

Integrated Regulatory Review Service Mission to the United States

MODULE 6: REVIEW AND ASSESSMENT

Overview

The NRC has a regulatory framework that provides structure for the review and assessment activities associated with the initial issuance, amendment, and renewal of licenses that implement the requirements of the Atomic Energy Act.

Review and Assessment Process

The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization. (GS-R-1, Requirement 25)

Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach. (GS-R-1, Requirement 26)

Regulatory Basis

The legislative basis of the NRC's review and assessment program is in Section 103 of the Atomic Energy Act which, in part, authorizes the Commission to issue commercial licenses subject to conditions that the Commission may establish by rule or regulation. The agency implements such regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The Office of Nuclear Reactor Regulation (NRR) is, in part, responsible for implementing policies, programs, and procedures for all aspects of licensing and inspection of production and utilization facilities and operators of such facilities. The Director of NRR is authorized to take action to issue licenses for manufacture, construction, possession, use, acquisition, and operation of utilization and production facilities required by the Atomic Energy Act of 1954, as amended; Sections 202(1), 202(2), and 203 of the Energy Reorganization Act of 1974; and 10 CFR Part 50. NRR is responsible for reviewing, evaluating, and processing all aspects of applications for licenses, and amendments to such licenses, for the construction, operation, safeguarding, and environmental protection of commercial NPPs.

Organization and Technical Resources for Review and Assessment

Those offices most frequently involved in the day-to-day review and assessment of an NPP licensee's technical submissions include NRR, the Office of Nuclear Security and Incident Response, the Office of the General Counsel, and the appropriate regional office. Other offices are involved as required by specific issues. 10 CFR 1.43, "Office of Nuclear Reactor

Regulation,” establishes the authority for NRR to develop and implement policies, programs, and procedures for all aspects of licensing, inspection, and safeguarding of manufacturing, production, and utilization facilities. Further, NRC Management Directive (MD) 9.27, “Organization and Functions of the Office of Nuclear Reactor Regulation,” authorizes the Director of NRR to act as necessary to issue, renew, and amend licenses for manufacture, construction, possession, use, acquisition, and operation of NPPs. NRR comprises technical review divisions for Safety Systems, Component Integrity, Risk Assessment, and Engineering; and program and project management divisions for License Renewal, Operator Reactor Licensing, Inspection & Regional Support, and Policy and Rulemaking. Within the technical divisions are experts capable of reviewing and assessing the licensees’ requests without compromising the public health and safety. If necessary, NRR uses consultants from research laboratories and universities.

Qualification of NRC Staff

Members of the NRC staff performing reviews are aware of and understand the review standards and criteria and are qualified to perform reviews. The NRC hires degreed scientists, engineers, and other personnel with relevant experience to fill positions on the technical staff. The agency has established a qualification program to ensure that reviewers understand the regulatory requirements and NRC technical positions. NRR Office Instruction (OI) ADM-504, “Qualification Program,” describes the requirements of the qualification process.

The goal of the qualification program is to prepare employees to perform regulatory duties and implement the agency’s policies, programs, and activities associated with the regulation of nuclear reactors. Qualification requirements are periodically revised to reflect the needs of NRR as determined by changes to regulatory requirements and guidance.

Use of Contractors and Consultant

In general, the NRC has technical experts capable of reviewing and assessing the licensees’ requests without compromising the public health and safety. If necessary, the NRC can contract with commercial firms and other Federal agencies (e.g., the U.S. Department of Energy, National Laboratories) to acquire technical assistance services. These services may be required in specific technical or functional areas where the need for required expertise cannot be met with the resources readily available within the agency.

These contractors and consultants provide review, findings, and recommendations for consideration by NRC staff in the regulatory decision making process. For all work on applications, including work supported by contractors, the final decision on acceptability is inherently the function of the Government and must be performed by NRC staff. The NRC’s objective is to employ the expertise and experience of consultants effectively and efficiently to achieve the agency’s mission.

Advisory Bodies

The NRC uses advisory bodies to provide advice on its regulatory process. The advice provided by the Committees does not relieve the NRC of its responsibilities. The Advisory Committee on Reactor Safeguards has statutory responsibilities as described in the Atomic Energy Act of 1954, as amended. The Committee reviews and advises the Commission with regards to the licensing and operation of production and utilization facilities and related safety issues, the adequacy of proposed reactor safety standards, technical and policy issues related

to the licensing of evolutionary and passive plant designs, and other matters referred to it by the Commission. On its own initiative, the Committee may conduct reviews of specific safety-related items.

