

**Process for Development of Interim Staff Guidance  
in Support of Reviews of Early Site Permit Applications**

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## **1.0 POLICY**

Subpart A of Part 52 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 52), hereafter referred to as "the rule," governs the issuance of early site permits (ESPs). To facilitate the implementation of the rule and the review and inspection of programs and activities associated with an ESP application, the staff has developed Review Standard (RS)-002, "Processing Applications for Early Site Permits." This document and its references serve as the primary sources of guidance to the staff for its review of ESP applications.

The principal purposes of RS-002 are to ensure the quality and uniformity of staff reviews and to present a well-defined base from which to evaluate ESP applications. The document is also intended to make information about regulatory matters widely available, to enhance communication with interested members of the public and the nuclear power industry, and to improve the public's understanding of the staff review process. Each of the individual guidance sections of RS-002 addresses (1) who performs the review, (2) the matters that are reviewed, (3) the basis for review, (4) the way the review is accomplished, and (5) typical conclusions.

The interim staff guidance (ISG) process supports RS-002 and the ESP review process by providing timely updated guidance to staff reviewers of ESP applications, as well as information for stakeholders, without requiring excessive numbers of formal revisions to RS-002. Guidance updates will likely be needed to address lessons learned from the ESP reviews, to document and provide guidance related to resolution of emerging issues, and to provide updated guidance based on significant revisions to documents referenced in RS-002. Approved ISGs will be used by staff reviewers and available for stakeholder information until the subjects of the ISGs are incorporated as appropriate into future revisions to RS-002.

## **2.0 OBJECTIVES**

This instruction ensures that proposed ESP ISGs reflecting new or revised guidance are properly evaluated, documented, and implemented. Further, this instruction establishes the responsibilities and authorities for the NRR staff in identifying needed changes to RS-002 using the ESP ISG process.

This instruction provides NRR staff with the basic framework for processing ESP ISGs. The goals of this instruction include the following:

- Helping provide reasonable assurance that the health and safety of the public are protected by supporting a rigorous and consistent ESP review process
- Promoting openness in the ESP application review process by making guidance to staff reviewers visible to stakeholders
- Implementing a documented and controlled review process for proposed ESP guidance, so as to support effective and efficient NRC regulation

### **3.0 BACKGROUND**

RS-002 has been developed to enhance the ESP application review process. It is expected that, during reviews of initial ESP applications, guidance to staff reviewers reflected in RS-002 may need to be modified to capture new insights or address emergent issues. This process serves to expeditiously address specific areas in RS-002 that need to be revised and to serve as a bridge until the entire document can be revised.

Public involvement is an important part of this process. The process, as described in Section 4.0 of this document, gives the public opportunities to obtain information and to comment on proposed ESP ISGs. The public will also be able to comment when RS-002 is revised to include the ISGs. Comments will be addressed in writing and/or discussed in public meetings. The NRC will make ESP ISGs available to the public by publishing them in the *Federal Register*, on the NRC web site, and in ADAMS. The NRC will also hold public meetings, as appropriate, to discuss the ESP ISGs.

### **4.0 ESP ISG PROCESS**

#### **4.1 Overview**

The staff, industry, or interested members of the public may comment on, raise issues regarding, or propose changes to information provided in RS-002 or its references. Some comments or issues may warrant the staff's developing and issuing an ESP ISG prior to the next update of the affected document. Each ESP ISG affecting RS-002 will be incorporated as appropriate into future updates of RS-002; updates of reference documents will be considered on a case-by-case basis. The ESP ISG coordinator will evaluate comments that do not rise to the threshold of an ESP ISG to determine if they should be addressed in a future revision of the affected document.

Failure to follow the ESP ISG process might adversely affect the stability and predictability of ESP application reviews. During the course of an ESP application review, the staff may discover an issue that would expand the scope of the issues being addressed under RS-002 or its references. The staff should not ask an applicant to address the new issue through a request for additional information (RAI) until an approved ESP ISG has been issued. The ESP ISGs may have schedule implications for current and future ESP applicants. Therefore, the structured approach described in this instruction should be followed.

