



U.S. Nuclear Regulatory Commission Office of Nuclear Reactor Regulation

NRR OFFICE INSTRUCTION

Change Notice

Office Instruction No.: **LIC-101, Revision 4**

Office Instruction Title: **License Amendment Review Procedures**

Effective Date: **May 25, 2012**

Approved By: **Susan Abraham**

Date Approved: **May 22, 2012**

Primary Contact: **Rick Ennis**
301-415-1420
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Responsible Organization: **NRR/DORL**

Summary of Changes: Changes in Revision 4 include: (1) overall streamlining and removal of unnecessary detail; (2) revisions to reflect NRR organizational name changes; (3) updates to discussion of work planning based on current Blue/Green sheet process; (4) updates to discussion on acceptance reviews based on Office Instruction LIC-109; (5) addition of specific regulatory requirements associated with each step in the amendment review process; (6) addition of references to ADAMS Accession Nos. for templates of each type of public notification; (7) further detail regarding when a commitment should be elevated into an obligation; (8) removal of detail on content of safety evaluations from Section 4.0 of the guide and addition of detail to the safety evaluation template attached to the guide; (9) addition of new discussion on amendment withdrawals, denials, and corrections; (10) removal of details in risk-informed licensing action guidance that is either covered in other documents (e.g., SRP, RGs) or is not needed for proper coordination with APLA; (11) removal of details on development of Technical Specifications Task Force travelers and consolidated line item improvement process models based on issuance of Office Instruction LIC-600; (12) update of license amendment worksheet (Attachment 1) to allow for better tracking of review status; (13) deletion of Attachment 2 (Amendment Routing Form) and addition of discussion about the form in Section 5.0 of the guide; (14) renumbering of Attachment 3 to Attachment 2 (safety evaluation template); (15) renumbering Section 9.0 regarding Official Agency Records as Section 10.0 and adding new Section 9.0 regarding emergency plan changes; and (16) miscellaneous editorial changes to better describe current practices.

Training: E-mail announcement with scheduled training sessions

ADAMS Accession No.: **ML113200053**



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ADAMS Accession No.: **ML113200053** *concurring via email

OFFICE	DORL/PM	DORL/LA	DORL/BC	DORL/D	DSS/D*	DE/D*
NAME	REnnis	ABaxter	MKhanna	MEvans	WRuland	PHiland
DATE	5/16/12	3/5/12	3/12/12	5/3/12	4/11/12	3/15/12
OFFICE	DRA/D*	DLR/D (A)*	DIRS/D*	DPR/D*	OGC	PMDA/D (A)
NAME	JGitter (Slee for)	MGalloway	FBrown (JLubinski for)	TMcGinty (RNelson for)	DRoth	SAbraham
DATE	4/19/11	5/3/12	3/27/12	3/26/12	5/15/12	5/22/12

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NRR OFFICE INSTRUCTION
LIC-101, Revision 4
License Amendment Review Procedures

1. POLICY

Section 187 of the Atomic Energy Act, "Modification of License," states that the "terms and conditions of all licensees shall be 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." This provision authorizes the Nuclear Regulatory Commission (NRC) to amend licenses. Regulatory requirements related to the amendment of operating licenses, including the appended Technical Specifications, are primarily contained in 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit," 10 CFR 50.91, "Notice for public comment; State consultation," and 10 CFR 50.92, "Issuance of amendment."

The general purpose of this office instruction is to provide guidance, to staff in the Office of Nuclear Reactor Regulation (NRR), for the processing of license amendment applications consistent with the applicable NRC regulatory requirements. It is NRR management's expectation that license amendments be processed in a manner consistent with the NRC's Principles of Good Regulation (i.e., independence, openness, efficiency, clarity, and reliability).

This guidance is applicable to amendments to licenses for operating and decommissioned plants. However, portions of this guidance are also applicable to other licensing actions and activities. For example, the guidance on requests for additional information (RAIs) should be utilized in reviewing any licensing action (e.g., exemptions, reliefs, etc.) for which the NRC staff asks the licensee for additional information.

2. OBJECTIVES

This office instruction, along with the guidance in Appendix B, "Guide for Processing License Amendments," provides NRR staff a basic framework for processing license amendment applications (and other licensing actions, where applicable).

These procedures should enhance NRR's efficiency in responding to the needs of both the licensees and the public. Specific objectives include the following:

- Ensure the public health and safety is maintained.
- Promote consistency in processing of license amendments.
- Improve internal and external communications.
- Increase technical consistency for similar licensing actions.
- Reduce delays in the issuance of license amendments (meet licensing action timeliness goals).

- Ensure that RAIs are adding value to the regulatory process.
- Provide NRR staff with an improved framework for processing license amendment applications.

Appendix B, “Guide for Processing License Amendments” provides a general description of the process.

3. BACKGROUND

LIC-101 was issued on August 20, 2001, and superseded NRR Office Letter 803, “License Amendment Review Procedures.” Revisions 1 and 2 to LIC-101 included changes to the format of safety evaluations (SEs), to resolve issues and suggestions offered through the NRR Process Improvement Program (PIP) (see ADM-101), and to support a pilot program on work planning and scheduling. Revision 3 was issued as a result of the implementation of the NRR work planning center; several additional changes suggested through the PIP; and several updates and clarifications related to the SE template, RAIs, and other parts of the license amendment process. Changes in Revision 4 include: (1) overall streamlining and removal of unnecessary detail; (2) revisions to reflect NRR organizational name changes; (3) updates to discussion of work planning based on current Blue/Green sheet process; (4) updates to discussion on acceptance reviews based on Office Instruction LIC-109; (5) addition of specific regulatory requirements associated with each step in the amendment review process; (6) addition of references to Agencywide Documents Access and Management System (ADAMS) Accession Nos. for templates of each type of public notification; (7) further detail regarding when a commitment should be elevated into an obligation; (8) removal of detail on content of SEs from Section 4.0 of the guide and addition of detail to the SE template attached to the guide; (9) addition of new discussion on amendment withdrawals, denials, and corrections; (10) removal of details in risk-informed licensing action guidance that is either covered in other documents (e.g., Standard Review Plan (SRP), Regulatory Guides (RGs)) or is not needed for proper coordination with the Probabilistic Risk Assessment Licensing Branch (APLA); (11) removal of details on development of Technical Specifications Task Force travelers and consolidated line item improvement process models based on issuance of Office Instruction LIC-600; (12) update of license amendment worksheet (Attachment 1) to allow for better tracking of review status; (13) deletion of Attachment 2 (Amendment Routing Form) and addition of discussion about the form in Section 5.0 of the guide; (14) renumbering of Attachment 3 to Attachment 2 (SE template); (15) renumbering Section 9.0 regarding Official Agency Records as Section 10.0 and adding new Section 9.0 regarding emergency plan changes; and (16) miscellaneous editorial changes to better describe current practices.

4. BASIC REQUIREMENTS

Appendix B describes a procedure for processing amendments to operating licenses requested by licensees pursuant to 10 CFR 50.90. The following are the primary activities covered in the procedure:

- Work planning and acceptance review.
- Public notification and comment resolution.

- Technical review, including preparation of RAIs and the SE.
- Amendment package processing.

5. RESPONSIBILITIES AND AUTHORITIES

All NRR staff who support the license amendment process are responsible for reading, understanding, and applying the guidance contained in the enclosed “Guide for Processing License Amendments” (Appendix B). They are also responsible for identifying possible improvements to the guidance and submitting suggestions for such improvements to their management or to the primary contact for this office instruction.

The following describes the NRC staff responsibilities for the primary activities associated with the license amendment process.

A. WORK PLANNING AND ACCEPTANCE REVIEW

Division of Operating Reactor Licensing (DORL)

DORL Project Managers (PMs) are responsible for the general oversight and coordination of NRR activities related to processing license amendments. PMs are responsible for the following specific activities with respect to work planning and acceptance review:

- Obtain a Technical Assignment Control (TAC) number for the amendment request from NRR’s Center for Planning and Analysis Branch (CPAB) to ensure fee recovery and allow tracking of the work activities.
- Complete the Work Planning and Characterization Form (Blue Sheet) to propose the NRR technical branches that should be involved in the review, the requested milestone dates and other work planning considerations.
- Review responses from NRR technical branches on the Work Planning and Characterization Forms (Green Sheet) and resolve any issues regarding review coordination, review characterization, and proposed milestone dates.
- Perform and coordinate the acceptance review of the amendment request in accordance with LIC-109, “Acceptance Review Procedures.”

CPAB (including division planning representatives)

CPAB is responsible for the following specific activities with respect to work planning and acceptance review:

- Assign TAC numbers to incoming applications as requested by PMs.
- Distribute applications and Work Planning and Characterization Forms (Blue and Green Sheets).

- Maintain and update the systems and databases associated with the Blue and Green sheet process and TAC status tracking.
- As requested, provide analysis and reporting of database information.

Technical Staff

The Technical staff is responsible for the following specific activities with respect to work planning and acceptance review:

- Technical staff shall work with the PM to ensure that the amendment processing plan (as described on the Blue and Green Sheets) is complete and that the scope, resources, and schedule are sufficient to perform the required safety review.
- Technical staff Branch Chiefs (BCs) are responsible for completing the Green Sheets including ensuring that technical reviewers are assigned promptly in order to support the LIC-109 acceptance review schedule.
- Technical staff BCs are responsible for ensuring that the assigned reviewers meet milestone dates agreed to on the Green Sheets. In the event a date cannot be met, technical staff BCs are responsible for notification of the PM prior to missing the due date and coordination with the PM to establish a new due date.
- Technical staff reviewers are responsible for providing acceptance review input to the PM in accordance with LIC-109.

B. PUBLIC NOTIFICATION AND COMMENT RESOLUTION

DORL

DORL PMs are responsible for the following activities regarding any required public notifications:

- Issuance of the public notification regarding the proposed issuance of the amendment. This includes the following actions:
 - review the licensee's analysis of no significant hazards consideration and determine its adequacy for use in the public notification;
 - review the proposed amendment, review schedule, and regulatory requirements and determine what type of public notification is required; and
 - prepare the notification for review by the DORL Licensing Assistant (LA) and the DORL BC.
- Resolve any public comments.
- Coordinate NRR activities related to the hearing process.

- Prepare and coordinate issuance of any additional public notifications, including those due to licensee changes in the amendment request and the final notification of amendment approval, denial, or withdrawal.

Technical Staff

If requested by the PM, technical staff shall assist in evaluating the licensee's analysis of issues related to no significant hazards considerations, resolving public comments, and participating in the hearing process. Technical staff BCs will work with the PMs to set expectations for technical staff support based on resource availability.

C. TECHNICAL REVIEW

DORL

DORL PMs are responsible for coordinating the technical review, including the processing of RAIs, and preparation of the SE. This includes the following activities:

- Review of technical staff RAIs to ensure that the questions have a regulatory basis and are necessary to make a decision on the proposed amendment.
- Transmittal of RAIs to the licensee. PMs should issue RAIs promptly upon receipt from the technical staff and should include the technical reviewers who provided the RAIs on distribution.
- Perform the technical review, when appropriate, based on the PM's knowledge of the technical area or if sufficient precedent is available.
- Coordinate assistance from technical staff personnel, as required.
- Coordinate with technical staff personnel if scope, resources, or due dates need to be changed for any reason. Inform all affected parties of changes to the previously established work plan.
- Consolidate all SE inputs into a single SE.
- Ensure that the regulatory basis and basis for the staff's conclusions are clearly articulated in the SE.
- The staff should use the format and content guidance for SEs that is described in Section 4.0 of Appendix B and the SE template attached to Appendix B.
- Generally, technical staff need only provide the regulatory and technical evaluations sections of an SE. PMs are responsible for providing the remaining sections of the SE.
- Determine if an Environmental Assessment (EA) is needed. If an EA is needed, the DORL PM should coordinate with NRR's Environmental Review and Guidance Update Branch (RERB) regarding whether the PM or RERB will prepare the EA.

Technical Staff

Technical staff is responsible for the following areas associated with the technical review:

- Provide RAIs to the DORL PM, as necessary, to make a decision on the proposed amendment. The technical staff reviewer and branch chief should ensure that there is a regulatory basis for the questions. Any proprietary information should be clearly marked in the RAI.
- Perform the technical review as assigned by the Green Sheet.
- Coordinate with the PM if scope, resources, or due dates need to be changed for any reason.
- Ensure that the regulatory basis and basis for the staff's conclusions are clearly articulated in the SE input submitted to DORL. Any proprietary information should be clearly marked in the SE input.
- The staff should use the format and content guidance for SEs that is described in Section 4.0 of Appendix B and the SE template attached to Appendix B.
- Generally, technical staff need only provide the regulatory and technical evaluations sections of an SE.
- Technical staff BCs are responsible for ensuring the quality and timeliness of RAIs and SE inputs provided to DORL.

NRR Management

NRR management shall assist in resolving staff concerns related to preparation of RAIs and SEs (e.g., scope, resources, schedule, technical issues).

D. AMENDMENT PACKAGE PROCESSING

DORL

DORL PMs are responsible for the following activities related to processing of the amendment package:

- Assemble the package for review and concurrence. Ensure that the concurrence chain includes all of the technical, legal, administrative, and management positions necessary for adequate review of the amendment and is consistent with the requirements in NRR Office Instruction ADM-200, "Delegation of Signature Authority." In general, technical branches not providing SE input do not need to be on concurrence unless the PM performed the review.
- Contact the State Official, in accordance with the requirements in 10 CFR 50.91(b).

- Ensure that technical staff hours charged are reasonable when compared to the status of the review, estimates in the Work Planning and Characterization Form (Green Sheet), experience with similar reviews, and possible efficiency gains anticipated from precedent reviews. Resolve any issues through interactions with appropriate staff and management.
- Track the status of the amendment package as it moves through the review and concurrence process.

DORL LAs are responsible for the following activities related to processing of the amendment package:

- Review the package for correct spelling, punctuation, format, distribution, etc., consistent with relevant administrative requirements (e.g., Management Directives, NRC Editorial Style Guide).
- Review the package to ensure consistency with latest boilerplate templates.
- Verify changes to Technical Specifications and License. Changes should be verified against the application, supplements and current version in the authority file.
- If an EA was not prepared, confirm that the correct categorical exclusion is cited in the SE.
- Verify that the amendment has been properly noticed.
- Verify whether there were any public comments on the proposed amendment and whether a hearing was requested.
- Assign amendment numbers to the package and perform a final quality assurance check before issuance.
- Follow-up activity (after amendment issuance): ensure that the changes to the Technical Specifications and License have been incorporated into the authority file.

Technical Staff

Technical staff is responsible for the following activities related to processing of the amendment package:

- Review and concur on amendment packages if the SE was prepared by the PM.
- Review and concur on amendment packages if the SE was prepared by technical staff when the PM has made substantial changes to the SE input (i.e., changes are more than editorial and change technical content or original intent).
- Review and concur on amendment packages as established during Blue/Green sheet processing.

Office of the General Counsel (OGC)

OGC shall review all amendment packages for legal adequacy and defensibility, unless an agreement is reached that specific amendments do not require OGC concurrence (e.g., see Section 8.2.2 of Appendix B regarding the Consolidated Line Item Improvement Process (CLIIP)).

NRR Management

NRR management shall, as necessary, resolve staff concerns regarding the issuance or denial of a license amendment, the scope of review, resources or schedules for a review, or other matters related to the NRC disposition of a license amendment application.

6. PERFORMANCE MEASURES

No performance measures are proposed beyond those related to the NRR Operating Plan.

