Office of Nuclear Regulatory Research*Date Approved:* October 28, 2016*Expiration Date:* October 28, 2021*Issuing Office:* Office of Nuclear Regulatory Research
Division of Engineering, Regulatory Guidance and Generic Issues Branch*Contact Name:* Kurt Cozens**EXECUTIVE SUMMARY**

Management Directive (MD) 6.5, "NRC Participation in the Development and Use of Consensus Standards," provides direction for implementing the National Technology Transfer and Advancement Act of 1995 (Public Law 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." This revision—

- Establishes new roles and responsibilities, including the Standards Steering Committee, Technical Forum, Program Manager, and Standards Development Organization (SDO) coordinator.
- Clarifies the roles and responsibilities for and NRC representatives to SDO committees.
- Eliminates the roles and responsibilities for the Chief Information Security Officer.
- References a new guidance document that contains detailed implementation steps, previously contained in the handbook, and cites additional implementation guidance.
- Updates the references cited in MD 6.5.

TABLE OF CONTENTS

I. INTRODUCTION.....3

II. NRC CONSULTATION AND PARTICIPATION IN THE DEVELOPMENT OF CONSENSUS STANDARDS3

A. Identifying Needed New or Revised Consensus Standards and Prioritizing Standards Development Organization (SDO) Activities Important to the NRC.....3

B. Searching for Suitable Consensus Standards.....4

C. Identifying SDO Committees on which to Participate5

D. Selecting NRC-Authorized Representatives6

E. Responsibilities of NRC Participants.....7

F. Coordinating with Stakeholders8

G. Training8

III. ROLES AND RESPONSIBILITIES FOR THE DEVELOPMENT AND USE OF CONSENSUS STANDARDS AT NRC8

A. Program Manager.....8

B. SDO Coordinator9

C. NRC Representative to a Standards Development Organization (SDO) Committee9

D. NRC Alternate Representative to the Standards Development Organization (SDO) Committee10

E. Observer.....10

F. Technical Support.....10

IV. NRC USE OF CONSENSUS STANDARDS.....10

A. Management of NRC Staff Activities for Consensus Standards.....11

B. Endorsing, Approving for Use, and Referencing Consensus Standards11

C. Timeliness of Endorsement or Approval for Use12

D. NRC Conditions on Consensus Standards13

E. Reporting.....13

F. Agency Use of Consensus Standards in Rulemaking14

G. Agency Use of Government-Unique Standards in Solicitations.....14

H. Exception to Using a Consensus Standard.....15

I. Monitoring and Assessment.....15

V. GLOSSARY15

I. INTRODUCTION

- A. The National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 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) issued OMB Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," as guidance to implement the NTTAA.
- C. The Office of the Federal Register (OFR) requirements governing incorporation by reference (IBR), in 1 CFR Part 51, were revised in a 2014 rulemaking to address the "reasonable availability" of documents to be incorporated by reference into the Code of Federal Regulations. Thereafter, the OFR issued implementing guidance for reasonable availability in the OFR IBR handbook (April 2016). NRC Management Directive (MD) 6.3, "The Rulemaking Process," provides guidance for NRC to implement the requirements and guidance of the OFR on IBR.
- D. This handbook provides guidance for NRC to implement the requirements of the NTTAA. The NRC Standards Executive may issue additional guidance consistent with this handbook.

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

The following guidelines provide a framework for implementing Public Law 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 Needed New or Revised Consensus Standards and Prioritizing Standards Development Organization (SDO) Activities Important to the NRC**
 - 1. Through participation of the Standards Steering Committee members, offices and regions identify and prioritize the needs for new or revised standards.
 - 2. The Standards Steering Committee will approve the development or new use of a Government-unique standard. Before deciding to use a Government-unique standard, staff should consider existing or planned voluntary consensus standards in a relevant technical area, the time frame in which the standard is needed, and the time needed to create a new or revised standard.