The process is administered and controlled by the New, Research and Test Reactors Program (RNRP), Division of Regulatory Improvement Programs (DRIP), Office of Nuclear Reactor Regulation (NRR).

The ESP ISG coordinator and the lead ESP project manager (PM) (who may be the same person) play vital roles in the overall review process. They are responsible for screening, documenting, planning, tracking, coordinating, and implementing resolutions of proposed ESP ISGs. Technical reviewers will be asked to support the development of each ESP ISG.

The staff evaluating ESP ISGs should be familiar with the following documents:

- 10 CFR Part 52 and the associated statements of consideration (54 FR 15372 as amended by 61 FR 65157, 62 FR 52184, and 64 FR 72002)
- 10 CFR Part 100 and the associated statements of consideration (27 FR 3509 as amended by 61 FR 65157 and 62 FR 52184)
- RS-002, "Processing Applications for Early Site Permits"

In using RS-002 or its references, the staff, industry, or other stakeholder may discover guidance that is unclear, incorrect, or incomplete, or may find that new guidance is warranted. Comments can be provided to the ESP ISG coordinator orally, by e-mail, or by letter. The ESP ISG coordinator will document the comment. Oral comments that are resolved during a meeting only need to be documented if the comment will result in a proposed ESP ISG. Once documented, the issue will be controlled by this process to ensure timely resolution. If the staff determines that development of an ISG is warranted, then it will issue a *Federal Register* notice requesting comments (60-day comment period) on the proposed ESP ISG. At any step during the process, a proposed ESP ISG can be modified or determined to be unnecessary. If an ESP ISG proposed by an external stakeholder is determined to be unnecessary, the staff will document the closure of the issue in a letter to the interested stakeholders and in a *Federal Register* notice. Such resolution for an ESP ISG proposed by the NRC staff will be documented in an internal memorandum from the Program Director - New, Research and Test Reactors Program (PD-RNRP) to the originator that will be made available to the public through ADAMS. If an ESP ISG is approved, it will be conveyed to interested stakeholders by letter, published in the *Federal Register*, published in ADAMS, and placed on the NRC web site under "New Reactor Licensing" as an approved ESP ISG. The ESP ISG will be considered for incorporation into the next revision of the affected document, as discussed above.

#### **4.2 Processing Proposed ESP ISGs**

The basic activities involved in processing an ESP ISG are as follows:

- Section 4.2.1 - Screening of Comments
- Section 4.2.2 - Development of an Evaluation Plan
- Section 4.2.3 - Evaluation and Transmittal of Proposed ISG
- Section 4.2.4 - Resolution of Comments on the ISG
- Section 4.2.5 - Implementation of the Approved ISG

These basic activities are described in the sections below and are shown graphically in Appendix B of this instruction.

#### 4.2.1 Screening of Comments

When RNRP is notified of a comment, issue, or other condition potentially warranting an ESP ISG, the item will be referred to the ESP ISG coordinator for review. The ESP ISG coordinator screens, tracks, and documents the comments.

The ESP ISG coordinator will screen the comments to determine if development of an ESP ISG is warranted. Development of an ESP ISG is not necessary if adequate staff guidance is already available. No ESP ISG is developed if the comments are determined to be editorial (comments that might improve the readability and consistency of the documents but would not cause a current or future applicant to revise their ESP application). The ESP ISG coordinator will determine and document whether the comments should be included in a future revision of the affected guidance document. The originator will be informed of the resolution. If the ESP ISG was proposed by an external stakeholder, the ESP ISG Coordinator will publish a notice of the resolution in the *Federal Register*.

An ESP ISG will be developed if the comment would result in a staff position or guidance that needs to be communicated to internal and external stakeholders. The staff will develop the ESP ISG in accordance with the guidance contained in this document.