7. PRIMARY CONTACT

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8. RESPONSIBLE ORGANIZATION

NRR/DORL

9. EFFECTIVE DATE

May 25, 2012

10. REFERENCES

None

Enclosures:

1. Appendix A: Change History
2. Appendix B: Guide for Processing Licensing Amendments, Revision 4

Appendix A - Change History

Office Instruction LIC-101, Revision 4 License Amendment Review Procedures

LIC-101 Change History - Page 1 of 3			
Revision Date	Description of Changes	Method Used to Announce & Distribute	Training
08/20/2001	Initial issuance (previously NRR Office Letter 803). Changes to the guidance include (1) correction to oath or affirmation requirements, (2) updating of Section 7.0, "Risk-informed Licensing Action Guidance," (3) adding Section 8.0, "Consolidated Line Item Improvement Process," (4) expanded the amendment tracking worksheet, (5) eliminating references to a NRR Priority System, (6) emphasizing that the goal to limit RAIs should not interfere with responsibility to make sound safety decisions, (7) adding guidance on noticing power uprate amendments, and (8) minor corrections and clarifications.	E-mail to NRR staff	<p>Recommended reading for technical staff supporting license amendments.</p> <p>Required Reading and Training Sessions(s) for DLPM</p> <p>Training presentation to be developed for NRR web page.</p>
03/27/2002	Changes in revision 1 include (1) revised Section 4.5, "Safety Evaluation Format," (2) added Section 9.0, "Official Agency Records (OARs)," to specify which licensing documents should be preserved in the agency's recordkeeping system (ADAMS), (3) revised Attachment 1, "Work Request Form and Instructions," to reformat the form and allow for interim milestones such as RAIs, (4) revised Attachment 2, "License Amendment Worksheet and Instructions," to add instructions and lines for comments, (5) added Attachment 4, "Safety Evaluation Template," to match the revised Section 4.5 and support long-term goal of consistency between safety evaluation content and licensee's applications, and (6) various updates and minor editorial changes.	E-mail to NRR staff	<p>Recommended reading for all DLPM staff and technical staff supporting license amendments.</p> <p>Training sessions for staff in DLPM, DE, and DSSA</p>

LIC-101 Change History - Page 2 of 3

Date	Description	Announce & Distribute	Training
12/12/2002	Changes in revision 2 include (1) support of a pilot program for work planning and scheduling, (2) additional guidance related to the use of topical reports to support license amendments, (3) clarification of the need to use the revised safety evaluation format described in Section 4.5, (4) revised performance goal to complete 96% of licensing actions in less than one year,(5) reference to template safety evaluation and related macros maintained on network server for DE and DSSA, (6) clarification of recordkeeping for staff's questions to licensees, (7) deletion of reference to cumulative risk tracking form, and (8) various updates and editorial changes.	E-mail to NRR staff	<p>Recommended reading for technical staff supporting license amendments</p> <p>Required reading and training session for DLPM</p> <p>emphasize change regarding use of topical reports (YT020020177)</p>
02/09/2004	Changes in revision 3 include (1) incorporation of work planning center into amendment process, (2) minor changes to guidance on safety evaluations, (3) changes to reflect rule change affecting NRC hearing processes (including noticing of license amendments), and (4) resolution of several NRR Process Improvement Forms.	E-mail to NRR staff	<p>Training sessions to be offered to NRR staff</p> <p>Required reading and training session for DLPM</p>

LIC-101 Change History - Page 3 of 3

Revision Date	Description of Changes	Method Used to Announce & Distribute	Training
05/22/2012	<p>Changes in Revision 4 include: (1) overall streamlining and removal of unnecessary detail; (2) revisions to reflect NRR organizational name changes; (3) updates to discussion of work planning based on current Blue/Green sheet process; (4) updates to discussion on acceptance reviews based on Office Instruction LIC-109; (5) addition of specific regulatory requirements associated with each step in the amendment review process; (6) addition of references to ADAMS Accession Nos. for templates of each type of public notification; (7) further detail regarding when a commitment should be elevated into an obligation; (8) removal of detail on content of safety evaluations from Section 4.0 of the guide and addition of detail to the safety evaluation template attached to the guide; (9) addition of new discussion on amendment withdrawals, denials, and corrections; (10) removal of details in risk-informed licensing action guidance that is either covered in other documents (e.g., SRP, RGs) or is not needed for proper coordination with APLA; (11) removal of details on development of Technical Specifications Task Force travelers and consolidated line item improvement process models based on issuance of Office Instruction LIC-600; (12) update of license amendment worksheet (Attachment 1) to allow for better tracking of review status; (13) deletion of Attachment 2 (Amendment Routing Form) and addition of discussion about the form in Section 5.0 of the guide; (14) renumbering of Attachment 3 to Attachment 2 (safety evaluation template); (15) renumbering Section 9.0 regarding Official Agency Records as Section 10.0 and adding new Section 9.0 regarding emergency plan changes; and (16) miscellaneous editorial changes to better describe current practices.</p>	E-mail to NRR staff	<p>Required reading for NRR staff supporting license amendment reviews.</p> <p>Training sessions to be offered to NRR staff.</p>

**U. S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation**

Appendix B

Guide for Processing License Amendments

Revision 4

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1.0 Introduction

This guide provides staff in the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Reactor Regulation (NRR) a basic framework for processing license amendment applications.⁽¹⁾ In addition, some of the guidance contained in this document may be used, where appropriate, for the processing of other licensing actions and activities where specific guidance is not provided in a related office instruction. For example, the guidance on requests for additional information (RAIs) may be utilized for any licensing action or activity for which the NRC staff asks the licensee for additional information.

NRR staff involved in processing license amendments should identify any possible improvements to this guidance and submit suggestions to their management or the contacts listed for LIC-101 or by submitting a Problem Identification Form (PIF) as described in NRR Office Instruction ADM-101, "Office of Nuclear Reactor Regulation Corrective Action Program."

1.1 Objectives

The objective of this guide is to provide NRR staff a basic framework to process license amendment applications, thereby improving NRR's efficiency and consistency in performing these reviews. Additional specific objectives are described in Section 2 of NRR Office Instruction LIC-101, "License Amendment Review Procedures."

1.2 Process Overview

The approval or denial of license amendment applications is part of a continuous process of managing issues related to nuclear power facilities. The review of license amendment applications is one of the primary mechanisms for regulating changes in the licensees' operation of their facilities. NRR staff and licensees should be in regular contact to discuss NRC's ongoing reviews and other regulatory matters requiring NRC review and approval. Frequent and early communications between the staff and the licensee can help avoid unnecessary delays in the processing of license amendment applications. Pre-application review meetings (discussions regarding future licensing action requests prior to licensee submittal) between the licensee and staff members may be beneficial in certain circumstances (e.g., complicated or first-of-a-kind applications).

The role of the NRR Division of Reactor Licensing (DORL) Project Manager (PM) in the license amendment process is to manage the NRC's review of the application, either by performing the review or by overseeing the review performed by other NRC staff. The PM ensures that the guidelines in Office Instruction LIC-101 and the NRC's Principles of Good Regulation are adhered to throughout the process. PMs and technical staff are jointly responsible for ensuring that NRR meets the goals established in the agency's operating and performance plans. The

(1) Certain types of license amendments may have additional guidance that supplements the guidance in LIC-101 (e.g., Office Instruction LIC-112 for power uprates, Office Instruction LIC-601 for processing of conversions to the improved Standard Technical Specifications, and Regulatory Guide 1.174 for risk-informed license amendments).

process employed for license amendment reviews can be characterized by the following sub-processes:

- Work planning and acceptance review.
- Public notification and comment resolution.
- Technical review, including preparation of RAIs and the safety evaluation (SE).
- Amendment package processing.

Each of these sub-processes is described in detail in the following sections.

License transfer applications may involve the need for a license amendment. In such cases, this guidance is applicable to the license amendment portion of the license transfer. For additional guidance on the license transfer review process, see NRR Office Instruction LIC-107, “Procedures for Handling License Transfers.”

Power uprate applications are within the regulatory framework of license amendments; thus, the guidance in this document applies. However, due to the complexity of such reviews, additional guidance is provided in NRR Office Instruction LIC-112, “Power Uprate Process.”

2.0 Work Planning and Acceptance Review

Planning the processing of an amendment application is a critical step in ensuring that the work is completed in a timely and effective manner. This section describes a series of steps that should be addressed by the staff in developing an amendment review work plan and performing the acceptance review.

2.1 PM Obtains TAC Number

Technical Assignment Control (TAC) numbers provide a means of billing the licensee and tracking the work. After the PM receives the license amendment application from the licensee, the PM should request a TAC number from NRR’s Center for Planning and Analysis Branch (CPAB) using the Time, Resource and Inventory Management (TRIM) software. For most license amendments, the TAC should be coded in TRIM as fee billable and Activity Type “LA.” Some exceptions include license transfers (Activity Type “LM”) and power uprates (Activity Type “LS”). See the latest Regulatory Information Tracking System (RITS) User Guide for further guidance.

Note: In order to meet acceptance review timeliness goals discussed in Office Instruction LIC-109, it is important that the PM request the TAC number as soon as possible after the application is received (generally within 1 working day).

The request for a TAC number initiates the process of distributing the Work Planning and Characterization Forms (Blue and Green Sheets), as discussed below in Sections 2.2 and 2.3. Note: License amendments processed under exigent circumstances and emergency situations (as discussed in Sections 3.4 and 3.5) do not require completion of Blue and Green Sheets. In addition, license amendments for which the technical review will be completed by organizations outside of NRR (e.g., security plan and emergency plan reviews by the Office of Nuclear Security and Incident Response (NSIR)) do not require completion of Blue and Green Sheets. In these cases, the DORL PM should use the NRR Work Request Form (Agencywide Documents Access and Management System (ADAMS) Accession No. ML101590507).

Consistent with the requirements in NRR Office Instruction LIC-109, for exigent and emergency amendments, the DORL PM should notify the DORL division planning representative that an acceptance review is not required before the TAC is closed.

2.2 PM Completes Blue Sheet

After requesting a TAC in TRIM (as discussed in Section 2.1), the PM will receive an email from CPAB with the TAC number. CPAB will send a subsequent email to the PM providing notification that the Blue Sheet is available to fill out.

The primary function of the Blue Sheet is to communicate a request from the PM to the technical staff for assistance in performing the technical review. The Blue Sheet provides some of the essential work planning information such as: (1) the technical branches (TBs) being requested to provide input to DORL for the review; (2) the proposed schedule for the TB's completion of the acceptance review; (3) the proposed schedule for the TB's submittal of the RAI to DORL; and (4) the proposed schedule for the TB's submittal of SE input to DORL. In filling out the Blue Sheet, the PM should review the amendment request in sufficient detail to develop a work plan that defines the scope, depth, resources, and schedule.

Note: In order to meet acceptance review timeliness goals discussed in Office Instruction LIC-109, it is important that the PM completes the Blue Sheet within 2 working days after the email notification from CPAB that the Blue Sheet is available.

2.3 TB Completes Green Sheet

After the PM completes the Blue Sheet (as discussed in Section 2.2), the Branch Chiefs (BCs) of the TBs requested by the PM for support in performing the review will receive an email from CPAB indicating that the Green Sheet is available to fill out.

The primary function of the Green Sheet is for the TB to assign the specific reviewer and to provide the TB's proposed schedule milestone dates.

Note: In order to meet acceptance review timeliness goals discussed in Office Instruction LIC-109, it is important that the TB BC completes the Green Sheet within 5 working days after the email notification from CPAB that the Green Sheet is available.

When the Green Sheet has been completed by the TB BC, the PM will be notified via email. The PM should assess the Green Sheet responses and ensure that the work plan meets schedule goals and covers all appropriate technical areas.

2.4 Acceptance Review

After the PM requests a TAC number and as soon as practical following receipt of the application, the task of performing the acceptance review should begin. This review should be completed by the PM and the technical staff in accordance with NRR Office Instruction LIC-109, "Acceptance Review Procedures." In addition to the guidance in LIC-109, the PM should review the licensee's application to ensure it meets the following regulatory requirements:

- (a) 10 CFR 50.90 requires that the application be submitted as specified in 10 CFR 50.4 and that it must fully describe the changes desired, and following as far as applicable, the form prescribed for original applications.
- (b) 10 CFR 50.4 specifies that the application must be addressed to the Document Control Desk (if submitted by mail). The application can also be submitted electronically (with certain restrictions as specified in 10 CFR 50.4(a)). A copy of the application must be sent to the appropriate Regional Office and the NRC Resident Inspector. The above requirements also apply to supplements to the application (e.g., responses to RAIs).
- (c) 10 CFR 50.30(b) requires that the application (and associated supplements) be submitted under oath or affirmation. NRC Regulatory Issue Summary 2001-18 (ADAMS Accession No. ML010990211) discusses acceptable means of meeting the oath or affirmation requirements in 10 CFR 50.30(b).
- (d) 10 CFR 50.91(a)(1) requires that the licensee provide its analysis of the issue of no significant hazards consideration (NSHC) using the standards in 10 CFR 50.92. NRC Regulatory Issue Summary 2001-22 (ADAMS Accession No. ML011860215) provides guidance to licensees on preparing an NSHC analysis.
- (e) 10 CFR 50.91(a)(5) requires that, for emergency amendments, the licensee must explain why the emergency situation occurred and why it could not avoid this situation.
- (f) 10 CFR 50.91(a)(6)(vi) requires that, for exigent amendments, the license must explain the exigency and why the licensee cannot avoid it.
- (g) 10 CFR 50.91(b)(1) requires that the licensee provide a copy of the application to the State.

(h) If the application contains proprietary information, the requirements in 10 CFR 2.390(b)(1) must be followed by the licensee. The NRC staff is required by 10 CFR 2.390(b)(3) to determine whether information sought to be withheld from public disclosure is a trade secret or confidential or privileged commercial or financial information (i.e., proprietary information) and, if so, whether it should be withheld from public disclosure. Specific guidance on proprietary reviews is contained in NRR Office Instruction LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure."

Licensees often include the information listed below in their license amendment request applications. However, although this information may be useful to the NRC staff, the following is not explicitly required per the regulations:

- Requested amendment issuance date;
- Requested implementation period;
- Discussion of whether the submittal includes any regulatory commitments;
- Discussion of environmental considerations (i.e., categorical exclusions in 10 CFR 51.22)*;
- Discussion of whether submittal is based on precedent;
- Inclusion of retyped technical specification pages (i.e., camera ready pages); and
- Inclusion of technical specification bases pages.

*Although licensees are not required to discuss environmental considerations in their license amendment application, the NRC may require the licensee to subsequently submit environmental information pursuant to 10 CFR 51.41 (aids the Commission to comply with National Environmental Policy Act (NEPA) requirements).

Industry guidance on a voluntary standard format for license amendment requests is contained in Nuclear Energy Institute (NEI) document NEI 06-02, "License Amendment Request (LAR) Guidelines," Revision 2, dated October 2010 (ADAMS Package Accession No. ML103360397).

3.0 Public Notification

As soon as practicable following completion of the acceptance review (as discussed in Section 2.4), PMs should prepare the appropriate type of public notification regarding the proposed issuance of the amendment. The associated requirements for this public notification are discussed below. The specific types of notices are discussed in Sections 3.1 through 3.7.

10 CFR 50.91(a)(2)(i) states that, under 10 CFR 2.105, the NRC may provide notification of the proposed issuance of an amendment: (1) through an individual notice in the *Federal Register*; or (2) by inclusion of a notice in the periodic *Federal Register* notice of proposed actions; or (3) by publishing both such notices.

Although the NRC staff publishes the periodic *Federal Register* notice for proposed amendments on a biweekly basis (except for the notices discussed below in Section 3.7), 10 CFR 50.91(a)(2)(i) only requires that the periodic *Federal Register* notice of proposed actions be published at least once every 30 days.

