

# Integrated Regulatory Review Service Mission to the United States

## MODULE 5: AUTHORIZATION

### Overview

The U.S. Nuclear Regulatory Commission (NRC) has a regulatory framework that provides authority for issuing, amending, suspending, or revoking licenses. Authorization by the NRC is a prerequisite for operation of all civilian, private and commercial, facilities and activities utilizing radioactive material. Contained in the regulations are the conditions necessary for safety and security. Through the authorization (licensing) process, the NRC allows an applicant to conduct any or all of the following activities:

- Construct, operate, and decommission commercial reactors and fuel cycle facilities.
- Possess, use, process, export and import nuclear materials and waste, and handle certain aspects of their transportation.
- The framework includes requirements for applicants to site, design, construct, operate, and close waste disposal sites.

The U.S. Nuclear Regulatory Commission's (NRC's) regulatory process consists of five main components: (1) developing regulations and guidance for our applicants and licensees; (2) licensing or certifying applicants to use nuclear materials or operate nuclear facilities or decommissioning that permits license termination; (3) overseeing licensee operations and facilities to ensure that licensees comply with safety requirements; (4) evaluating operational experience at licensed facilities or involving licensed activities; and (5) conducting research, holding hearings to address the concerns of parties affected by agency decisions, and obtaining independent reviews to support regulatory decisions.

### Legal Basis for Authorization

*Authorization of facilities and activities by the regulatory body Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.  
(GS-R-1, Requirement 23)*

*The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.  
(GS-R-1, Requirement 24)*

The types of authorization that the NRC issues include construction permits; operating licenses; license amendments; licenses to receive and possess special, byproduct, or source materials; and amendments to such licenses.

The legal basis for the authorization process of production and utilization facilities is described in Sections 103, 104.b, or 185 of the Atomic Energy Act of 1954, as amended (the Act). Section 103 of the Act grants the Commission the authority to issue commercial licenses "to persons

applying therefore to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import or export under the terms of an agreement for cooperation arranged pursuant to section 123 (cooperation with other nations), utilization or production facilities for industrial or commercial purposes.”

This section further prescribes certain threshold conditions required for issuance of a license. For instance, the Commission must find that the proposed activities will serve a useful purpose proportionate to the quantities of special nuclear material utilized, that licenses are issued to those who are equipped to observe safety standards to protect health and to minimize danger to life and property, and that those who are granted licenses agree to make available to the Commission technical information and data.

Section 104.b of the Act allows the Commission to issue licenses to production and utilization facilities for industrial or commercial purposes, for medical therapy, and for research and development. The 104.b license, which originally was aimed at research and development leading to commercial application, was to entail “the minimum amount” of regulation needed to permit the Commission to fulfill its obligations. These statutes thus consider the potential magnitude and nature of the hazard associated with the facility and therefore meets the intent of the draft GS-R-1, which emphasizes “a graded approach to safety.”

The NRC issues construction permits to entities that apply for authorization to construct a production or utilization facility under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities.” The entity later applies for a license that authorizes operation of the constructed facility. However, Section 185 of the Act also authorizes the agency to grant applicants a combined construction and operating license before they begin construction of production or utilization facilities. As part of this combined license, the Commission must identify the “inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform....” The NRC issues these licenses after a safety and environmental review and an opportunity for a public hearing. Section 189 of the Act specifies those actions for which a hearing is required. That section of the Act also specifies the requirements to be followed in issuing amendments to licenses. Amendments that involve no significant hazards considerations can be granted before a hearing is held. The NRC’s regulations specify in detail the licensing and hearing procedures.

