

Nuclear Regulatory Commission Office of New Reactors Office Instruction

Office Instruction: **NRO-REG-301**

Office Instruction Title: **Development and Issuance of Interim Staff Guidance for the Office of New Reactors**

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Responsible Organization: **NRO/DNRL/NGRA**

Summary: This initial issuance of Office Instruction NRO-REG-301, "Development and Issuance of Interim Staff Guidance for the Office of New Reactors," is to provide guidance to the staff by which the Office of New Reactors staff develops and issues interim staff guidance.

Training: **NONE**

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Concurrence			
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OFFICIAL RECORD

NRO Office Instruction

NRO-REG-301

Development and Issuance of Interim Staff Guidance for the Office of New Reactors

1. PURPOSE

The purpose of this Interim Staff Guidance (ISG) process is to support Standard Review Plan (SRP, NUREG-0800), and the review process for combined license (COL), Early Site Permit (ESP) and design certification (DC) applications reviews by providing timely updated guidance information to stakeholders, until such time as the Standard Review Plan (SRP) or guidance documents are updated. Updates will likely be needed to address lessons learned from the COL applications and DC 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 NUREG-0800. Approved ISGs can be useful to the applicants in facilitating expedited resolution of emerging licensing issues, and also provide a regulatory framework to staff reviewers to proceed with the review.

The SRP is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches which the staff has found acceptable for meeting U.S. Nuclear Regulatory Commission (NRC) requirements. Implementation of the criteria and guidelines contained in the SRP for the review of applications, including COL and DC applications provides assurance that a given design will comply with NRC regulations and provide adequate protection of the public health and safety. The SRP is also intended to make information regarding 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. The SRP is not a substitute for the NRC's regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria, and evaluate how the proposed alternatives to the SRP acceptance criteria provide an acceptable method of complying with the NRC regulations. Likewise, regulatory guides (RGs) and other NRC guidance documents are developed to support licensing reviews and to inform applicants of acceptable approaches to resolve technical and licensing issues. An example is RG 1.206, "Combined License Applications for Nuclear Power Plants," which provides format and content guidance for preparing COL applications.

2. GENERAL REQUIREMENTS

The objective of this Office Instruction (OI) is to provide basic guidance to the staff by which the Office of New Reactors staff develops and issues interim staff guidance. This instruction ensures that proposed ISGs that cover new or emerging staff guidance are properly evaluated, documented, and implemented. Additionally, this instruction establishes the responsibilities and authorities for the staff in identifying needed changes to NUREG-0800 and other guidance documents using the ISG process.

The goals of this instruction include the following:

- a. Provide reasonable assurance that the health and safety of the public are protected by supporting a rigorous and consistent ISG review process.
- b. Promote openness in the new reactor application review process by making guidance to staff reviewers available to stakeholders.
- c. Implement a documented and controlled review process for proposed guidance so as to support effective and efficient regulatory guidance.

3. SPECIFIC REQUIREMENTS

3.1 Objective

NUREG-0800 and other guidance documents have been developed to enhance the COL and DC application review process. It is expected that, during reviews of COL and DC applications, guidance to staff reviewers and applicants may need to be modified to capture new insights or address emergent issues. In using NUREG-0800 or its references, the staff, industry, or other stakeholders may discover guidance that is unclear, incorrect, or incomplete, or may find that new guidance is warranted. This process serves to expeditiously address specific areas in guidance documents that need to be revised and to serve as a bridge until the documents can be revised. Branches with SRP section review responsibility should not expand the criteria of any specific SRP section without management approval. The staff should be particularly sensitive to actions it initiates that may constitute a departure from a previous position. Additional guidance and cautions related to changing staff positions or imposing changes to previously approved designs or licenses is provided in NRO OI REG-111, "NRC Staff Initiated Amendments or Changes to Previously Approved Designs or Programs."

3.2 ISG Process

Comments proposing new or revised guidance may be provided to the ISG coordinator by e-mail, if the revisions are minor or administrative in nature, with a copy to the Branch Chiefs of the technical branch originating the change. If the revisions are substantial, or constitute new or different staff positions relative to the staff guidance previously issued, they shall be transmitted by a memorandum with the Division Director's concurrence. Alternatively, technical branches may work with the Rulemaking, Guidance, and Advanced Reactor Branch (NRGA) of the Division of New Reactor Licensing (DNRL) in NRO, to prepare the ISG and related *Federal Register* Notice (FRN), and provide concurrence on the final package.