10 CFR 50.91(a)(2)(ii) states that each notice will: (1) contain the staff's proposed determination under the standards in 10 CFR 50.92 (i.e., proposed NSHC determination); (2) provide a brief description of the amendment and the facility involved; (3) solicit comments on the proposed NSHC determination; and (4) provide for a 30-day comment period. For biweekly notices, item 3 (solicit comments) and item 4 (provide 30-day comment period) are included in the boilerplate language in the *Federal Register* notice (i.e., text preceding the plant-specific notices).

Although 10 CFR 50.91 requires that the NRC solicit comments only on the proposed NSHC determination, the NRC staff has routinely addressed comments related to any aspect of the application. Comments received are normally addressed in the SE. See Section 7.0 of Attachment 2, "Safety Evaluation Template" for further details.

In accordance with 10 CFR 2.309(b)(3), the *Federal Register* notice for the proposed issuance of an amendment must provide a hearing request period of at least 60 days. For biweekly notices, the hearing request period is included in the boilerplate language in the *Federal Register* notice (i.e., text preceding the plant-specific notices).

10 CFR 50.58(b)(5) states that the Commission may make the amendment immediately effective, notwithstanding the pendency before it, of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that NSHC is involved. As such, the NRC staff must include a final NSHC determination in the SE if a hearing is requested. In addition, the NRC staff must include a final NSHC determination in the SE if the amendment is issued prior to expiration of the 60-day period to request a hearing (i.e., in case a hearing is requested after the amendment is issued). If the NRC staff intends to issue an amendment for which a hearing has been requested, the staff needs to notify the Commission via issuance of a "Notification of Significant Licensing Action," in accordance with the guidance in an NRR memorandum dated December 13, 2000 (ADAMS Accession No. ML003779315).

Some exceptions to the noticing requirements discussed above include the following:

- 10 CFR 50.58(b)(3) states that if the NRC finds that exigent circumstances exist, as defined in 10 CFR 50.91, the NRC may reduce the period provided for public notice and comment.
- 10 CFR 50.58(b)(3) states that if the NRC finds, in an emergency situation, as defined in 10 CFR 50.91, that the amendment involves NSHC determination, the NRC may dispense with public notice and comment and issue the amendment.
- 10 CFR 50.91(a)(7) states that, where the NRC finds that significant hazards considerations are involved, it will issue a *Federal Register* notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR Part 2.

- Consistent with 10 CFR 2.307(c), for applications containing either sensitive unclassified non-safeguards information (SUNSI) or safeguards information (SGI), the *Federal Register* notice also contains an order, signed by the Secretary of the Commission, which establishes procedures to allow potential parties to gain access to the SUNSI or SGI documents.
- In accordance with Subpart K of 10 CFR Part 2 (10 CFR 2.1101 through 10 CFR 2.1119), hybrid hearing procedures apply to proposed amendments regarding expansion of spent fuel storage capacity at the site of a civilian nuclear power plant. 10 CFR 2.1107 provides requirements regarding noticing of proposed amendments of this type and requirements that the *Federal Register* notice identify the availability of the hybrid hearing procedures.

Further information regarding NSHC determinations can be found in the *Federal Register* publication of a final rule dated March 6, 1986 (51 FR 7744). This rulemaking is sometimes referred to as the “Sholly rule.” The NSHC standard is a procedural criterion that governs whether an opportunity for a prior hearing must be provided before action is taken by the NRC (i.e., issuance of amendment), and whether prior notice for public comment may be dispensed with in emergency situations or shortened in exigent circumstances.

10 CFR 50.91(a)(1) requires that the licensee provide its analysis of the issue of NSHC using the standards in 10 CFR 50.92. NRC Regulatory Issue Summary (RIS) 2001-22 (ADAMS Accession No. ML011860215) provides guidance to licensees on preparing an NSHC analysis. As part of the process in preparing the public notification regarding the proposed issuance of the amendment, the PM should review the licensee’s analysis to determine if it adequately supports a proposed determination that all three of the NSHC standards are satisfied. If the review determines that it appears that the three standards in 10 CFR 50.92 are satisfied, the PM should use the licensee’s analysis in the public notification. If the review determines that the licensee’s analysis does not appear to satisfy the three standards in 10 CFR 50.92, the PM may prepare a public notification containing the NRC’s NSHC analysis or request the licensee to resubmit a revised NSHC analysis. Alternatively, the PM can prepare a notice without a proposed NSHC determination (see Section 3.3 below).

Power uprate amendments were originally listed in the Sholly rule as an example of amendments that would likely involve a significant hazards consideration (see 51 FR 7751, example v). However, based on the discussion in SECY-01-0142 dated July 27, 2001 (ADAMS Accession No. ML011930574), SECY-06-0136 dated June 9, 2006 (ADAMS Accession No. ML061240351), and a memorandum dated February 6, 2006, “Power Uprate Review Guidance,” (ADAMS Accession No. ML060400439), there has been sufficient experience in performing power uprate reviews such that it is likely PMs will be able to notice the proposed amendment using a proposed NSHC determination.

Licensees often supplement applications with additional information, and may make changes to the original application. If the changes or additional information are within the scope of the original NSHC notice such that the notice still applies, the NRC staff should add the following statement to Section 1.0, “Introduction,” of the SE for the amendment:

The supplement[s] dated [], provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the Nuclear Regulatory Commission (NRC or the Commission) staff’s original proposed no significant hazards consideration

determination as published in the *Federal Register* (FR) on [...date (Federal Register citation)].

If the supplemental information expanded the scope of the proposed amendment beyond the description on the NRC staff's original notice, then the proposed amendment should be re-noticed. As such, it is recommended that, for the original notice, the description of the amendment should be brief and broadly characterize the aspects of the license amendment (including TSs proposed for modification) in a form such that the general public can readily understand the purpose of the amendment. The notice should not be proscriptive as to a precise section number, technical specification, wording, or specific engineering parameter values.

The following sections describe the various methods of public notification. Associated with each method is a time period (i.e., for public comment or to request a hearing). Computation of the time period is in accordance with the requirements in 10 CFR 2.306.

3.1 Biweekly Notice With Proposed NSHC Determination (30-Day Comment Period, 60 Days to Request a Hearing)

The most common form of public notification is for the NRC staff to issue a proposed NSHC determination in the *Federal Register* as part of a biweekly collection (i.e., the Biweekly Report) of notices in the *Federal Register*. This type of notice (typically called a biweekly notice) provides a 30-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is first issued as an internal non-public memo from the PM to the Biweekly Notice Coordinator. The memos (for a specific time interval) are compiled by a DORL Administrative Assistant to develop the Biweekly Report which is subsequently published in the *Federal Register*. See ADAMS Accession No. ML103230524 for a template of the memo for this type of notice.

PMs should coordinate with the DORL Licensing Assistant (LA) regarding the schedule for publication of the biweekly notices to ensure that the time period for comments and hearing requests are compatible with the schedule for proposed issuance of the amendment. If the biweekly schedule is not compatible, the PM should consider issuing the notice as an individual notice as discussed below in Section 3.2.

3.2 Individual Notice With Proposed NSHC Determination (30-Day Comment Period, 60 Days to Request a Hearing)

If the required schedule for issuance of an amendment cannot be accommodated by the normal biweekly publication of the notice, an individual notice can be published in the *Federal Register*. This type of notice is (typically called an individual notice) provides a 30-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee. The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML082130171 and ML082130341 for templates of the notice and transmittal letter, respectively.

10 CFR 50.91(a)(2)(i) states that, under 10 CFR 2.105, the NRC may provide notification of the proposed issuance of an amendment: (1) through an individual notice in the *Federal Register*; or (2) by inclusion of a notice in the periodic *Federal Register* notice of proposed actions; or (3) by publishing both such notices. Although not required by this regulation, NRC standard practice is to publish what is typically called a “repeat notice” in the “periodic *Federal Register* notice of proposed actions” (i.e., biweekly notice). The repeat notice is a brief abstract of the information provided in the individual notice. Similar to the discussion above in Section 3.1, this type of notice is first issued as an internal non-public memo from the PM to the Biweekly Notice Coordinator. See ADAMS Accession No. ML082250714 for a template of the memo.

3.3 Individual Notice Without NSHC Determination (Category 3) (No Request for Comments, 60 Days to Request a Hearing)

For those amendments for which the PM does not find that the criteria for an NSHC determination have clearly been satisfied, an individual notice can be published in the *Federal Register* that describes the amendment request and provides neither a proposed NSHC determination nor a definitive finding that the subject amendment involves a significant hazards consideration. As a result of previous NRR procedures for processing license amendments, these notices are sometimes referred to as “Category 3” notices. This type of notice does not solicit any comments (i.e., since an NSHC determination is not included) but provides a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee. The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML082130138 and ML082130323 for templates of the notice and transmittal letter, respectively.

If a hearing is requested for an amendment that was noticed using a “Category 3” notice, the PM should issue a notice with a proposed NSHC determination (allowing 30 days for public comment) and include a final NSHC determination in the SE. Consistent with the requirements in 10 CFR 50.58(b)(5), the amendment may be made immediately effective in advance of the holding and completion of any required hearing. Note, the notice with the proposed NSHC determination should not include an opportunity for a hearing since the opportunity for a hearing was already provided in the original Category 3 notice. See ADAMS Accession No. ML053490030 for an example of a notice with a proposed NSHC determination that was issued following issuance of a Category 3 type notice.

3.4 Exigent Circumstances (Reduced Comment Period, Hearing Period Ends After Issuance)

If a licensee believes that a proposed amendment is needed in a time frame that does not permit the NRC staff to publish a *Federal Register* notice allowing for the normal 30-day period for public comment on the proposed NSHC determination, the licensee may apply for the amendment under exigent circumstances using the provisions of 10 CFR 50.91(a)(6). Processing a license amendment under exigent circumstances allows a reduced period for public comment. In addition, due to the shortened timeframe for issuance of the amendment, the hearing request period will end after the amendment is issued. Although 10 CFR 50.58(b)(4) states that the NRC will provide 30 days notice of opportunity for a hearing in exigent

circumstances, the staff practice has been to allow a hearing request period of 60 days (i.e., consistent with 10 CFR 2.309(b)(3)).

Since the amendment will be issued prior to expiration of the period to request a hearing, the SE must include a final NSHC determination. The SE must also justify the issuance of the amendment under exigent circumstances. See Sections 4.0 and 6.0 of the SE template (Attachment 2) for further discussion on the SE content.

The regulation provides two methods of public notification under exigent circumstances (assuming the NRC staff determines the amendment involves NSHC): (1) via issuance of a *Federal Register* notice; or (2) via use of local media. Each of these methods is discussed below.

Method 1 - Federal Register Notice

The first method provides a 14-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee (i.e., as an individual notice). The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML082110449 and ML082130369 for templates of the notice and transmittal letter, respectively.

10 CFR 50.91(a)(2)(i) states that, under 10 CFR 2.105, the NRC may provide notification of the proposed issuance of an amendment: (1) through an individual notice in the *Federal Register*; or (2) by inclusion of a notice in the periodic *Federal Register* notice of proposed actions; or (3) by publishing both such notices. Although not required by this regulation, NRC standard practice is to publish what is typically called a “repeat notice” in the “periodic *Federal Register* notice of proposed actions” (i.e., biweekly notice). The repeat notice is a brief abstract of the information provided in the individual notice. Similar to the discussion above in Section 3.1, this type of notice is first issued as an internal non-public memo from the PM to the Biweekly Notice Coordinator. See ADAMS Accession No. ML082250714 for a template of the memo.

Method 2 - Local Media

For those proposed amendments submitted under exigent circumstances that require disposition in less time than needed for a 14-day comment period, 10 CFR 50.91(a)(6) provides an alternative such that the NSHC determination can be published in the local media to provide “reasonable notice” to the public in the area near the plant. The PM should coordinate with the Office of Public Affairs (in the specific Regional office) to determine which local media will be used to publish the notice.

The standard practice for this method has been to secure advertising in local newspapers. The NRC process to prepare an announcement, receive concurrences, and arrange funding normally requires at least 2 to 3 days. Newspapers usually require receipt of the announcement 2 working days before publication. Allowing several working days for a comment period results in a minimum time of approximately 7 working days from the submittal of the request to the issuance of the license amendment. The process to secure advertising for an exigent amendment involves preparing the announcement and securing funding and financial approval for the advertisement. These two processes need to be done in parallel. See ADAMS Accession No. ML113080514 for further instructions on the process for publication of the notice.

Because the notice will refer the public to the Public Document Room and ADAMS to review the licensee's amendment application, the PM must ensure that the incoming amendment application is publicly-available in ADAMS before the notice is published in the local media.

See ADAMS Accession No. ML082120592 for a template of the local media notice. Since this type of notice does not provide an opportunity to request a hearing, the biweekly notice of issuance provides a 60-day period to request a hearing (see ADAMS Accession No. ML082120510 for the notice of issuance template).

3.5 Emergency Situation (Opportunity for Hearing and Comment after Issuance)

If a licensee believes that a proposed amendment is needed even sooner than can be issued under exigent circumstances, the licensee may apply for the amendment per the provisions of 10 CFR 50.91(a)(5). This regulation states, in part, that:

Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a nuclear power plant, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the Commission will not publish a notice of proposed determination on no significant hazards consideration, but will publish a notice of issuance under § 2.106 of this chapter, providing for opportunity for a hearing and for public comment after issuance.

Consistent with the above-cited requirements, the NRC staff is not required to publish a proposed NSHC determination and the opportunity for hearing and public comment is only included in the notice of issuance. See ADAMS Accession No. ML082110353 for a template of the emergency biweekly notice of issuance.

Although 10 CFR 50.58(b)(4) states that the NRC will provide 30 days notice of opportunity for a hearing in an emergency situation, since the 10 CFR Part 2 rule change in 2004 (69 FR 2182), the staff practice has been to allow a hearing request period of 60 days (i.e., consistent with 10 CFR 2.309(b)(3)).

As noted above, 10 CFR 50.91(a)(5) requires that the staff provide an opportunity for public comment after issuance of an emergency amendment. For amendments not issued in an emergency situation, the solicitation of public comment pertains to comments on the NRC staff's proposed NSHC determination in accordance with 10 CFR 50.91(a)(2)(ii). However, for an emergency amendment, a proposed NSHC determination is not issued. The regulations do not specify the intent of soliciting comments for an emergency amendment. However, the NRC staff has routinely addressed comments related to any aspect of the application. For an emergency amendment, any comments received will likely be after amendment issuance (i.e., staff will not be able to address comments in the SE). As such, it is recommended that any significant comments received be treated as controlled correspondence and processed in accordance with NRR Office Instruction ADM-311, "Controlled Correspondence Process."

Since the amendment will be issued prior to expiration of the hearing request period, the SE must include a final NSHC determination. The SE must also justify the issuance of the amendment under emergency circumstances. See Sections 5.0 and 6.0 of the SE template (Attachment 2) for further discussion on the SE content.

3.6 Notices for Spent Fuel Storage Capacity Expansion

In accordance with Subpart K of 10 CFR Part 2 (10 CFR 2.1101 through 10 CFR 2.1119), hybrid hearing procedures apply to proposed amendments regarding expansion of spent fuel storage capacity at the site of a civilian nuclear power plant. As discussed in 10 CFR 2.1103, the scope includes “use of high density fuel storage racks, fuel rod compaction, the transshipment of spent nuclear fuel to another civilian nuclear power reactor within the same utility system, the construction of additional spent nuclear fuel pool capacity or dry storage capacity” or any other means to expand the spent fuel storage capacity.