Process of Review and Assessment

The NRC follows the development of a facility or activity through its entire life cycle. Through the various stages of a facility's life cycle, a project manager (PM) will be assigned responsibility for individual facilities. Depending on the specific licensee submission, the PM may require additional support from other technical staff from various program offices during the review process. The PM will normally be the central point of contact for the licensee when addressing licensing issues such as a design certification, construction license application, or a license amendment. The PM communicates regularly with the NRC regional field offices and is kept current on the plant events to assess any impact on the plant licensing bases. The PMs participate in daily telephone calls to discuss the status of the facility and have frequent contact with licensees regarding the status of current and anticipated applications. PMs are also aware of changes to facilities based on review of changes provided in the final safety analysis report. For operating reactors, the Divisions of Operator Reactor Licensing and License Renewal normally receive submissions from licensees and coordinate the required reviews with the appropriate technical divisions. OIs provide the staff with a basic framework for the review process (e.g., LIC-101, "License Amendment Review Procedures," presents the review process for license amendment requests). In this process, the technical reviewers from the technical divisions perform an acceptance review of the application to ensure that inadequate submittals are identified early and returned to licensees. OI LIC-109, "Acceptance Review Procedures," provides guidance for the staff to follow in determining if an application is acceptable for detailed review. Typically, within a month of receiving a license amendment request, NRR provides the licensee with the results of the acceptance review; that is, NRR accepts the application for detailed review or rejects the application. This acceptance review ensures the completeness of the application and minimizes the number of NRC requests for additional information (RAIs) from the licensee. During detailed review, the NRC staff may identify additional information required to support its review and send RAIs to the licensee to obtain that information. The PM coordinates the technical reviews among the different divisions to ensure that crosscutting issues are adequately addressed. Based on the licensee's original application and RAI responses, the technical reviewers from appropriate technical divisions provide input to a safety evaluation (SE) detailing the specific review and assessment performed. The SE provides the technical, safety, and legal basis for the NRC's disposition of a proposed licensing action. The evaluation documents any independent analysis performed by the staff or NRC-hired consultants that was used in the decisionmaking process. Finally, the SE includes the staff's conclusion with respect to the impact of the proposed authorization as it relates to public health and safety.

Technical work products that result from NRR staff reviews and assessments must be consistent with established guidance and meet standards for quality. OI ADM-405, "NRR Technical Work Product Quality and Consistency," communicates these expectations to the staff to facilitate a common understanding of the minimum quality and consistency standards for technical work products.

Maintaining the Validity of the Safety Evaluation

Completeness and Accuracy of Information

Regulations require that information submitted to the NRC by licensees in support of applications be submitted under oath or affirmation by a licensee or a duly authorized officer of the licensee (10 CFR 50.30(b)). 10 CFR 50.9, "Completeness and Accuracy of Information," requires that licensee submittals be complete and accurate. It is the responsibility of the licensee to ensure the quality of all documentation provided to the NRC. The licensee ensures the suitability of documentation produced by another body or organization through application of quality assurance programs required by 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." If the NRC staff determines that the information submitted is incomplete such that the staff cannot complete its SE, the staff may request additional information from the licensee in the form of an RAI as discussed above. During its review of requested licensing actions, the NRC may take measures to verify the accuracy of information provided by licensees or other parties, including but not limited to independent calculations, inspections or audits of licensee or contractor facilities, and other such means as the NRC staff deems necessary. The NRC has various reporting requirements for those instances where a licensee discovers, after information has been submitted to the Commission, that the information may not be true and accurate in all respects (e.g., 10 CFR 50.9, 10 CFR 54.13, 10 CFR Part 21, 10 CFR 50.72, 10 CFR 50.73). The NRC has enforcement guidance and policies in place, which provide methods for assessing levels of severity and consequences to any licensee or any employee of a licensee, and any contractor (including a supplier or consultant), subcontractor, or any employee of a contractor or subcontractor, of any licensee who provides incomplete or inaccurate information. These regulations and their associated NRC processes and enforcement policies ensure that information submitted on the docket by licensees is complete and accurate.