-
3. The need for consensus standards may be specifically identified through ongoing staff reviews, to determine the suitability of the following:
 - (a) Replacing existing Government-unique standards with consensus standards, and
 - (b) Updating or revising existing references to consensus standards.
 4. Consistent with Public Law 104-113 and OMB Circular No. A-119, this directive focuses on the use of consensus standards developed by SDOs, but does not require in all cases the selection of consensus standards in favor of non-consensus standards developed in the private sector (e.g., guidance developed by the Nuclear Energy Institute or the Electric Power Research Institute). The standard that best expresses the guidance that otherwise would be conveyed 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-based standards when such standards may reasonably be used instead of prescriptive standards.
 5. International standards that are not consensus standards (e.g., International Atomic Energy Agency (IAEA) Safety Standards) may be consulted as a useful point of reference for U.S. regulations and guidance, but Public Law 104-113 implies no legal obligation to endorse these standards.
 6. Periodically, the Standards Steering Committee will request input to identify needed new consensus standards and existing consensus standards requiring significant revision. The offices and regions will identify and analyze the regulatory need. The Standards Steering Committee will assess the input and provide to the NRC Standards Executive a list of recommended new and revised consensus standards for discussion with the SDO stakeholders. If the NRC recommends revising a standard or creating a new standard, the NRC Standards Executive will communicate the recommendation to the SDO as appropriate.
 7. The phrases “defined current or anticipated regulatory need,” “standards-related activities important to the NRC,” and “activities important to the NRC” may be used interchangeably.

B. Searching for Suitable Consensus Standards

1. Before proposing the development of a new consensus standard or Government-unique standard for regulatory use, cognizant staff will perform a search for existing private sector or consensus standards that may suitably meet the regulatory need. Staff will obtain approval from the Standards Steering Committee prior to developing a new Government-unique standard or requesting that an SDO develop a new consensus standard.

2. 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.
3. A decision to use a Government-unique standard instead of a consensus standard is reported to OMB as part of the annual report. The content of this report is discussed in Section IV.E.1 of this handbook.

C. Identifying SDO Committees on which to Participate

1. When a regulatory need exists, the cognizant office determines which SDO and SDO committee has the scope and technical expertise for developing new or revising existing consensus standards.
2. Discussions with the candidate SDO are important for decisionmaking and determining whether to use a consensus standard instead of a Government-unique standard. If an office (or region), rather than the NRC Standards Executive, initiates the discussion with an SDO, the office should inform the NRC Standards Executive of the discussion. The office should provide the following to the NRC Standards Executive:
 - (a) Ongoing SDO activities to develop or revise a consensus standard that addresses a technical scope important to the NRC,
 - (b) The SDO's interest in developing a new consensus standard or revising an existing consensus standard,
 - (c) The time frame for the work product to be published in comparison to the time frame associated with the regulatory need,
 - (d) Previous performance of the SDO, and
 - (e) The most effective committee level(s) for staff participation in the development or revision of the consensus standard.
3. NRC staff also 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 standards committees 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 an acceptable means of meeting its regulatory

requirements by participating in a process that is compliant with the Administrative Procedure Act provisions for notice and comment.

D. Selecting NRC-Authorized Representatives

1. A decision to provide an NRC representative to an SDO committee to assist in the writing of a standard should consider the regulatory prioritization established by the Standards Steering Committee.
2. Agency employees who participate on behalf of the agency, at Government expense, in the SDO activities do so as specifically authorized NRC representatives. Individuals are nominated by their office management to be an NRC participant on a specific SDO committee based on their ability to contribute to the consensus standards development effort, their technical expertise, and their NRC functional responsibilities.
3. Procedures for administering staff participation in consensus standards committees are outlined in this handbook. Staff members who participate on international non-consensus committees follow procedures defined in office level documents that may differ from those described in this handbook.
4. An NRC representative is nominated to participate on an SDO committee by means of a letter prepared by the nominee's office to the appropriate SDO official. All appointments, replacements, and terminations of staff on SDO committees are communicated through such letters signed by the NRC Standards Executive. SDO procedures for submitting relevant nominee background information are to be followed.
 - (a) The nomination letter is signed by the NRC Standards Executive with concurrence through the nominee's office director, regional administrator, or a designee.
 - (b) 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.
 - (c) All staff will complete NRC Form 652, "Record of Standards Committee Assignments," when nominated for the position of NRC-authorized representative.
 - (d) NRC Form 652 accompanies the concurrence package for the nomination letter but is not transmitted with the letter. Its purpose is to capture the reasons for engaging in this standards activity and to provide information for an NRC list of agency employees who participate on SDO committees. This list is available to the public on the external NRC Standards Development Web site at <http://www.nrc.gov/about-nrc/regulatory/standards-dev.html>.

-
5. An office or region is required to reaffirm its NRC participants on SDO committees on an annual basis. The NRC Standards Executive provides to each office or region a list of its NRC participants with a request to reaffirm, reassign, or terminate each committee membership. A key consideration in the decision to reaffirm, reassign, or terminate should be the list of standards activities that are important to the NRC, prioritized by the standards steering committee. 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 the NRC's use of standards.

E. Responsibilities of NRC Participants

NRC staff who participate on SDO committees will follow these 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 an officer of the committee.
2. As part of committee activities, express views that are consistent with the agency views and strive to reconcile key differences within the staff or between the SDO and agency views on SDO actions. Where there is no agency position on an issue, authorized agency representatives are to use their best judgment based on their experience, technical expertise, and discussions with other NRC staff. When the NRC Representative is unable to attend a consensus standards development meeting, an NRC Alternate Representative should be designated to ensure that agency interests 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. Issues of paramount importance to the NRC and Federal Government counterparts should be elevated to the appropriate office director for coordination.
4. Discuss fully the NRC's position relative the code, but present the NRC's positions in a respectful manner which demonstrates NRC's thoughtful and reasoned consideration of differing views held by other stakeholders.
5. Keep the SDO coordinator and other cognizant NRC staff and management informed of the progress toward development of consensus standards, using pre- and post-meeting communications and briefings of appropriate technical forum members.
6. During the development and SDO issuance of new or revised consensus standards, coordinate standards actions, including preparation of ballot responses, with SDO coordinators, cognizant staff, and technical forum members to ensure that key issues are identified and conflicts are resolved.

7. Present technical and regulatory topics to the SDO for consideration during development or revision of consensus standards. Attempt to resolve these topics 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 (see Management Directive 10.43, "Time and Labor Reporting").
9. Follow the additional guidance issued by the NRC Standards Executive.

F. Coordinating with Stakeholders

1. The NRC Standards Executive conducts periodic coordination meetings with key SDOs and other stakeholders to communicate on topics important to the NRC, and to convey NRC recommendations for new or revised consensus standards. Such meetings should include participation by cognizant NRC offices.
2. The Office of Nuclear Regulatory Research provides additional information regarding NRC staff participation in consensus standards development activities. A list of SDO committees is available on the external NRC Standards Development Web site at <http://www.nrc.gov/about-nrc/regulatory/standards-dev.html>.

G. Training

The program manager provides training to NRC participants (representatives and alternate representatives) and SDO coordinators on implementation of this management directive and additional guidance issued by the NRC Standards Executive. This training includes updates to related Federal and NRC requirements and staff experiences on SDO committees.

III. ROLES AND RESPONSIBILITIES FOR THE DEVELOPMENT AND USE OF CONSENSUS STANDARDS AT NRC

A. Program Manager

The standards program manager is an NRC staff member, appointed by the Standards Executive. The program manager's duties are described below.

1. Provides the standards program overall coordination in accordance with this management directive and other guidance issued by the NRC Standards Executive.
2. Facilitates internal NRC stakeholder participation in technical discussions.
3. Manages and retains the records associated with the coordination of the agency's standards activities and SDO committee memberships.
4. Organizes the steering committee meetings and issues the meeting minutes.