10 CFR 2.1107 provides requirements regarding noticing of proposed amendments of this type and requires that the *Federal Register* notice identify the availability of the hybrid hearing procedures. See ADAMS Accession No. ML082110411 for boilerplate hybrid hearing language to be added to any of the notices discussed above as applicable.

3.7 Guidance for Noticing Amendments Containing SUNSI or SGI

Consistent with 10 CFR 2.307(c), for applications containing either sensitive unclassified non-safeguards information (SUNSI) or safeguards information (SGI), the *Federal Register* notice also contains an order, signed by the Secretary of the Commission, which establishes procedures to allow potential parties to gain access to the SUNSI or SGI documents.

Notices for applications containing SUNSI or SGI can either be issued as part of a monthly report that is issued in the *Federal Register* (via a memo to the SUNSI/SGI Notice Coordinator) or as an individual notice. PMs should coordinate with the LA regarding the schedule for publication of the monthly report to ensure the time period for public comments and hearing requests are compatible with the schedule for proposed issuance of the amendment.

See ADAMS Accession No. ML082660487 for a template of the Memo to the SUNSI/SGI Notice Coordinator: For an individual notice, the templates discussed above in Sections 3.2 and 3.3 can be used with added text depending on whether the notice contains SUNSI (ADAMS Accession No. ML092870614), SGI (ADAMS Accession No. ML092870626), or SUNSI and SGI (ADAMS Accession No. ML092870630). Further information regarding noticing amendments containing SUNSI or SGI is contained in NRR Office Instruction LIC-201, “NRR Support to the Hearing Process.”

4.0 Safety Evaluation

Although there is no specific regulatory requirement to issue a safety evaluation (SE) as part of the disposition of a license amendment request, the NRC staff is obligated to document significant decisions in accordance with NRC Management Directive (MD) 3.53, “NRC Records and Document Management Program,” Handbook 1, Part I, “Recordkeeping Requirements.”

Specifically, MD 3.53 requires that, in order to provide adequate documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the NRC, records shall be created and maintained that are sufficient to document the formulation and execution of basic policies and decisions and necessary actions taken, including all significant decisions and commitments reached orally (person to person, by telecommunications, or in conference). MD 3.53 provides the Commission's interpretation of its obligations under the Federal Records Act (which is codified in Title 44 of the United States Code, Chapters 21, 29, 31 and 33) and regulations promulgated by the National Archives and Records Administration (36 CFR Part 1220).

Consistent with the above discussion, the SE provides the technical, safety, and legal basis for the NRC's decision regarding a license amendment request. The SE should provide sufficient information to explain the staff's rationale to someone unfamiliar with the licensee's request. The SE includes a brief description of the proposed change, the regulatory requirements related to the issue, and an evaluation that explains why the staff's disposition of the request satisfies the regulatory requirements. Given that the SE serves as the record of the staff's disposition of an application for amendment, the information relied upon in the SE and supplied by the licensee must be docketed and under oath or affirmation (see Regulatory Issue Summary 2001-18 (ADAMS Accession No. ML010990211)). This is not meant to hamper questions and clarifications by telephone or in meetings. However, if the information is important in the staff's decision-making process and is not otherwise in the public domain or reasonably inferred by the staff, it must be formally provided by the licensee.

NRC staff SEs are not part of a plant's licensing basis. As discussed in NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," the NRC staff should not attempt to establish licensing bases information in SEs. It is important that the licensees provide the licensing bases information so that there is no confusion following the licensing action and to avoid a perception of staff-imposed backfits (see 10 CFR 50.109). A useful application of the staff's SEs, by both licensees and the staff, can be in assessing what information should be incorporated into mandated licensing bases documents following issuance of the amendment (e.g., revision to the Updated Final Safety Analysis Report (UFSAR)).

PMs and technical branch (TB) reviewers should establish the appropriate scope and depth for the review as part of the work planning discussed in Section 2.0 (giving due consideration to the technical complexity of the proposed change, availability of applicable precedent, timeliness goals, and guidance such as the Standard Review Plan). General guidance regarding SE planning and control, the use of precedent, guidelines on requesting additional information and proper use of regulatory commitments is provided below. A template for a typical SE and guidance for preparing an SE is provided in Attachment 2, "Safety Evaluation Template."

4.1 SE Planning and Control

Safety evaluations can be prepared by PMs and technical staff personnel, with or without contractor assistance. The determination of who performs the lead reviewer function depends on a number of factors such as the technical complexity of the review, technical background of the PM, and the availability of appropriate precedent. The determination is made via the work planning process discussed in Section 2.0.

Occasionally, technical staff will use contractors to assist in performing a review. PMs should treat the SE the same as a technical staff review and communicate with the technical staff member designated as the contractor's technical monitor.

4.2 Use of Precedent and References to Topical Reports

There are a number of considerations and cautions regarding the use of a precedent SE by NRR staff. These include, but are not limited to, the following:

- ▶ Use precedents, as applicable, to achieve efficiency and consistency.
- ▶ Ensure that the precedent is appropriate for use with the intended amendment.
- ▶ Ensure that the precedent meets current expectations for format, findings, internal NRR guidance for the item, NRR guidance to industry, and technical content.
- ▶ Ensure that previous plant-specific information is replaced with information relevant to the current plant.
- ▶ Obtain TB concurrence, unless formal guidance has been issued that provides an alternative concurrence process.
- ▶ Ensure that the precedent being used corresponds to the issued SE and not to intermediate versions or drafts. Use of the final SE (as issued) for the precedent will ensure that the staff is consistent and will improve efficiency by incorporating changes made by NRR and OGC as part of the concurrence process for the precedent SE. Significant feedback received during the concurrence process from other NRR organizations, NRR managers, or OGC, should be provided to the primary authors of the SE for consideration and incorporation into ongoing and future work products.
- ▶ Decisions to not apply specific precedents, especially precedents cited by a licensee, should be clearly explained in the SE (to avoid the appearance of being arbitrary and/or inconsistent). The staff should assess any change in a prior staff position to ensure that the safety or regulatory issue is consistent with the NRC principles of good regulation (e.g., efficiency, clarity, and reliability). The staff should also ensure that changes in staff position are assessed to determine whether the change could constitute a plant-specific or generic backfit (see NRR Office Instructions LIC-202, "Procedures for Managing Plant-Specific Backfits and 50.54(f) Information Requests," LIC-400, "Procedures for Controlling the Development of New and Revised Generic Requirements for Power Reactor Licensees," and NRC Management Directive 8.4, "Management of Facility-specific Backfitting and Information Collection").

Referencing topical reports in license amendment applications and associated NRC SEs improves the efficiency of the licensing process by allowing the staff to coordinate the review of a methodology or proposal that will be used by multiple licensees. Guidance for the staff's review of a topical report is provided in LIC-500, "Processing Requests for Reviews of Topical Reports." As with the use of precedent amendments, the staff should ensure that a reference in a license amendment application to a staff accepted Approved Version of the topical report is

appropriate for the subject change and its supporting analysis. The reviewer should ensure that supporting analyses that refer to a staff accepted Approved Version of the topical report are performed consistent with the limitations and conditions identified within the topical report and the staff's SE for the topical report. Some SEs for topical reports may include specific guidance for licensees referencing the topical report in a plant-specific application.

If a licensee in its application or the NRC staff during its review identifies a deviation from the process or limitations associated with a topical report, the staff should address the deviation in its SE for the plant-specific license amendment application. To address deviations from approved topical reports, the SE for the subject amendment should identify the limitation or condition, evaluate the proposed deviation against appropriate regulatory criteria, and specifically explain why the deviation is acceptable (or not acceptable).

4.3 Requests for Additional Information

10 CFR 2.102 states that during review of an application by the NRC staff, an applicant may be required to supply additional information. 10 CFR 2.108 states that the NRC may deny an application if the applicant fails to respond to a request for additional information (RAI) within 30 days of the date of the request, or within such other time as may be specified.

RAIs serve the purpose of enabling the staff to obtain all relevant information needed to make a regulatory decision on a license amendment request that is fully informed, technically correct, and legally defensible. RAIs are necessary when the information is not included in the initial submittal, is not contained in any other docketed correspondence, or cannot reasonably be inferred from the information available to the staff. RAIs should be directly related to the applicable regulatory requirements associated with the amendment request. RAIs should also be consistent with the plant's licensing basis and applicable codes, standards, and guidance (e.g., Regulatory Guides, Standard Review Plan). RAIs should not be used as general information requests or as a means to encourage commitments from licensees.

In some cases, it may be warranted to perform a regulatory audit in order to identify additional information that a licensee should formally submit. Following the audit, the information needed should be requested via the RAI process. Further information on the audit process is contained in NRR Office Instruction, LIC-111, "Regulatory Audits."

The transmittal of RAIs from technical branches to DORL should follow ADM-200, "Delegation of Signature Authority." Specifically, for internal correspondence between Divisions, the signature authority lies with the technical staff Branch Chief (or re-delegated to a staff member qualified in accordance with Office Instruction ADM-504). The transmittal of RAIs from the technical staff Branch Chief to DORL may be in the form of e-mails or memoranda, as long as the RAIs are appropriately preserved by the technical staff as Official Agency Records in ADAMS (see Section 10.0 for additional guidance for when an internal document may warrant preservation as an Official Agency Record).

The staff is accountable for the appropriateness of RAIs and should ensure that each question in an RAI was developed with proper consideration of the following:

- ▶ regulatory basis for the question
- ▶ technical complexity of the proposed amendment
- ▶ risk significance of the issue in question
- ▶ existence of precedent amendments
- ▶ appropriate scope and depth of the review
- ▶ resource implications for both the staff and the licensee
- ▶ information already on the docket

The following guidance should be used for the RAI process. The intent of this guidance is not to limit the staff from getting the information that is needed to perform a technical review. Rather, it is intended to make the RAI process productive and to focus staff and licensee resources on the pertinent issues necessary for the NRC staff to make a regulatory decision.

1. It is recommended that the draft SE be developed before preparing RAIs such that any “holes” in the SE would inform the staff’s determination of the additional information that is required.
2. Before developing an RAI, the staff should ensure that the information is not already available to the staff or that the answer could not reasonably be inferred from general knowledge, existing regulatory requirements, previously docketed correspondence, or generally accepted industry practice.
3. Questions should be specific rather than overly broad. Questions should not include unnecessary detail and should clearly state the information that is required.
4. Questions included in the RAI should ask for information that is required to make the necessary regulatory finding. Each question should have a clear nexus to the staff’s regulatory finding. Including the regulatory basis in the question is a good practice.
5. The staff should not issue any RAIs if the staff has (or can infer with a reasonable degree of confidence) the necessary information to make the regulatory finding. When an RAI is necessary, the staff should make every effort to limit itself to one round of RAIs per TB for an amendment request. The established timeliness goals are likely to be exceeded if multiple RAIs are needed to complete the staff’s review of a license amendment application.

Caution: The desire to limit ourselves to one round of RAIs for the purpose of efficiency should not interfere with our primary mission of ensuring that we maintain public health and safety. If necessary to ensure public health and safety, multiple rounds of RAIs are appropriate. Reviewers should work with the PM and the licensee to determine the best way to resolve questions (e.g., have a meeting, prepare additional round of RAIs, arrange for a site visit, etc).

6. The staff should not use RAIs as an opportunity to force licensees to take actions beyond those that relate directly to the amendment. Occasionally, the staff may encounter peripheral issues that warrant regulatory attention while the staff is reviewing an amendment application; those peripheral issues should be addressed under the appropriate

program/process under NRC's regulatory framework (e.g., backfit, inspection, generic communication, enforcement, allegation).

7. Frequent and early communications between the PM, TB staff, and the licensee can avoid the need for many RAIs. To ensure an effective and efficient review, PMs should notify the licensee prior to requesting the licensee to submit additional information to support the staff's review. This notification should be a meeting or conference call attended by the PM, TB reviewer, and licensee. The proposed RAI questions should be discussed and, if the licensee is requested to submit additional information, a mutually agreed upon due date should be established. The due date should be established consistent with the review schedule agreed to between DORL and the TBs during the Blue/Green sheet process. The RAI response due date should be reflected in the RAI on its issuance.

To help resolve the issues, preliminary questions (i.e., draft RAI) may be faxed or e-mailed to the licensee prior to the meeting or conference call. Licensee answers to RAIs that are needed to make a regulatory finding (i.e., that are not merely clarifications of information already on the docket) need to be placed on the docket via letter from the licensee. All of the staff's questions shall be documented as Official Agency Records using one or a combination of the following methods: (1) forwarding a formal RAI to the licensee by letter; (2) generating a publicly available memo to the PM's Branch Chief that documents the draft RAI; or (3) having the licensee include the questions from the teleconference, e-mail, or fax in their docketed response. The specific method or combination used is case-specific and depends on the needs of the licensee, the potential public interest, and the needs of the NRC staff.

For the above described interactions between the licensee and the NRC staff, the PM should decide whether a conference call versus a public meeting is appropriate. In general, conference calls between the staff and the licensee (i.e., without external stakeholders) is acceptable as long as the interaction is a general information exchange (call is intended to ensure that the draft RAI questions are understandable, the regulatory basis for the questions was clear, and to determine if the information requested was previously docketed). Further guidance on whether a public meeting is warranted is contained in NRR Office Instruction COM-202, "Meetings with Applicants, Licensees, Vendors or Other Members of the Public."

8. As discussed above, 10 CFR 2.108 states that the NRC may deny an application if the applicant fails to respond to an RAI within 30 days of the date of the request, or within such other time as may be specified. If the staff intends to invoke the provisions of 10 CFR 2.108, it is important that the RAI response date agreed to by the licensee be documented as an Official Agency Record. This documentation can be included in a formal RAI letter using words such as the following:

During a phone call with [licensee contact name] of your staff on [date] it was agreed that a response would be provided by [date]. Please note that if you do not respond to this letter by the agreed-upon date or provide an acceptable alternate date in writing, we may deny your application for amendment under the provisions of Title 10 of the *Code of Federal Regulations*, Section 2.108.

9. If the license does not respond by the agreed-upon date or if the response does not fully address the RAI, the PM and TB reviewers should discuss possible actions with NRR management (e.g., another round of RAIs, conference call, meeting, denial of application in accordance with 10 CFR 2.108). See Section 6.3 for discussion on the procedural steps to take if it is decided that the application should be denied.

4.4 Regulatory Commitments and License Conditions

In addition to the license amendment process, the discussion in Section 4.4 also applies to the license renewal process.

4.4.1 Regulatory Commitments

NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," Revision 1, dated January 7, 2004 (ADAMS Accession No. ML033530249), states that "[t]he licensing bases for a nuclear power reactor can be represented by a few categories of information that form a hierarchy structure in terms of associated change controls and reporting requirements." LIC-100 lists obligations, mandated licensing bases documents, and regulatory commitments as the categories in this hierarchy and defines these categories as follows:

1. Obligations - conditions or actions that are legally binding requirements imposed on licensees through applicable rules, regulations, orders, and licenses (including technical specifications and license conditions). The imposition of obligations (sometimes referred to as regulatory requirements) during routine interactions with licensees should be reserved for matters that satisfy the criteria of 10 CFR 50.36 or are otherwise found to be of high safety or regulatory significance. The major distinction between obligations and other parts of the licensing bases is that changes generally cannot be made without prior NRC approval.
2. Mandated Licensing Bases Documents - documents, such as the UFSAR, the quality assurance program, the security plan, and the emergency plan, for which the NRC has established requirements for content, change control and reporting. Information that should be included in these documents is specified in applicable regulations and regulatory guides. The change control mechanisms and reporting requirements are defined by regulations such as 10 CFR 50.59, 50.54, and 50.71.
3. Regulatory Commitments - explicit statements to take a specific action agreed to, or volunteered by, a licensee and submitted in writing on the docket to the NRC. A regulatory commitment is appropriate for matters in which the staff has a significant interest but which do not warrant either a legally binding requirement or inclusion in the UFSAR or a program subject to a formal regulatory change control mechanism. Control of such commitments in accordance with licensee programs is acceptable provided those programs include controls for evaluating changes and, when appropriate, reporting them to the NRC.