### **Authorization Control for Complex Facilities**

The NRC requires authorization for initial licensing of complex facilities, major changes to those facilities, for renewal of licenses of such facilities, and for their decommissioning. Applications for such authorizations must address both safety and environmental issues. Some steps of these processes are spelled out in statute (see, for example, Section 189 of the Atomic Energy Act), but NRC regulations and guidance provide the details. The Atomic Energy Act of 1954, as amended, established the NRC’s authority to regulate all private and commercial uses of radioactive materials including nuclear power plants. The NRC maintains control of authorization for complex facilities, such as new construction and major modifications through its regulations. Siting, early site permits, standard design certifications, construction permits, operating licenses, and combined license applications are submitted by the applicant to the NRC under either 10 CFR Part 50 or 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” In addition, applications must address the applicable regulations of the National Environmental Policy Act in 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.”

Included in the initial application for authorization and subsequent requests for revision of an authorization are the requirements to submit an adequate demonstration of safety. In an initial application the requestor is required to submit the full body of documents that demonstrates the safety of the facility or activity. Included (but not limited to) in the application are the Safety Analysis Report, Proposed Technical Specifications, Environmental Report, Emergency Plan, Quality Assurance Plan, Conduct of Operations and Training Plans. In subsequent requests for revision to the authorization, the authorization holder is required to submit those documents affected by the requested change. These requirements are primarily based in 10 CFR 50.34, 10 CFR 50.90, 10 CFR 50.4, and 10 CFR 50.71.

Modification to programs, such as quality assurance and emergency planning, may be performed without NRC approval if the changes do not reduce commitments or decrease the effectiveness of the program.

To help prioritize work and establish a graded approach to safety, the regulations establish a threshold for when program modifications must be submitted to the NRC for prior approval. The regulations also provide procedural guidance for determining if a change needs to be submitted to the NRC for prior approval.

NRC regulations control all stages of a nuclear reactor facility—siting, construction, special nuclear material license, low-power license, full power/commissioning, possession-only license, and decommissioning. Further guidance, such as the Standard Review Plan, is available to applicants and reviewers. Before issuing an authorization, the NRC staff performs a technical review. The NRC staff inspects and provides oversight during the entire process

### **Authorization Amendment, Suspension, or Revocation**

Licensees may seek amendments to their licenses. Section 189 of the Atomic Energy Act and 10 CFR 50.90 through 10 CFR 50.92 of the Commission's regulations control the amendment process. The regulations in Title 10 of the Code of Federal Regulations (10 CFR), Part 2, prescribe the requirements for determining the acceptability of an application for amendment of a license. In accordance with 10 CFR 2.102(a), the U.S. Nuclear Regulatory Commission (NRC) staff may evaluate an application requesting approval of a proposed action for completeness. All requests for an amendment to an existing authorization which require NRC approval prior to implementation are subject to review prior to acceptance of the request.

### ***Acceptance Review Process***

The acceptance review process helps minimize the likelihood that the staff will expend significant resources reviewing a request for modification of an authorization if there are major deficiencies in the submittal. A request for modification of an authorization will be accepted by the NRC when it is determined that the application reasonably appears to contain sufficient technical information, both in scope and depth, for the NRC staff to complete the detailed technical review and render, in an appropriate time frame for the associated action, an independent assessment of the proposed action with regard to applicable regulatory requirements and the protection of public health, safety, and security. The application must contain adequate demonstration of the applicant's ability to ensure adequate protection of public health and safety, and to protect the environment. Within 25 working days after submittal of an application the NRC will complete an acceptance review of the application. There are generally three outcomes of the acceptance review:

- ***Acceptable for Review***

A determination made by the NRC staff that the application reasonably appears to contain sufficient technical information, both in scope and depth, for the NRC staff to complete the detailed technical review and render, in an appropriate time frame for the associated action, an independent assessment of the proposed action with regard to applicable regulatory requirements and the protection of public health, safety, and security. Acceptance of an application indicates that all of the required information is either present in the application or should be able to be addressed in the technical review process via the Request for Additional Information process.

