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**

Revision Number: **1**

Effective Date:

Primary Contact: **Ram Subbaratnam**

Responsible Organization: **NRO/DNRL/NRGA**

Summary**:** This revision provides guidance to the Office of New Reactors (NRO) staff for developing and issuing interim staff guidance (ISG). This current revision includes an ISG process flow shown as Figure 1.

Training: NONE

ADAMS Accession No.: ML090610152

Concurrence			
Primary Office Owner	Rulemaking and Guidance Development Branch		
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Division Director	DCIP/NRO	GTracy	08/05/2010*
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Division Director	ARP/NRO	MMayfield	08/09/2010
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OGC	OGC	MZobler	07/13/2010
ODNRO	Deputy Director	GHolahan/ GTracy for	09/29/2010

* Comments incorporated as appropriate

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, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," and the review process for combined license (COL), early site permit (ESP) and design certification (DC) application reviews by providing timely updated guidance information to stakeholders, until such time as the SRP or guidance documents are updated. Updates will likely be needed to address lessons learned from the COL, ESP 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 both applicants and staff, in facilitating expedited resolution of emerging licensing issues.

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, ESP and DC applications, provides assurance that a given design, site, or license 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. As an example, RG 1.206, "Combined License Applications for Nuclear Power Plants," 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 about how NRO develops and issues ISGs. 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 timely guidance, continually evaluated and updated to facilitate staff reviews and capture staff positions and review practices.

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 reviews.

3. SPECIFIC REQUIREMENTS

3.1 Objective

NUREG-0800 and other guidance documents have been developed to enhance the ESP, COL and DC applications review process. It is expected that, during reviews of COL, ESP 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.

3.2 ISG Process

Comments proposing new or revised guidance may be provided to the ISG coordinator via e-mail, if the revisions are minor or administrative in nature; with a copy to the branch chief 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 must be transmitted by a memorandum with the division director's concurrence. Alternatively, technical branches may work with the Rulemaking and Guidance Development Branch (NRGA) of the Division of New Reactor Licensing (DNRL) in the Office of New Reactors (NRO), to prepare the ISG and related *Federal Register* Notice (FRN), and provide concurrence on the final package. Figure 1 shows the process for initiating and implementing an ISG.

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 *Federal Register* (FR) and simultaneously placed on the NRC Web site (http://www.nrc.gov/reading-rm/doc-collections/isg/). The public may comment on the published ISG at the link provided on the NRC Web page under ISG, or send written comments to NRC as directed in the FRN. 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. Background
3. Issue Discussion
4. Issuance Status: Proposed/Revision/Final
5. Rationale
6. Staff Guidance or Position: Proposed/Revision/Final
7. Final Resolution Method (e.g., update SRP or guidance documents as appropriate)
8. Congressional Review Act
9. Applicability
10. Backfit Determination
11. 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 meetings 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.

Under the Congressional Review Act of 1996 (CRA or the Act), most ISGs will be considered “rules” subject to the CRA, and the staff should confirm this categorization with the Office of the General Counsel. Although it is unlikely that any ISG would result in an economic impact sufficient to make it a “major rule” under the Act, the staff must briefly assess the impact of the guide and forward its assessment to the Office of Administration (ADM), Rules, Announcements, and Directives Branch, which will verify this determination with the Office of Management and Budget.

In addition, the CRA mandates review of all final “rules” by both houses of Congress and General Accounting Office (GAO). Therefore, the staff must prepare a simple submission package (which goes through the Office of Congressional

Affairs) for Congress and GAO. The CRA submission form can be found at: http://www.gao.gov/decisions/majrule/fedrule2.pdf. The staff should attach a copy of the final ISG to the submission form for each the House of Congress and GAO. This action is required only in situations where the staff identifies any impact to or need for rule making. These cases will be handled by ADM.

For more information, see Chapter 4 of NUREG/BR-0053, "NRC Regulations Handbook," Rev. 6, which briefly describes the procedural requirements of the CRA. ADM guidance describes NRC's internal process in further detail at: http://www.internal.nrc.gov/ADM/DAS/cag/RM01/researching/sbrefa.html

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 follow an ISG prior to its approval. However, 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 an ESP, 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 NRO/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 FRNs and ISGs, both in ADAMS and on the NRC external Web page indicated above.

4.1 NRO Review

Technical branches evaluate the technical aspects of the proposed ESP, COL, DC, and ISG and provide written technical positions to NRO/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.

4.2 Office of Nuclear Reactor Regulation (NRR) Review

The technical staff that 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/DNRL/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. NRO/DNRL/NRGA coordinates the review of the staff guidance with OGC.