Caution: Since commitments made by a licensee in support of a license amendment request are not legally binding, the staff's SE should not rely on commitments as a basis for any part of the staff's approval of a proposed amendment. However, as discussed below, the staff may rely on a commitment if it is escalated into an obligation or subsequently incorporated into a mandated licensing basis document.

The issue of inappropriately applied commitments was discussed in an audit report by the NRC's Office of the Inspector General dated September 19, 2011, "Audit of NRC's Management of Licensee Commitments" (ADAMS Accession No. ML112620529). Guidance to DORL staff was provided in a memorandum dated November 29, 2011, "Commitment Management Audit - Identification of Inappropriately Applied Commitments" (ADAMS Accession No. ML113190085). Further information on proper use of commitments is provided in a memorandum dated November 26, 2008, "Assessment of Regulatory Processes that Utilize Regulatory Commitments" (ADAMS Accession No. ML083150618).

Under certain conditions, it may be appropriate to escalate a licensee's regulatory commitment to a legally binding regulatory requirement. Specifically, and consistent with the definition in LIC-100 of an "obligation," escalating a regulatory commitment into a legally binding regulatory requirement should be reserved for matters that warrant: (1) inclusion in the technical specifications based on the criteria in 10 CFR 50.36; or (2) inclusion in the license based on determination by the NRC staff that the issue is of high safety or regulatory significance. See Section 4.4.2 below on the format and content for license conditions. If the staff determines that a commitment should be escalated into an obligation, the PM should request the licensee to submit the appropriate technical specification changes or license changes as part of a docketed submittal. This is typically done through the RAI process.

For those regulatory commitments that don't warrant escalation into an obligation but are relied on by the staff as an element of the staff's approval of the proposed amendment, the staff's SE can rely on the commitment if the commitment is subsequently incorporated into a mandated licensing basis document (e.g., UFSAR). For example, many amendments involve relocation of information from the technical specifications to a licensee-controlled document (e.g., UFSAR, technical requirements manual). Relocation of this information is typically identified as a commitment in the licensee's application. For these types of amendments, the staff's SE will usually need to make a conclusion that future changes to the relocated material will be adequately controlled under the provisions of 10 CFR 50.59. In order to ensure that the provisions of 10 CFR 50.59 apply to the information removed from the technical specifications when the licensee implements the amendment, the PM should add language to the implementation statement on the amendment page similar to the following:

The license amendment is effective as of its date of issuance and shall be implemented within [insert per application] days. Implementation of the amendment shall also include revision of the Updated Final Safety Analysis Report as described in the licensee's letter dated [insert date].

In addition, some amendments involve approving a change in the licensing bases with no accompanying technical specification or license change (e.g., a commitment to revise the UFSAR to reflect the approved licensing bases change). For these types of amendments, the language for the implementation statement on the amendment page would also authorize revision to the UFSAR. Suggested wording for the implementation statement (for amendments which approve a change to the UFSAR) is contained in Section 3.1, "Final Safety Analysis Report (FSAR)," of NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors."

4.4.2 License Conditions

License conditions are a form of obligation (i.e., legally binding condition or action) and are formal statements included in the license necessary to establish, implement, or maintain applicable rules, regulations, or licensing bases.

The NRC staff may impose license conditions without agreement from the licensee. However, to ensure no unintended consequences, it is strongly recommended that the NRC staff request licensee agreement on the language of NRC-proposed license conditions. The NRC request is typically done through the RAI process. Licensee agreement should be documented via a formal docketed submittal (under oath or affirmation) fully describing the proposed changes to the license.

License conditions should:

- address issues of high safety or regulatory significance;
- be worded such that the meaning is clear and not open to different interpretations; and
- explicitly define the conditions for satisfaction of the condition.

License conditions should not:

- address issues already addressed by an existing rule, requirement, order or regulation;
- require NRC action to complete;
- be open-ended;
- address a facility not controlled by the license; nor,
- address voluntary requests.

4.5 Environmental Considerations

Most proposed amendments fit under one of the categorical exclusions in 10 CFR 51.22(c) and, as such, do not require an environmental assessment (EA). However, it is a good practice for the PM to determine if an EA is needed early during the license amendment review. Further guidance on whether an EA is required is contained in the Section 8.0 of the attached SE template (Attachment 2). Specific guidance on preparing EAs and considering environmental issues is contained in NRR Office Instruction LIC-203, "Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues."

5.0 Amendment Package Preparation and Concurrence

5.1 Amendment Package Preparation

After the PM has received all the required SE inputs (or the PM has prepared the SE), the PM should begin assembly of the amendment package so it is ready for review and concurrence. SE inputs should be integrated into a single SE using the guidance in Attachment 2, "Safety Evaluation Template."

After the PM integrates all the SE inputs, if the draft SE contains proprietary information (or potentially contains proprietary information), the PM may send the draft version of the SE to the licensee to determine if it appropriately identifies information which is considered to be

proprietary. Any information considered by the NRC staff to be proprietary should be marked within double brackets (i.e., [[.....]]). The transmittal letter to the licensee should clearly state that the requested review is in regard to proprietary information only. The following are examples of letters transmitting draft SEs for licensee review: (1) letter transmitting SE potentially containing proprietary information (ADAMS Accession No, ML112430591); and (2) letter transmitting SE containing proprietary information (ADAMS Accession No. ML102710032). Following receipt of the response from the licensee, the PM should revise the draft SE, as required, to correctly denote the information considered to be proprietary. At this time, the PM should also prepare a redacted version of the SE which can be made publicly available if the amendment is approved for issuance. See ADAMS Package Accession No. ML102700263 for an example of an amendment which transmitted proprietary and non-proprietary versions of the SE. Further guidance on transmittal of proprietary information is provided in NRR Office Instruction LIC-204.

Note: The NRC staff should strive to make as much information in the SE publicly available as is reasonable consistent with our organization value regarding openness. If feasible, it is preferred that the staff create an SE that does not contain any proprietary information.

Before the SE has been completed, it is recommended that the PM contact the licensee to provide the “clean” technical specification and license pages to be included in the amendment package (i.e., pages without markup of changes).

The PM should assemble the amendment package with following parts in this order:

- Transmittal letter.
- License amendment pages.
- List of revised license and technical specification pages.
- Revised license and technical specification pages.
- Safety Evaluation.
- Notice of Issuance.

To assist those requested to concur (discussed further below in Section 5.2), the PM should include the following in the amendment package (in addition to items listed above):

- Copy of the incoming license amendment application and all licensee supplements.
- Copy of the *Federal Register* notice which provided public notification regarding the proposed issuance of the amendment.
- Copy of TB SE inputs.
- Copy of any relevant background information, including information used in preparing the SE

(e.g., UFSAR sections, guidance documents) and documents referenced in the SE (if not readily available in ADAMS or on the NRC website).

5.2 Concurrence

Review and concurrence is the process by which the quality and consistency of the amendment package is verified. Concurrence involves obtaining the approved signatures required for amendment issuance. It is the PM's responsibility to ensure that appropriate concurrences are received for the amendment package.

Licensing Assistant (LA) concurrence is required for all license amendments. See LIC-101 Section 5.0, "Responsibilities and Authorities," Sub-section D, "Amendment Package Processing," for specific LA responsibilities related to review and concurrence.

Amendment packages prepared by PMs must always be concurred on by the TBs associated with the technical area(s) of the proposed change unless the TBs have agreed that a PM or lead PM may perform their function (e.g., for amendments adopting an approved Traveler under the consolidated line item improvement process). PMs should review the responses to the Work Planning and Characterization Forms (Green Sheets) to determine those organizations that have requested concurrence.

TBs providing SE input should be listed in the concurrence chain. When SE input is prepared by the TBs, the PM has the responsibility for integrating it into the overall SE. If, during this integration, the PM makes substantial changes to the SE input (i.e., changes are more than editorial and change technical content or original intent), the TB providing the input should provide concurrence on the amendment package. SE input from a TB that is used with only minor editorial changes does not need additional concurrence by that TB. In this case, the concurrence block for the TB should add an asterisk next to the branch name and the following note should be added above the concurrence block: "* via SE dated [insert TB SE input date]." Additional guidance on when re-concurrence is necessary due to changes to a document is provided in NRR Office Instruction ADM-200.

OGC must review all license amendments except under previously agreed upon conditions (e.g., see Section 8.2.2 regarding the Consolidated Line Item Improvement Process (CLIIP)). OGC reviews the amendment package for legal adequacy and defensibility (i.e., no legal objection).

Caution: If the NRC staff intends to issue an amendment for which a hearing has been requested, the staff needs to notify the Commission (at least 5 days before amendment issuance) via issuance of a "Notification of Significant Licensing Action," in accordance with the guidance in an NRR memorandum dated December 13, 2000 (ADAMS Accession No. ML003779315). In accordance with this guidance, the associated amendment needs to be concurred on by the NRR Office Director.

Additional guidance and signature authority for special categories of amendments, such as changes in licensed power level and denial of amendment requests, are provided in NRR Office Instruction ADM-200, "Delegation of Signature Authority."

Parallel concurrence may be used to expedite the review and concurrence process if the amendment requires several concurrences and timing is of concern. PMs should ensure that comments incorporated during the concurrence process do not affect the bases for concurrences received prior to changing the amendment package.

An amendment routing sheet is placed on top of the amendment concurrence package by the LA (during the LA review) to facilitate the routing and concurrence of the package. The amendment routing sheet also serves as a checklist to help ensure the necessary coordination, regulatory, and administrative tasks have been completed prior to amendment issuance (e.g., check of expiration dates for comment and hearing request periods, contacting the State Official, checking for comments/petitions on the proposed amendment). See ADAMS Accession No. ML081980829 for the template Amendment Routing Sheet. The DORL PM, LA, and administrative assistant responsibilities are delineated on the routing sheet.

During the early stages of review and concurrence, it is recommended that:

(1) the PM request the LA to check www.regulations.gov to determine if there were any public comments on the proposed amendment;

(2) the PM request the LA to contact the Office of the Secretary to determine whether a hearing was requested; and

(3) the PM contact the State Official in accordance with the requirements in 10 CFR 50.91(b).

The PM should take any additional actions required (e.g., revision of SE to address comments) as a result of the above actions. The PM and LA should also mark the Amendment Routing Sheet accordingly upon completion of the above tasks (see discussion above).

6.0 Amendment Issuance, Denial, Withdrawal, and Corrections

6.1 Regulatory Background

As discussed in 10 CFR 50.92(a), in determining whether an amendment to a license will be issued, the Commission will be guided by the considerations that govern the issuance of initial licenses to the extent applicable and appropriate. The specific considerations governing the Commission's decision of whether an operating license will be issued are discussed in 10 CFR 50.40, "Common standards." In addition, 10 CFR 50.57, "Issuance of operating license" lists the specific findings the Commission must make in order to issue a license. Other than considerations and findings related to financial requirements (as discussed in 10 CFR 50.40(b) and 10 CFR 50.57(a)(4) and (a)(5)), the findings shown on the first page of the license amendment in the DORL amendment boilerplates (i.e., page before the Branch Chief signature page) very closely follow the language in 10 CFR 50.40 and 10 CFR 50.57. Specifically,

consistent with 10 CFR 50.92(a), 10 CFR 50.40, and 10 CFR 50.57, the staff must make the following findings (shown in the DORL boilerplates) to issue an amendment:

The Nuclear Regulatory Commission (the Commission) has found that:

- A. The application for amendment filed by [licensee] dated [insert date] complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I;
- B. The facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission;
- C. There is reasonable assurance: (i) that the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the Commission's regulations set forth in 10 CFR Chapter I;
- D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public; and
- E. The issuance of this amendment is in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

6.2 Amendment Issuance

After the required concurrence signatures are obtained, and the NRC staff determines that the proposed amendment is acceptable and should be issued, the PM should forward the original amendment package to the LA. The package should include the following parts in this order:

- Transmittal letter.
- License amendment pages.
- List of revised license and technical specification pages.
- Revised license and technical specification pages.
- Safety Evaluation.
- Notice of Issuance.

The LA will assign the amendment number(s) to the package and do a final quality assurance check before forwarding the package to the DORL administrative assistant for final ADAMS processing and dispatch.

6.3 Amendment Denial or Withdrawal

If the NRC staff's review of the proposed amendment determines that the amendment should be denied, the staff must prepare an SE documenting the basis for the denial. The denial SE does not need to address all aspects of the licensee's request, but should be sufficient to support a conclusion that the amendment is not acceptable (i.e., SE does not need to address aspects of the request that are acceptable). The PM should also prepare a denial transmittal letter (see ADAMS Accession No. ML082040984 for a template) and a *Federal Register* Notice of Denial (see ADAMS Accession No. ML082040994 for a template). Consistent with NRR Office Instruction ADM-200, the DORL Division Director is added to the concurrence block and is the signature authority for the denial transmittal letter.

The PM should obtain concurrences from the LA, applicable TBs, OGC, and the DORL Branch Chief. However, the DORL Division Director concurrence and signature will initially be left blank. Following receipt of the DORL Branch Chief concurrence to deny to amendment, the PM and Branch Chief will brief the DORL Division Director and Deputy Director regarding the intent to deny the amendment. Assuming the Division Director agrees with this path going forward, the PM will contact the licensee to arrange for a call with the DORL Division Director. During the initial contact, the PM should inform the licensee that the staff plans to deny the amendment and that the staff will discuss the basis for denial during the call with the DORL Division Director. The PM should also coordinate with the applicable TB reviewers to arrange for them to be available during the call between the DORL Division Director and the licensee. TB reviewers should be prepared to discuss their technical positions during the call.

During the call, the DORL Division Director (with assistance from TB reviewers as necessary) will provide the basis for the staff's plan to deny the amendment. The DORL Division Director will offer the licensee an opportunity to withdraw the amendment or to request a public meeting for further discussion of the issues. The DORL Division Director should make clear that if the licensee does not either submit a formal withdrawal in writing by a specific date (e.g., 2 or 3 days from the call) or request a public meeting by the same date, the NRR staff will issue the denial.

If the licensee decides to withdraw the amendment, the PM should prepare a transmittal letter documenting the withdrawal (see ADAMS Accession No. ML082260953 for a template) and a *Federal Register* Notice of Withdrawal (see ADAMS Accession No. ML082260993 for a template). Following issuance of the transmittal letter and Notice of Withdrawal, the PM should prepare an internal non-public memo to the DORL Branch Chief which documents the call with the licensee and the decision by the licensee to withdraw the proposed amendment. The draft SE documenting the basis for the planned denial of the amendment should be included as an enclosure to the memo to ensure that an adequate record of the staff's decision-making process is captured as an Official Agency Record (i.e., consistent with requirements in MD 3.53 as discussed in Section 10.0 of this Office Instruction).

If the licensee does not withdraw the amendment or request a public meeting by the date set during the DORL Division Director call, the PM should obtain the Division Director's concurrence and signature on the denial package and formally issue the denial.