- ***Unacceptable With Opportunity to Supplement***

A determination made by the NRC staff that the application does not contain sufficient information for the staff to perform a technical review, but the NRC is sufficiently confident that the requestor will be able to address the deficiencies in the application in a short period of time.

- ***Unacceptable Without Opportunity to Supplement***

A determination by the NRC staff which finds deficiencies so significant that they impede completion of the acceptance review. The request is then returned to the applicant as unacceptable for review, pursuant to 10 CFR 2.101. Alternately, at the completion of the review, the NRC staff may have identified major deficiencies that would be better addressed by terminating the review and returning the license amendment to the applicant for resolution.

The quality of a submitted request to modify an authorization has a significant impact on the amount of NRC staff's resources expended in the review process. Requests that include information of a sufficient scope and depth allow the NRC staff to focus its efforts on reviewing the safety, technical, and regulatory merits of the arguments put forth by the licensee or applicant. A thorough acceptance review is integral to the efficient review of an application. The early identification of insufficient information benefits both the NRC staff and the applicant.

The acceptance review process ensures that all required safety related information that the requestor is required to submit is available to the NRC or will be readily available as required during the review process.

Once the agency accepts the application, the staff begins a safety and environmental review. After the application is found acceptable, the staff reviews the information and requests additional information in specific areas as necessary. Under certain circumstances on site inspections may be utilized to verify plant conditions associated with a requested license amendment.

Once the staff has completed its review and has determined that the amendment satisfies the Commission's regulations, that there is reasonable assurance that the activities will not endanger the health and safety of the public, and that the amendment is not inimical to the common defense and security, the staff prepares a safety evaluation report, which contains the basis for the staff's determination that the amendment should be granted. Also, in cases in which the agency action is not categorically excluded from environmental analysis, the staff also prepares either an environmental assessment or an environmental impact statement, as

appropriate. The extent of the review and the regulatory controls applied to the application is commensurate with the relative risks associated with the initial application or proposed changes to an existing authorization. An opportunity for a hearing is provided for all license amendments. If the amendment does not involve consideration of significant hazards, the hearing may be held after the amendment is issued. The amendment does not involve significant hazards considerations if it meets the following criteria:

- It does not involve a significant increase in the probability or consequences of an accident previously evaluated.
- It does not create the possibility of a new or different kind of accident from any accident previously evaluated.
- It does not involve a significant reduction in the margin of safety.

For amendments that do not satisfy these criteria, any requested hearing must be completed before issuance of the amendment.

At the end of the authorization review process the NRC formally records and makes public the decision and the basis of the determination on the authorization.

### ***Types of Licensing Actions:***

#### ***Amendment***

An amendment is a document issued by the NRC in response to a utility's request to change its technical specifications and/or license

#### ***Exemption***

An exemption is a legal document which grants a utility relief from a requirement of the regulations. A licensee may request an exemption from the requirements of an NRC regulation provided that the exemption is authorized by law, does not present an undue risk to the public health and safety, is consistent with the common defense and security, and involves special circumstances as discussed in 10 CFR 50.12(a)(2).

If the exemption request is approved by the NRC, an exemption will be issued, relieving the licensee from implementing the requirements of the regulation involved.

#### ***Relief Request***

When a licensee finds that it is not possible to meet American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (Code), Section XI requirements, there are provisions for requesting relief. The most common types of relief concern the Code, Section XI, Inservice Inspection (ISI) and Inservice Testing (IST).

The licensee is required by the rules to examine and periodically test pumps and valves whose function is required for safety, to verify operational readiness. The licensee shall comply with the requirements of the latest edition and addenda of the Code. If the licensee can't comply with certain Code requirements, the licensee should notify the Commission and submit, as specified in 10 CFR 50.4, information to support the determination

## ***License Transfer***

The provisions of Section 184 of the Atomic Energy Act of 1954, as amended, and the Nuclear Regulatory Commission's (NRC's) regulations at Title 10 of the Code of Federal Regulations (10 CFR) 50.80, "Transfer of licenses," stipulate that NRC approval is required for transfer of control of the ownership and/or operating authority responsibilities within the facility operating license. An application for transfer of a license is required by 10 CFR 50.80(b) to include as much of the technical and financial qualifications information on the proposed transferee as would be required for an initial license.

## ***Orders***

Orders are written NRC directives to: (1) modify, suspend, or revoke a license; (2) cease and desist from a given practice or activity; or (3) take such action as may be proper. The NRC may also issue orders to unlicensed persons (including vendors, contractors, and their employees).

Licenses are suspended or revoked by issuance of an order to the licensee. These orders may be immediately effective. The regulation in 10 CFR 2.202, "Orders," describes procedures for challenging the immediate effectiveness of an order. To make such a challenge, the licensee must answer the order, request an immediate hearing, and move for the presiding officer to set aside the order on the grounds that it is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. The Commission may revoke licenses pursuant to Section 186 of the Atomic Energy Act if it is determined that, had the Commission been aware of the information it now has, it would not have issued the license in the first instance. Interested parties may seek a hearing on an order to suspend or revoke. The hearing would be before impartial NRC administrative judges; their decision can be appealed to the Commissioners and, ultimately, to a Federal court of appeals.

## ***Notice of Enforcement Discretion***

On occasion, circumstances may arise in which a licensee's compliance with a technical specification (TS) limiting condition for operation or with other license conditions would involve:

- 1) an unnecessary plant transient; or
- 2) performance of testing, inspection, or system realignment that is inappropriate for the specific plant conditions; or
- 3) unnecessary delays in plant startup without a corresponding health and safety benefit; or
- 4) the potential for an unexpected plant shutdown during severe weather or other natural phenomena that could exacerbate already degraded electrical grid condition and could have an adverse impact on the overall health and safety of the public.

Under such circumstances, the NRC staff may choose not to enforce the applicable TS or other license condition. This enforcement discretion will only be exercised if the NRC staff is clearly satisfied that the action is consistent with protecting the public health and safety. A licensee

seeking to request enforcement discretion must provide a written justification, or in circumstances where good cause is shown, oral justification followed as soon as possible by written justification. The justification must document the safety basis for the request and provide whatever other information the NRC staff deems necessary in making a decision to exercise enforcement discretion. Appropriate enforcement actions consistent with the NRC's Enforcement Policy must be considered for the root causes that led to the need for enforcement discretion.

### ***Denials***

If after a detailed review the NRC determines that the technical basis in support of a request to amend an authorization is insufficient for the staff to conclude that there is reasonable assurance of adequate protection of public health and safety, the NRC will inform the licensee that it plans to issue a letter denying the request. Similarly, if it is later determined that there are deficiencies in the application, that were not identified during the acceptance review process, and that the deficiencies are unlikely to be addressed through a request for additional information, the NRC will notify the licensee that it plans to issue a letter denying the application. Under these circumstances, the licensee may choose to withdraw the request instead of receiving a letter of denial from the NRC. In practice, most licensees will choose to withdraw the application rather than receive a letter from the NRC denying the request. The licensee still has the option of resubmitting a new application that addresses the deficiencies at a later date.

### **Assessment Summary**

NRC regulations and programs are in a mature state, in that essentially all areas regarding a licensee's authorization for safe use of radioactive material are covered. The NRC's regulations define the processes for amending, suspending, revoking, or renewing licenses.

The draft GS-R-1 places great emphasis on allocating the agency's resources according to a "graded approach to safety." The approach outlined in the draft GS has the clearest application when the full range of regulated activities is being considered, and here the NRC obviously takes a graded approach, ranging from low level of resources applied to administrative changes to a plants technical specifications to highly resource-intensive reviews of complex licensing actions for nuclear power plants.

### **Areas for Improvement**

The NRC will continue to assess additional ways to increase public participation in the licensing process.