Updated Final Safety Analysis Report

10 CFR 50.71(e) requires the licensee to periodically amend the final safety analysis report (FSAR). This regulation states that each person licensed to operate a nuclear power reactor shall periodically update the originally submitted FSAR to ensure that the information included in the report contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submittal of the original FSAR, or as appropriate, the last update to the FSAR. The submittal shall include the effects of all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee, either in support of approved license amendments or in support of conclusions that changes did not require a license amendment; and all analyses of new safety issues performed by or on behalf of the licensee at the Commission's request. The updated information shall be appropriately located within the update to the FSAR.

When a licensee submits its revised FSAR, the NRR PM will typically review the material to determine that the licensee has appropriately addressed changes to the facility or procedures previously made since the last update. The PM may also verify that associated commitments have been incorporated into the FSAR. The NRC assesses whether licensees are maintaining their facilities and related procedures consistent with the FSAR as part of the NRC inspection program (see Modules 7 and 8).

Changes to the Facility Mandated by the NRC

As necessary, the NRC requires changes to the licensing basis for NPPs through the release of new or revised regulations, the issuance of orders, and acceptance of licensee commitments to modify NPP designs and procedures. In such cases, the NRC follows established processes to ensure that the appropriate NRC actions are taken, with full consideration of the safety significance of the issue and opportunity for stakeholder involvement (e.g., rulemaking, hearing process, backfit analysis).

Changes to the Facility without Prior NRC Review and Approval

Before making any safety-related modifications (i.e., design changes, tests, or experiments), a licensee is to first examine the proposed modification under the provisions of 10 CFR 50.59, "Changes, Tests, and Experiments." Using the provisions of this regulation and the industry-issued guidance document, a planned modification would fall under one of two categories: the licensee may make the modification without prior NRC approval, or the licensee must first seek NRC approval before effecting the modification. If a proposed modification is not governed by a technical specification requirement and does not meet any of eight criteria given in 10 CFR 50.59, the licensee may proceed to effect the modification without prior NRC approval. The licensee must keep a record of its analysis per this regulation, have the record available for NRC inspection, and submit a description of the subject modification and a summary of its analysis in a periodic report to the NRC.

License Amendment Requests

In addition to NRC-required changes in the licensing basis, or changes that may be made by the licensee under 10 CFR 50.59, a licensee may also voluntarily seek changes to the current licensing basis for its NPP. These requests to change the license are required to be submitted for NRC review and approval under 10 CFR 50.90, "License Amendments." License amendments involve changes to the operating license or the technical specifications. NPPs are encouraged to use guidance provided by the NRC when developing license amendment applications. The review and approval or denial of license amendment applications is one of the primary mechanisms for regulating changes in the operation of licensed facilities. The NRC requires the operators of facilities to conduct the necessary research and development work to support license amendments and to address safety-related issues. The NRC does not accept a safety submission that is not supported by sufficient technical arguments and, if necessary, will require the operator to justify the assumptions made and data used.

Licensee's Use of Contractors

The NRC expects contractors, vendors, or consultants to provide licensees with complete and accurate information and to not knowingly provide licensees with components, materials, and any other goods or services that may affect the safe operation of the facility or would cause a licensee to be in violation of any rule, regulation, order, or condition of its license. To do otherwise may constitute an incident of misconduct in accordance with the provisions of 10 CFR 50.5, "Deliberate Misconduct," and may be subject to civil action in accordance with the NRC Enforcement Policy Manual or referral to the U.S. Department of Justice for criminal prosecution. This applies to documentation provided by the licensee, including documentation developed by its contractors. The NRC addresses the use of contractors employed by

licensees (either directly or indirectly) in its inspection of the licensee's implementation of quality assurance programs (see Modules 7 and 8 for a discussion of the NRC inspection program).

Guidance Documents

The NRC's review and assessment principles are included in the regulations and regulatory documents that are available to all NPP applicants, licensees, the NRC staff, and the public. These documents include laws, statutes, and regulations, standard review plans (SRPs), interim staff guidance, OIs, MDs, regulatory guides, NUREG reports, standard technical specifications, Technical Specification Task Force reports, topical reports, NRC-endorsed industry guidance, generic communications, Commission papers, branch technical positions, and public meetings, workshops, and technical discussions. When an NPP licensee submits a license application, amendment, or renewal request (application), the NRC staff reviews the request and verifies compliance with the assessment principles and criteria in the above-referenced regulations and guidance.

Guidance on the format and content of documents to be submitted by the licensee in support of applications is provided, and the licensee is required to submit or make available to the NRC all information that is specified or requested. The regulations provide explicit guidance with respect to the content of applications and changes to the technical specifications. This guidance includes guidance on written communications (10 CFR 50.4); content of technical specifications (10 CFR 50.36); general information contained in applications (10 CFR 50.33); technical content of applications (10 CFR 50.34); application for amendment of license, construction permit, or early site permit (10 CFR 50.90); and notice for public content and State consultation (10 CFR 50.91). Handling of proprietary information submitted by the licensee is addressed in 10 CFR 2.390. To facilitate understanding of the requirements for format, quality, and standards for regulatory submittals, the NRC, licensees, and other stakeholders communicate frequently.

Performance of the Review and Assessment Process

Internal Guidance for Review and Safety Evaluation

While both licensees and NRC staff use many of the documents mentioned in the preceding section ("Guidance Documents"), NRR has established internal guidance and procedures, which provide specific guidance to the staff in performing reviews. Technical guidance appears in the SRPs: NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition"; NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants"; and NUREG-1801, "Generic Aging Lessons Learned (GALL) Report." The SRPs are the principal documents used by the NRC staff for guidance in performing independent safety reviews of applications to construct or operate NPPs. The principal purpose of the SRP is to ensure the quality and uniformity of staff safety reviews. The SRP is intended to be a comprehensive, step-by-step, integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements.

The SRPs provide for a graded approach to the review of a license application or amendment request. Because the staff's review constitutes an independent audit of the applicant's analysis, the staff may emphasize or deemphasize particular aspects of an SRP section, as appropriate for the application being reviewed. Before starting a review, the technical branch chief and assigned reviewer establish the scope and depth of the review to be performed, including the

use of acceptance criteria and review guidelines to be used. Examples of acceptable variations in the scope of a review include (1) reduced emphasis on design reviews where the design and its underlying conditions of acceptance are identical to those of another unit that was recently reviewed and approved or (2) increased emphasis on certain aspects of the design review as a result of recent operating experience or consideration of a unique design. Risk insights can also be used in determining the depth of review (see “Risk-Informed Regulation” later in this document). Process guidance for the NRC staff appears in NRR OIs, including LIC-101; LIC-109; LIC-111, “Regulatory Audits”; RNWL-100, “License Renewal Application Review Process”; and LIC-203, “Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues.”

Independent Analyses

The NRC often performs independent analyses in support of its regulatory function. The purpose is to confirm the results of testing and analysis provided by the licensees. Examples of independent analysis include review of vendor computer codes, methodologies, and calculations. The NRC staff may perform alternate calculations, either detailed or simplified, to provide a high level of confidence in the results presented by the licensee. NRR receives additional analytical support from contractors as discussed above (“Use of Contractors and Consultants”) and from the Office of Nuclear Regulatory Research in performing independent analyses (as discussed below).

Research and Development Initiated by the NRC

The NRC initiates research and development work when it determines a need for additional studies, either to provide independent verification of work performed by industry or to extend the state of knowledge. In some situations, the NRC requires independent research work so that it can adequately accomplish its review and assessment function.

The NRC Office of Nuclear Regulatory Research supports the agency’s review and assessment process by providing technical advice, analytical tools, and information as needed. This information supports the technical staff’s ability to identify and resolve safety issues, develop regulations and guidance, conduct independent analyses, evaluate operating experience, and issue license amendments.

The NRC issues contracts for research projects and to gain access to independent technical expertise. The NRC’s major source of this expertise is the U.S. National Laboratory system. The National Laboratory system includes research facilities, located throughout the United States, with extensive and varied technical capabilities. The NRC also contracts with other Federal agencies, universities, and commercial businesses to conduct research projects and to obtain technical expertise.