4.4 Advisory Committee on Reactor Safeguards (ACRS) Review

NRO/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. 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. NRO/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

NRO/DNRL/NRGA will forward the proposed staff guidance to the CRGR via a memorandum when it is 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, highlighting any backfit concerns raised by the stakeholder. 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. NRO/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.

NRO-REG-301 - Change History			
Date	**Description of Changes**	**Method Used to Announce & Distribute**	**Training**
11/06/2008	This initial issuance of NRO-REG-301, "Process for Issuance of Interim Staff Guidance for New Reactors Office (NRO)" is to define the process and responsibilities by which the NRO staff can issue ISGs for the new reactor licensing office.	Posting on NRO website	NONE
09/29/2010	ISG process flow (Figure 1) added; Includes minor editorial revisions (i.e., ESP). Added notation for Congressional Act Review requirement (see Section 3.4)	Posting on NRO website	NONE

Interim Staff Guidance Process Flow

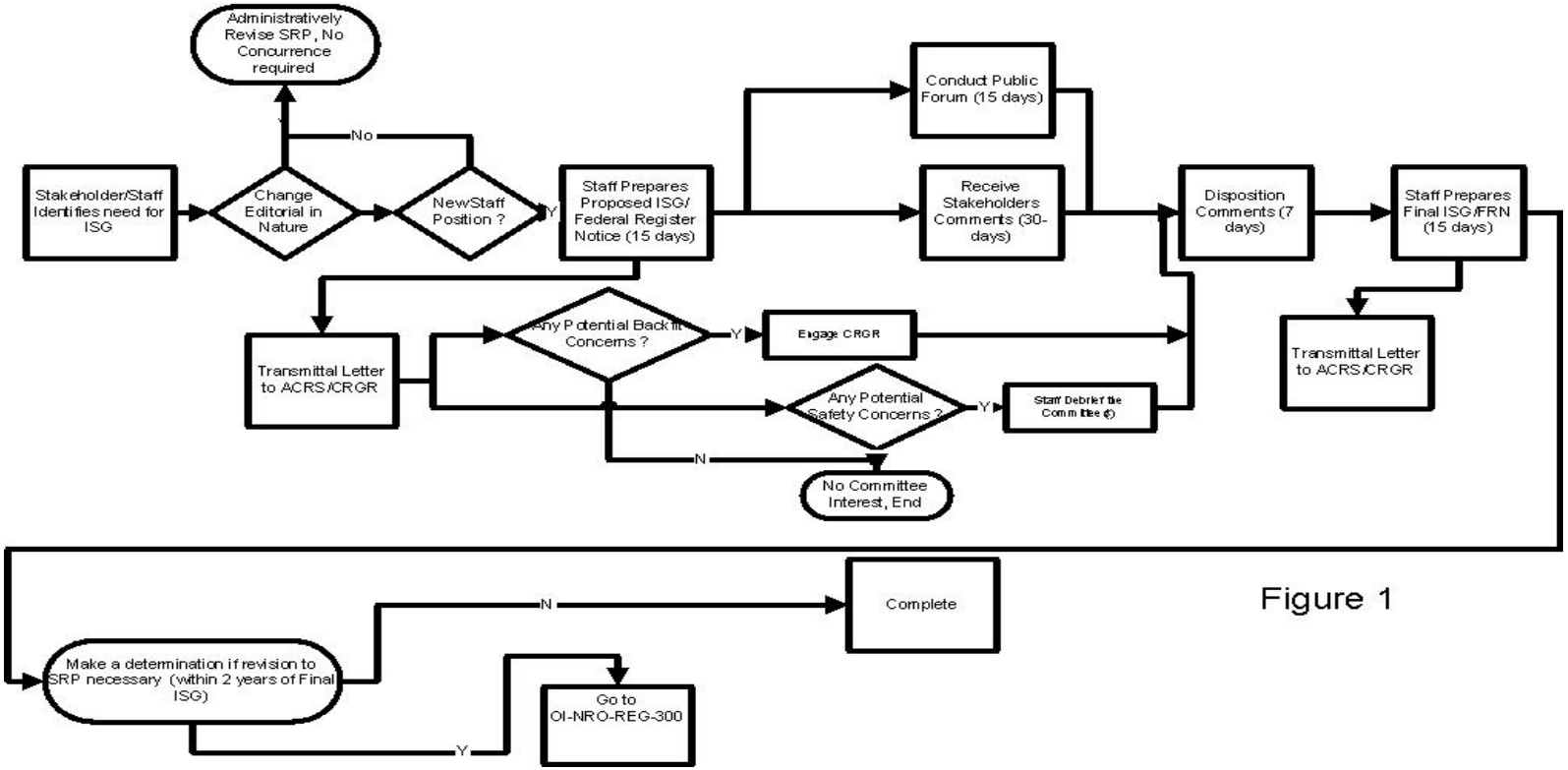

Figure 1