POLICY ISSUE
(Information)

September 24, 2008 SECY-08-0140

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: DEVELOPMENT AND REGULATORY APPLICATION OF CONSENSUS STANDARDS BY U.S. NUCLEAR REGULATORY COMMISSION STAFF

PURPOSE:

The purpose of this paper is to inform the Commission of the staff's ongoing activities to develop, promulgate, and endorse voluntary consensus standards in the Nuclear Regulatory Commission's (NRC's) regulatory framework, as a means of increasing the efficiency and effectiveness of the regulatory process. The paper does not propose any changes to current policy, nor does it address any new commitments or resource implications.

SUMMARY:

In 2007, over 160 NRC staff members participated in over 300 standards development committees. These committees included the American Society of Mechanical Engineers, the Institute of Electrical and Electronics Engineers, the National Fire Protection Association, the American Concrete Institute, and many others. The NRC's use of consensus standards is consistent with the requirements of Public Law 104-113, the National Technology Transfer and Advancement Act of 1995 and Management Directive 6.5, "NRC participation in the Development and Use of Consensus Standards." Work is underway with standards development organizations to update voluntary consensus standards that may be applied to license renewal or new nuclear plant construction, including advanced reactor technologies. Participation of NRC staff in voluntary consensus standards development is essential, as the

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Agency relies on many standards as part of its regulatory framework. The benefits include cost savings, improved efficiency and transparency, and high technical quality of regulatory requirements.

BACKGROUND:

The NRC works with standards organizations to develop consensus standards associated with systems, structures, equipment, or materials used by the nuclear industry. A standard contains technical requirements, safety requirements, guidelines, characteristics, and recommended practices for performance[1]. Standards or groups of standards that have been incorporated by reference into the regulations of one or more governmental bodies, and have the force of law, are referred to as codes[2].

Standards are typically developed by a group of individuals with a high level of experience and knowledge in the area being addressed by the standard. These individuals form a standards committee, sub-group, or working group, and through a series of committee meetings over time, develop and document a consensus on how to carry out activities in their area of expertise. For example, the American Society of Mechanical Engineers (ASME) developed the Boiler and Pressure Vessel (B&PV) Code, which is widely acknowledged as an acceptable set of standards used to design, construct, and inspect pressure-retaining components (including nuclear vessels, piping, pumps, and valves). Similarly, the National Fire Protection Association (NFPA) developed a series of consensus standards to define acceptable methods to design, install, inspect, and maintain fire protection systems. Most codes and standards continually evolve over time, through a process that includes the development of new standards and the revision of existing ones.

Under the Atomic Energy Act of 1954, as amended, the NRC has authority to promulgate regulations governing both nuclear materials and production and utilization facilities. In many cases, the NRC has developed and promulgated such regulations. However, in other areas, the NRC has incorporated by reference into NRC regulations several consensus standards. The NRC's reasons for incorporation by reference include (but are not limited to) providing the level of regulatory certainty and predictability desired by stakeholders, recognizing and considering the broad range of technical expertise and experience of the individuals who are represented on many consensus standards organizations, and minimizing the expenditure of NRC resources that would otherwise be necessary to develop regulations which provide the level of detail comparable to that provided by consensus standards. The NRC staff also issues documents providing guidance on acceptable methods for complying with NRC regulations, such as regulatory guides. These guidance documents frequently reference consensus standards as acceptable methods for compliance with NRC regulations.

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[1] In U.S. Office of Management and Budget (OMB), Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," technical standards are defined to include common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices. Also included are 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.

[2] Within the structural engineering community, the terms "code" and "standard" are sometimes used interchangeably. In this context, the term "code" should not be confused with analytical and computational codes used for analyses such as fluid flow and stress distributions in components.

The NRC's use of consensus standards, as described above, is consistent with the requirements of Public Law 104-113, the National Technology Transfer and Advancement Act of 1995 (NTTAA). That law established as policy Government participation in the development and adoption of consensus standards. As an independent agency, the NRC voluntarily complies with the NTTAA by endorsing voluntary consensus standards in lieu of developing Government unique standards. OMB Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," provides guidance for implementing the NTTAA. The circular authorizes the National Institute of Standards and Technology (NIST) to coordinate conformity assessment activities of the participating agencies. The circular defines voluntary consensus standards bodies as "domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures." The NTTAA and the circular encourage the participation of Federal representatives in these bodies to increase the likelihood that the standards they develop will meet both public and private sector needs.

The NRC staff participates in several voluntary consensus standards developing organizations (SDOs), including the ASME, the Institute of Electrical and Electronics Engineers (now known simply as IEEE), the NFPA, the Health Physics Society (HPS), the American Concrete Institute (ACI), and the American Nuclear Society (ANS). NRC staff members participate and contribute at all levels of the standards developing process, from working groups that write standards through consensus boards that vote on approval of standards to be promulgated by the SDO. A list of the main standards-developing organizations with which the NRC interacts is enclosed. In 2007, over 160 NRC staff members participated in over 300 standards development committees.

The American National Standards Institute (ANSI), a not-for-profit membership organization, serves as administrator and coordinator of the U.S. private-sector voluntary standardization system. ANSI has established several criteria for accrediting standards developing organizations that adhere to due process for voluntary consensus standards development, including a balance of interests, public review and comment with documented resolution, and a process for appeals. A standard that meets such requirements is eligible to be designated by ANSI as an American National Standard. The NRC prefers consensus standards that have been developed by ANSI-accredited SDOs when considering standards for incorporation by reference.

DISCUSSION:

Standards Development Activities

Management Directive 6.5, "NRC Participation in the Development and Use of Consensus Standards," provides guidance for the NRC staff members participating in standards development activities. Each office is directed to prioritize its needs for new or revised technical standards, and to evaluate whether an existing, new, or revised consensus standard could be used instead of a Government unique standard. Each office is responsible to identify SDO committees on which to participate and to recommend NRC-authorized representatives. The NRC has designated the Director, Division of Engineering, Office of Nuclear Regulatory Research, as the NRC Standards Executive. The NRC Standards Executive coordinates Agency participation in standards developing organizations, and nominates staff for membership on relevant SDO committees.

In standards activities, staff participants are directed to express views that are consistent with established Agency views, if any, and otherwise to use their own technical judgment. Staff participants are to coordinate standards actions, including preparation of ballots, with knowledgeable staff at headquarters and the regions, and to communicate emerging issues to management. Participation on a committee as 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. NRC reserves the authority to review standards for endorsement, in whole or in part, separate from staff participation in standards committees.

To foster communication and coordination, the NRC Standards Executive holds periodic meetings with key SDOs and other stakeholders. Internal meetings are also arranged among staff members who participate in consensus standards development. A staff point of contact has been established for each SDO, and an internal web page that lists staff participants and other information is periodically updated. The NRC Standards Executive also participates in the Interagency Committee on Standards Policy to share information, successes, and challenges among Federal agencies that use consensus standards.

Development of Standards for New Reactors

In a June 15, 2006, memorandum [ML072420378], the Commission directed the staff to update and revise 476 regulatory guides, 58 of which were needed to support new, near-term reactor licensing activities, and many of which cite consensus standards. Similarly, many consensus standards are not up to date with respect to the needs of new and advanced reactor licensing and construction. The industry is working with SDOs to update voluntary consensus standards that incorporate new methods, materials and technologies that will be applied to license renewal and new construction. For example, SDOs are working on ASME B&PV Code, Section III, Division 1, Subsection NH, "Class I Components in Elevated Temperature Service." The NRC has not formally reviewed Subsection NH, which was not considered to be of high priority for the current U.S. fleet of light-water reactors (LWRs). Subsection NH was referenced in the design of the Fort St. Vrain gas-cooled reactor, which operated from 1977 to 1989, but these standards have not been updated recently to reflect advances in reactor design, inspection methods, or safety criteria. This subsection will be cited in the design of components for advanced high-temperature gas-cooled reactors, and it may also be invoked for some components in near-term new reactor designs. Because of the heightened level of development activity, this is a critical time for NRC participation in the consensus standards development process.

Designers of advanced reactor technologies also will employ consensus standards wherever practicable, in order to realize cost savings and increased standardization of designs. The NRC staff is participating in new working groups formed to develop the ASME B&PV Code sections needed for advanced reactors. New standards are also expected from ANS and other SDOs that anticipate structures, fabrication methods, and materials needed for new and advanced reactor designs. Standards developers are, at this time, writing new standards for gas-cooled reactors with a risk-informed approach to maintaining the integrity of structures, systems, and components that support passive safety functions. This reliability and integrity management approach differs significantly from the design philosophy that has been employed for LWRs, which focuses on maintaining coolant pressure boundary integrity. In addition to design, the inspection of advanced reactors also should be governed by updated standards, such as ASME B&PV Code, Section XI, Division 2, "Rules for Inspection and Testing of Components of

Gas-Cooled Plants," and Division 3, "Rules for Inspection and Testing of Components of Liquid-Metal Cooled Plants." Work has not yet begun in earnest to update these divisions.

In order to maintain the integrity and efficiency of the voluntary consensus standards development process for new reactor technologies, standards developers must consider the many international stakeholders. With increasing globalization of the nuclear industry, the major SDOs are undertaking efforts to position their standards for global applicability. At the same time, it is the NRC's policy to exchange relevant information with regulators in other countries. This is particularly true for newer reactor designs, for which much of the technical expertise resides in other countries such as Japan, China, France, South Africa, and the United Kingdom. New reactor construction will likely involve multinational corporations and international projects. At this time, for example, a new reactor is being constructed in Finland, with France, Japan, the United States, and other countries supplying component parts. NRC is participating in the efforts of various SDOs to update quality assurance standards used in the procurement of components requiring long lead times. In addition, the NRC is a member of the Multinational Design Evaluation Program (MDEP), which has as one of its goals the harmonization of international standards. Ideally, uniform standards would be developed to facilitate specification, procurement, and safety review of components manufactured for new reactors. Recognizing that this goal probably will not be achieved, however, the MDEP working group on component manufacturing oversight is working to identify major differences in several countries' design code requirements and to reconcile those differences. Continued international cooperation will be necessary to ensure efficiency, consistency, commercial viability, and regulatory stability.

International Standards Activities

The NRC staff is involved in numerous other international exchanges and cooperative efforts, for which this paper does not attempt a comprehensive catalog. These contacts and interactions help us maintain an awareness of developments, ideas, and best practices for use in our domestic programs, and allow us to influence international activities consistent with Commission programs and policy. One such activity is our active participation in the International Atomic Energy Agency (IAEA) Safety Standards Committees, including the Commission on Safety Standards, the Radiation Safety Standards Committee, the Waste Safety Standards Committee, the Nuclear Safety Standards Committee, and the Transportation Safety Standards Committee. These Committees' primary role is to provide advice to the IAEA on the development and revision of the IAEA's Safety Standards. In the safeguards area, the NRC is also an active participant in the Convention on Physical Protection of Nuclear Materials (CPPNM) convened by the IAEA Secretariat. The NRC staff's active involvement in these Committees carries out an important function in the IAEA standards development process, affording the staff an opportunity to influence international guidance, to discuss emerging issues, and to consider improvements in the domestic regulatory regime. Specifically, NRC's participation in the IAEA standards development process is important at a time when there is increased interest among countries to embark in or enhance their nuclear power programs.

As an intergovernmental body, the IAEA does not adhere to due process for voluntary consensus standards development as defined by ANSI, including a balance of interests, public review and comment with documented resolution, and a process for appeals. However, the IAEA Safety Standards have a key role to play in helping to define a framework that is both effective and efficient. It is in our interest to participate in the development of the IAEA Safety

Standards. We continue to emphasize that the IAEA standards provide a point of reference for the requirements, standards, and practices that a member state can use to establish or enhance its national program. Although we do not incorporate by reference the IAEA Safety Standards into our regulations, it is clear that the NRC's mature regulatory program addresses the IAEA Safety Fundamentals (i.e., the highest level requirements) as well as the underlying safety intent of IAEA's safety guidance. We need to continue to work together with IAEA to develop an approach that emphasizes worldwide alignment and harmonization to the underlying interests embodied in the IAEA Safety Standards.

The NRC staff is also involved in standards development activities through the International Organization for Standardization (ISO), through Technical Committee (TC) 85 on Nuclear Energy. Our participation is in cooperation with the U.S. Department of Energy (DOE) and NIST. This arrangement permits continued voting representation of U.S. technical and policy interests in the development and maintenance of international nuclear energy documentary standards. In support of our ISO involvement, NRC staff participates in the Nuclear Technical Advisory Group (NTAG) associated with TC 85.

Benefits and Costs of NRC Participation in Standards Development

The NRC relies on voluntary consensus standards to serve as part of its regulatory framework. In particular, some regulatory guides and NUREGs cite consensus standards, and in some cases regulations incorporate standards by reference, thereby making them binding legal requirements. For example, 10 CFR 50.55a incorporates by reference the ASME B&PV Code, the ASME Code for Operations and Maintenance of Nuclear Power Plants (OM Code), and associated code cases, as well as IEEE Standard 279, "Criteria for Protection Systems for Nuclear Power Generating Stations," and IEEE Standard 603, "Criteria for Safety Systems." The ASME B&PV Code contains over 14,000 pages, including several sections used by the nuclear industry for the design, construction, and inservice inspection of nuclear power plants. Regulatory guides and NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," reference numerous other standards. In a recent study of standards that may be used in construction of new nuclear plants, a contractor for DOE identified approximately 520 standards referenced by NRC in regulations and regulatory guides.

Incorporating by reference voluntary consensus standards eliminates the effort and cost that would be needed to develop Government unique standards for numerous detailed activities. Incorporation by reference also reduces the amount of rulemaking language that otherwise would need to be written. Industry commitment to standards also reduces the staff level of effort needed to review license applications and amendments. The NRC can take exception to some or all aspects of a particular standard, and the Agency has done so in some cases. However, for those standards incorporated by reference into NRC regulations, doing so requires documenting these exceptions within the rule language and documenting the associated justification in the Statements of Consideration. Moreover, if the NRC staff concludes that a standard is significantly flawed such that it cannot be endorsed, the staff will inform the SDO. Often, the SDO will not promulgate the standard until the staff's concerns have been satisfied. To avoid such conflicts, the NTTAA and OMB Circular A-119 encourage the active participation of Federal representatives in SDOs to increase the likelihood that the standards they develop will meet both public and private sector needs.

Participating in the voluntary consensus standards process provides several advantages for the NRC. Consensus standards complement the NRC's broad general design criteria. Active participation in the standards development process enhances the credibility of associated regulatory positions. The standards development process incorporates years of good engineering practice, along with state-of-the-art technology, resulting in practicable requirements that are of high technical quality. NRC staff participation in standards development activities reduces the number of necessary exceptions to consensus standard provisions, resulting in the more efficient use of NRC resources. In addition, the Agency's participation provides opportunities for early involvement in evolving issues and the consideration of technical issues with wide-ranging application. Frequent technical communication with industry stakeholders leads to the early exchange of information, concerns, and relevant operations data.

SDOs developing voluntary standards also benefit from having regulatory staff involved and informed about technical issues related to standards. Staff participation helps to reduce regulatory uncertainty and increase stability, and it also encourages active participation by industry personnel. Government endorsement of standards increases the likelihood that a standard will be used, thus increasing the value of a published standard and the stature of the SDO. Through the standards development process, emerging issues of safety and public concern may be identified, considered, and resolved.

These benefits outweigh the costs to the NRC, which include the staff time to prepare for and attend meetings, travel costs, and some contractor support. Because participation on a committee is voluntary, the attendance of individual committee members can be influenced by fluctuating commitments and changing priorities of their supporting organizations, jeopardizing the continuity of the committee's efforts. In addition, some SDOs do not permit voting in absentia, and the written record does not provide all technical details, so NRC presence is important. Also, as globalization of the nuclear industry increases, many SDOs are pursuing international expansion and have begun holding committee meetings in other countries. Consequently, it is essential for some Agency staff and contractors to travel to the SDO meetings, including occasional foreign travel, in order to participate effectively in standards development activities. This requirement presents a challenge when travel is restricted due to funding limitations.

CONCLUSIONS:

Because the Agency relies on many standards as part of its regulatory framework, the participation of NRC staff in voluntary consensus standards development is essential. The Agency realizes substantial resource savings by participating in the standards development process. The benefits include cost savings, when compared with the costs of developing Government unique standards, as well as a variety of intangible benefits, such as improved efficiency and transparency, and high technical quality of regulatory requirements. Effective standards development requires interaction with other stakeholders, domestic and foreign, particularly for new and advanced reactors. Overall, active NRC participation in the voluntary consensus standards development process provides high value to the Agency and is an important activity.

RESOURCES:

This information paper does not recommend any changes in current resource allocations. In future budgets, resources that support consensus standards development activities should continue to be made available.

COORDINATION:

The Office of the General Counsel reviewed this package and has no legal objection. The Chief Financial Officer reviewed this package and determined that it has no financial impact.

/RA Martin Virgilio for/

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Enclosure:
List of Standards Developing
Organizations in which NRC Participates

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ADAMS ACCESSION NO.: ML081610737 **EDATS: RES-2008-0059**

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