#### ESP ISG Coordinator Actions

Once a proposed ESP ISG is received, the ESP ISG coordinator will:

- Screen the proposed ESP ISG to determine whether an ISG is necessary. The ESP ISG coordinator may involve technical branches from other NRR divisions or NRC offices during the evaluation of the issue.
- Request that the originator forward the basis for the proposed ESP ISG in writing. The basis should include the need and the underlying regulatory requirement that the proposed ESP ISG would address. The originator should, but is not required to, provide a markup of the affected guidance document to communicate their proposed resolution. External stakeholders should be encouraged to submit their comments in a letter or e-mail to the RNRP program director (PD-RNRP). If needed, the ESP ISG coordinator will arrange a conference call or public meeting to discuss the ESP ISG.
- Ensure that a written response (or e-mail, for internal originators) has been provided to the originator within 30 days following receipt of the proposed ESP ISG. The response should indicate how the issue was resolved or the current status of the review. The final resolution should be provided or made available to all interested stakeholders.
- Track the status of the ESP ISG.

#### **4.2.2 Development of an Evaluation Plan**

Planning the processing of a proposed ESP ISG is a critical step in ensuring that the review is completed in a timely and effective manner. The plan is intended to define the scope of the review, the resources needed for the review, and the schedule for resolution. There is no intent to create a burdensome ISG planning process, so the evaluation plan should be concise and may be as informal as a short e-mail or internal memorandum.

Developing the evaluation plan involves the following activities:

- The ESP ISG coordinator should determine the schedule for completing initial review and development of a proposed ESP ISG and discuss this determination with the lead ESP PM and the section chief of the New Reactors Section for confirmation.
- The ESP ISG coordinator should discuss the schedule for completing the initial review and developing the proposed ISG with the originator.
- The section chief of the New Reactors Section (or the lead ESP PM, if delegated by the section chief) will assign a PM to develop a proposed resolution.
- The assigned PM will develop the evaluation plan and will obtain a technical assignment control (TAC) number, if necessary. This provides a means of tracking the resources expended and the work activities on each review. Separate TAC numbers are appropriate if significant resources (i.e., more than eight hours) are expected to be expended for a particular issue.
- In preparing the evaluation plan, the assigned PM will assess the proposed ESP ISG to define the scope, resources, and schedule for resolution. The assigned PM will identify the cognizant technical branch or branches and will work with the branch(es) to ensure their timely participation in the development process for the ESP ISG. The assigned PM and cognizant technical branch will determine the type of ESP ISG (i.e., clarification or compliance, as discussed in Section 4.2.3.1).
- The assigned PM will be responsible for coordinating the activities documented in the evaluation plan, monitoring the progress of these activities, and reporting the status of the review to the ESP ISG coordinator for tracking.
- The assigned PM will be responsible for obtaining clarification of the input from the originator or stakeholder if required. It is expected that the input will be clearly written with a proposed resolution for the identified concern. The input should, but is not required to, include a markup of the guidance document that warrants modification.
- The ESP ISG coordinator will track and monitor the proposed ESP ISG's progress toward resolution.

## **4.2.3 Evaluation and Transmittal of Proposed ESP ISGs**

### **4.2.3.1 Evaluation of Proposed ESP ISGs**

There are two types of ESP ISGs: (1) clarification ESP ISGs and (2) compliance ESP ISGs. Clarification ESP ISGs provide additional guidance to applicants that the staff or stakeholders feel is necessary to reduce unnecessary RAIs. The staff may note the need for such clarification if it finds that similar RAIs are being sent to multiple applicants. Clarification ESP ISGs do not create new staff positions that have not been addressed by previous applicants. Clarification ESP ISGs can inform ESP applicants or prospective ESP applicants that more information is needed on an issue already addressed in the ESP guidance documents.

Compliance ESP ISGs involve issues regarding compliance with the regulations and may result in new staff positions. Imposition of such positions on existing holders of ESPs will require meeting the finality provisions of 10 CFR 52.39.

The assigned PM will coordinate the review and the proposed resolution of the issue proposed to be the subject of an ISG. Unless the proposed ISG relates to administrative issues, the resolution will begin with an internal memorandum from the cognizant technical staff branch chief to the PD-RNRP that transmits the technical position on the issue. The memorandum will specify whether the ESP ISG is a clarification or compliance ESP ISG. The transmittal memorandum for clarification ESP ISGs may be signed by the section chief. The transmittal memorandum for compliance ESP ISGs will contain a documented evaluation of the issue raised and will require the cognizant branch chief or division director concurrence in the memorandum in accordance with NRR Office Instruction ADM-200.

Where more than one technical branch is involved in a given ISG, the assigned PM will work with the involved branches to determine how best to proceed. Typically, one technical branch will be the lead, and other involved branches will be provided the opportunity to concur.

### **4.2.3.2 Transmittal of Proposed ESP ISG**

After the assigned PM receives the approved memorandum from the cognizant technical branch conveying the staff's technical position and evaluation, the assigned PM will develop the proposed ISG in the format described in this subsection, along with a cover letter to transmit the proposed ISG to stakeholders and the originator for comment and feedback (60-day comment period). At the same time, a *Federal Register* notice requesting comments on the proposed ISG will be issued with the same comment period as the letter. The following provides guidance for the format and content that should be used for all ESP ISGs:

#### **Issue Heading:**

A short summary or description of the issue (one or two sentences). [Keyword searches in ADAMS could be generated from the summary, so it is beneficial to be specific.]

#### **Staff Position:**

This section describes the proposed ESP ISG and the proposed resolution.

**Rationale:**

This section should provide a description of the issue in sufficient detail, such that an informed reader can understand the issue, its basis, significance, applicability, and ramifications. The staff will document its analysis of the proposed ESP ISG in terms of regulatory requirements, established staff positions, industry standards, or other relevant criteria.

**References:**

List references mentioned in the ESP ISG text. These could include NUREGs, other ESP ISGs, applicable regulations, and Regulatory Guides (Rgs).

**Attachments:**

This section contains the staff's markup of existing or new guidance that implements or incorporates the staff's proposed resolution of the issue and should normally be provided for all proposed changes.

The draft cover letter and proposed ISG should be reviewed by the technical branch supporting the ESP ISG, any other involved technical branches, OGC, and the PD-RNRP. Review and concurrence should ensure the quality and consistency of the proposed resolution of the issue. The PD-RNRP will normally sign letters conveying proposed ISGs, unless otherwise specified by NRR Office Instruction ADM-200, "Delegation of Signature Authority." Typically, the letter will request comments on the proposed ESP ISG within a 60-day period. For complex issues, a longer comment period may be considered.

The assigned PM will also issue a *Federal Register* notice requesting comment on the proposed ESP ISG (60-day comment period). The notice will be a short summary of the proposed ESP ISG and will include the ADAMS accession number for the proposed ESP ISG.

Some proposed ESP ISGs may involve policy issues that warrant Commission involvement. These issues can be identified at any time in the planning and evaluation process and need to be discussed with the PD-RNRP as soon as the potential for a Commission-level issue is identified. RNRP will document the proposed ESP ISG, the proposed options, and a staff recommendation before presenting the proposed ESP ISG to management for submittal to the Commission. Upon receipt of the Commission's directions on the ESP ISG, the staff will take the appropriate action to implement the Commission's decision.

**4.2.4 Resolution of Comments on Proposed ESP ISGs**

Comments on proposed ESP ISGs should be provided in writing to the PD-RNRP within the comment period. A public meeting or conference call (minutes to be published in ADAMS) may be conducted if necessary to clarify the concern. The staff will communicate with the stakeholders to clarify, and if possible, resolve their comments.



Once the staff has made its determination after considering comments, the proposed ESP ISG will be considered resolved. The final resolution could be approval or a determination that the proposed ESP ISG is unnecessary. The staff will send the final ESP ISG to interested stakeholders by letter and will post the approved ESP ISG on the NRC New Reactor Licensing web page for staff and industry use. It will also publish the ESP ISG in ADAMS and will publish a notice of approval of the ESP ISG in the *Federal Register*. At this point, the approved ESP ISG will have a number designation and an implementation date. The ESP ISG can then be referenced in an ESP application or as part of the regulatory review process for an ESP application. The ESP ISG will be considered for incorporation into the next revision of the affected ESP guidance document.

