

Integrated Regulatory Review Service Mission to the United States

MODULE 9: REGULATIONS AND GUIDES

Overview

The NRC has a well-established framework for developing and implementing necessary safety regulations (i.e., rules) and supporting regulatory guidance. It is the policy of the NRC to develop quality rules that are consistent with the requirements of all applicable laws and regulations. In doing so, the NRC strives to conduct its activities in the most effective, efficient, and open manner; by soliciting stakeholder input and through the use of consensus standards. The regulations are revised over time to reflect operating experience and technological advances.

Development of Regulations and Guides

The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based. (GS-R-1, Requirement 32)

Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained. (GS-R-1, Requirement 33)

The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available. (GS-R-1, Requirement 34)

The development of regulations and guides is a key component in the overall regulatory program. Regulations are legal requirements that are binding on all persons and organizations who receive a license from the NRC to use nuclear materials or operate nuclear facilities. Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 1 to 199 contain the current regulations.

New NRC regulations are generated through a process known as “rulemaking.” The authority for NRC rulemaking is vested in the Commission by the Atomic Energy Act, as amended by the Energy Reorganization Act (42 U.S.C. 2201). A system of internal procedures known as “management directives” describes the authorities, responsibilities, policies, and procedures for the major functions of the NRC. Management Directive 6.3, “The Rulemaking Process,” and NUREG/BR-0053, “United States Nuclear Regulatory Commission Regulations Handbook,” contain the procedures for developing new regulations. Individual program offices within the NRC may have additional rulemaking instructions that apply to the specific office (for example, the Office of Nuclear Reactor Regulation’s Office Instruction LIC-300, “Rulemaking Procedure”). The Office of the General Counsel provides detailed legal support throughout the rulemaking process.

The NRC also prepares nonmandatory guidance and information documents to assist licensees, applicants, and staff with regulatory compliance. These nonbinding documents, such as regulatory guides, Standard Review Plans, NUREGs, and the NRC Inspection Manual are

developed to aid individuals and organizations in meeting the agency's requirements. The nonmandatory guidance is authorized by 10 CFR Part 1, "Statement of Organization and General Information," which gives the NRC the authority to publish additional information to support agency activities. In some cases, licensees may incorporate the nonmandatory guidance into a facility's operating license; when that occurs, the guidance becomes mandatory for that specific facility.

Most of the nonmandatory guidance documents provide detailed methods for a licensee to demonstrate compliance with a specific portion of the regulations. If the licensee opts to demonstrate compliance in an alternate manner, the NRC's review may take longer, and the licensee may be required to submit evidence demonstrating that the alternative method fully meets the intent of the regulations.

The need for new regulatory documents can come from many sources. For regulations, Congress can direct changes, industry or members of the public can petition for changes in accordance with 10 CFR 2.802, "Petition for Rulemaking," or the agency itself may identify the need from its ongoing activities. Priority for completion of new or revised regulations depends on applicable statutory requirements, contributions to safety (level of risk) or security, Commission direction, or the role of the revision in improving effectiveness and efficiency of NRC or licensee activities.

The NRC has a Rulemaking Coordinating Committee to ensure that the rulemaking process remains consistent among the program offices. The Office of Administration chairs the committee, which consists of representatives from the primary offices involved in rulemaking. The focus of the committee is to ensure consistency in methods used to develop and promulgate rules and to facilitate initiatives for improving all aspects of the rulemaking process. Part of the committee's responsibility is ensuring that the rulemaking activities follow the guidance in Management Directive 6.3, which describes the NRC's rulemaking activities and provides guidelines for coordinating, concurring, and reporting on rulemakings.

The NRC's management directives describe the internal NRC procedures for developing and approving regulations and nonmandatory guidance documents. One of the program offices (Office of Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, New Reactors, Nuclear Safety and Incident Response, Nuclear Regulatory Research, or Federal and State Materials and Environmental Management Programs) normally prepares the technical portion of the guidance document and helps route it through the concurrence process for approval. All new or revised draft regulations and draft regulatory guides or similar publicly available documents undergo a multilevel internal review and approval process that involves appropriate program offices, the Advisory Committee on Reactor Safeguards, and the Office of the General Counsel. The NRC staff must perform a regulatory analysis for proposed agency actions that establish or communicate requirements, guidance, requests, or staff positions that would result in a change in licensee resources. In addition, new requirements and NRC staff positions regarding operating power reactors must comply with the requirements in 10 CFR 50.109, "Backfitting." The backfit requirements are to ensure that the safety benefit is commensurate with the licensee's cost of implementation. However, the backfit requirements enable the NRC to issue new requirements without consideration of cost when those new requirements satisfy one of the backfit exception criteria (i.e., compliance, adequate protection, or redefining adequate protection). For external review, the regulation or guidance or a notice of its availability is published in the *Federal Register*. The public normally has 75 to 90 days to submit written comments on regulations and 60 days or fewer for regulatory guides or other

nonbinding guidance documents. Additionally, the NRC frequently holds public meetings and open forums to allow members of the public and industry to discuss and comment on the proposed regulation or guidance.

After the public comment period is closed, the draft regulation or guidance document is revised to incorporate appropriate comments and routed through the internal concurrence process for a second time when the modifications are significant. Once the Advisory Committee on Reactor Safeguards and the Office of the General Counsel have completed their review of the final document, guidance documents can be approved and issued, whereas regulations and major reports are presented to the five-member Commission for review and approval before their publication in the *Federal Register*.

Use of Regulations and Guides

Regulatory guides and other nonmandatory guidance documents usually become effective upon publication in the *Federal Register*. Mandatory compliance with new or revised regulations is normally delayed for an appropriate period of time to allow the licensees to implement program or process revisions needed to comply with the new regulations. Once finalized and promulgated, the regulations form the basis for all NRC licensing action. Each facility that uses radioactive material, be it a commercial nuclear power plant, nonpower reactor facility, hospital, or industrial manufacturer, must be licensed by the NRC or, in some cases, a State that has assumed NRC regulatory authority in accordance with Section 274 of the Atomic Energy Act, as amended. The license for each facility is based on the regulations in 10 CFR Parts 1 to 199, but each license also incorporates detailed requirements that reflect the specific needs of the type of facility being licensed. These detailed requirements are drawn from multiple sources including national and international consensus standards, prior staff and industry experience with differing types of plant operation and radiation sources, and local or regional laws and requirements. Once finalized and agreed to by the agency and the facility, the license becomes the legally binding basis for operation of the facility. All NRC audits and inspections of the facility are based on the current approved license, and any failure of the licensee to comply with the conditions in the license can result in a civil penalty or criminal prosecution.

The license issued by the NRC for each nuclear facility covers operation of the facility from initial groundbreaking to final site release. The environmental report issued as part of the license includes decommissioning regulations and guidance documents. The radiological release criteria for decommissioning are delineated in 10 CFR Part 20, "Standards for Protection against Radiation," Subpart E, "Radiological Criteria for License Termination," while power reactor decommissioning and license termination requirements are defined in 10 CFR 50.82, "Termination of License." The environmental report also includes discussions of predisposal waste segregation and characterization, disposal of radioactively contaminated waste, and decommissioning and release of the site. The NRC has developed the multichapter Standard Review Plan (NUREG-0800) to assist the applicant and the NRC staff with the proper preparation and review of the license application.

Consensus Standards in Regulations and Guides

Consensus standards are frequently incorporated by reference in the regulations and guidance documents. Management Directive 6.5, "NRC Participation in the Development and Use of Consensus Standards," recommends the use of consensus standards and encourages NRC staff to participate in the development of both national and international consensus standards to support the NRC's mission and to encourage the industry to develop codes, standards, and

guides that can be endorsed by the NRC and implemented by the industry. The endorsement of consensus standards reduces the need for the development of standards unique to the Government, which reduces the cost to both industry and the Government. Participation in the development of consensus standards also allows the NRC to interact with licensees and industry representatives in an open manner, which helps facilitate better understanding and knowledge transfer within the nuclear arena.

Purpose of Regulations and Guides

The NRC uses mandatory regulations and nonmandatory guidance documents to regulate most commercial nuclear activities in the United States, including commercial nuclear power reactors and the use of radioactive materials in industry, medicine, agriculture, and scientific research. The primary purposes of the regulations and guides developed and maintained by the NRC are the following:

- Ensure the protection of public health and safety and the environment, and the secure use and management of radioactive materials, by the effective use of the NRC's regulatory processes, including regulatory commitments made by power reactor licensees.
- Ensure effectiveness, efficiency, realism, and timeliness in licensing actions by establishing a common understanding of the control of regulatory commitments, by promoting the use of regulatory commitments when they are appropriate to achieve the desired results, and by establishing a vehicle for periodically assessing licensees' processes for implementing and managing subsequent changes to regulatory commitments.
- Ensure the openness of the licensing process by establishing a publicly available common reference for processes, communications, and decisionmaking involving regulatory commitments.

Assessment Summary

NRC will continue to assess additional ways to utilize international standards developed by organizations such as IAEA and the International Organization for Standardization, and explore ways to harmonize U.S. and international standards.