6.4 Amendment Corrections

Occasionally, typographical errors are introduced by an amendment into the technical specifications (TSs), or the staff discovers, when processing an amendment, that typographical errors were introduced by a previous amendment. In SECY-96-238 dated November 19, 1996 (ADAMS Legacy Library Accession No. 9611250030), the NRC staff informed the Commission of the intent to issue guidance to staff members for determining what action is necessary to correct a typographical error associated with power reactor TSs. In a Staff Requirements Memorandum dated December 17, 1996 (ADAMS Accession No. ML003754054), the Commission provided comments on the guidance and stated that it did not object to the proposed guidance. The actual guidance was issued in a memorandum from Roy P. Zimmerman dated January 16, 1997 (ADAMS Accession No. ML103260096). The guidance states, in part, that:

In general, correction of a typographical error discovered in the TSs must be treated the same as any request to amend the license. Thus, typographical errors discovered in the TSs for which the origin of the error is unknown must be corrected through the normal processing of a license amendment request to change the TSs. An exception to this general rule is the case in which the staff or licensee can demonstrate that the error was introduced inadvertently in a particular license amendment and that the erroneous change was not addressed in the notice to the public nor reviewed by the staff. Under these limited circumstances, the change that introduced the typographical error was not a proper amendment to the license because it was neither addressed in the notice nor reviewed, and correction of the typographical error is not a “change” to the TS. Accordingly, the typographical error may be corrected by a letter to the licensee from the NRC staff, instead of an amendment to the license. The limitation on tracing the introduction of a typographical error to a specific amendment application is necessary to establish that the change introduced by the error was in fact improperly made.

The above discussion only pertains to typographical errors in the TSs. An amendment package consists of other documents, such as the SE and the transmittal letter. These other documents, since they are not legally binding and not specifically addressed by SECY-96-238, may be corrected by letter. Note, changes to the SE must be consistent with docketed information provided in the licensee’s application and associated supplements.

The amendment itself (i.e., the two-page document usually signed by the DORL Branch Chief) is legally binding, but the issue of errors in it is not addressed by SECY-96-238. In the absence of a policy, the staff should follow the same principle set forth in SECY-96-238 (for correction to the TSs) for the correction of errors in the amendment itself.

Amendments often change operating license pages. Operating license pages are legally binding, but the issue of errors in them is not addressed by SECY-96-238. In the absence of a policy, the staff should follow the same principle set forth in SECY-96-238 (for correction to the TSs) for the correction of errors in operating license pages.

7.0 Risk-informed Licensing Action Guidance

7.1 Introduction

A risk-informed licensing action is defined as any licensing action that uses quantitative or qualitative risk assessment insights or techniques to provide a key component of the basis for the acceptability or unacceptability of the proposed action. The mere mention of quantitative or qualitative risk insights does not in itself make a licensing action risk-informed. This section provides guidance for processing risk-informed license amendment requests, as well as non-risk-informed amendment requests which should be reviewed for risk insights by the Division of Risk Assessment (DRA) Probabilistic Risk Assessment Licensing Branch (APLA).

7.2 Responsibilities

7.2.1 DORL PMs

PMs should apply the criteria in the following table in determining whether DRA/APLA should be involved in the review of the licensee’s application. If the criteria indicate that APLA may need to review the application for “special circumstances,” the PM should discuss this potential need with the APLA Branch Chief. Under these conditions, the request for APLA involvement in the review should be consistent with SRP 19.2, Appendix D, and the PM or responsible technical branch (TB) should be prepared to develop, with APLA support, the basis for requesting a review for special circumstances. If APLA review is determined to be needed, the PM should check “Yes” next to the “Risk Perspective” on the Blue Sheet.

Guidance on APLA Involvement in Reviews

	Submittal Review Issue Identification	
	<i>For each issue, consider the following questions</i>	
	Question	If yes, then...
If “NO,” continue to next question	Invokes RG 1.174, RG 1.175, RG 1.176, RG 1.177, RG 1.178, RG 1.200, RG 1.201, RG 1.205, et al.?	APLA Risk-Informed Review
	Significantly changes the allowed outage time (e.g., outside the range previously approved at similar plants), probability of initiating event, probability of successful mitigative action, functional recovery time, or operator action requirement?	APLA Special Circumstances Review
	Significantly changes functional requirements or redundancy?	APLA Special Circumstances Review
	Significantly changes operations that affect the likelihood of undiscovered failures?	APLA Special Circumstances Review

	Significantly affects the basis for successful safety function?	APLA Special Circumstances Review
	Could create “special circumstances” per SRP 19.2, Appendix D, under which compliance with existing regulations may not produce the intended level of safety, and plant operation may pose an undue risk?	APLA Special Circumstances Review
	Completely consistent with deterministic requirements?	Conventional Review (No APLA Review)

For reviews for which APLA involvement was deemed not necessary as part of the Blue Sheet process, the PM should review supplements to the licensee’s application to assess whether there are any unaddressed, potentially significant risk effects (e.g., potentially significant changes in core damage frequency (CDF), large early release frequency (LERF), design safety margins, or defense-in-depth) that approval of the licensing action could precipitate. If the PM suspects that there is such a potential, the PM should coordinate with APLA Branch Chief to determine if APLA review is warranted.

7.2.2 Technical Review Branches (other than APLA)

This section applies to technical review branches other than APLA.

For reviews in which APLA is involved, the responsible technical review branch should be identified as the lead technical review branch (i.e., APLA is typically not the lead branch for risk-informed licensing action reviews). The technical review branch staff should interact with the assigned APLA staff if there are any concerns with regard to the technical review branch’s area of review that might also affect the APLA review. This will ensure that, if there are any risk-related review issues that need to be addressed, the APLA branch staff will be aware of them and will pursue them under the APLA review scope. As needed, the technical review Branch Chief should discuss with the APLA Branch Chief any concerns related to the risk-informed aspects of a review to determine the appropriate approach to the review.

For reviews for which APLA involvement was deemed not necessary as part of the Blue Sheet process, the TB reviewer should review supplements to the licensee’s application to assess whether there are any unaddressed, potentially significant risk effects (e.g., potentially significant changes in CDF, LERF, design margins, or defense-in-depth) that approval of the licensing action could precipitate. If the TB reviewer suspects that there is such a potential, the reviewer should coordinate with the DORL PM and the APLA Branch Chief to determine if APLA review is warranted. Under these conditions, the request for APLA involvement in the review should be consistent with SRP 19.2, Appendix D, and the TB should be prepared to develop, with APLA support, the basis for requesting a review for special circumstances.

For risk-informed reviews, the TB reviewer should use the guidance in Standard Review Plan (SRP) Section 19.2, “Review of Risk Information Used to Support Permanent Plant-Specific

Changes to the Licensing Basis: General Guidance.” See the discussion in Section 7.2.3 below regarding the scope of the APLA review versus the scope of the TB review.

7.2.3 APLA

The APLA Technical Reviewer should coordinate closely with the TB reviewers in other branches to ensure that the SE inputs to DORL, for risk-informed submittals, cover the 5 principles of risk-informed regulation discussed in Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis” and SRP 19.2. These principles are as follows:

- 1) The proposed change meets the current regulations, unless it explicitly relates to a requested exemption.
- 2) The proposed change is consistent with the defense-in-depth philosophy.
- 3) The proposed change maintains sufficient safety margins.
- 4) When proposed changes increase CDF or risk, the increase(s) should be small and consistent with the intent of the Commission’s Safety Goal Policy Statement (reference, “Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Correction and Republication,” 51 FR 30028, dated August 21, 1986).
- 5) The impact of the proposed change should be monitored using performance measurement strategies.

Typically, as part of the deterministic evaluation, the TB review provides the SE input for principles 1, 2, 3 and 5 above, while APLA provides the input for principle 4 and supports the TB in developing its input on principle 5. The specific scope of the review should be worked out early in the review process and the DORL PM should be informed if the scope of the review by the branches is different than the typical scope.

If the APLA review scope is for “special circumstances,” per SRP 19.2, Appendix D, then the process laid out in that appendix should be followed. Note that if such a review proceeds beyond the initial screening considerations, then management agreement must be obtained regarding special circumstances before requesting risk-related information from the licensee and, upon management agreement, the Commission will need to be notified of the review consistent with the discussion in the Staff Requirements Memorandum for SECY-99-246 dated January 5, 2000 (ADAMS Accession No. ML003671433). As such, reviews involving “special circumstances” will involve additional interactions and the review schedules will need to be extended beyond what would be expected for normal licensing action reviews.

8.0 Technical Specifications Task Force Travelers

8.1 Background

The Standard Technical Specifications (STS) for the five vendor designs include Babcock & Wilcox (NUREG-1430), Westinghouse (NUREG-1431), Combustion Engineering (NUREG-1432), General Electric Boiling Water Reactor (BWR)/4 (NUREG-1433), and General Electric BWR/6 (NUREG-1434).

Changes to the STS NUREGs, which are potentially applicable to multiple plants, are typically proposed to the NRC by the Technical Specifications Task Force (TSTF). The NRC staff reviews the changes to the STS proposed by the TSTF. The STS changes are referred to as "Travelers." Travelers that are approved by the NRC are considered to be part of the STS. The actual updating of the STS by incorporation of approved Travelers is done on an as-needed basis.

Using the Traveler process to change the STS improves the efficiency of the licensing process by allowing the NRC staff to review and approve a proposed change that will be used and referenced in the preparation of license amendment requests by multiple licensees following approval of the Traveler. The Traveler provides the model technical and regulatory bases for the license amendment request.

Additionally, selected TSTF Travelers are approved as part of the Consolidated Line Item Improvement Process (CLIIP). When TSTF Travelers are CLIIPed, additional efficiencies are gained. CLIIP Travelers, when adopted by a licensee, require minimal plant-specific information or justification for use. Therefore, the NRC staff can review a CLIIP license amendment request in less time than that of a non-CLIIP request. CLIIP license amendment requests typically do not require review by the NRR technical branches. Only the NRR Division of Safety Systems (DSS) Technical Specifications Branch (STSB) and the plant PM in DORL typically need to review a CLIIP license amendment request, unless it is a risk-informed CLIIP license amendment request, which would also need to be reviewed by the NRR Division of Risk Assessment (DRA) Probabilistic Risk Assessment Licensing Branch (APLA).

In the past, model SEs were not prepared for all approved Travelers. However, that is no longer the case. Model SEs are prepared for all approved Travelers, whether or not they are part of the CLIIP. Also, the NRC staff no longer prepares the model application. The model application is now submitted by the TSTF as an attachment to the Traveler.

For approved TSTF Travelers, the NRC staff prepares: (1) a model SE that the NRC staff can use for review of a plant-specific license amendment request; (2) a notice of opportunity for public comment (NFC) on the proposed model SE that is published in the *Federal Register*; and (3) a notice of availability (NOA) for the approved Traveler that is published in the *Federal Register*. Both the NFC and NOA reference the TSTF-prepared model application and the NRC staff-prepared model SE.

Approved Travelers (non-CLIIPed and CLIIPed) may be adopted by licensees that have converted to the STS, as well as licensees that have not converted to the STS but have determined that the TS changes are applicable to their facilities. The NOA and model

application will cite any plant-specific verification or other information required in licensees' applications.

The process for review of TSTF Travelers is described in detail in NRR Office Instruction LIC-600.

The NRC's Technical Specifications website at <http://www.nrc.gov/reactors/operating/licensing/techspecs/post-revision3-sts.html> provides links to documents associated with specific Travelers.

8.2 Processing of Amendment Requests Based on Approved Travelers

The processing of license amendment requests based on approved Travelers generally follows the process for review of other license amendment requests described throughout this Office Instruction. Differences from the normal amendment process are described in Sections 8.2.1 and 8.2.2 below.

During the acceptance review, the NRC staff should review the licensee's application to ensure that that it is consistent with the model application for the approved Traveler.

The NRC staff should follow as closely as possible the model SE when preparing the plant-specific SE. The model SE approving a Traveler has been approved by OGC, the STSB staff, and appropriate technical branch(es). If the model SE is not followed closely, then the efficiency gains are lost and the plant-specific SE may receive additional OGC comments and need to be reviewed by the technical branch(es).

8.2.1 Amendments to Adopt Approved Travelers Not Part of the CLIIP

The DORL PM should consult with STSB to determine which technical branches need to review or concur on any amendment request to adopt approved Travelers that are not part of the CLIIP. These amendment requests will be treated as normal license amendments and, as such, will be subject to the normal licensing action review timeliness metrics. The licensee's application should follow the model application as closely as possible and provide any required plant-specific information.

8.2.2 Amendments to Adopt Approved Travelers as Part of the CLIIP

When the DORL PM receives an application submitted based on an approved Traveler as part of the CLIIP, before the TAC number is requested, the PM should review the application to assess whether the licensee provided the necessary plant-specific verifications and other information as cited in the NOA and model application. The PM should also make note of any exceptions or deviations discussed in the licensee's application. The level of conformity to the model application (including differences between the plant-specific TSs and the STS) will determine whether the amendment will be reviewed as a CLIIP amendment (with an accelerated review schedule) or as a normal license amendment (with a review schedule consistent with the

normal timeliness goals). As needed, the PM should coordinate with STSB in making the determination.

For amendments that will be reviewed under an accelerated scheduled (i.e., processed as a CLIIP amendment), the PM should request a TAC with the TAC title formatted as follows:

[TSTF Traveler Title] Using CLIIP (TSTF-[number])

When filling out the Blue Sheet (discussed in Section 2.2), the PM should identify STSB as the recommended lead branch. The PM should consult with STSB to determine the need for input or concurrence from other technical branches.

After several amendments are issued for a particular CLIIP item, STSB may recommend to OGC that OGC review should not be required for subsequent amendment packages for that CLIIP. If OGC has no legal objection to the recommendation, STSB should ensure that this decision is documented as an Official Agency Record in ADAMS (see ADAMS Accession No. ML073130139 as an example). STSB should then update the list of CLIIP items for which OGC has waived mandatory review. As discussed in a memorandum dated October 29, 2007 (ADAMS Accession No. ML072980209), the list of CLIIP items that do not require OGC review is contained in ADAMS Accession No. ML072980233.

9.0 Amendments for Emergency Plan Changes

9.1 Background and Regulatory Requirements

In a final rule dated November 23, 2011 (76 FR 72560), the NRC amended its regulations pertaining to emergency preparedness. The final rule, in part, revised the regulatory process for NRC approval of emergency plan changes. This section describes the regulatory requirements associated with emergency plan changes including those changes made by the final rule. Section 9.2 provides guidance on processing of emergency plan changes consistent with the final rule.

The specific requirements for emergency plans are contained in 10 CFR 50.47, "Emergency Plans," and in Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," to 10 CFR Part 50. The requirements associated with changes to emergency plans, including changes to emergency action levels (EALs), are contained in 10 CFR 50.54(q) and in Section IV.B.2 of Appendix E to 10 CFR Part 50. These requirements are discussed in Sections 9.1.1 and 9.1.2 below.

The requirements in 10 CFR 50.47(a) preclude the issuance of an operating or combined license if the NRC cannot make a finding that it has reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. In accordance with the requirements in 10 CFR 50.54(q)(2), once an operating license is issued, the licensee is required to follow and maintain the effectiveness of its emergency plan.

9.1.1 Emergency Plan Changes

In accordance with the requirements in 10 CFR 50.54(q)(3), the licensee may make changes to the emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the emergency plan and the emergency plan, as changed, continues to meet the requirements in Appendix E to 10 CFR Part 50 and the planning standards of 10 CFR 50.47(b).

As defined in 10 CFR 50.54(q)(1), a “reduction in effectiveness” means a change in an emergency plan that results in reducing the licensee’s capability to perform an emergency planning function in the event of a radiological emergency. As also defined in 10 CFR 50.54(q)(1), an “emergency planning function” means a capability or resource necessary to prepare for and respond to a radiological emergency, as set forth in the elements of Section IV of Appendix E to 10 CFR Part 50, and the planning standards of 10 CFR 50.47(b). Prior to the final rule dated November 23, 2011, the term “reduction in effectiveness” was referred to as “decrease in effectiveness.”