Risk-Informed Regulation

In August 1985, the Commission issued its severe accident policy statement, which led to a requirement that existing U.S. NPPs perform a systematic examination to identify any plant-specific vulnerabilities to severe accidents. As a result, all current licensees have a probabilistic risk assessment (PRA) of their plant, which addresses the risks from internal events that occur at power. In August 1995, the Commission issued its policy statement on the use of PRA, which included four main goals: (1) increase use of PRA to the extent supported by the state of the art and in a way that complements traditional engineering approaches,

(2) use PRA both to reduce unnecessary conservatism in current requirements and to support proposals for additional regulatory requirements, (3) be as realistic as practicable, and (4) consider uncertainties appropriately. One result of these policy statements and other factors is the increased use of risk insights in the licensing and oversight of nuclear reactors.

Risk-informed regulation is a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety. Risk-informed license amendment requests are evaluated against five key principles. Any proposed change must do the following:

1. Meet current regulations, unless an exemption is being requested under 10 CFR 50.12, "Specific Exemptions."
2. Be consistent with the defense-in-depth philosophy.
3. Maintain sufficient safety margins.
4. Increase risk no more than a small amount, consistent with the intent of the Commission's Safety Goal Policy Statement.
5. Employ performance measurement strategies to monitor the impact of the change.

The NRC has developed guidance documents for use by licensees and NRC staff in the submittal and review, respectively, of risk-informed license amendment requests. The primary guidance document for licensees is Regulatory Guide 1.174, "An Approach for Using

Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis." SRP Chapter 19, "Severe Accidents," contains the NRC staff guidance.

The agency has granted risk-informed license amendment requests in the following areas:

- technical specification completion times and surveillance frequencies
- inservice inspection and testing
- containment integrated leak rate testing

Records of NRC Review and Assessment

The results of NRC reviews and assessments are documented and become part of the plant's licensing basis. When an operating license or license amendment is granted, the NRC issues a revised license, revised technical specifications if applicable, and an SE document developed by the NRC. The SE summarizes the NRC staff's review and includes a regulatory evaluation and a technical evaluation.

Final license amendments, technical specification changes, and the SE are transmitted to the appropriate stakeholders, including the licensee, members of the public who have asked to be on the server list, NRC staff, and NRC resident inspectors. The NRC maintains all documents that constitute the plant's licensing basis, including all information relied on for making the final safety and licensing decision, and the SE itself, in the Agencywide Documents Access and Management System (ADAMS).

Public Interaction/Stakeholder Involvement

The NRC places a high priority on stakeholder involvement and keeping its stakeholders informed of its activities. The guidance documents for both the licensee and for the NRC staff are publicly available through ADAMS. Further, the agency actively seeks stakeholder comments during the development of rules and key guidance documents, including regulatory guides and the SRP.

According to 10 CFR 50.91, "Notice for Public Comment; State Consultation," the NRC must notify stakeholders of a proposed licensing action, so that concerned individuals have an opportunity to identify issues or concerns. These issues and concerns may result in a judicial hearing on the proposed amendment. In addition, the NRC publishes other information and documents to support its regulatory mission, inform the public of its activities, and assist licensees in complying with its regulations. All official agency records, including all information supporting the NRC's decisions on licensing actions, are available in ADAMS. Much of this information is also available on the NRC's public Web site.

For additional information on the NRC's interaction with the public and other stakeholders, refer to the "Elective Policy Issue: Transparency and Openness."

Assessment Summary

The regulations of the U.S. Nuclear Regulatory Commission (NRC) provide the structure for the review and assessment activities associated with the initial issuance, amendment, and renewal of licenses that implement the requirements of the Atomic Energy Act. These regulations are supported by guidance to nuclear power plant (NPP) licensees and agency staff for the review and assessment of the licensing basis. The NRC has developed internal capabilities to maintain broad technical expertise and the knowledge bases needed to provide the agency with the ability to make reliable and technically sound regulatory decisions. The NRC uses contractors, when necessary, to perform reviews and may perform research or independent analyses to confirm the adequacy of a submittal. Risk insights are sometimes used in determining the level of effort associated with a review. The NRC's review and evaluation methods ensure that NPPs are licensed and operated in a manner that adequately protects public health and safety and that safeguards special nuclear material used in NPPs. The review and assessment process is controlled through internal procedures. The process permits public involvement, and the results of the reviews are documented and made publicly available.