The ISG coordinator will document the comments. If the comments are administrative or minor as described above, revision of the SRP guidance may be included in the next revision to the applicable SRP section update (biennial), as appropriate. The same is true for revising other documents. However, if the staff determines that development of an ISG is warranted, it will issue the proposed ISG requesting public comments (usually

providing a 30-day comment period). Once documented as a proposed ISG, the issue will be controlled by this process to ensure timely resolution. When a draft ISG is prepared for comment, it will be conveyed to interested stakeholders via issuance of a notice in the FR, published in ADAMS, and simultaneously placed on the NRC web site (<http://www.nrc.gov/reading-rm/doc-collections/isg/>). The public may comment on the published ISGs at the web link provided on the NRC web page under ISG, or send written comments to the NRC as directed in the FR notice. Comments will be processed by the staff for a final resolution. Following its review and resolution of public comments, the NRC staff will post the final ISG on the NRC web site and publish another notice in the FR as to availability of the final guidance.

3.3 ISG Format

The staff should develop and post the ISG in a prescribed format to include the following headings:

1. ISG Title
2. Issuance Status: Proposed/Revision/Final
3. Background
4. Issue Discussion
5. Rationale
6. Staff Guidance or Position: Proposed/Revision/Final
7. Final Resolution Method (e.g., update SRP)
8. Applicability
9. Backfit Determination
10. References

3.4 Resolution of Public Comments

Processing the comments received on the proposed ISG is a critical step in ensuring that the ISG is completed in a timely and effective manner. The staff may conduct optional public meeting(s) to help develop ISGs and to solicit and resolve public comments. The technical lead/staff will make an estimate of the resources needed for the review, and the schedule for resolution. There is no intent to create a burdensome ISG planning process and the evaluation plan should be concise.

3.5 Final ISG Issuance

The ISG coordinator will issue the final ISG for adoption by the NRC staff and applicants. The ISG, at this point, becomes an official agency position for that issue and will remain in effect until the guidance is formally incorporated into regulatory guidance through a revision to the SRP, RG, or other NRC document.

3.6 Implementation

An applicant may choose to adopt an ISG prior to its approval. However, in doing so the applicant should recognize that differences between the proposed ISG and the approved ISG may need to be addressed. The ISGs may have schedule implications for current and future COL or DC applicants. Therefore, the structured approach described in this instruction should be followed. During the course of a COL or DC application review, the staff may discover an issue that expands the scope being addressed under the regulatory guidance documents. The staff should use caution in asking an applicant to address the new issue through a request for additional information until an approved ISG has been issued.

4. ROLES AND RESPONSIBILITIES

The process is administered and controlled by DNRL/NRGA. The primary contact for this OI will serve as the ISG Coordinator for the ISG process within NRO. The ISG coordinator is responsible for publishing the FR notices and ISGs, both in ADAMS and on the NRC external webpage indicated above.

4.1 Technical Branches within NRO

Technical branches evaluate the technical aspects of the proposed COL and DC ISG and provide written technical positions to DNRL/NRGA on the subject of the proposed ISG (including technical evaluations for compliance ISGs). The Division Director of the primary technical review branch signs out the final guidance.

Other Reviews within the Agency for the ISG process are the following:

4.2 Office of Nuclear Reactor Regulation (NRR) Review

The technical staff who originates the ISG (or the primary branch in NRO that originates the interim guidance) is encouraged to communicate and coordinate its activities with the corresponding technical branch in NRR. Early interactions are the most effective way to coordinate activities and reach a consensus view on possible changes. NRO/NRGA will, if appropriate, seek NRR concurrence on an ISG unless NRR concurrence was obtained by the NRO primary review branch during the development of the revision.

4.3 Office of the General Counsel (OGC) Review

Review and concurrence (statement of no legal objection) by OGC is required on all ISGs before issuance for public comment and before issuance in final form. DNRL/NRGA coordinates the review of the staff guidance with OGC.

4.4 Advisory Committee on Reactor Safeguards (ACRS) Review

DNRL/NRGA will forward the proposed staff guidance to the ACRS via a memorandum when it is issued for public comment. A similar memorandum will be used to forward to

the ACRS the final issuance of an ISG following disposition of public comments and the incorporation of editorial/administrative changes. The ACRS, or ACRS staff, may request additional interactions with the staff regarding changes (proposed or final) to determine if a subject is added to its agenda or to better understand the guidance documents. DNRL/NRGA will, as necessary, coordinate interactions between the NRO staff and ACRS regarding the maintenance and updating of SRP sections.

4.5 Committee to Review Generic Requirements (CRGR) Review

DNRL/NRGA will forward the proposed staff guidance to the CRGR via a memorandum when they are issued for public comment. It will use a similar memorandum to forward the final guidance to the CRGR following disposition of public comments and incorporating these into the final guidance. The CRGR, or CRGR staff, may request additional interactions with the staff regarding changes (proposed or final) to determine whether a subject will be added to its agenda or to better understand the guidance documents. DNRL/NRGA will, as necessary, coordinate interactions between the NRO staff and CRGR regarding the maintenance and updating of SRP sections.

4.6 Resolving Public Comment

The branch with primary review responsibility for an ISG considers and addresses public comments typically within 60 days of receipt depending on the nature of the comments. Once public comments have been addressed for the staff guidance, the entire package will be distributed for final review and concurrence.