The requirements in 10 CFR 50.54(q)(4) state that:

The changes to a licensee's emergency plan that reduce the effectiveness of the plan as defined in paragraph (q)(1)(iv) of this section may not be implemented without prior approval by the NRC. A licensee desiring to make such a change after February 21, 2012 shall submit an application for an amendment to its license. In addition to the filing requirements of §§ 50.90 and 50.91, the request must include all emergency plan pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the licensee's emergency plan, as revised, will continue to meet the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b).

A licensee’s evaluation that the proposed change would reduce the effectiveness of its emergency plan does not establish whether a proposed change would impact reasonable assurance determinations; the evaluation only establishes whether the licensee has the authority to implement the proposed change without prior NRC approval. In other words, the “reduction in effectiveness” standard merely identifies the threshold for when prior NRC approval is warranted.

In accordance with the final rule, proposed changes to the emergency plan, for which the licensee has determined represent a reduction in effectiveness, and which would continue to meet the requirements in Appendix E to 10 CFR Part 50 and the planning standards of 10 CFR 50.47(b), are submitted to the NRC for prior approval as a license amendment request pursuant to 10 CFR 50.90. The NRC staff acceptance criteria for these type of amendment requests relates to whether the proposed change: (1) continues to meet the requirements in Appendix E to 10 CFR Part 50 and the planning standards in 10 CFR 50.47(b); and (2) continues to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

If a licensee’s analysis of a proposed change determines that the change represents a reduction of effectiveness, and the change would not meet the requirements in Appendix E to

10 CFR Part 50 and the planning standards of 10 CFR 50.47(b), the licensee would need to request an exemption from the affected requirements in accordance with 10 CFR 50.12.

Appendix A to NRC Regulatory Guide (RG) 1.219, "Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors," dated November 2011 (ADAMS Accession No. ML102510626), provides a flowchart of the licensee's decision-making process for whether a proposed emergency plan change requires NRC prior approval. A detailed discussion of this process is included in Section C.5, "Review Process" of the RG. Section C.4, "Emergency Planning Functions," of the RG provides examples of changes that are expected to represent a reduction of effectiveness and examples of changes that would likely not represent a reduction in effectiveness. As explained in Section C.4.a, these examples are not all inclusive or exclusive and that site-specific situations may possibly make a particular example inapplicable to that site. Even if a particular example completely encompasses the change under consideration, the licensee's evaluation must explain why the site-specific implementation of the change would not reduce the effectiveness of the emergency plan for that particular site. Such an analysis cannot simply cross-reference an example in the RG.

9.1.2 EAL Changes

In accordance with planning standard 10 CFR 50.47(b)(4), the emergency plan must include a standard emergency classification scheme (e.g., notification of unusual event, alert, site area emergency, general emergency). This planning standard also requires that the emergency plan include a standard EAL scheme. An EAL is a pre-determined, site-specific, observable threshold for a plant condition that places the plant in an emergency class.

In November 1980, the NRC issued Revision 1 of NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," (ADAMS Accession No. ML040420012). Appendix 1 to this document provided guidance for development of EALs. In October 1981, the NRC endorsed NUREG-0654/FEMA-REP-1 in Revision 2 of RG 1.101, Revision "Emergency Planning and Preparedness for Nuclear Power Reactors" (ADAMS Accession No. ML090440294).

Subsequent to the issuance of NUREG-0654/FEMA-REP-1, the industry developed a number of EAL scheme guidance documents due to lessons-learned. As discussed in Revision 4 of RG 1.101 dated July 2003 (ADAMS Accession No. ML032020276), the following guidance documents have been endorsed as acceptable alternatives to the guidance in Appendix 1 to NUREG-0654/FEMA-REP-1 for development of an EAL scheme:

- Nuclear Management and Resources Council, Inc./National Environmental Studies Project, NUMARC/NESP-007, Revision 2, dated January 1992, "Methodology for Development of Emergency Action Levels," (ADAMS Accession No ML041120174).
- Nuclear Energy Institute, NEI 99-01, Revision 4, dated January 2003, "Methodology for Development of Emergency Action Levels," (ADAMS Accession No. ML041470143).

In addition to the above documents, Revision 5 of NEI 99-01 dated February 2008 (ADAMS Accession No. ML080450149), was endorsed as an acceptable method for EAL scheme development as discussed in an NRC letter dated February 22, 2008 (ADAMS Accession No. ML080430535).

In accordance with the final rule dated November 23, 2011, licensees must request prior NRC approval, pursuant to 10 CFR 50.90, for: (1) a proposed change to an entire EAL scheme; or (2) proposed changes to individual EALs for which the licensee has determined represent a reduction in effectiveness to its approved emergency plan. Specifically, Section IV.B.2 of Appendix E to 10 CFR Part 50 states that:

A licensee desiring to change its entire emergency action level scheme shall submit an application for an amendment to its license and receive NRC approval before implementing the change. Licensees shall follow the change process in § 50.54(q) for all other emergency action level changes.

Consistent with the discussion in Section 9.1.1, the NRC staff acceptance criteria for these type of amendment requests relates to whether the proposed change: (1) continues to meet the requirements in Appendix E to 10 CFR Part 50 and the planning standards of 10 CFR 50.47(b); and (2) continues to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

9.2 Processing of Emergency Plan Changes

Prior to issuance of the final emergency plan rule dated November 23, 2011, guidance on processing emergency plan changes was provided in a memorandum dated August 26, 2009 (ADAMS Accession No. ML091370012). This memorandum stated that proposed changes to emergency plans and individual EALs that would reduce the effectiveness of the emergency plan must be submitted to the NRC as license amendment requests. The memorandum also stated that EAL scheme changes were to be processed as letters with attached safety evaluations (i.e., not by license amendment). Due to the issuance of the final rule, all of the guidance in the above referenced memorandum is no longer applicable.

One of the major impacts of the final rule is that EAL scheme changes will be need to be submitted to the NRC as license amendment requests. In accordance with the implementation requirements in the final rule, EAL scheme changes must be submitted to the NRC as license amendment requests on or after June 20, 2012. All EAL scheme changes submitted to the NRC prior to June 20, 2012, that were not submitted as license amendment requests, may continue to be processed as letter approvals with an attached safety evaluation. Consistent with the requirements stated in 10 CFR 50.54(q)(4), the final rule requires that proposed changes to emergency plans and individual EALs that would reduce the effectiveness of the emergency plan must be submitted to the NRC as license amendment requests after February 21, 2012.

In general, the processing of a license amendment request for a proposed emergency plan change (including EAL changes) follows the processing for typical license amendment requests (i.e., changes to the technical specifications). The following provides guidance for some aspects that are different than the typical process.

9.2.1 Work Request

Proposed emergency plan changes, for which the licensee has requested prior NRC approval, are not included in the Blue/Green Sheet process since the reviews are performed outside of

NRR. The DORL PM should prepare a Work Request (using the standard NRR Work Request Form (ADAMS Accession No. ML101590507)). The Work Request should be forwarded with the licensee's application to the Office of Nuclear Security and Incident Response (NSIR), Division of Preparedness and Response (DPR), Operating Reactor Licensing and Outreach Branch (ORLOB).

In addition to proposed changes to emergency plans, for which the licensee has requested prior NRC approval, the emergency preparedness regulations require certain submittals to the NRC pursuant to the requirements in 10 CFR 50.4 (e.g., emergency plan changes which have been evaluated by the licensee as not representing a reduction in effectiveness, updates to the licensee's evacuation time estimates, and biennial exercise scenarios). For submittals that do not request NRC prior approval, Work Request forms (as well as TAC numbers) are not required unless specifically requested by NSIR. In addition, since NSIR staff receive these submittals via e-mail distribution from the NRC's Document Control Desk, the DORL PM does not need to forward these types of incoming documents to NSIR.

9.2.2 SUNSI Review

In accordance with the guidance in SECY-04-0191, "Withholding Sensitive Unclassified Information Concerning Nuclear Power Reactors from Public Disclosure," dated October 19, 2004 (ADAMS Accession No. ML042310663), incoming emergency planning documents are initially profiled by the NRC's Document Control Desk as non-publicly available. The DORL PM should perform a SUNSI review for all licensee emergency plan submittals supporting a proposed license amendment to determine if they can be made publicly available. If the PM determines that the document does not contain SUNSI, the PM should send an email to ADAMSIM requesting that the ADAMS profile be changed to publicly available. In general, the easiest way to do this is to forward the ERIDs email for the subject document to ADAMSIM with a message such as the following:

ADAMSIM,

I have completed the SUNSI review for the document below. The document can be made "Publicly Available."

Thanks,

[Project Manager Name]
NRR Project Manager for [Plant Name]

If the SUNSI review determines that the document contains SUNSI, the PM should request that the licensee submit a redacted version of the document with the SUNSI removed.

9.2.3 Safety Evaluation

The safety evaluation for all emergency plan changes, including EAL changes, should include a conclusion regarding whether the proposed change: (1) continues to meet the requirements in Appendix E to 10 CFR Part 50 and the planning standards in 10 CFR 50.47(b); and

(2) continues to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

The safety evaluation should not include any conclusions by the NRC staff regarding whether the proposed change is considered to be a reduction in effectiveness since that determination is the responsibility of the licensee and merely identifies the threshold for when prior NRC approval is warranted.

9.2.4 Environmental Considerations

Most proposed amendments for technical specification changes fit under one of the categorical exclusions in 10 CFR 51.22(c) and, as such, do not require an environmental assessment (EA). However, while some emergency plan changes would meet the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9) (e.g., changes that would affect a component located within the restricted area), some emergency plan changes are likely to require that an EA be done. The DORL PM should determine whether an EA is needed early in the review.

9.2.5 Amendment Page Wording

The amendment page for a typical amendment affecting the technical specifications would include wording such as the following on the amendment page:

2. Accordingly, the license is amended by changes to the Technical Specifications as indicated in the attachment to this license amendment, and paragraph 2.C.(2) of Facility Operating License No. [license number] is hereby amended to read as follows:

Technical Specifications and Environmental Protection Plan

The Technical Specifications contained in Appendix A, as revised through Amendment No. _____, and the Environmental Protection Plan contained in Appendix B, are hereby incorporated into the license. [Licensee Name] shall operate the facility in accordance with the Technical Specifications and the Environmental Protection Plan.

3. The license amendment is effective as of its date of issuance and shall be implemented within [insert per application] days.

Changes to emergency plans typically will not involve a change to the technical specifications or to any of the license pages. As such, the above amendment page wording should be replaced with words similar to the following:

2. Accordingly, by Amendment No. _____, Facility Operating License No. [license number] is hereby amended to authorize revision to the [name of emergency plan] as set forth in [Licensee Name]'s application dated [enter date], as supplemented by letters dated [enter dates], and evaluated in the NRC staff's safety evaluation dated [enter date of safety evaluation]. The

license amendment is effective as of its date of issuance and shall be implemented within [insert per application] days.

9.2.6 Stakeholder Contacts

As noted above, prior to issuance of the final rule dated November 23, 2011, guidance on processing emergency plan changes was provided in a memorandum dated August 26, 2009 (ADAMS Accession No. ML091370012). The memorandum, in part, included the following guidance regarding contacting the State and NRC Regional office:

If the licensee's forwarding letter does not specifically state that the licensee has informed the associated State emergency planning officials of the proposed change, the staff should contact the licensee to verify that this contact has been made in the form of a request for additional information or other docketed query.

The Project Manager should ensure that the region (the appropriate Branch Chief in the Division of Reactor Projects) is aware of any significant proposed changes.

Since the final rule supersedes the guidance in the above referenced memorandum, the PM should follow the normal license amendment process of contacting the State Official in accordance with the requirements in 10 CFR 50.91(b). No other stakeholder contacts are required. However, as with any amendment, the potential need for additional stakeholder communication should be assessed based on the nature of the amendment or stakeholder interest.

9.2.7 Signature Authority

Signature and concurrence authority for various documents and correspondence issued by NRR is governed by NRR Office Instruction ADM-200, "Delegation of Signature Authority." As noted in ADM-200, Revision 11, the approvals and denials related to emergency plan and EAL changes is based on the Staff Requirements Memorandum for SECY 08-0024 dated May 19, 2008 (ADAMS Accession No. ML081400510). The signature authority for emergency plan related licensing actions is as follows:

- 1) Emergency plan and EAL changes submitted for NRC approval in accordance with 10 CFR 50.54(q) or Section IV.B of Appendix E to 10 CFR Part 50 (except for exemptions and relocations of emergency operations facilities as noted below) shall be signed by the NRR Office Director or NRR Deputy Office Director (when acting for the Office Director).
- 2) Exemptions from 10 CFR 50.47(b) and Appendix E to 10 CFR Part 50 that represent a reduction in effectiveness of the licensee's emergency plan require Commission approval. Guidance on processing exemptions is provided in NRR Office Instruction LIC-102, "Exemptions from NRC Regulations."
- 3) Relocation of an emergency operations facility, if it is located more than 25 miles from the nuclear power plant, requires Commission approval.

All of the 3 items above require review by the Office of the General Counsel.

Item 1 above does not require Technical Editor review. Items 2 and 3 will require Technical Editor review on the SECY paper requesting Commission approval.

10.0 Official Agency Records (OARs)

10.1 Introduction

Management Directive (MD) 3.53, “NRC Records Management Program,” describes how the NRC complies with the regulations governing Federal records management. In order to apply the guidance in MD 3.53, a distinction must be made between OARs, which are preserved in the NRC recordkeeping system, ADAMS, and materials that are not preserved. As stated in MD 3.53, OARs meet both of the following conditions:

- They are made or received by an agency of the United States Government under Federal law or in connection with the transaction of agency business, and
- They are preserved or are appropriate for preservation as evidence of agency organization and activities or because of the value of the information they contain.

NUREG-0910, “NRC Comprehensive Records Disposition Schedule,” contains information on how long an OAR must be retained. In general, nuclear power plant docket files are retained until 20 years after the termination of the license. The retention requirement is met by adding the OAR to ADAMS. Some OARS cannot be added to ADAMS, such as video or audio tapes, and in these cases the OAR should be retained in the NRC File Center. For more information on ADAMS and OARs, refer to NUREG/BR-0273, “ADAMS Desk Reference Guide.”

Caution: In the event that a hearing is granted, associated with a specific license amendment application, the NRC staff must preserve documentation necessary to support the hearing consistent with the requirements in 10 CFR 2.1203 and 10 CFR 2.336. Specific guidance is provided in NRR Office Instruction LIC-201, “NRR Support to the Hearing Process.”

10.2 Identification of OARs

This guidance on identification of OARs is intended to address the more common records associated with the license amendment process. For unusual types of records, refer to MD 3.53 and NRR Office Instruction COM-203, “Informal Interfacing and Exchange of Information with Licensees and Applicants,” for additional guidance. The records considered to be OARs in the license amendment process include the following:

- licensee amendment submittals
- requests to a licensee for additional information
- licensee responses to requests for additional information
- NRC letters and memos transmitting notices for publication in the *Federal Register*
- SEs written by NRC staff

- technical evaluation reports (TERs) provided to the staff from contractors
- license amendments issued by the NRC (including final SE and, if applicable, TERs)
- environmental assessments
- proprietary document review letters

The above records shall be entered in ADAMS as OARs.

