

# *Question and Response Report*

*for:*

## **Module 06: Review and Assessment**

# IRRS Question and Response Report

Question No: 114

Module 06: Review and Assessment

## Question

How does the Regulatory Body define the review and assessment principles and associated criteria on which its review and assessment judgment is based to the:  
Operators, and Regulatory Body staff?

## Response

The U.S. Nuclear Regulatory Commission's (NRC's) review and assessment principles are included in the regulations and regulatory documents that are available to all nuclear power plant (NPP) applicants and licensees (hereafter referred to as licensees) and NRC staff. These documents include laws, statutes, and regulations, Standard Review Plans (SRPs), interim staff guidance, office instructions (OIs), management directives, 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. For additional information on these documents, refer to the response to Question 122.

When an NPP licensee submits a license application, amendment, or renewal request (hereafter referred to as application), NRC staff reviews the request and verifies compliance with the assessment principles and criteria in the above-referenced regulations and guidance. Although many of the above-referenced documents are used by both licensees and NRC staff, the Office of Nuclear Reactor Regulation (NRR) has established internal guidance and procedures that provide specific guidance to staff in performing reviews. Key documents include SRPs (NUREG 0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition"; NUREG 1800, Revision 1, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants," issued September 2005; and NUREG 1801, "Generic Aging Lessons Learned (GALL) Report," Revision 1, issued September 2005); and OIs LIC 101, "License Amendment Review Procedures"; RNWL-100, "License Renewal Application Review Process"; and LIC 203, "Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues."

NRC staff performing reviews is aware of and understands the review standards and criteria and is qualified to perform reviews. OI ADM 504, "Qualification Program," describes the requirements of the qualification process, so that staff is provided with sufficient information to regulate in accordance with NRC regulations, policies, and procedures. Additional information on the NRC staff qualification program can be found in the response to Question 121.

Question No: 115

Module 06: Review and Assessment

## Question

- I. Are the results of the review and assessment recorded?  
II. Does the regulatory body have predefined criteria or precedent cases for decisions regarding the acceptance of applications and the granting of approvals and authorizations?

## Response

The results of reviews and assessments of applications are recorded in NRC documents that become part of the licensing basis, including the license and technical specifics, and a safety evaluation (SE) developed by the NRC. Additional information on the documents that constitute the licensing basis and a description of the SE can be found in the response to Question 134. Upon issuance, documents are entered into the Agencywide Documents Access and Management System (ADAMS) as official agency records.

Predefined criteria and precedent cases for applications are provided in the regulations and guidance documents. See the response to Question 122 for a complete list of regulatory guidance documents.

OIs (e.g., LIC 101) contain guidance for the staff to follow for processing applications to operating licenses requested by licensees, including the search for precedent licensing actions. Precedent licensing actions are those with a similar proposed change and regulatory basis. These can be searched through ADAMS. Documents resident in ADAMS are profiled to be retrievable according to attributes such as the document date, the author's name and affiliation, the date of availability in ADAMS, the document type (according to a structured list of choices), document title, and document text. Logical operators such as "greater than" and "less than" permit searches by ranges of values. Licensees are encouraged to identify applicable precedents as part of submitting applications. Searching for, identifying, and using precedents in the review process maximizes staff efficiency, minimizes the need to issue requests for additional information, and ensures consistency of licensing actions. The search for a precedent continues until the NRR staff is satisfied that either (1) they have identified one or more appropriate precedents, or (2) that no appropriate precedents exist. The identification of similar precedent licensing actions increases the efficiency of the license application review process by reducing expended resources of both the NRC and the licensee.

# IRRS Question and Response Report

Question No: 116

Module 06: Review and Assessment

## Question

How has the Regulatory Body and each applicant/licensee agreed on the format, quality and standard of documentation to be presented?

## Response

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 (Title 10 of the Code of Federal Regulations (10 CFR) 50.4, "Written Communications"), content of technical specifications (10 CFR 50.36, "Technical Specifications"), general information contained in applications (10 CFR 50.33, "Contents of Applications; General Information"), technical content of applications (10 CFR 50.34, "Contents of Applications; Technical Information"), application for amendment of license, construction permit, or early site permit (10 CFR 50.90, "Application for Amendment of License, Construction Permit, or Early Site Permit"), and notice for public content and State consultation (10 CFR 50.91, "Notice for Public Comment; State Consultation:"). Handling of proprietary information submitted by the licensee is also addressed in 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding."

The guidance documents given in the response to Question 122 include guidance on format, quality, and standards for submittals. Key NRC and industry documents that include specific information on format and quality include SRPs, technical specification task force reports (TSTFs), standard technical specifications (STSs), and topical reports.

To facilitate understanding of the requirements for format, quality, and standards for regulatory submittals, frequent communication between the NRC, licensees, and other stakeholders occurs at regular intervals and in a variety of ways. For specific licensing issues, licensees keep project managers (PMs) informed of upcoming submittals, seek guidance from PMs, and, as appropriate, hold preapplication meetings with PMs and technical staff who perform reviews in order to understand any specific insights related to its application. For more generic licensing issues, these communications include the annual Regulatory Information Conference, licensing forums, and a broad range of NRC generic communications. Additionally, NRC communication with industry groups (e.g., the Licensing Action Task Force, the TSTF, the Nuclear Energy Institute (NEI), the American Society of Mechanical Engineers (ASME)) to discuss the development of new requirements and ways to improve the quality of the licensees' submissions.

All correspondence between the NRC and licensees, including information on past licensing actions, is stored in ADAMS and can be accessed and used by other licensees as precedent for format, quality, standards, and technical quality in preparing its application.

Question No: 117

Module 06: Review and Assessment

## Question

Does each applicant/licensee understand the requirements placed on it to produce documentation and is it capable of meeting these requirements.

## Response

The regulations provide explicit guidance for licensees to understand requirements and produce documentation. For example, the Commission produces 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). A variety of regulatory guidance exists to help licensees understand the technical basis for current requirements and content of applications (additional information can be found in the response to Question 122). Frequent contact between the licensees and the NRC PMs assigned to the licensees' respective nuclear facilities occurs and is often utilized by licensees to clarify any ambiguous or unclear requirements or guidance (see the response to Question 116 on PM communications).

With respect to licensees' capabilities to produce the regulatory documents required, the NRC staff conducts reviews of information provided pursuant to 10 CFR 50.33 and 10 CFR 50.34 for applications. If licensees are incapable of providing the required information, the application would not be approved.

The NRC has implemented procedures for an early acceptance review of many applications to ensure that inadequate submittals are identified early and returned to licensees. For example, OI LIC 109, "Acceptance Review Procedures," provides guidance for the staff to follow in determining if an application is acceptable for detailed review. The conclusion of the acceptance review is based upon the NRC staff's assessment as to whether or not the application reasonably appears to contain sufficient technical information, both in scope and depth, for the NRC staff to complete the detailed technical review in an appropriate timeframe. Goals of the acceptance review process are to establish a higher quality of contents of applications and to facilitate submittal of acceptable applications, resulting in fewer requests for additional information (RAIs).

Based on the extensive guidance, communication, and experience of both the NRC and the industry, the requirements are well understood by licensees. Evidence of this is the low number of applications returned during the acceptance review process and denied after the detailed review.

# IRRS Question and Response Report

Question No: 118

Module 06: Review and Assessment

## Question

If documentation is produced by another body or organization, how is an applicant or licensee able to ensure its suitability? How does the regulatory body monitor the contractors employed by the operating organization (directly, indirectly)?

## Response

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 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities. 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.

The NRC expects contractors, vendors, or consultants to provide licensees with complete and accurate information and to not knowingly provide licensees or 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 their 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 (DOJ) for criminal prosecution. This applies to documentation provided by the licensee, including documentation developed by its contractors. Additional information on accuracy and sufficiency of information provided by licensees can be found in the response to Question 130.

In 10 CFR Part 21, "Reporting of Defects and Noncompliance," the NRC implements the requirements of Section 206 of the Energy Reorganization Act of 1974, as amended. In 10 CFR Part 21, the NRC requires firms and organizations building, operating, or owning NRC-licensed facilities, firms conducting NRC-licensed activities, and firms and organizations supplying safety-related components and safety-related design, testing, inspection, and consulting services to evaluate identified deviations or to inform licensees or purchasers of these deviations to determine whether the identified deviation could constitute a substantial safety hazard.

Additional information pertaining to 10 CFR Part 21 reports may also be found in OI LIC 403, "Procedures for Handling 10 CFR Part 21 and 10 CFR 50.55(e) Notifications of Deviations, Defects, and Failures to Comply Associated with Substantial Safety Hazards at Nuclear Power Reactors and Their Vendors."

# IRRS Question and Response Report

Question No: 119

Module 06: Review and Assessment

## Question

How does the Regulatory Body organize itself to perform its review and assessment of the operator's technical submissions?

## Response

The Atomic Energy Act of 1954, as amended (AEA), passed by the U.S. Congress and signed by the President, provided the framework for all subsequent regulation of nuclear installations in the United States. The regulations are further governed by the Energy Reorganization Act of 1974. The practices and procedures of the Commission are also affected substantially by numerous other statutes. Chapter 10, Section 103, "Commercial Licenses," of the AEA, grants the NRC authority to issue licenses for nuclear reactor facilities. In addition, Section 103 states that such licenses are subject to such conditions as the NRC may by rule or regulation establish to effectuate the purposes and provisions of the AEA. There are two alternative approaches to the licensing process. The traditional approach under 10 CFR Part 50 requires two steps. The NRC reviews a preliminary application and grants a construction permit and later reviews the final application and grants an operating license. All currently operating plants in the United States were licensed according to this process. In 1989, the Commission established an alternative licensing system, published in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," that provides for certified standard designs and combined licenses that resolve design issues before construction, and for early site permits that resolve site issues before construction.

The Acts cited above establish an agency headed by a five-member Commission. Commissioners serve for fixed 5-year terms. The Chairman of the Commission initiates the appointment, subject to the approval of the Commission, of the Executive Director for Operations, the General Counsel, the Secretary, the members of the commission's adjudicatory panel, the Chief Financial Officer, and the directors of the Commission's major program offices and the regional administrators. The program offices are established in 10 CFR Part 1, "Statement of Organization and General Information," and the organization structure is included on the NRC Web site. Those offices most frequently involved in the day-to-day review and assessment of the operator's nuclear power reactor-related technical submissions include NRR, the Office of Nuclear Security and Incident Response, the General Counsel, and the regional offices. Other offices are involved as required by specific issues. Recent reorganizations have resulted in the designation of NRR to deal with currently operating reactors and the Office of New Reactors (NRO) to deal with applications for new reactor licenses. In 10 CFR 1.43, "Office of Nuclear Reactor Regulation," the NRC 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," dated July 13, 1989, authorizes the director of NRR to take such actions as necessary to issue, renew, and amend licenses for manufacture, construction, possession, use, acquisition, and operation of nuclear power plants. MD 9.27 also provides for the distribution of the functions authorized to NRR within its stated organizational structure. NRR includes technical review divisions for safety systems, component integrity, risk assessment, and engineering, and program and project management divisions for license renewal, operating reactor licensing, inspection, and regional support, and policy and rulemaking. The technical divisions have the technical experts that are capable of reviewing and assessing the licensees' requests without compromising the public health and safety. If necessary, consultants from research laboratories and universities are utilized.