#### **4.2.5 Implementation of the Approved ESP ISG**

Implementation affects both future and current applicants. Future ESP applications will address the ESP ISG (until it is reflected in a revision to the affected guidance document). Current ESP applicants will need to address the approved ESP ISG by responding to an RAI, by addressing an open item in the draft SER, or by supplementing their application.

### **5.0 RESPONSIBILITIES AND AUTHORITIES**

All NRC staff members who participate in the review of ESP applications and inspections of related activities are responsible for reading, understanding, and applying the guidance in this instruction.

#### **5.1 Roles and Responsibilities for the Review of ESP ISGs**

##### Division of Regulatory Improvement Programs (DRIP)

The Director, DRIP is responsible for the overall development and implementation of the ESP program and ESP application review activities.

##### New, Research and Test Reactors Program (RNRP)

The PD-RNRP is responsible for oversight of ESP activities, process development activities, overall regulatory compliance, and implementation of the ESP program.

The section chief of the New Reactors Section is responsible for the general oversight and implementation of ESP work planning activities. The section chief of the New Reactors Section will provide direction and assistance in the development and approval of evaluation plans to ensure effective allocation of resources, responsiveness, and quality of work. The section chief of the New Reactors Section assigns the ESP ISG coordinator and the assigned PM for each ISG.

The ESP ISG coordinator is responsible for the initial review of proposed ESP ISGs, for tracking proposed ESP ISGs through to resolution, for monitoring performance in accordance with Section 6.0, for reporting performance to RNRP management, and for proposing corrective action for any performance issues identified. The ESP ISG Coordinator is also responsible for notifying stakeholders of resolution of issues raised that are not considered to rise to the threshold of an ESP ISG.

The assigned PM for each ISG is responsible for clarifying the issue with the originator, drafting or revising the assigned proposed ESP ISG, obtaining a TAC number, working with the cognizant staff to address the issue, requesting public comments, resolving any comments received during the ESP ISG review process, and processing the draft ESP ISG through the various levels of review both inside and outside of RNRP.

#### Technical Branches

The technical branches evaluate the technical aspects of the proposed ESP ISG and provide written technical positions to RNRP on the subject of the proposed ESP ISG (including technical evaluations for compliance ISGs). Staff involved with the review should be familiar with the requirements of the applicable regulations; the guidance provided in the statements of consideration that accompanied the applicable regulations, and sections of RS-002 and its references applicable to their areas of review responsibility.

#### NRR Management

Division directors, program directors, and the regions will assist in resolving concerns relating to ESP ISGs, including schedules, resources, priorities, and technical issues.

#### The Office of the General Counsel

The Office of the General Counsel reviews proposed ESP ISGs from a regulatory and legal perspective and provides legal and regulatory advice to NRR management.

#### Offices/Divisions/Branches

Other offices, divisions, and branches are responsible for reviewing and concurring on ESP ISGs consistent with the established schedule.

### **6.0 PERFORMANCE MEASURES**

The ESP ISG coordinator should provide an annual status update to the RNRP program director. The performance measures provide the following goals:

1. Provide a response to the originator on the status and potential resolution approach within 30 days of initial contact with RNRP.
2. Issue 90 percent of the proposed ESP ISGs for comment within 180 days of initial contact with RNRP.
3. Issue 90 percent of the final ESP ISG positions within 120 days of the end of the comment period provided in the comment letters.
4. Issue 100 percent of the final ESP ISG positions within two years.

**7.0 PRIMARY CONTACT**

Mike Scott, NRR/DRIP/RNRP, (301) 415-1421, mls3@nrc.gov

**8.0 RESPONSIBLE ORGANIZATION**

NRR/DRIP/RNRP

**9.0 EFFECTIVE DATE**

**10.0 REFERENCES**

1. 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants."
2. 10 CFR Part 100, "Reactor Site Criteria."
3. RS-002, "Processing Applications for Early Site Permits."

## **Appendix A: Change History**

This is a new instruction.

## Appendix B

### Interim Staff Guidance for Early Site Permit Application Reviews Process Flow