-
5. Trains SDO coordinators and NRC participants on their roles and responsibilities and processes associated with their activities.
 6. Tracks NRC efforts to endorse published SDO standards that are important to the NRC.
 7. Maintains an NRC external Web site that provides information about NRC standards activities.

B. SDO Coordinator

The SDO coordinator provides guidance to and receives feedback from the NRC representatives on the SDO committees in all participating NRC offices.

1. May serve as the coordinator for one or more SDOs, or for a part of an SDO.
2. Gathers and organizes information from the NRC representatives associated with the assigned SDO committees.
3. Coordinates pre- and post-SDO committee meeting discussions.
4. Arranges meetings with the NRC Standards Executive, steering committee, technical forum, and SDOs, as needed.
5. Communicates guidance to the NRC representatives from the NRC Standards Executive, steering committee, technical forum or program manager.
6. Recommends priorities for NRC participation in standards activities of the assigned SDO.
7. Works with NRC representatives to develop and coordinate formal NRC positions on issues in standards.
8. Encourages authorized NRC participants on SDO committees to ascertain the views of the agency on matters of interest, and to express views that are consistent with formal NRC positions.
9. Prepares information to be presented to the Standards Steering Committee regarding NRC activities in the SDO.

C. NRC Representative to a Standards Development Organization (SDO) Committee

The NRC representative provides the NRC committee vote, in accordance with the policies and procedures established by the SDO.

1. Participates as an authorized agency representative on one or more SDO committees, in accordance with guidance established by the NRC Standards Executive.
2. Provides the NRC committee vote, in accordance with policies and procedures established by the SDO.

3. As an SDO committee member, promotes NRC positions in accordance with this management directive and NRC Standards Executive guidance.
4. Provides information to the SDO coordinator to support the following:
 - (a) Pre- and post-SDO committee meeting discussions, and
 - (b) Meetings with the Standards Executive, steering committee, technical forum, and SDOs.

D. NRC Alternate Representative to the Standards Development Organization (SDO) Committee

1. Functions as the NRC representative when the NRC representative is not able to participate in the SDO committee meeting.
2. When authorized, attends the SDO committee meeting with the NRC representative and provides discussion input, as appropriate, during the committee meeting.
3. Does not vote on SDO committee actions, unless acting for the NRC representative.

E. Observer

1. An individual selected by an NRC office or region to attend an SDO committee meeting to learn about the SDO process or technical content.
2. The observer's supervisor determines which SDO committee meetings will be attended.
3. The observer is not a voting member of the SDO committee.

F. Technical Support

1. If authorized by the office or region, the NRC representative may request a technical support participant to attend an SDO committee meeting to provide technical input during committee discussions.
2. The technical support participant does not vote on SDO committee actions.

IV. NRC USE OF CONSENSUS STANDARDS

Public Law 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 IV.H of this handbook). The following guidelines provide a framework for implementing the law as it pertains to NRC use of consensus standards.

A. Management of NRC Staff Activities for Consensus Standards

Through participation on the standards steering committee, offices establish and implement a process to identify and prioritize consensus standards to be endorsed for use in their regulatory framework.

1. The Standards Steering Committee periodically defines and prioritizes standards activities important to the NRC. These may include new standards that should be written or existing standards that require revision to more efficiently implement the NRC mission. The list will also include a prioritization of on-going SDO activities important to the NRC. Standards important to the NRC include, especially, those ultimately intended for use in regulatory documents, and those used in licensing actions submitted to the NRC and for which the staff will need to determine the adequacy of the standard. The list of standards and SDO activities important to the NRC should be shared with NRC management, SDOs, and other external stakeholders to assist in the management of standards efforts and the effective and efficient use of NRC staff resources. All items on this list should have an identified regulation or NRC guidance document where the standard, new or revised, is planned to be referenced or endorsed. The NRC Standards Executive should keep the Standards Steering Committee members informed of the content of the Annual Report to OMB (see Section IV.E of this handbook).
2. When offices are creating or revising regulations or other NRC guidance, consideration should be given to endorsing, approving for use, or referencing the most current version of issued standards. Should more than one consensus standard exist that addresses the needs of regulations or NRC guidance, an effort should be made to utilize all acceptable standards.

B. Endorsing, Approving for Use, and Referencing Consensus Standards

The following is a compilation of current NRC practices for endorsing, approving for use, or referencing consensus standards.

1. The citation of a standard may occur in various types of NRC documents, such as regulations, regulatory guides (RGs), NUREGs, generic correspondence, safety evaluation reports (SERs), inspection manual chapters (IMCs), inspection procedures (IPs), etc. A citation of a standard may have differing significance depending on the context.
2. Endorsement, approval for use, and the referencing of standards may be implemented by two methods; (1) incorporation by reference (IBR) as part of rulemaking in accordance with 1 CFR Part 51, and (2) by citation in NRC documents.
3. IBR applies to standards that are endorsed or approved for use through rulemaking and that are required to be implemented by applicants or licensees in accordance

with NRC regulations. An example of an IBR is the incorporation of portions of the ASME Boiler and Pressure Vessel Code in 10 CFR 50.55a.

4. In a RG, or when a NUREG is used for regulatory guidance, the reference to a standard may mean that it is a condition of being within the scope of the guidance. If the NRC is not incorporating by reference a standard in an NRC regulation, then the preferred method of endorsing or approving for use standards is to communicate the NRC's position in a guidance document such as a regulatory guide.
5. In other NRC documents, the context of endorsing, approving for use, or referencing a standard may vary. Examples include a suggestion or a pointer to best practices, a description of an acceptable method to meet NRC staff positions, or simply a listing in a bibliography.
6. Regardless of how NRC documents endorse, approve for use, or reference a standard, the NRC may establish conditions (limitations and modifications) on how the standard is to be used.
7. Not all issued standards, new or revised, will be endorsed or approved for use by the NRC. Only standards that help to meet a demonstrated need in support of regulatory activities will be endorsed or approved for use.

C. Timeliness of Endorsement or Approval for Use

Endorsement and approval for use of standards occurs only when it supports activities important to the NRC. Therefore, it is important that the program manager, SDO coordinators, and NRC representatives provide information to the Standards Steering Committee justifying why the standards activity is important to the NRC and the timing of its need. If there is not a regulatory need to support a licensing activity, then the timing of a standard endorsement or approval for use will be controlled by other regulatory factors, including the following:

1. Endorsement and approval for use by IBR is controlled by the need for new or revised regulations.
2. Endorsement and approval for use by RG citation may be controlled by emerging needs to revise an existing RG or create a new RG. Otherwise, the timeliness may be controlled by the assessment cycle for the need to revise, withdraw, or accept-as-is an existing RG.
3. Whenever the staff is creating or revising regulations or other NRC guidance, consensus standards should be considered for endorsement, or approval for use. If the NRC is revising an existing regulation incorporating by reference a standard, the staff should consider updating to the most current published revision or version, consistent with the requirements of NRC backfitting regulations and the issue finality provisions in 10 CFR Part 52.

D. NRC Conditions on Consensus Standards

Endorsement of standards occurs only when it supports activities important to the NRC. Therefore, it is important that the program manager, SDO coordinators, and NRC representatives justify to the Standards Steering Committee (1) why the standards activity is important to the NRC and (2) how the urgency of the work was determined. If there is not a regulatory need to support a licensing activity, then the timing of a standard endorsement will be controlled by other regulatory factors, including the following:

1. The NRC reserves the right to apply conditions, 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 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 concerns 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. Conditions and limitations 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 the Office of Management and Budget

The NRC Standards Executive consolidates information outlined below to be submitted by each office or region, for inclusion into an annual report. (The annual report is based on the data submitted through the NIST Web site <http://www.nist.gov/standardsgov/nttaa.cfm>.) The NRC Standards Executive submits the report to NIST each year on behalf of the agency. NIST then summarizes the information it receives from Federal agencies and submits it to OMB. When requested, each office or region submits the following:

- (a) Decisions in the previous fiscal year to use Government-unique standards instead of consensus standards (including an explanation as to why use of the voluntary consensus standard would be inconsistent with applicable law or otherwise impractical);

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

2. Annual Report on the NRC Standards Program

The program manager will create an internal annual report of the activities of the NRC Standards Program. The report should address the following:

- (a) Identification of standards activities that the Standards Steering Committee has deemed important to the NRC;
- (b) The status of standards activities that the Standards Steering Committee has deemed important to the NRC, including an estimate of when the new or revised standards are anticipated to be published by the SDO;
- (c) The endorsement status (where and when) of the published standards that the Standards Steering Committee has deemed important to the NRC; and
- (d) An assessment of the effectiveness of the NRC Standards Program, with recommendations, if appropriate, to make the program more efficient.

3. The annual Report on the NRC Standards Program will be shared with the Standards Steering Committee for discussion on the progress of the NRC Standards Program.

F. Agency Use of Consensus Standards in Rulemaking

Statements are included in the preamble for proposed and final rulemakings to, respectively, request comment, and to report on the final resolution of comments, on the use or non-use of consensus standards. The NRC Standards Executive and MD 6.3 will provide guidance for developing the appropriate statements in both proposed and final rules.

G. 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 IV.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.

H. 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 annual report (see Section IV.E.1 of this handbook) on the NRC's 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.

I. Monitoring and Assessment

1. Decisions by NRC offices to authorize staff participation on SDO committees should consider the standards steering committee's list of standards activities important to the NRC, the necessary timing, the status of standards development, and anticipated publication date.
2. The program manager will meet periodically with the SDO Coordinators to assess the effectiveness and efficiency (lessons learned) of the NRC Standards Program and report the results to the NRC Standards Executive and the standards steering committee.

V. GLOSSARY

Approve for Use

To establish or indicate the NRC's approval of a standard, but without any NRC preference for its use as opposed to any other standard or approach.

Consensus Standards Body (from OMB Circular No. A-119)

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 endorsement of standards 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.

Endorse

To establish or indicate the NRC's preference for the use of a standard.

Government-Unique Standard (from OMB Circular No. A-119)

A Government-unique standard is a technical standard developed by the Federal Government for its own use. For a more complete definition, see the Office of Management and Budget Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Standards and in Conformity Assessment Activities,".

Interagency Committee on Standards Policy (ICSP)

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 Public Law 104-113 and OMB Circular No. A-119.

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.

Participant

The term participant includes the individuals acting as an NRC Representative, NRC Alternate Representative, Observer, and Technical Support.

Reference

To cite to a standard for information or to provide context for a statement in an NRC document, but without any NRC preference or approval of the standard,

Standard (from OMB Circular No. A-119)

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

1. Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices;
2. 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; formats for information and communication exchange; or descriptions of fit and measurements of size or strength; and
3. Terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process, or production method.

Standards Development Organization (also “SDO Committee”)

An external organization that develops standards. SDO committees are independent of the agency’s standards steering committee. One or more SDO committees may be involved in the development, approval, and publication of an SDO standard. The NRC maintains a list of SDO committees on which the NRC staff participates. This list is available on the NRC external Web site at <http://www.nrc.gov/about-nrc/regulatory/standards-dev.html>.

Standards Steering Committee

An agencywide committee composed of senior-level managers whose staff participate on SDO committees. The members determine the agency’s selection and use of Federal or private-sector consensus standards and provide insight on which SDO committees that the NRC staff should participate. The NRC Standards Executive leads the committee and is also a member of the committee. The committee meetings will occur periodically.

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.

Voluntary Consensus Standard (from OMB Circular No. A-119)

Voluntary consensus standards, or consensus standards, are standards developed or adopted by voluntary consensus standards bodies. 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.