The Divisions of Operating Reactor Licensing (DORL) and License Renewal (DLR) normally receive submissions from licensees and coordinate the required reviews with the appropriate technical divisions. The technical reviewers from these technical divisions perform an acceptance review of the application for technical adequacy. Within a month, NRR provides the licensee the results of the acceptance review; that is, accept the application for detailed review or reject the application. This acceptance review ensures the completeness of the application and minimizes NRC RAIs for the licensee. During detailed review, the staff may identify deficiencies via RAIs to the licensee and include a mutually agreed upon due date for the response. A licensee's failure to provide responses to the RAIs within the agreed upon schedules could result in delays in the overall project schedule and in issuance of the license. The PM coordinates the technical reviews among the different divisions to ensure cross-cutting issues are adequately addressed. Based on the licensee's original application and RAI responses, the technical reviewers from appropriate technical divisions provide SEs detailing the specific review and assessment that was performed. All these SEs are then combined into one SE, and this SE is enclosed along with the NRC approval of the licensee's request. The SE provides the technical, safety, and legal basis for the NRC's disposition of a proposed authorization. The evaluation documents any independent analysis performed by the staff, or by the NRC's hired consultants, that was used as part of 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. (See the response to Question 134 regarding a description of the SE.)

# IRRS Question and Response Report

Question No: 120	Module 06: Review and Assessment
<b>Question</b> How does the Regulatory Body prepare a program of review and assessment of the facilities and activities under scrutiny? How is this program coordinated with the needs of the authorization process?	
<b>Response</b> <p>The traditional approach under 10 CFR Part 50 requires two steps. The NRC (1) reviews a preliminary application and grants a construction permit, and (2) later reviews the final application and grants an operating license. All currently operating plants in the United States were licensed according to this process.</p> <p>Most current submittals are routine applications, such as license amendments, and are submitted by licensees for review by NRC staff. The staff follows the review process identified in the response to Question 119. The staff's goal is to respond to a very high percentage of these requests within a 12 month period. Following establishment of the review schedule, all interactions between the technical staff and the licensee are managed by the assigned PM. DORL or DLR normally receives submissions from licensees and coordinates the required reviews with the appropriate technical divisions. The technical reviewers from these technical divisions follow this process: (1) performing an acceptance review, (2) performing a detailed technical review, (3) developing an RAI to obtain additional information necessary to complete the technical review, (4) developing a final recommendation to approve or deny the application, and (5) writing an SE to document the technical review and conclusions. The PM (1) provides the licensee the results of the acceptance review, (2) reviews RAIs before sending them to the licensee, (3) coordinates cross-cutting issues across the technical divisions, (4) evaluates and combines SEs from the technical reviewers into a final, comprehensive SE, and (5) issues the amended license, technical specifications, and SE.</p>	
Question No: 121	Module 06: Review and Assessment
<b>Question</b> What management arrangements (procedures) are in place in order to ensure that a comprehensive and consistent review and assessment process is established? How is project management used to control the review and assessment?	
<b>Response</b> <p>In general, the procedures governing the review process include the regulations and guidance included in response to Question 122. PMs are assigned to each NPP and each application review. The PM manages the review and assessment, as noted in response to Question 119. A combination of the identified guidance, the work flow process, and the management by the PM provides for a comprehensive and consistent review. The NRC also ensures a comprehensive and consistent review through implementation of staff qualification programs and specific guidance on quality and consistency.</p> <p>The NRC staff has the required training and follows guidance documents to ensure consistency of the reviews. OI ADM 504 describes the requirements of the Qualification Program. 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. Staff implementing the regulatory process must understand the associated facilities, equipment, processes, and activities, as well as the criteria, techniques, and mechanics of implementing nuclear reactor and power plant operations. The qualification process is intended to provide staff with sufficient information to regulate in accordance with NRC regulations, policies, and procedures. Qualification requirements are periodically revised to reflect the needs of NRR as determined by changes to regulatory requirements and guidance.</p> <p>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 common understanding of the minimum quality and consistency standards for technical work products. The process set forth in this instruction seeks to maintain or improve the quality of selected NRR technical work products by the following:</p> <ul style="list-style-type: none"><li>-requiring preparation by appropriate technical staff</li><li>-requiring a technical review by a second technically competent individual</li><li>-defining the role of the branch chief in ensuring technical quality and consistency</li><li>-defining the role of division senior level staff in implementing this process</li><li>-implementing the NRR self-assessment process</li></ul> <p>NRR OI ADM 405 is applicable to NRR technical work products that meet any of the following criteria:</p> <ul style="list-style-type: none"><li>-involve a new or first-of-kind review or activity</li><li>-are technically complex</li><li>-involve the use of new methodologies or technologies (e.g., that could set new precedents)</li><li>-represent a significant departure from past, similar activities</li><li>-involve special or unique features that are not well covered by current regulatory guidance or require extensive judgments to be made</li><li>-appear to involve policy issues</li><li>-involve unresolved safety issues or other issues that are ongoing and currently in the process of resolution</li><li>-are determined by supervision or management to be within scope</li></ul>	



# IRRS Question and Response Report

Question No: 122

Module 06: Review and Assessment

## Question

What guidance (e.g. standards, regulatory guides) do the technical assessors have in order to perform their work? How are they revised?

## Response

The NRC has established a review and assessment program that covers the multiple phases of an NPP throughout the life cycle of the facility. Regulations, standards, and guidance have been developed for each phase of the facility from design certification and initial site selection, through operations, and to eventual decommissioning and closure. In each of the licensing phases, regulatory procedures exist to address the administrative, legal, and technical review and assessment process appropriate to the phase. The technical staff uses the following types of documents in performing their reviews:

- Laws, Statutes, and Regulations—Applicable laws and statutes provide both the authorities and requirements for NRC regulations of NPPs. The NRC follows all applicable laws and statutes in developing the regulations for NPPs that are included in 10 CFR, “Energy.” Key regulations for the technical review and assessment of applications are included in 10 CFR Part 50.
- Standard Review Plans—These plans provide specific guidance for licensees and the NRC in the development and review of applications. Key SRPs include NUREG 0800, NUREG 1800, and NUREG 1801. A description of the standard structure of SRPs is included in the response to Question 130.
- Interim Staff Guidance—Interim staff guidance provides further SRP guidance. These documents are issued in a timely manner as questions arise regarding implementation of SRPs, and the guidance included in interim staff guidance is included in the applicable SRP during its next revision.
- Office Instructions—OIs are procedures and guidance developed by an NRC office for its staff to meet the requirements and performance goals established in legislation, regulations, the agency’s strategic plan, and office-level operating plans.
- Management Directives—MDs specify policy, objectives, responsibilities, authorities, and other requirements in specific functional areas. MDs guide, inform, and instruct NRC employees in the performance of their jobs and communicate policies to enable employees to work effectively within the agency and with other agencies, regulated entities, and the public.
- Regulatory Guides (RGs)—RGs provide guidance to licensees on implementing specific NRC regulations, including guidance for program and application development.
- NUREG Reports—The NRC produces reports on regulatory decisions, results of research, results of incident investigations, and other technical and administrative issues that support license applications.
- Standard Technical Specifications—Licensees are required to provide proposed technical specifications as part of applications. Technical specifications are included as Appendix A to the license. STSs are published for each reactor type as NUREG reports and can be used by licensees as one form of submittal of technical specifications in their application.
- Technical Specification Task Force Reports—TSTF reports are provided to the NRC for review that provide a generic approach to changes to the STSs. These may be submitted by a vendor or licensee. Once TSTFs are reviewed and approved by the NRC, other licensees may reference the TSTFs in its application.
- Topical Reports—Topical reports are provided to the NRC for review that provide a generic approach to the format, quality, and content of a specific license change. These may be submitted by a vendor or licensee. Once TSTFs are reviewed and approved by the NRC, other licensees may reference the topical report in its application.
- NRC-Endorsed Industry Guidance—Industry develops guidance for licensees to use in the development of applications or to meet NRC requirements; such guidance is endorsed by the NRC.
- Generic Communications—Generic communications are formal documents (i.e., bulletins, generic letters, regulatory issue summaries, information notices) that provide guidance to licensees or request responses on how licensees are meeting NRC requirements. They typically address potential generic issues. Licensees may make commitments in response to these communications that become part of the licensing basis.
- Commission Papers (SECYs) —SECYs are written communication that either informs the Commission of how the staff is addressing a specific issue or requests a Commission decision on policy, rulemaking, and adjudicatory matters. These SECYs, combined with the Commission’s response, provide guidance to staff and licensees.
- Branch Technical Positions—These provide guidelines to the NRC technical staff to perform reviews and assessments.
- Public meetings, Workshops, and Technical Discussions—Oral communications with licensees provide guidance or facilitate the generation of guidance documents (see additional information in the response to Question 116).

Each document system has its own process for development, consideration of stakeholder input, review, revision, and implementation. The structure and formality depends on the type of document. For example, development and revision of regulations requires following the Administrative Procedure Act and requires extensive public participation, including review and resolution of stakeholder comments. Other documents (e.g., RGs, NUREGs, OIs, MDs) have specific programs and instructions that control development and maintenance.

All regulations and guidance documents are available to stakeholders through multiple forms of communication (e.g., Federal Register, Federal and NRC publications, NRC internal and external Web sites, ADAMS). All NRC staff has access to the information through internal and external publications, the internal and external NRC Web site, and through ADAMS. External stakeholders are provided access to information through publications, the NRC Web site, and through ADAMS.

# IRRS Question and Response Report

Question No: 123

Module 06: Review and Assessment

## Question

How does the regulatory body conduct or commission research and development to support its review and assessment activities?

## Response

The NRC requires the operators of facilities to conduct the necessary research and development work 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. The NRC accomplishes this through several processes. For applications for changes to the license of an operating reactor, the NRC performs an acceptance review to determine whether the technical justification is adequate to start a more detailed NRC review. If not, the NRC can reject the application. Once the more detailed review commences, the NRC staff can request the operator of the facility to provide additional technical justification for the proposed license change. This may require the submission of additional information, or may require additional research and development work. If the operator of the facility cannot adequately justify the requested change, the NRC can deny the operator's change request. Ultimately, it is the operator's responsibility to technically justify proposed changes.

For more generic safety issues, the NRC may work through industry groups to ensure that the industry carries out the necessary research and development work to address safety-related issues. Examples of industry organizations that perform this function include NEI, the Electric Power Research Institute (EPRI), ASME, and various industry owners and specialized working groups. The NRC may collaborate with the industry in some of these research efforts. The results of these research and development activities are included in reports (e.g., topical reports, NRC Endorsed Industry Guidance, NUREGs) that may be used or referenced by licensees.

The NRC initiates research and development work when it is determined that there is a need for additional studies beyond those undertaken by the industry. There may also be situations in which the NRC requires independent research work so that it can apply suitable critical considerations in its review and assessment. Most research at the NRC is conducted by the Office of Nuclear Regulatory Research (RES) and is identified through User Needs from other NRC offices.

RES supports the NRC's regulatory decisionmaking processes by providing technical advice, analytical tools, and information as requested by other NRC offices to support the technical staff's ability to identify and resolve safety issues, make regulatory decisions, develop regulations and guidance, conduct independent analyses to support decisions to grant or deny licensee proposed changes, renew plant operating licenses, evaluate operating experience, evaluate proposed designs and technologies, and enhance the efficiency and effectiveness of NRC programs and processes. Additional information on NRC research to support independent analysis can be found in the response to Question 127.

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. Commercial sources are selected through competitive solicitation. RES provides the technical monitoring for all of these sources.

Section 170A of the Atomic Energy Act of 1954, as amended, and the implementing NRC acquisition regulation (48 CFR 2009.570, "NRC Organizational Conflicts of Interest"), require the agency to avoid, eliminate, and neutralize organizational conflict of interest (OCOI). This regulation applies to potential or actual OCOIs with contractors potentially supporting the NRC's mission. To this end, the NRC requires every prospective contractor to submit information describing any relationship it may have with other persons or organizations that might result in an actual or potential OCOI if it were to serve as a contractor. The NRC's policy ensures that NRC independence is not compromised by using contractors that may have relationships with others which may diminish their capacity to give impartial, technically sound, objective technical assistance and advice or may result in an inferior work product.



# IRRS Question and Response Report

Question No: 124

Module 06: Review and Assessment

## Question

How does the Regulatory Body make use of external consultants to assist in its review and assessment of an operator's submission? To what extent is it general practice to use external consultants?

## Response

The NRC contracts with commercial firms and other Federal agencies (e.g., 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. The NRC's objective is to employ the expertise and experience of consultants in an effective and efficient manner to achieve the agency's mission. In so doing, the NRC follows Federal acquisition requirements that include, in part, developing statements of work describing the work requested, requesting proposals from prospective contractors, evaluating proposals against preestablished acceptance criteria, evaluating OCOI (see additional information in the response to Question 123), awarding contracts, and monitoring work through NRC technical monitors and monthly reports from contractors.

Overall, contractors support approximately XX% of work on applications. A key area in which the NRC uses contractors is for technical assistance in reviewing license renewal applications for nuclear power plants. The assistance typically consists of a contractor team of experts assigned to perform a portion of the review and to provide recommendations and findings for consideration by NRC staff in the preparation of a regulatory report. In addition, the NRC may utilize external sources for technical assistance in instances where there is a highly specialized technical requirement and the NRC's staff has a limited number of individuals with this expertise (e.g., hydrology), or if there is an increased number of licensing actions requiring specialized expertise (e.g., an increase in number of criticality analysis-related applications). Again, these contractors and consultants provide review, findings, and recommendations for consideration by NRC staff in the regulatory decisionmaking process.

For all work on applications, including work supported by contractors, the final decision on acceptability is an inherently governmental function and must be performed by NRC staff.

Question No: 125

Module 06: Review and Assessment

## Question

Is the Regulatory Body assisted in the review and assessment process by any Advisory Bodies?

## Response

As discussed in the response to Question 55, the NRC receives advice from three advisory committees.

Question No: 127

Module 06: Review and Assessment

## Question

Does the Regulatory Body carry out independent analyses (e.g. computer code calculations etc.) to support its own assessment activities?

## Response

The NRC often performs independent analyses in support of its regulatory function. The purpose is to confirm, through independent analysis, the results of testing and analysis that is provided by the licensees. Examples of independent analysis include review of vendor computer codes, methodologies, and calculations. When analyzing computer code calculations, the confirmatory analyses may be performed using the vendor's computer code or codes in addition to the calculations using the regulatory body's computer code. The independent confirmatory analyses provide assurance that the licensee's codes are performing as intended, their performance is well understood by the regulatory body, and the results are consistent.

NRR receives additional analytical support from contractors and RES in performing independent analyses. Examples include expertise in the areas of criticality safety, thermal-hydraulic and severe accident phenomenology, accident source terms, and accident sequence analysis.

Additional information on the support from contractors and NRC independent analysis of applications is included in the responses to Questions 123 and 124.

# IRRS Question and Response Report

Question No: 128

Module 06: Review and Assessment

## Question

To understand more fully the process of review and assessment prepare a discussion or presentation of some specific examples (e.g. a modification to a single system or a Technical Specification, an upgrade to or a backfit of an entire system to an existing [or new plant or ] the review and assessment of a major construction project)?

## Response

In one specific example, Duke Energy Corporation (Duke Energy) submitted a license application on August 5, 2002, to temporarily extend the completion time of the Keowee Hydro Units (KHUs) at Oconee Nuclear Station, Units 1, 2, and 3, to allow additional time for maintenance and upgrades. In conducting its review, the NRC staff used the guidance provided in OI LIC 101. The application request dealt with the unavailability of the KHUs for purposes of performing planned maintenance and upgrades. The KHUs are the emergency alternating current power sources to the three Oconee nuclear units when offsite power is lost. The licensing basis for the KHUs is provided in the Oconee Unit 1 licensing SE dated December 29, 1970. The regulatory evaluation that the NRC staff applied in its review of the risk associated with the licensee's proposed changes had been developed consistent with the objectives of the NRC staff's Probabilistic Risk Assessment (PRA) Policy Statements, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," for enhanced decisionmaking and will result in more efficient use of resources, improvement in safety, and reduction of unnecessary burden. The NRC staff based its acceptance of the licensee's request, in part, on NRC RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis."

The NRC staff had numerous discussions with Duke Energy over an almost 2 year period regarding this application. The concerns centered primarily on the simultaneous outage of both KHUs. NRC staff identified a number of technical concerns. Duke Energy added a number of additional compensatory measures in response to these concerns. The compensatory measures that were added to the technical specification resolved the NRC staff's concerns and provided reasonable assurance that the safety of the Oconee site will not be unduly affected by the KHU online refurbishment outages. The SE included an assessment of the full complement of compensatory measures and commitments.

The reviewers of the application included technical experts in the areas of electrical power systems and probabilistic risk assessment. To respond to NRC requests for additional information, the licensee provided 10 supplements to the August 5, 2002, application, and committed to a number of previously identified compensatory measures. Several conference telephone calls and a public meeting on December 16, 2003, were conducted between the licensee and the NRC staff to discuss the application. On August 5, 2004, the NRC staff issued the amendment and the SE ("Safety Evaluation by the Office of Nuclear Reactor Regulation Related to Amendment No. 339 to Renewed Facility Operating License DPR-38, Amendment No. 341 to Renewed Facility Operating License DPR-47, and Amendment No. 340 to Renewed Facility Operating License DPR-55") providing the basis for approval. A notice of issuance of the amendment was published in the Federal Register. The SE and supporting documents were recorded in ADAMS.

In another specific example, Southern Nuclear Operating Company, Inc. (the licensee) submitted a license application request on August 28, 2007, to increase the licensed thermal power level by 1.7 percent to 3625.6 megawatts thermal (MWt) for the Vogtle Electric Generating Plant, Units 1 and 2 (Vogtle 1 and 2). This increase will be achieved by the installation of the Caldon leading edge flow measurement (LEFM) CheckPlus ultrasonic flow measurement system, which allows for more accurate measurement of feedwater flow. In conducting its review of this LAR associated with measurement uncertainty recapture power uprate, NRC staff used the guidance provided in OI LIC 101. The licensee and NRC staff utilized the guidance in RG 1.105, "Setpoints for Safety-Related Instrumentation," in performing their analyses and review. The licensee utilized two topical reports which previously had been reviewed and approved by the NRC (John N. Hannon, NRC, letter to C.L. Terry, TU Electric, "Staff Acceptance of Caldon Topical Report ER-80P: Improving Thermal Power Accuracy While Increasing Power Level Using the LEFM System," dated March 8, 1999, and "Acceptance for Referencing of Licensing Topical Report, EPRI NP-2511-CCM, 'VIPRE-01: A Thermal-Hydraulic Code for Reactor Cores,' Volumes 1, 2, 3, and 4" May 1, 1986"), which set precedents for performing this type of analysis.

The reviewers of the application included technical experts in the areas of instrumentation and controls, reactor systems, electrical systems, mechanical and civil engineering, component performance and testing, steam generator tube integrity and chemical engineering, operator licensing and human performance, vessels and internals integrity, fire protection, accident dose and meteorological analyses, plant systems, piping and nondestructive examination, and technical specifications. To respond to NRC RAIs, the licensee provided four supplements to the August 28, 2007, application. Several conference telephone calls were conducted between the licensee and the NRC staff to discuss the application. Upon completing its review and assessment of the submittal, on February 27, 2008, the NRC staff issued the amendment and the SE ("Safety Evaluation by the Office of Nuclear Reactor Regulation Related to Amendment No. 149 to Facility Operating License NPF-68 and Amendment No. 129 to Facility Operating License NPF-81, Southern Nuclear Operating Company, Inc., Vogtle Generating Plant, Units 1 and 2"), providing the basis for approval. A notice of issuance of the amendment was published in the Federal Register. The SE and supporting documents were recorded in ADAMS, providing the basis for approval. A notice of issuance of the amendment was published in the Federal Register.

# IRRS Question and Response Report

<b>Question No:</b> 129	<b>Module 06: Review and Assessment</b>
<b>Question</b>	
How is it ensured that safety related modifications are subject to review and assessment commensurate with the extent and nature of the hazard presented?	
<b>Response</b>	
<p>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 has to first seek NRC approval before effecting the modification:</p> <p>-No need for prior NRC approval—If a proposed modification is not governed by a Technical Specification requirement and does not meet any of eight criteria set forth 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.</p> <p>-Prior NRC approval needed—If a proposed modification is governed by a Technical Specification requirement or meets any one of eight criteria set forth in 10 CFR 50.59, the licensee is to first seek NRC review and approval via the license amendment process set forth in 10 CFR 50.90. The review would follow the amendment process.</p> <p>The licensee is required to amend the final safety analysis report (FSAR) to include both categories of modifications performed in a period of time. The requirements for periodically updating the FSAR are described in 10 CFR 50.71(e). This regulation states that each person licensed to operate a nuclear power reactor shall periodically update the originally submitted FSAR to assure 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 Commission request. The updated information shall be appropriately located within the update to the FSAR.</p> <p>Each licensee shall submit revisions containing updated information to the Commission on a replacement-page basis that is accompanied by a list that identifies the current pages of the FSAR following page replacement. The submittal shall include (1) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made and (2) an identification of changes made under the provisions of 10 CFR 50.59 but not previously submitted to the Commission. Revisions to the FSAR must be filed annually or 6 months after each refueling outage, provided the interval between successive updates does not exceed 24 months. The revisions must reflect all changes up to a maximum of 6 months prior to the date of filing.</p> <p>Both categories of modifications are subject to the NRC’s inspection program to ensure that the modifications have been carried out consistent with NRC regulations. Because modifications under the first category had not been previously reviewed and approved by the NRC, the inspection program would include sampling of modifications under this category to ensure that the analysis under 10 CFR 50.59 had been performed correctly. See additional information in the response to Question 131 regarding how PMs and inspectors follow up on changes made under 10 CFR 50.59.</p>	

<b>Question No:</b> 129AS	<b>Module 06: Review and Assessment</b>
<b>Question</b>	
How is it assured that organizational changes by the Regulatory body that could have safety relevance are subject to review and assessment commensurate with the extent and nature of the hazard presented?	
<b>Response</b>	
<p>The Energy Reorganization Act of 1974 gave the Commission its structure and established its major offices. The organizational structure is described in the response to Question 119.</p> <p>Organizational changes within the NRC are reviewed and approved by senior management, assuring that the safety performance of the licensee is not adversely affected. Processes contain the designation of appropriate levels of review and approval for organizational changes. For example, major changes require Commission approval. The process also includes involvement of internal stakeholders, including coordination with the employee labor union and discussions with affected staff. The process for review and approval of organizational changes is included in MD Volume 9, “NRC Organization and Functions.”</p> <p>While a mature regulator, the NRC (with Commission approval), has reorganized (as examples, creation of NRO in 2006 in anticipation of new reactor construction and NSIR in 2002 for post-September 11, 2001, security concerns) to adapt to an evolving regulatory environment and to improve organizational effectiveness and efficiency.</p>	

# IRRS Question and Response Report

Question No: 130

Module 06: Review and Assessment

## Question

How does the Regulatory Body satisfy itself that:

I. the information made available to it demonstrates the safety of the facility or proposed activity

## Response

To determine that information submitted by licensees adequately demonstrates the safety of the facility or proposed activity, the NRC staff thoroughly reviews the information submitted by the licensee and performs an independent safety review of the proposed activity (e.g., application for operating license, request for facility license amendment). NRC regulations describe in detail the information that licensees must submit, for review and approval by the NRC staff, with applications for operating licenses and license amendment requests. Information on regulations and guidance is included in the response to Question 122.

SRPs are one of the principal documents used by NRC staff for guidance in performing independent safety reviews of applications to construct or operate nuclear power plants. The principal purpose of the SRP is to assure 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. Each SRP section is organized as follows:

- Areas of Review—This subsection describes the scope of review for the identified functional area and contains a description of the systems, components, analyses, data, or other information that is reviewed.
- Acceptance Criteria—This subsection identifies the applicable NRC requirements, including specific regulations, NRC orders, and industry codes and standards referenced by regulations. This subsection also identifies the regulatory guidance that the staff has determined to provide an acceptable approach for satisfying the applicable requirements. This subsection also contains, as necessary, the technical bases for applicability of the requirements to the subject areas of review or relationship of regulatory guidance to the associated requirement.
- Review Procedures—This subsection discusses how the review is accomplished and is a step-by-step procedure to be implemented by the reviewer to obtain reasonable assurance that the applicable regulatory requirements have been met.
- Evaluation Findings—This subsection presents the type of conclusion that is sought for the particular review area. For each SRP section, the staff's conclusion is incorporated into a published SE. A description of the SE is included in the response to Question 134.
- Implementation—This subsection provides guidance to licensees regarding the NRC's plans for using the SRP section. In 10 CFR 50.34(h), the NRC requires each application to include an evaluation of the facility against the SRP of record, including all differences between the design features, analytical techniques, and procedural measures proposed for a facility and those in the SRP acceptance criteria. If the application proposes an approach different from the SRP, the licensee must provide a discussion of the differences and adequate justification for how the application still meets all regulatory requirements.
- References—The references used in the review process can be found in the response to Question 122.

Regulations require that information submitted to the NRC by licensees in support of applications be submitted under oath or affirmation by a licensee or duly authorized officer thereof (10 CFR 50.30(b)). In 10 CFR 50.9, "Completeness and Accuracy of Information," the NRC requires that licensee submittals are complete and accurate. If the information submitted is determined by the NRC staff to be incomplete such that the staff cannot complete its safety evaluation, the staff may request additional information from the licensee in the form of an RAI. In these cases, the licensee will provide supplemental information to the NRC, under oath or affirmation, addressing the staff's request. 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, "Completeness and Accuracy of Information," 10 CFR Part 21, 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors," 10 CFR 50.73, "Licensee Event Report System"). The NRC has enforcement guidance and policies in place, which provide methods for assessing levels of severity and consequential actions 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.

Occasionally, there are aspects of regulated facilities presented to the NRC that are unique, novel, or otherwise not well understood in the U.S. nuclear power industry. For such cases, the NRC requires the licensee to conduct the necessary evaluation, research, and development work to understand the technical solution and provide sufficient justification to the NRC that the solution meets NRC requirements and standards. In such cases, the NRC encourages licensees and industry groups to perform the necessary research and development work to further the understanding of nuclear safety-related issues. The staff will independently verify the adequacy of the new analysis or testing methodology and results. In some cases, the NRC staff may elect to conduct audits or contract independent research or testing to national laboratories or other independent consultants to verify the adequacy of the proposed technical solutions (see the responses to Questions 123, 124, and 127). When all required information concerning the new process, equipment, or methodology is available, the NRC staff will perform a thorough review and prepare a safety evaluation to assess whether the new approach meets all applicable technical and regulatory requirements using the regulations, guidance, and procedures identified in the response to Question 122.

# IRRS Question and Response Report

Question No: 131

Module 06: Review and Assessment

## Question

How does the regulatory body confirm periodically whether the safety assessment for a facility or activity remains valid?

## Response

It is the responsibility of the licensee to maintain and evaluate changes to its licensing basis. In 10 CFR 50.59, the NRC requires licensees to evaluate changes and receive approval of amendments when the changes meet certain requirements. In 10 CFR 50.71(e), the NRC includes the requirements for report changes to the NRC. Refer to the response to Question 129 for 10 CFR 50.59 and 10 CFR 50.71(e) requirements.

The NRC assesses how licensees are maintaining their facilities and related procedures consistent with the FSAR as part of the NRC inspection program. These inspection activities are primarily coordinated through the NRC Regional Offices and include the following procedures:

Inspection Procedure 71111.17 – “Evaluations of Changes, Tests, or Experiments and Permanent Plant Modifications,” dated October 31, 2008, is used to monitor the effectiveness of a licensee’s implementation of changes to facility structures, systems, and components (SSCs), risk-significant normal and emergency operating procedures, test programs, and the FSAR in accordance with the requirements of 10 CFR 50.59, and to also provide assurance that required license amendments have been obtained. The inspection activity monitors the implementation of modifications to SSCs, since modifications to one system may also affect the design bases and functioning of interfacing systems as well as introduce the potential for common cause failures. The inspection objectives are as follows:

- Verify that evaluations were performed in accordance with 10 CFR 50.59.
- Verify that the design bases, licensing bases, and performance capability of SSCs have not been degraded through modifications.
- Verify that procedures and design and license basis documentation affected by changes have been adequately updated.
- Verify that design and license basis documentation used to support changes, and that procedures and design and license basis documentation affected by changes, reflect the design and license basis of the facility after the change has been made.

Inspection Procedure 71111.18, “Plant Modifications,” dated October 31, 2008, is utilized to monitor modifications to risk-significant SSCs that can adversely affect their availability, reliability, or functional capability, to verify that (1) modifications have not affected the safety functions of important safety systems, (2) the design bases, licensing bases, and performance capability of risk significant SSCs have not been degraded through modifications, and (3) that modifications performed during increased risk-significant configurations do not place the plant in an unsafe condition. Modifications to one system may also affect the design bases and functioning of interfacing systems. Similar modifications to several systems could introduce potential for common cause failures that affect plant risk. A temporary modification may result in a departure from the design basis and system success criteria. Modifications performed during increased risk configurations could place the plant in an unsafe condition. The NRC periodically screens active temporary and permanent modifications on systems that are ranked high in risk. The annual goal is to review the details of three to five temporary modifications and one to two permanent plant modifications performed online as they occur. Although the sample sizes are an annual goal, the inspection effort can be distributed on a quarterly basis. NRR assesses the licensees’ submittals of various parts of the licensing bases to ensure consistency and a general compliance with requirements of content and timing.

- In addition to, and in support of, NRC inspections, the NRR PM will typically perform the following upon receipt of an FSAR:
- Perform an in-house review of the FSAR update to determine that for those FSAR update changes that the PM is familiar are appropriately addressed by licensing actions (changes to the facility or procedures previously described in the FSAR), 10 CFR 50.59 submittals, or regional inspection activities.
- For those licensing actions in which NRC approval was contingent upon the licensee placing commitments relied upon by the staff in their regulatory decision into the FSAR, all of these commitments should be verified to be incorporated into the FSAR. The PM should also ensure that there are no other licensing actions and related regional inspection activities that have been completed since the last update for which changes should have been submitted.
- The PM will confirm that changes due to power uprates are incorporated into the next update of the FSAR.
- Any questions or concerns identified during the reviews should be discussed with the regional staff office. The completed review will be documented and any significant findings discussed by an input included in an inspection report.

In addition to inspection of licensee compliance with the 10 CFR 50.59 and 10 CFR 50.71(e) requirements, NRC inspectors, including resident inspectors, verify compliance with NRC requirements, including the licensing basis, on a sampling basis. More information on the NRC oversight program is included in the response to the questions in Module VI.



# IRRS Question and Response Report

Question No: 132

Module 06: Review and Assessment

## Question

How does the assessment specialist in the Regulatory Body follow the development of a facility or an activity, as applicable, from initial site selection, through design, construction, commissioning, operation and decommissioning or closure?

## Response

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 PM will be assigned responsibility for individual facilities that, dependent upon the assessment situation, may require additional support from other technical staff from various program offices during the review process. The application and review processes allow for the PM to follow the development of a facility or an activity. 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 maintains regular communications 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 status of current and anticipated applications. PMs are also aware of changes to facilities based on review of changes provided in the FSAR. Refer to Questions 129 and 131 regarding changes and updates to the FSAR.

During facility operations, the ROP is administered through the NRC Inspection Manual. The Inspection Manual and inspection procedures are available by active links through the NRC's Document Collections Web page. PMs are informed of inspection results from resident and regional office inspectors, including receiving copies of all inspection reports. Information on the NRC oversight process is included in the response to questions in Module VI.

As the facility status changes from one stage of licensing to the next, the NRC PM assigned to the facility may also change. The various stages in the facility's life cycle are assigned responsibility to different program offices within the NRC. However, turnover of critical information between the different PMs for a nuclear facility is conducted to ensure a timely and efficient conveyance of information specific to each nuclear facility. The types of documents transferred in the turnover process include documents supporting the original plant license; safety evaluations and supporting draft safety evaluations and requests for additional information to support license amendments during plant operation; and decommissioning plans. All documents are recorded in ADAMS.

There is additional information on the responsibilities of PMs in the responses to Questions 116 and 119.

Question No: 134

Module 06: Review and Assessment

## Question

I. How does the Regulatory Body document its review and assessment activities?

II. How are the results of assessment communicated within the Regulatory Body, and to the operator?

## Response

In accordance with its mandated responsibilities in the Atomic Energy Act of 1954, as amended, the NRC issues licenses (written documents) and can modify, revoke, or suspend these licenses. The terms and conditions of all licenses are subject to amendment, revision, or modification, by reason of amendments of this Act, or by reason of rules and regulations issued in accordance with the terms of this Act. The licensing basis consists of the set of NRC requirements and documents applicable to a specific plant and are a licensee's written regulatory commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The licensing basis includes the regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 54, 55, 70, 72, 73, 100, and appendices thereto; initial license; amendments to the license; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2, "Definitions," as documented in the most recent FSAR; and the licensee's commitments remaining in effect that were made in docketed licensing correspondence, such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

Although not part of the licensing basis, a key document that explains the NRC's review and assessment of applications is the SE. The SE contains the following:

- the current licensing basis
- the proposed change
- the regulatory requirements and criteria upon which the change is evaluated
- the methodology, including input assumptions, used by the licensee
- the agency's evaluation of the acceptability of the proposed request, which may include the following, as appropriate:
  - comparisons with similar facilities or similar actions
  - independent analyses performed by or on behalf of the regulatory body
  - any conditions or formal regulatory commitments to be fulfilled by the licensee organization

After the license amendment, technical specification changes, and SE have received appropriate NRC concurrences, they are transmitted to the appropriate stakeholders, including the licensee, members of the public that have requested to be on the server list, NRC staff, and NRC resident inspectors. The NRC maintains all documents that constitute the licensing basis, all information relied on for making the final safety and licensing decision (including all licensee submitted information in support of the application), and the SE in ADAMS. ADAMS is accessible through the NRC Web site, and NRC staff has access to all information in ADAMS.



# IRRS Question and Response Report

Question No: 137

Module 06: Review and Assessment

## Question

Is there an adequate documentation regime for the outcome of the review process?

## Response

As noted in the response to Question 134, the licensing basis consists of the set of NRC requirements and documents applicable to a specific plant and a licensee's written regulatory commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The licensing basis includes the regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 54, 55, 70, 72, 73, 100, and the appendices thereto; initial license; amendments to the license; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent FSAR; and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports. In addition, an explanation of the NRC's review and assessment of a particular application is included in the SE.

Final license amendments, technical specification changes, and SE are transmitted to the appropriate stakeholders, including the licensee, members of the public that have requested to be on the server list, NRC staff, and NRC resident inspectors. The NRC maintains all documents that constitute the licensing basis, all information relied on for making the final safety and licensing decision (including all licensee-submitted information in support of the application), and the SE in ADAMS. ADAMS is accessible through the NRC Web site, and NRC staff has access to all information in ADAMS.