In some cases working files may meet criteria to be considered OARs. However, NRR has determined that working files associated with the license amendment process, such as preliminary drafts, work requests, worksheets, routing slips, Blue Sheets, Green Sheets, etc., are not OARs. This is because they do not contain unique information that adds to a proper understanding of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities. The written guidance associated with the license amendment process, such as this office instruction, clearly states that the basis and reasons for granting a license amendment must be contained in the SE issued with the license amendment.

10.3 Responsibilities

10.3.1 DORL PM

PMs should ensure that the OARs noted in Section 10.2 are retained as OARs, usually by entry into ADAMS.

10.3.2 Technical Review Branches

Branch Chiefs should ensure that the RAIs and SEs authored by their branches in support of license amendments are entered in ADAMS as OARs.

Attachment 1 - License Amendment Worksheet and Instructions

This attachment to the *Guide for Processing License Amendments* contains the License Amendment Worksheet and related instructions. The License Amendment Worksheet helps the PM to plan the work involved in processing a license amendment. It also provides a place to keep track of the status of the license amendment. Use of the worksheet is optional.

Work Planning and Acceptance Review (Reference Section 2.0)

- TAC Number(s) requested
 - TAC Nos.:
- Blue Sheet completed
 - Date completed:
- All Green Sheets received
 - Branches involved in the review:
- Acceptance Review completed
 - Date of email or letter to licensee:
 - ADAMS Accession No.: ML

Comments/Notes:

Public Notification (Reference Section 3.0)

- Public Notification issued
 - Date of internal memo or letter to licensee:
 - ADAMS Accession No.: ML
 - Federal Register notice date:
 - Federal Register notice citation: (FR)

Comments/Notes:

Proprietary Information (Reference LIC-204)

1) Does the application and/or supplements contain any proprietary information?

Yes No

2) If “Yes,” to question 1 above, has PM issued the proprietary determination letter?

Yes N/A

3) If proprietary and non-proprietary versions of the safety evaluation (SE) were prepared, has the PM confirmed with the licensee that the proprietary SE appropriately identifies the information considered to be proprietary?

Yes N/A

Comments/Notes:

Environmental Assessment (Reference Section 4.5)

1) Do the changes in the proposed amendment meet any of the categorical exclusions in 10 CFR 51.22(c)? Note, see Section 8.0 of the SE template (Attachment 2) for further guidance.

Yes No

2) If “No” to question 1 above, has the PM issued the EA?

Yes N/A

Comments/Notes:

Requests for Additional Information (Reference Section 4.3)

Technical Branch	Reviewer Name	RAI to DORL Forecast Date	RAI to DORL Actual Date	RAI to Licensee Actual Date	Licensee Response Forecast Date	Licensee Response Actual Date

 Comments/Notes:

Safety Evaluation Inputs (Reference Section 4.0)

Technical Branch	Reviewer Name	SE to DORL Forecast Date	SE to DORL Actual Date

 Comments/Notes:

Attachment 2 - Safety Evaluation Template

General Directions: This template provides the format for a typical safety evaluation (SE). The **bolded** bracketed information shows text that should be filled in for the specific amendment. The *italicized* wording provides guidance on what should be included in each section. The first page of the SE should be printed on NRC letterhead paper.

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

RELATED TO AMENDMENT NO. _____ TO FACILITY OPERATING LICENSE NO. [XXX-XX]

AND AMENDMENT NO. _____ TO FACILITY OPERATING LICENSE NO. [XXX-XX]

[NAME OF LICENSEE]

[NAME OF FACILITY]

DOCKET NOS. 50-[XXX] AND 50-[XXX]

1.0 INTRODUCTION

The introduction section of the SE (usually prepared by the PM for use in the final amendment package) should provide a brief description of the licensee's amendment request.

Supplementary submittals and their effects on the scope of the original notice and the no significant hazards consideration determination, if not re-noticed, are also described in this section. A typical introduction consists of one or two paragraphs. The description of the amendment included in the public notice may be useful in preparing the description in the SE's introduction.

Reference to licensee applications, supplemental submittals, or other publicly-available agency records should provide the ADAMS accession number. The ADAMS accession number may be provided: (1) in parentheses immediately following the reference; (2) in the optional reference section; or (3) in the form of a footnote.

The introduction section may also provide a summary of the licensee's rationale for the proposed change, including operating problems, changes in technology, or changes in analytical approaches. This information forms the "why" of a licensee's request. Although the reason the licensee is requesting an amendment may be irrelevant to the acceptability of the proposal, it may warrant inclusion in the evaluation. This information may also support the conclusions of the evaluation, in that the proposed change has minimal safety consequences but offers advantages in terms of reduced radiation exposures, reduced costs, or resolution of other hardships.

By application dated **[enter date]**, as supplemented by letters dated **[enter dates]** (Agencywide Documents Access and Management System (ADAMS) Accession Nos. **[MLXXXXXXXXXX, MLXXXXXXXXXX, and MLXXXXXXXXXX]** respectively, **[name of licensee]** (the licensee) requested changes to the Technical Specifications (TSs) **[or facility operating license]** for **[name of facility]**. The proposed changes would revise **[give concise description which can often be developed from the licensee's application or the Federal Register Notice]**.

The supplements dated **[enter dates]**, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the Nuclear Regulatory Commission (NRC or the Commission) staff's original proposed no significant hazards consideration determination as published in the *Federal Register* on **[enter date] [(XX FR XXXX)]**.

2.0 REGULATORY EVALUATION

The regulatory evaluation section (provided by the primary reviewer(s)) provides the regulatory framework for the licensing action. This section should give a clear compilation of the regulatory requirements, guidance and licensing basis information that form the acceptance criteria for the proposed changes. The following structure is recommended:

- 1. A description of the system, function, or program that is the primary subject of the application. This information can usually be found in the licensee's application, the associated TS Bases or the UFSAR.*
- 2. A description of the proposed changes (e.g. comparison of the current TS requirements against the proposed TS requirements). The bases for the current requirements should also be discussed. This information can usually be found in the associated TS Bases section of the plant-specific TSs or the corresponding Standard TSs.*
- 3. A description of the regulatory requirements, licensing basis information and guidance documents the NRC staff considered in its review of the proposed amendment. Reviewers should ensure that the acceptance criteria being used are applicable to the licensing basis for the plant (e.g., some older plants were designed and constructed to a draft version of the General Design Criteria (GDC) rather the final GDC that were incorporated into Appendix A to 10 CFR Part 50). The staff should avoid adding references to regulations or other documents that are not directly related to the Technical Evaluation section of the SE.*

3.0 TECHNICAL EVALUATION

The technical evaluation section (provided by the primary reviewer(s)) documents the staff's evaluation of the proposed changes against the relevant criteria discussed in SE Section 2.0. The staff should consider the following in developing the technical evaluation:

- 1. The staff should explain the method of its review of the request (e.g., a comparison of licensee proposal against regulatory criteria, a review of input*

assumptions combined with use of approved methodology, or an independent analysis to confirm results presented by a licensee).

2. *When citing NRC documents, the SE should clearly distinguish between items that are “requirements” and items that are “guidance.”*
3. *The SE should be specific as to what information is relied on to form the basis for approving or denying the amendment request.*
4. *The SE should contain the basis for the staff's conclusions regarding whether the proposed changes are acceptable. For example:*

“The NRC staff has reviewed the licensee’s analysis provided in section [specific section of licensee’s submittal] of its submittal dated [date] and finds that [cite specific findings]. Based on these findings, the NRC staff concludes that there is reasonable assurance that the requirements of [cite regulation] will continue to be met. Therefore, the staff finds the proposed change acceptable.”

Very broad statements such as “the staff evaluated the changes and found them acceptable” do not provide sufficient documentation of why the staff found the proposal acceptable.

4.0 EXIGENT CIRCUMSTANCES

This section to be prepared by the PM and is provided only if the amendment is issued under exigent circumstances.

Background

The NRC’s regulations contain provisions for issuance of amendments when the usual 30-day public comment period cannot be met. These provisions are applicable under exigent circumstances. Consistent with the requirements in 10 CFR 50.91(a)(6), exigent circumstances exist when: (1) a licensee and the NRC must act quickly; (2) time does not permit the NRC to publish a *Federal Register* notice allowing 30 days for prior public comment; and (3) the NRC determines that the amendment involves no significant hazards consideration. As discussed in the licensee’s application dated **[enter date]**, the licensee requested that the proposed amendment be processed by the NRC on an exigent basis.

Under the provisions in 10 CFR 50.91(a)(6), the NRC notifies the public in one of two ways: (1) by issuing a *Federal Register* notice providing an opportunity for hearing and allowing at least 2 weeks from the date of the notice for prior public comments; or (2) by using local media to provide reasonable notice to the public in the area surrounding the licensee’s facility. In this case, the NRC **[describe which of the two ways the staff used]**.

[Provide description of licensee’s basis for exigent circumstances]

NRC Staff Conclusion

Based on the above circumstances, the NRC staff finds that the licensee made a timely

application for the proposed amendment following identification of the issue. In addition, the NRC staff finds that the licensee could not avoid the exigency **[provide basis (e.g., “without significant impact to the outage schedule”)]**. Based on these findings, and the determination that the amendment involves no significant hazards consideration as discussed below, the NRC staff has determined that a valid need exists for issuance of the license amendment using the exigent provisions of 10 CFR 50.91(a)(6).

5.0 EMERGENCY SITUATION

This section to be prepared by the PM and is provided only if the amendment is issued in an emergency situation.

Background

The NRC’s regulations in 10 CFR 50.91(a)(5) state that where the NRC finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a nuclear power plant, or in prevention of either resumption of operation or of increase in power output up to the plant’s licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the NRC will publish a notice of issuance under 10 CFR 2.106, providing for opportunity for a hearing and for public comment after issuance.

As discussed in the licensee’s application dated **[enter date]**, the licensee requested that the proposed amendment be processed by the NRC on an emergency basis. **[Provide description of licensee’s basis for emergency situation]**.

NRC Staff Conclusion

The NRC staff reviewed the licensee’s basis for processing the proposed amendment as an emergency amendment (as discussed above) and agrees that an emergency situation exists consistent with the provisions in 10 CFR 50.91(a)(5). Furthermore, the NRC staff determined that: (1) the licensee used its best efforts to make a timely application; (2) the licensee could not reasonably have avoided the situation; and (3) the licensee has not abused the provisions of 10 CFR 50.91(a)(5). Based on these findings, and the determination that the amendment involves no significant hazards consideration as discussed below, the NRC staff has determined that a valid need exists for issuance of the license amendment using the emergency provisions of 10 CFR 50.91(a)(5).

6.0 FINAL NO SIGNIFICANT HAZARDS CONSIDERATION

This section to be prepared by the PM and is only provided if: (1) a hearing has been requested regarding the proposed amendment; or (2) the amendment is being processed as an exigent or emergency amendment; or (3) the amendment will be issued prior to the expiration of the hearing request period.

The NRC’s regulations in 10 CFR 50.92 state that the NRC may make a final determination that a license amendment involves no significant hazards consideration if operation of the facility, in accordance with the amendment, would not: (1) involve a significant increase in the probability

or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

As required by 10 CFR 50.91(a), an evaluation of the issue of no significant hazards consideration is presented below:

[Insert no significant hazards consideration analysis provided in either the licensee's application, the initial public notification (i.e., proposed no significant hazards consideration determination) or provide NRC analysis]

Based on the above evaluation, the NRC staff concludes that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff has made a final determination that no significant hazards consideration is involved for the proposed amendment and that the amendment should be issued as allowed by the criteria contained in 10 CFR 50.91.

7.0 STATE CONSULTATION

This section is to be prepared by the PM.

The requirements with respect to State consultation are contained in 10 CFR 50.91(b). 10 CFR 50.91(b)(3) and (b)(4) require that: (1) the NRC make a good faith effort to telephone the State official, prior to amendment issuance, to determine if the State has any comments; and (2) consider any comments of the State official. If there are State comments, they should be addressed in this section. Comments received from members of the public should be addressed within the technical evaluation section or in a separate section of the safety evaluation. See ADAMS Accession No. ML102710156 (Safety Evaluation Section 5.0, "Public Comments") for an example of a safety evaluation which addresses public comments.

In accordance with the Commission's regulations, the **[Name of State]** State official was notified of the proposed issuance of the amendment. The State official had **[no]** comments. **[If comments were provided, they should be addressed here].**

8.0 ENVIRONMENTAL CONSIDERATION

This section is to be prepared by the PM.

10 CFR 51.20 provides criteria to determine if a licensing action requires an environmental impact statement (EIS). The specific types of actions requiring an EIS, as listed in 10 CFR 51.20(b), generally do not fall into the types of license amendments processed by DORL, with the exception of license renewals which are covered by 10 CFR 51.20(b)(2). Note, amendments involving a renewed license are issued by the Division of License Renewal with DORL on concurrence.

10 CFR 51.21 states that all licensing and regulatory actions subject to this subpart require an environmental assessment (EA) except: (1) those requiring an EIS in accordance with 10 CFR 51.20(b); (2) those identified in 10 CFR 51.22(c) as categorical exclusions; and (3) those identified in 10 CFR 51.22(d) as other actions not requiring environmental review.

10 CFR 51.22(b) states that, except in special circumstances as determined by the Commission, an EA or an EIS is not required for any action within a category of actions listed in 10 CFR 51.22(c).

10 CFR 51.22(c) lists the specific categorical exclusions for which an EA is not required. The categorical exclusions which typically relate to amendments issued by DORL are as follows:

- 10 CFR 51.22(c)(9)
- 10 CFR 51.22(c)(10)
- 10 CFR 51.22(c)(12)
- 10 CFR 51.22(c)(21)

Specific guidance on preparing EAs and considering environmental issues is contained in NRR Office Instruction LIC-203.

If one or more of the categorical exclusions applies, the PM should use the appropriate paragraph(s) below as applicable:

Use the following if 10 CFR 51.22(c)(9) applies:

The amendment changes a requirement with respect to installation or use of a facility component located within the restricted area as defined in 10 CFR Part 20 [**if amendment changes surveillance requires add “and changes surveillance requirements”**]. The NRC staff has determined that the amendment involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released offsite, and that there is no significant increase in individual or cumulative occupational radiation exposure. The Commission has previously issued a proposed finding that the amendment involves no significant hazards consideration, and there has been no public comment on such finding [**enter Federal Register citation (XX FR XXXX) and date**]. Accordingly, the amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendment.

Use the following if 10 CFR 51.22(c)(10) applies:

The amendment relates to changes in recordkeeping, reporting, or administrative procedures or requirements. Accordingly, the amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(10). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendment.

Use the following if 10 CFR 51.22(c)(12) applies:

This amendment relates solely to safeguards matters and does not involve any significant construction impacts. Accordingly, this amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(12). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of this amendment.

Use the following if 10 CFR 51.22(c)(21) applies:

The amendment is for the transfer of licenses issued by the NRC and conforming amendments.

Accordingly, this amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(21). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with approval of the application.

In the event that an environmental assessment has been completed and published, the following paragraph should be used:

Pursuant to 10 CFR 51.21, 51.32, and 51.35, an environmental assessment and finding of no significant impact was published in the *Federal Register* on **[enter date] [(XX FR XXXX)]**. Accordingly, based upon the environmental assessment, the Commission has determined that issuance of this amendment will not have a significant effect on the quality of the human environment.

Note that PMs should plan for the fact that the environmental assessment and finding of no significant impact must be published in the Federal Register prior to the issuance of the amendment.

9.0 CONCLUSION

This section is to be prepared by the PM.

The Commission has concluded, based on the considerations discussed above, that: (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public.

10.0 REFERENCES

Optional section to be prepared by the PM and primary reviewers. If document is publicly available, the ADAMS Accession No. should be listed.

Principal Contributor:

Date: