



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

NRR OFFICE INSTRUCTION

Change Notice

Office Instruction No.: LIC-101, Revision 3
Office Instruction Title: LICENSE AMENDMENT REVIEW PROCEDURES
Effective Date: February 9, 2004
Primary Contacts: William Reckley
301-415-1323
wdr@nrc.gov
Responsible Organization: NRR/DLPM/PD3

Summary of Changes: 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.

Training: E-mail announcement with scheduled training sessions
ADAMS Accession No.: ML040060258



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*See Previous Concurrence

Position	Primary Contact	Responsible Manager	D:PMAS:NRR
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Date	01/06/2004	01/23/2004	02/09/2004

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NRR OFFICE INSTRUCTION
LIC-101
Revision 3
License Amendment Review Procedures

1. POLICY

Section 182a of the Atomic Energy Act (the "Act") requires applicants for nuclear power plant operating licenses to include technical specifications (TSs) as part of the license. The Commission's regulatory requirements related to the content of TSs are stated in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.36, "Technical specifications." Regulatory requirements related to the amendment of operating licenses, including the appended TSs, are contained in 10 CFR 50.90, "Application for amendment of license or construction permit," 10 CFR 50.91, "Notice for public comment; State consultation," and 10 CFR 50.92, "Issuance of amendment."

This guidance should be utilized to the greatest extent possible for operating and decommissioned plants. Where license amendments are specifically mentioned in this document and its attachment, it is understood that the guidance should apply, where appropriate, to other licensing actions. For example, the guidance on Requests for Additional Information (RAIs) should be utilized in dealing with any licensing action (exemptions, reliefs, etc.) for which the staff asks the licensee for additional information.

2. OBJECTIVES

This office instruction, along with the attached document, provides all staff in NRR a basic framework for processing license amendment (and other licensing actions, where applicable) applications.

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 are 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) of 96% < 1 year old and 100% < 2 years old)
- Ensure that staff RAIs are adding value to the regulatory process
- Provide NRR staff with an improved framework for processing license amendment applications.

The attached "Guide for Processing License Amendments" provides a general description of the process.

3. BACKGROUND

LIC-101 was issued on August 20, 2001 and superceded NRR Office Letter 803, "License Amendment Review Procedures." Revisions 1 and 2 to LIC-101 included changes to the format of safety evaluations, 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 is being issued as a result of the following:

- implementation of the NRR work planning center (WPC)
- several additional changes suggested through the PIP
- several updates and clarifications related to template safety evaluation, requests for additional information, and other parts of the license amendment process

4.0 BASIC REQUIREMENTS

The attached guidance describes a procedure for processing amendments to operating licenses requested by licensees. The process includes the following subprocesses:

- work plan preparation, which, in conjunction with the WPC and appropriate technical review branches, the NRR Project Manager (PM) is expected to coordinate. The guidance addresses planning the license amendment action, including obtaining a Technical Assignment Control (TAC) number, reviewing the application for completeness, searching for precedent licensing actions, identifying technical issues, determining technical complexity, developing estimates of resources required, and coordinating activities of various personnel involved in reviewing and issuing the amendment
- public notification and comment resolution, which provides guidance on procedures for the public notification of license amendment actions
- safety evaluation preparation which provides guidance for the planning and conduct of the safety review and the preparation of the safety evaluation
- review and concurrence which provides guidance for the concurrence process by which the quality of the amendment package is assured
- amendment preparation and issuance which provides guidance on the final issuance or denial of the amendment.

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 attached "Guide for Processing License Amendments." They also are responsible for identifying possible improvements to the guidance and submitting suggestions for such improvements to their management or to the assigned contacts for this office instruction.

The following describes these responsibilities in greater detail.

LICENSE AMENDMENTS FOR OPERATING REACTORS

The sections that follow describe specific responsibilities and authorities for each sub-process in processing a license amendment request.

A. PREPARATION OF THE WORK PLAN

Division of Licensing Project Management

Project managers (PMs) are responsible for the general oversight and coordination of NRR activities related to processing license amendments. They are responsible for the following specific activities in preparing a work plan:

- Obtain a Technical Assignment Control (TAC) number for the amendment to ensure fee recovery and allow tracking of the work activities.
- Review the amendment request for completeness and acceptability.
- Perform the initial search for precedent licensing actions.
- Complete the PM's Work Planning and Characterization Form (Blue Form)
- Coordinate the initial work plan, as necessary, with the WPC and technical branches.
- Review responses from other organizations on Work Planning and Characterization Forms (Green Forms) and resolve any issues regarding review coordination, review characterization, and essential planning information.

Licensing assistants (LAs) shall assist PMs perform the activities listed above.

Section Chiefs (SCs) and other managers shall help in the development and approval of work plans, as requested by PMs, to ensure effective allocation of resources, responsiveness to licensees' requests, and quality work.

NRR Work Planning Center (including divisional planning representatives)

- Assign TAC numbers to incoming applications
- Distribute applications and appropriate work planning and characterization forms (blue and green forms)
- Update electronic databases
- Periodically review data for problems, trends, or other insights

Technical Divisions/Branches

Staff from the technical branches shall work with PMs, and WPC to ensure that the amendment processing plan is complete and the scope, resources, and schedule are sufficient to perform the required safety review.

Section chiefs, senior staff, and other managers shall, as necessary, help in the development and approval of work plans to ensure effective allocation of resources, minimal changing of staff reviewers midstream, responsiveness to licensees' requests, and quality work.

Staff responsible for Standard Technical Specifications (STs) shall help resolve questions regarding the relevance of STs to the amendment request.

B. PUBLIC NOTIFICATION AND COMMENT RESOLUTION

Division of Licensing Project Management

Project managers are responsible for the following activities regarding any required public notifications:

- Prepare and submit the first public notification. This includes the following actions:
 - reviewing the licensee's analysis of no significant hazards consideration issues and determining its adequacy for use in the public notification
 - reviewing the proposed amendment, implementation dates, and other information and determining what type of public notification is required
 - preparing the notification for submittal to the Federal Register
- Resolve any public comment.
- Coordinate NRR activities related to the hearing process.
- Prepare and submit any additional public notifications, including those due to licensee changes in the amendment request and the final notification of amendment approval, denial, or withdrawal.

Licensing assistants shall help PMs coordinate the publication of notices related to license amendments.

Technical Divisions/Branches

If asked by the PM, personnel from the technical branches shall assist in evaluating the licensee's analysis of issues related to no significant hazards considerations, preparing the *Federal Register* notification, resolving public comments, and participating in the hearing process.

C. PREPARATION OF THE SAFETY EVALUATION

Division of Licensing Project Management

Project managers are responsible for the following in preparing the safety evaluation (SE):

- Perform the safety review, when appropriate.
- Coordinate assistance from technical branch personnel, as required.
- Coordinate with technical branch personnel if scope, resources, or due dates need to be changed for any reason. Inform all affected parties of changes PM initiates to the previously established work plan, including the divisional planning representatives for each section involved in the review.
- Ensure that the regulatory basis and framework are clearly articulated in the SE.
- The staff should use the format and content guidance for SEs that is described in Section 4.5 of the attached guidance. An exception to this is those SEs prepared using previously issued SEs as a precedent. The staff should use their judgment regarding the benefits of using the precedent (e.g., efficiency, consistency) versus the benefits of the standardized format.
- Generally, technical branches need only provide the regulatory and technical evaluations sections of an SE. PMs are responsible for providing the remaining sections of the SE.

Technical Divisions/Branches

Staff from the technical branches are responsible for the following in preparing the safety evaluation:

- Provide informal guidance to the PMs on the safety review, if asked.
- Perform safety evaluations, when appropriate, within scope, resources, and time limits established in the work plan (green form as modified by discussions with PM)
- Coordinate with the PM if scope, resources, or due dates need to be changed for any reason. Inform the divisional planning representative of changes to the previously established work plan so that databases may be updated.
- Ensure that the regulatory basis and framework are clearly articulated in the SE.
- The staff should use the format and content guidance for SEs that is described in Section 4.5 of the attached guidance. An exception to this is those SEs prepared using previously issued SEs as a precedent. The staff should use their judgment regarding the benefits of using the precedent (e.g., efficiency, consistency) versus the benefits of the standardized format.
- Generally, technical branches need only provide the regulatory and technical evaluations sections of an SE.

NRR Management

Division of Licensing Project Management (DLPM) and technical branch management shall resolve any disagreements between PMs and technical staff regarding the scope, resources, and deadlines for safety reviews.

D. REVIEW AND CONCURRENCE OF THE AMENDMENT PACKAGE

Division of Licensing Project Management

Project managers are responsible for the following activities regarding review and concurrence:

- Ensure that the review and concurrence chain includes all of the individuals responsible for the quality of the amendment. Check the review guidance responses from other organizations on the work planning and characterization form (green form) and have organizations concur, or resolve that concurrence is not needed.

- Ensure that staff hours charged are reasonable when compared to the status of the review, estimates in the work planning and characterization form (green form), 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.

Licensing assistants shall review the amendment package and ensure that it is complete and correct.

The Office of the General Counsel (OGC) shall review all amendment packages for legal adequacy and defensibility, unless an agreement is reached that specific amendments do not require OGC concurrence (as described in Section 8 of the attached guide on the Consolidated Line Item Improvement Process (CLIIP)).

Technical Divisions/Branches

Staff from the technical branches are responsible for the following activities:

- Review and concur on amendment packages if the SE was not prepared by technical branch staff (except when concurrence authority has been given to PMs or lead PMs for actions such as amendments under the CLIIP).
- Review and concur on amendment packages if the SE was prepared by technical branch staff when the PM has made substantial changes.
- Review and concur in a timely manner, consistent with the amendment implementation schedule and NRC concurrence policies.

NRR Management

DLPM and technical branch management shall, as necessary, resolve any disagreements between the staff 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.

E. PREPARATION AND ISSUANCE OF THE AMENDMENT

Division of Licensing Project Management

Project managers and LAs shall coordinate and perform those activities related to issuing the approval or denial of license amendments.

6. **PERFORMANCE MEASURES**

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

7. **PRIMARY CONTACTS**

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8. **RESPONSIBLE ORGANIZATION**

NRR/DLPM/PDIV

9. **EFFECTIVE DATE**

February 9, 2004

10. **REFERENCES**

None.

Attachments:

1. Appendix A: Change History
2. Appendix B: Guide for Processing Licensing Amendments, Revision 3

Appendix A - Change History

**Office Instruction LIC-101, Revision 3
“License Amendment Review Procedures**

LIC-101 Change History - Page 1 of 2			
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	Recommended reading for technical staff supporting license amendments. Required Reading and Training Sessions(s) for DLPM Training presentation to be developed for NRR web page.
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	Recommended reading for all DLPM staff and technical staff supporting license amendments. Training sessions for staff in DLPM, DE, and DSSA

LIC-101 Change History - Page2 of 2

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>

**United States
Nuclear Regulatory Commission**

Appendix B

**Guide for Processing License
Amendments
Revision 3**

Contents

Abbreviations iii

1.0 Introduction 1.1

 1.1 Objectives 1.1

 1.2 Process Overview..... 1.2

2.0 Work Planning 2.1

 2.1 Obtain TAC Number 2.1

 2.2 Review Application for Completeness and Acceptability..... 2.2

 2.3 Search for Precedent Licensing Actions..... 2.3

 2.4 Develop a Work Plan..... 2.5

3.0 Public Notification 3.1

 3.1 Routine Bi-weekly Notice..... 3.2

 3.2 Individual Notice (w/ NSHCD) 3.3

 3.3 Individual Notice (w/o NSHCD) 3.3

 3.4 Exigent (14-day) Notice 3.4

 3.5 Exigent Local Notice..... 3.4

 3.6 Emergency Amendments 3.4

 3.7 Other Comments on Notifications..... 3.5

4.0 Safety Evaluation 4.1

 4.1 Evaluation Planning and Control 4.1

 4.1.1 Contractor Review 4.2

4.2 Using Precedent Safety Evaluations and References to Topical Reports.....	4.2
4.3 Requests for Additional Information.....	4.3
4.4 Regulatory Commitments	4.5
4.5 Safety Evaluation Format	4.6
4.5.1 Introduction	4.6
4.5.2 Regulatory Evaluation	4.7
4.5.3 Technical Evaluation	4.8
4.5.4 Other	4.8
5.0 Review and Concurrence	5.1
6.0 Amendment Preparation and Issuance	6.1
7.0 Risk-Informed Licensing Action Guidance	7.1
7.1 Introduction.....	7.1
7.2 Responsibilities	7.1
7.2.1 Definitions	7.1
7.2.2 DLPM	7.2
7.2.3 The Lead Technical Review Branch.....	7.3
7.2.4 SPSB.....	7.4
7.3 Guidelines for Using Risk-Informed Information in Regulatory Decision-making.....	7.4
7.4 SPSB Involvement in Licensing Action Reviews.....	7.5
8.0 Consolidated Line Item Improvement Process	8.1
9.0 Official Agency Records.....	9.1
Attachment 1 - License Amendment Worksheet and Instructions	A.1-1
Attachment 2 - Amendment Routing Form	A.2-1
Attachment 3 - Safety Evaluation Template.....	A.3-1

Abbreviations

ADM	Office of Administration
ADPT	Associate Director for Project Licensing and Technical Analysis
CLIIP	Consolidated Line Item Improvement Process
CFR	<i>Code of Federal Regulations</i>
DE	Division of Engineering
DIPM	Division of Inspection Program Management
DSSA	Division of Systems Safety and Analysis
DLPM	Division of Licensing Project Management
EA	Environmental Assessment
FR	<i>Federal Register</i>
IROP	Reactor Operations Branch
LA	Licensing Assistant
LAN	Local Area Network
NRC	Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NSHC	no significant hazards consideration
NSHCD	no significant hazards consideration determination
OAR	Official Agency Record
OGC	Office of the General Counsel
PD	Project Director or Project Directorate
PDR	public document room

PM	Project Manager
PMAS	Program Management, Policy Development and Analysis Staff
PRA	probabilistic risk assessment
RAI	request for additional information
RILA	risk-informed licensing action
RLEP	License Renewal and Environmental Impacts Program Directorate
SC	Section Chief
SE	safety evaluation
SECY	Office of the Secretary of the Commission
SPSB	Probabilistic Safety Assessment Branch
SRP	Standard Review Plan
STS	Standard Technical Specifications
TAC	technical assignment control
TB	Technical Branch
TRIM	Time, Resource, and Inventory Management System
TS	Technical Specifications
TSTF	Technical Specifications Task Force (also used for a proposed generic change to STS)
UFSAR	Updated Final Safety Analysis Report
WPC	Work Planning Center

1.0 Introduction

This guide provides staff in the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Reactor Regulation (NRR) with a basic framework for processing license amendment applications.⁽¹⁾ The guide is for use by Project Directors (PDs), Section Chiefs (SCs), Project Managers (PMs), Licensing Assistants (LAs), and their management; as well as Technical Branch (TB) staff and management. This guide provides a general description of the process to be followed. However, it is recognized that amendments are reviewed and issued under various conditions that require flexibility in the planning and execution of application reviews. This guide is intended to allow that necessary measure of flexibility. In addition, guidance contained in this document may be used, where appropriate, for the processing of other licensing action requests such as exemption requests, relief requests, Quality Assurance (QA) Plan changes, Emergency Plan (EP) changes, Security Plan changes, and other requests requiring prior NRC approval where specific guidance is not provided in a related office instruction.

1.1 Objectives

The objective of this guide is to help NRR enhance its efficiency in responding to the needs of both the licensees and the public. Specific objectives include the following:

- ensure the public health and safety are maintained
- promote consistency in processing of license amendments
- improve internal and external communications

(1) Although some guidance in this document may be relevant to the processing of conversions to the improved Standard Technical Specifications and for the renewal of operating licenses in accordance with 10 CFR Part 54, separate processes and staff guidance govern the disposition of these types of licensing actions (see Office Instruction RNWL-100 for license renewal). In addition, additional guidance may be available for specific types of license amendments (e.g., Review Standard (RS)-001 for extended power uprates and Regulatory Guide 1.174 for risk-informed licensing actions).

- increase technical consistency for similar licensing actions
- reduce delays in the issuance of license amendments (e.g., meet licensing action completion timeliness goals)
- ensure that staff RAIs add value to the regulatory process
- provide NRR staff with an improved framework for processing license amendment applications.

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. PMs, TB 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 applications. Pre-application review meetings or conference calls (discussions regarding future licensing action requests prior to the request being submitted) between the licensee and staff members are encouraged to allow sufficient exchange of information about technical and/or resource planning issues. See RITS Users Guide for appropriate time reporting information.

The PM's role 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 these guidelines associated with Office Instruction LIC-101, "License Amendment Review Procedures," and the principles of good regulation are adhered to throughout the process. PMs and TB staff are jointly responsible for ensuring that NRR meets the goals established in operating and performance plans. The process employed for amendment request applications can be characterized by the following subprocesses:

- work planning
- public notification and comment resolution
- evaluation of proposed amendment
- document conclusion and independent basis in safety evaluation
- amendment preparation
- review and concurrence
- amendment issuance

Each of these subprocesses is described in detail in the following chapters. Section 2.0 discusses the work planning process, Section 3.0 discusses the public notification process,

Section 4.0 discusses the safety evaluation (SE) process, Section 5.0 discusses the review and concurrence process, and Section 6.0 discusses the amendment preparation and issuance process. Section 7.0 addresses the use of risk insights in the licensing process. Section 8.0 discusses the use of the Consolidated Line Item Improvement Process (CLIIP). Section 9.0 provides guidance on recordkeeping requirements for the license amendment process.

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 Process Improvement Form (PIF) as described in ADM-101, "NRR Process Improvement Program."

With respect to the processing of license transfer applications, this guidance should be utilized for the license amendment portion of the license transfer. Requirements for license transfer applications are contained in 10 CFR 50.80 and additional guidance is available regarding transfer-specific orders, notices, and reviews. Please consult Office Instruction LIC-107, "License Transfers," for more information.

2.0 Work Planning

Planning the processing of an amendment application is a critical step in ensuring that the work is completed in a timely and effective manner. As in most planning activities, the basic questions to be addressed are *Who?*, *What?*, *Where?*, and *When?* This section describes a series of steps that should be addressed by the staff in developing an amendment review work plan. These steps are:

1. Obtain a technical assignment control (TAC) number using the Time, Resource and Inventory Management (TRIM) software. This provides a means of billing the licensee and tracking the work.
2. Review the application to ensure that it contains sufficient information for the staff to begin a meaningful review. The PM may involve the technical branches in this initial review of the application based on its technical complexity and feedback may be received during the work planning and characterization process. (refer to Section 2.2)
3. The staff should identify, assess, and review information about precedents set by similar licensing actions, after determining that an application is complete (i.e., sufficient to initiate a formal staff review).
4. Review the amendment and related information in sufficient detail to develop a work plan that defines the scope, depth, resources, and schedule of the remaining work (e.g., to complete the appropriate work planning and characterization forms (blue and green forms)).
5. Upon completion of the work planning and characterization forms, the PM and technical branches should ensure that the work plan reflected in the responses are complete and reasonable (e.g., appropriate branches will be providing input or concurrence, resource estimates reflect complexity and similarity to precedent, and schedules meet defined needs).

The remainder of this chapter provides guidance concerning the performance of each of these five planning activities. During periodic calls with the licensee, the PM should provide feedback to the licensee on the status of license amendment processing activities for the licensee's applications (such as on the results of the acceptance review, work plan, and technical review). Additional information related to the staff's responsibilities for environmental assessments is contained in LIC-203, "Environmental Assessments and Considerations" More detailed information pertaining to risk-informed licensing submittals is contained in Section 7.0 of this Office Instruction. The handling of license amendments associated with CLIIP is described in Section 8.0.

2.1 Obtain TAC Number

Technical assignment control (TAC) numbers are used to categorize work and determine fee recovery. The Program Management, Policy Development and Analysis Staff (PMAS) within NRR routinely issues guidance for obtaining TAC numbers. The request for a TAC number initiates the WPC process of distributing the Work Planning and Characterization Forms (blue and green forms). PMs should request a TAC number as soon as possible following the receipt of the application.

2.2 Review Application for Completeness and Acceptability

After the PM requests a TAC number and as soon as practical following receipt of the application, the task of reviewing the amendment application for completeness should begin. The PM may involve the technical branches in this initial review of the application based on its technical complexity. The PM may also receive input for the acceptability review on the work planning and characterization forms (green forms) received from other branches. The minimal requirements for amendment applications are described in 10 CFR 50.4, 50.90, 50.91, and 50.92. The following guidance highlights key elements that should be contained in a license amendment application. It is provided to assist PMs in their initial screening process. The guidance is not an interpretation or a substitute for conforming with the legal requirements of the regulations, nor does the guidance itself constitute an absolute requirement. The key elements in an amendment application are listed below:

- description of the amendment (including discussions on the content of the current license condition or technical specification, the proposed change and why the change is being requested, how it relates to plant equipment and/or operating procedures, whether it is a temporary or permanent change, and the effect of the change on the purpose of the technical specification or license condition involved.)
- no significant hazards consideration determination (50.92)
- licensee's safety analysis/justification for the proposed change (The application should specify the current licensing basis that is pertinent to the change (e.g., codes, standards, regulatory guides, or Standard Review Plan (SRP) sections). The safety analysis that supports the change requested should include technical information in sufficient detail to enable the NRC staff to make an independent assessment regarding the acceptability of the proposal in terms of regulatory requirements and the protection of public health and safety. It should contain a discussion of the analytical methods used, including the key input parameters used in support of the proposed change. The discussion also should state whether the methods are different from those previously used and whether the methods have been previously reviewed and approved by the staff.
- oath and affirmation (O&A)⁽²⁾

(2) Oath or affirmation may be in the form of a notarized statement or may be within the cover letter for an amendment in the form of a sentence similar to the following:

"I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on [date]".

- requested review schedule and/or implementation period
- appropriate technical specification (TS) pages
- environmental assessment, or categorical exclusion pursuant to 10 CFR 51.22(c)
- copy to appropriate State

If a licensee's amendment application does not include one or more of the preceding items, the PM should contact the licensee and arrange for the information to be submitted. Under these circumstances, the licensee may withdraw the request or may correct the deficiencies within a mutually agreed upon time. In some circumstances, the staff may elect early in the review process to identify the deficiencies in a submittal via an RAI to the licensee and include a due date for the response. If the licensee does not correct the deficiencies within the specified time, the amendment may be denied (see 10 CFR 2.108, "Denial of application for failure to supply information"). If an application is withdrawn or denied due to a deficiency in the submittal (as opposed to a definitive, negative finding by the staff based on the technical merits of the proposed changes), then a licensee may submit a new application (with the identified discrepancies corrected) in the future.

The PM should also perform a preliminary assessment to determine the subject and scope of the licensee's proposed amendment. This assessment is necessary for the subsequent steps in this guide and should also provide an initial position regarding the reasonableness of the proposed changes and the adequacy of the licensee's no significant hazards consideration determination (NSHCD). If, based upon this review, the staff finds the licensee's NSHCD to be inadequate, the PM may prepare a staff determination for publication in the *Federal Register* (or in rare cases may request that the licensee supplement the original submittal). If a proposed change does not satisfy the criteria in 10 CFR 50.92 for publication of a proposed NSHCD, an individual notice allowing an opportunity for a hearing must be published without including a proposed NSHCD (see Section 3.0).

The PM should determine if the licensee's submittal includes any proprietary information. The PM is responsible for the review of the material requested to be withheld from the public to ensure that the information satisfies the criteria of 10 CFR 2.790. PMs may find additional guidance pertaining to proprietary information in LIC-204, "Handling Requests to Withhold Proprietary Information From Public Disclosure," and may also get assistance in making this determination from LAs, TB staff, and OGC.

Oath or affirmation statements are required on license amendment requests and supplements to such requests, including responses to requests for additional information.

2.3 Search for Precedent Licensing Actions

Precedent licensing actions are those with a similar proposed change and regulatory basis for the SE. Searching for, identifying, and using precedents in the review process maximizes staff efficiency, minimizes the need to issue requests for additional information and ensures consistency of licensing actions. The search for a precedent should continue until NRR staff are satisfied that either 1) they have identified one or more appropriate precedents, or 2) that no appropriate precedents exist. PMs have the primary responsibility for conducting a precedent search but can be assisted by TB staff familiar with specific technical areas. The identification of similar precedent licensing actions will increase the efficiency of the license amendment review process by reducing expended resources of both the NRC and the licensee. It is the expectation that PMs will utilize the following resources in their precedent search as early as possible in the planning process to realize this efficiency. Staff should consult with their colleagues or managers to obtain training or guidance if they are unfamiliar with the use of any of these mechanisms.

Licensees - Licensees and their contractors have developed systems to identify precedent amendments and often share information related to requests and the staff's evaluation. Some licensees include such information in the submittal while others will provide the information informally following a request by the PM.

Staff Input - Discussion with other PMs and TB staff is frequently useful in identifying precedents. If necessary, PMs should consult the License Renewal and Environmental Impacts Branch (RLEP) about environmental issues (see LIC-203).

Staff Guidance - Guidance issued by lead PMs and TB staff may include model safety evaluations for some classes of amendments. Examples include the guidance related to the relocation of TS requirements to the Updated Final Safety Analysis Report (UFSAR), generic letters that provide line item improvements, and the CLIP.

Internal NRC Home Page (<http://nrr10.nrc.gov/projects/sersrch.htm>) - This software application can be used to search for safety evaluations related to the subject(s) of the amendment request as well as searches of the SRP, generic communications, and other NRC documents. Safety evaluations dating from 1990 to 2000 were entered into the set of searchable safety evaluations.

Agency-wide Documents Access and Management System (ADAMS) - This software application can be used to search for amendments as well as other official agency records. Full-text searches are available for all records submitted to the NRC after October 31, 1999, (records submitted prior to or on this date can be searched using a combination of bibliographic data and full text documents in the ADAMS Legacy Library).

Time, Resource and Inventory Management (TRIM) System - This software application can be used to identify precedent licensing actions by searching for TAC titles or individual words used in TAC titles.

Standard Technical Specifications (STSs) - A comparison of the amendment request with appropriate sections of the corresponding improved STS may result in the identification of current policy pertinent to the amendment request being processed. If the licensee is

proposing a change that is modeled after the STS, the expanded bases sections of the STS will often contain discussion that will aid in preparing a safety evaluation.

Federal Register Notices - The biweekly collection of proposed and issued amendment notices in the *Federal Register* can be scanned to search for similar amendment requests. Searches of notices in the *Federal Register* are possible via the web site of the National Archives and Records Administration.

In general, preference should be given to the most recent precedents identified. Additional considerations for the use of precedents is provided in Section 4.2. Discussions with the appropriate TB(s) may help determine the appropriate precedent to use for a specific amendment review. Upon completing the assessments of available precedents, the information should be used to complete the work planning and characterization forms (blue and green forms).

If one or more appropriate precedents are identified, the PM should note if an Environmental Assessment (EA) was necessary for the amendment or if the precedents referenced a categorical exclusion. Actions that are categorically excluded are identified in 10 CFR 51.22. If no precedent exists the PM should determine if an EA is necessary. Additional guidance related to environmental assessments is provided in LIC-203.

2.4 Develop a Work Plan

Following the preliminary assessment and search for precedent actions, the necessary information should be available to develop a detailed plan for processing the amendment application. This plan is intended to define the scope and depth of the review, resources needed for the review, and the schedule for completion of the review. Increasingly, license amendment applications are submitted in the same time frame that affect multiple facilities (operated by a single licensee or separate licensees as part of cooperative arrangements). The staff should ensure that it is aware of and properly accounts for such applications when they develop work plans.

The work plan is developed by the PM and technical branches. PM work planning and characterization forms (blue forms) are used to initiate the process.⁽³⁾ Following the completion of the blue form, the application is distributed by the WPC for input from other branches. The branches may indicate that review or concurrence is appropriate. Estimates of hours and schedules are included. Following the return of the green forms, the PM should assess the responses and ensure that the process has resulted in a work plan that meets desired goals, includes reasonable estimates given complexity/risk-significance of application and availability of precedents, and includes all appropriate technical areas. Questions regarding responses to the green forms should be directed to the appropriate branches and the WPC (through divisional representatives).

(3) Amendments processed under emergency circumstances are coordinated by PM and do not require completion of work planning forms.

Upon completion of the planning process, the PM should communicate the results (i.e., the categorization of the application on the work planning and characterization forms, estimated technical review staff-hours, and completion times) to the licensee. The PM and TB should resolve any concerns or issues raised by the licensee with respect to the staff's planning of the application review. The PM and TB should also monitor progress to ensure the review will be completed within a reasonable range of staff-hour estimates.

For reviews being performed by a TB, changes in the safety evaluation completion date or estimated staff hours need to be negotiated between the PM and TB designee. Requests for additional information (RAIs) should be prepared such that a licensee can respond and the initially agreed upon schedule can be maintained. However, the timeliness of a licensee to respond to RAIs may occasionally impact the schedule and require a revised schedule be developed. Issues should be elevated to the next higher level of management for resolution if there are internal disagreements about a schedule change, if a proposed schedule change adversely affects meeting the Agency's performance goals, or if a change introduces a significant burden on a licensee or other external stakeholder. Any significant changes in the expected staff-hours associated with a review or the schedule of the review should be coordinated with all affected parties, including divisional planning representatives, and discussed with the licensee.

3.0 Public Notification

The public notification process is the primary mechanism for the NRC to meet its goal regarding openness to the public. The staff requirement to determine whether an amendment request involves no significant hazards consideration (NSHC) and to seek public comment and provide an opportunity for a hearing regarding the proposed amendment is defined in 10 CFR 50.91 and other regulations. Additional guidance regarding NSHC determinations (NSHCD) can be found in the *Federal Register* publication of the final rule and supplementary information (51 FR 7751). The no significant hazards consideration standard is a procedural criterion that governs whether an opportunity for a prior hearing must be provided before action is taken by the NRC, and whether prior notice for public comment may be dispensed with in emergency situations or shortened in exigent circumstances⁽⁴⁾.

Power uprates were originally listed as an example of amendments that would likely involve a significant hazards consideration (see example v in supplementary information (51 FR 7751)). The staff informed the Commission in SECY-01-0142, "Proposed No Significant Hazards Consideration Determinations

(4) Although it may be legally permissible to issue an amendment for which a hearing has been requested, provided that the staff prepares a final no significant hazards determination, NRR Office Director concurrence and Commission notification are required if the staff plans to do this (see Section 5.0).

for Amendments to Increase Rated Thermal Power for Nuclear Power Reactors,” dated July 27, 2001, that the staff would assess power uprates using the criteria in 10 CFR 50.92, “Issuance of amendment.” As described in SECY-01-0142, the staff may use the experiences gained to date in issuing power uprates to support a likely finding that a requested power uprate involves a NSHC. The staff should be cautious in noticing proposed extended power uprates (uprates of more than several percent power) with proposed NSHC determinations until experience with such reviews demonstrates that such applications can meet the standards of 10 CFR 50.92. Power uprates may meet the standards for NSHC determinations and thereby may seem to satisfy categorical exclusion criterion 9 in 10 CFR 51.22. The staff should review the Final Environmental Statement (FES) for the subject unit(s) before applying the categorical exclusion. If the power level or value of other parameters assumed in the FES do not bound the proposed conditions associated with a power uprate amendment, an environmental assessment (EA) should be prepared even if the uprate amendment is noticed with a proposed NSHC determination.

The majority of amendment requests are found to satisfy the no significant hazards consideration criteria and can therefore be handled in the routine fashion. The regulations specify that the normal course of business is to provide a 30-day comment period following publication of a description of the proposed amendment, along with its associated proposed NSHCD. If the staff determines that the request involves no significant hazards consideration, the regulations allow for issuance of the amendment with less than a 30-day comment period. A brief summary of the various public notification alternatives is provided below. Licensing PMs are expected to prepare the notice as soon as practicable following receipt of an incoming amendment request and completion of the acceptance review. Early publication of the NSHCD notice ensures that the desired notice period is met. Template formats exist for both the staff's acceptance of the licensee's NSHCD and a determination prepared by the staff. The latter is occasionally used by PMs when they prepare the proposed NSHCD (e.g., when PMs choose to write the NSHCD for technical or editorial reasons). 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.

Licenses will often supplement submittals with additional information and changes to the original proposed amendment. The SE should include a discussion of any changes submitted by the licensee. Supplements to the amendment request, including those that revise TS pages or provide clarifying information in response to an RAI, should be submitted under oath or affirmation. The Office of the General Counsel (OGC) has advised that any significant change to the original submittal should be re-noticed. The amendment issued should be all or part of the amendment application noticed with only changes that are within the scope of the notice description permitted without re-notice. Changes or additional information that are within the scope of the notice description need to be addressed in the SE or notice of amendment issuance and provided in a submittal from the licensee on the docket with a finding that they were within the scope of the original notice and initial proposed no significant hazards consideration determination. Early consultation and coordination with licensees is extremely valuable in terms of minimizing the potential need for re-noticing.

3.1 Biweekly 30-day Proposed⁽⁵⁾ (30-day comment period on proposed NSHCD)

The normal process is to publish a notice in a biweekly collection of notices in the *Federal Register*. The Biweekly Report only deals with proposed no significant hazards consideration determinations (NSHCDs). The deadline for collection of the notices for a given biweekly publication is approximately two weeks prior to the publication date. This time combined with the 30-day comment period results in an effective minimum period of between six to eight weeks from the date of submittal to the end of the comment period. The proposed NSHCDs to be included in the biweekly notice are collected and compiled by the administrative staff in DLPM.

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- (5) In early 2004, a rule change related to the NRC's hearing processes will become effective. The rule change extends the period for the opportunity to request a hearing period from 30 days to 60 days. The period for commenting on the NSHCD remains 30 days. Note that although 10 CFR 50.91 solicits comments only on the proposed NSHCD, the NRC staff has routinely addressed comments related to any aspect of the application. The change from a 30-day period for opportunity to request a hearing to a 60-day period reinforces the need for the staff to promptly notice the receipt of and NRC consideration of amendment requests (i.e., the noticing process should not be allowed to delay the overall amendment process and noticing should occur as soon as practicable after receipt). When the rule becomes effective, the minimum time period from receipt of an application to issuance an amendment using the routine biweekly process is changed from 6-8 weeks to 10-12 weeks.

3.2 Individual 30-day Proposed ⁽⁶⁾ (30-day comment period on proposed NSHCD)

If the required schedule for issuance of an amendment will not accommodate the normal biweekly publication of the notice, an individual notice can be published in the *Federal Register*. The staff should use the standard notice format and consult with the Rules and Directive Branch (ADM) to accomplish this task. Publication of an individual notice can be accomplished in three to four working days depending on the time of day that the notice is submitted to the Rules and Directive Branch; an individual notice will therefore support issuance of an amendment approximately five weeks after the amendment request is submitted.

3.3 Individual 30-day No Proposed⁽⁷⁾ (30-day period to request a hearing)

For those amendments for which the staff does not find that the criteria for a NSHCD have been clearly satisfied, an individual notice in the *Federal Register* will describe the amendment request and state that the amendment will not be issued prior to a hearing unless the staff makes a determination that the amendment involves no significant hazards considerations. When the staff issues a Notice of Consideration of Issuance of Amendment to Facility Operating

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- (6) The rule change becoming effective in early 2004 will also affect the individual notice with a proposed NSHCD. The notice will provide a 60-day period to request a hearing and a 30-day comment period for the proposed NSHCD. Following the rule change, an individual notice (most likely with a proposed NSHCD) should be used for amendment requests where the timing of the application allows for a 30-day comment period but may not allow for the full 60-day period to request a hearing. If appropriate, amendment requests that can not provide the full 30-day comment period will continue to be processed using the exigent provisions discussed in Sections 3.4 and 3.5. The staff must prepare and include in the SE a final NSHCD for amendments issued prior to the end of the 60-day period available for a person to request a hearing.
- (7) The rule change becoming effective in early 2004 will extend to 60 days the period to request a hearing. The staff must prepare and include in the SE a final NSHCD for amendments issued prior to the end of the 60-day period available to request a hearing.

License And Opportunity For a Hearing without a proposed NSHC determination, the notice includes the following statement:

If a request for a hearing is received, the Commission's staff may issue the amendment after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 50.92.

The notice issued by the staff provides neither a proposed NSHC determination nor a definitive finding that the subject amendment involves a significant hazards consideration. In such cases, the staff will make a finding regarding NSHC only if a request for a hearing is received. As a result of previous NRR procedures for processing license amendments, these notices are sometimes referred to as "Category 3" notices. These amendments would not meet the categorical exclusion criteria in 10 CFR 51.22 and require an EA.

3.4 Exigent 14-day Proposed ⁽⁸⁾

If a license amendment request is submitted with a need date of more than seven days but less than four or five weeks in the future, the request should be processed under the exigent circumstances discussed in 10 CFR 50.91. The preferred exigent process is to use a shortened public notice period in the *Federal Register*. The regulation states that the comment period must be at least two weeks and maintains the normal 30-day period to request a hearing. In general, the content of the notice is the same as a normal individual notice except for the shortened comment period. The safety evaluation must include a final NSHCD and a section that justifies the use of the exigent circumstances process. Because of the time required for document distribution, incoming amendment applications should be sent to the public document room (PDR) and placed in ADAMS as soon as possible for exigent amendment requests.

(8) Note that the exigent and emergency provisions of Sections 3.4, 3.5, and 3.6 are basically unchanged by the rule change becoming effective in early 2004. The period available to request a hearing is extended to 60 days, but otherwise the exigent and emergency amendment processes, including the noticing requirements and need to include a final NSHCD in the SE, are not changed.

3.5 Exigent Local Proposed

For those amendment requests that require disposition in less time than needed for a 2-week comment period in the *Federal Register*, the regulation provides an alternative. The second type of exigent amendment application involves the use of local media to provide reasonable notice to the public in the area of the licensee's facility. The standard practice for this alternative has been to secure advertising in local newspapers. The NRC process to prepare an announcement, receive concurrences, and arrange funding normally requires at least two to three days. Newspapers usually require receipt of the announcement two working days before publication. Allowing several workdays for a comment period results in a minimum time of approximately seven workdays 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. Because the announcement refers the public to the PDR and ADAMS to review the licensee's request, PMs need to ensure that copies of the incoming amendment application are placed in those locations before publication of the advertisements. While there is no legal minimum time required for notification prior to granting the amendment, the PM should try to provide several days of prior notice. The safety evaluation must include a final NSHCD and a section that justifies the use of the exigent circumstances process.

3.6 Emergency

The provision for issuing amendments under emergency situations is contained in 10 CFR 50.91(a)(5) where it states,

“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 hearing or for public comment.”

A final NSHCD is provided in the safety evaluation and the notice of amendment issuance announces the opportunity for a hearing and public comment after issuance. Another limitation related to the use of this alternative is that the licensee must explain why the emergency situation occurred and why it could not avoid the situation, and the staff must determine, and document in the SE, that the licensee has not abused the emergency provision.

Use of the emergency provisions should be limited to those cases in which the staff cannot solicit public comment using the exigent circumstances discussed in the previous sections. As a rule of thumb, if a valid amendment request is submitted with less than seven days before the need to issue the amendment, the request should be processed under emergency circumstances if the licensee has shown that an emergency situation exists.

The emergency provisions are also used for those amendment requests that have been noticed, remain within the comment period, and changes in circumstances require issuance prior to the expiration of the comment period. Because the use of the emergency provision requires licensees to explain why the condition could not have been avoided, the licensee is requested to submit an explanation of the change in circumstances and formally request the issuance of the amendment before the expiration of the comment period.

3.7 Other Comments on Notifications

For spent fuel pool expansion applications, a hybrid hearing process (see 10 CFR Part 2, Subpart K) is used and specific wording to that effect must be placed in the FR notice.

The NRC will occasionally receive a response to its publishing of a notice regarding the NRC's consideration of issuing an amendment, proposed NSHCD, and opportunity for a hearing. Requests for hearings are addressed in NRR Office Instruction LIC-201, "NRR Support to Hearing Process."

The NRC may also receive comments or questions about a proposed license amendment from members of the public or designated State officials. Although the notice published by the NRC is officially requesting comments on the proposed NSHCD, the staff has traditionally addressed any comments received regarding a proposed amendment. The staff should respond to questions about a proposed license amendment in a manner appropriate to the form of the inquiry. For example, a question from a designated State official about a proposed amendment that is posed during a routine telephone conversation might be responded to by the staff during that conversation and need not be addressed in an official agency record. Questions or comments received from the public or State may, however, warrant a written response from the NRC staff. The staff may elect to respond to questions or comments upon rendering its decision on the proposed amendment. In this case, the staff would normally include in the SE associated with the license amendment a description of the comment and the staff's response to the comment. If the comment is from the designated State official, this description should be provided in the section of the SE entitled "State Consultation." Comments from members of the public may either be addressed within the technical evaluation section of an SE (e.g., a paragraph might be added in that part of the SE addressing the subject matter of the comment) or a separate section entitled "Public Comments" may be inserted into the SE. The staff should consider whether it would be helpful to respond to questions or comments from the public or designated State officials by telephone or correspondence prior to issuing an amendment.

4.0 Safety Evaluation

The SE provides the technical, safety, and legal basis for the NRC's disposition of 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 a license amendment request, the information relied upon in the SE must be docketed correspondence.

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. This guide does not provide specific guidance on the technical performance of evaluations. PMs and 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 risk-significance and technical complexity of the proposed change, the availability of precedent reviews, the timeliness goals, the principles of good regulation, the operating plan, and other governing procedures such as the Standard Review Plan). General guidance regarding SE planning and control, the use of precedents, guidelines on requesting additional information, and the recommended format of SE reports is provided below. A template for a typical SE is provided in Attachment 3. In addition, a template with macros to assist in preparing the SE and forwarding memorandum from a technical branch to DLPM is available on a common network drive (S:\macros) for DE and DSSA (See Michael Waterman for assistance with or questions about using the template and macros on the DE/DSSA S: drive).

4.1 Evaluation 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 the technical complexity of the review, the risk significance of the proposed change, and the availability of an appropriate precedent SE.

Tools for completing the evaluation include those previously described for finding precedent reviews. In addition, various applications on the NRC Local Area Network include documents containing technical guidance (regulations, regulatory guides, the Standard Review Plan, generic communications) and selected other documents. Using the computer applications to perform word searches on this collection of documents enhances the PM's ability to prepare evaluations. This is especially true for amendment applications that are not introducing significant changes to the traditional licensing-basis methodologies. The PM must review the precedent for accuracy, applicability, and completeness against the details of the submittal and the plant.

PMs may also request some assistance from technical staff during a review for which the PM is preparing the SE. This request can be accomplished informally by discussing the amendment request with appropriate technical staff or by negotiating technical staff assistance using the work planning process (see Section 2).

The PM may also provide input regarding the licensee's performance for use in the assessment of licensee performance. The PM is responsible for assembling the appropriate input (whether input is initiated by the PM or by the TB), for the proper documentation of the assessment in the amendment cover letter to the licensee, and the forwarding of the assessment to the appropriate regional contact for possible entry into the plant issues matrix. As appropriate, the PM should provide feedback, either orally for routine situations or in the amendment cover letter for special circumstances, to the licensee regarding the quality of its submittals. This feedback should identify specific instances of good or bad performance with respect to meeting regulatory requirements and supporting effective and efficient NRC staff reviews.

4.1.1 Contractor Review

Occasionally, technical staff will use contractors to assist in performing a review. PMs should treat the amendment the same as a technical staff review and communicate with the technical staff member designated as the contract's technical monitor. PMs should work with the technical monitor to establish the level of review, schedule, and the statement of work.

4.2 Using Precedent Safety Evaluations & References to Topical Reports

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

- ▶ maximize the use of precedents 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 giving an alternative concurrence process
- ▶ ensure that the precedent being used corresponds to the issued SE and not intermediate versions or drafts. Use of the final SE (as issued) for the precedent will ensure that the staff is consistent and 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 (to avoid the appearance of being arbitrary and/or inconsistent). The staff should assess any change in position to ensure that the safety or regulatory issue warrants the negative implications regarding our principles of good regulation (e.g., efficiency, clarity, and reliability). The staff should also ensure that changes in staff position are assessed to determine if the change could constitute a plant-specific or generic backfit (see LIC-202 and LIC-400).

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 an approved topical report is appropriate for the subject change and its supporting analysis. The reviewer should ensure that supporting analyses that refer to an approved 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 their 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

Requests for additional information (RAIs) serve the purpose of enabling the staff to obtain all relevant information needed to make a decision on a licensing action request that is fully informed, technically correct, and legally defensible. RAIs are necessary when the information was 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 requirements related to the amendment application, and consistent with the applicable codes, standards, regulatory guides, and/or the applicable Standard Review Plan sections. RAIs should not be used as general information requests or as a means to encourage commitments from licensees. This guidance can be utilized for other licensing actions such as exemption and relief requests.

The transmittal of RAIs from technical branches to DLPM should follow ADM-200, "Delegation of Signature Authority" (i.e., the questions should be approved by the appropriate Section Chief, team leader, or senior staff member, as authorized by the Section Chief). The transmittal of RAIs from technical branches to DLPM may be in the form of e-mails or memoranda (see Section 9.0 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 of request
- ▶ technical complexity of request
- ▶ risk significance of issue in question
- ▶ existence of precedent amendments
- ▶ appropriate scope and depth of review
- ▶ resource implications for both the staff and the licensee
- ▶ information already on the docket

The following guidance is provided for common RAI concerns:

1. Questions included in the formal RAI should ask for information that is required to make the 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.
2. 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 application. 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 safety, multiple 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 multiple RAIs, arrange for a site visit, etc).

3. 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 are required to notify the licensee prior to requesting the licensee to submit additional information to support the staff's review of a licensing action. 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. This due date should be reflected in the RAI on its issuance. To help resolve the issues, preliminary questions may be faxed or e-mailed to the licensee prior to the meeting or conference call. Answers 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. All of the staff's questions shall be docketed using one or a combination of the following methods: (1) forwarding an official RAI to the licensee by letter, (2) generating a memo to file (publicly available), 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.

4. 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.⁵ Questions should be specific rather than overly broad, and the response to the RAI should be of value to the staff's safety evaluation basis.
6. If an RAI is issued and the licensee's response does not fully address the RAI, the PM will set up a meeting or conference call attended by the PM, TB reviewer and licensee management to discuss the discrepancy and what needs to be provided to the staff on a timely basis in order to complete the amendment review. Failure of the licensee to provide timely information may result in a denial or withdrawal of the amendment based on a deficiency in the submittal as opposed to a definitive, negative finding by the staff based on the technical merits of the proposed change. The licensee may submit a new application (with the identified discrepancies corrected) in the future.
7. If a disagreement arises with the licensee regarding the appropriateness of an RAI or whether or not the information was provided, the issues should be raised immediately to the appropriate level of management for proper resolution.
8. Consistent with Section 4.2, the staff should make use of previous reviews in order to avoid asking unnecessary questions.
9. The staff should not use license amendments as an opportunity to force licensees to take actions beyond those that relate directly to the amendment and are needed to provide reasonable assurance of plant safety (see LIC-202 (OL 901), "Plant-Specific Backfits").
10. The timely issuance of an RAI, if necessary, and the licensee's agreed upon time to respond should be factored into the schedule established to complete the review within the licensing action timeliness goals.

The intent of this guidance is not to limit the staff from getting the information that is needed to perform a technical review; rather, this practice is needed to ensure that the information requests will be productive and focus staff and licensee resources on the pertinent issues necessary to make a regulatory decision.

4.4 Regulatory Commitments

During the review of license amendment applications, the staff will base its findings on a variety of information provided by the licensee. Some information considered important by the reviewer will not be addressed specifically in the affected technical specifications (which would require prior NRC approval of subsequent changes). Those matters considered important to the staff but not requiring the staff's prior approval of subsequent changes have been traditionally referred to as commitments. It is important to consider commitment management in its proper context as an integral part of licensees' and the NRC staff's control of each facility's licensing-basis information. A hierarchy of licensing-basis information relating to the change control and reporting processes is described in LIC-100, "Control of Licensing Bases for Operating Reactors."

As to the part of the licensing basis that involves regulatory commitments, the staff's acceptance of guidance issued by the Nuclear Energy Institute (NEI) on managing commitments made to the NRC is described in Regulatory Issue Summary (RIS) 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to The NRC Staff." Additional guidance related to regulatory commitments is provided in Office Instruction LIC-105, Office Instruction LIC-105, Managing Commitments Made by Licensees to the NRC."

The escalation of an action proposed by a licensee as a commitment into a license condition, requiring prior NRC approval of subsequent changes, should be reserved for matters that satisfy the criteria for inclusion in technical specifications by 10 CFR 50.36 or inclusion in the license to address a significant safety issue. Routine commitments on technical matters that do not satisfy the above criteria for license conditions should be discussed in the staff's safety evaluation but should not be escalated into formal license conditions; licenses that have been amended to

capture routine commitments may be revised in future license amendment requests to delete the special appendix. If the staff determines that a license condition imposed in a recently created appendix should be maintained as an obligation as described in the hierarchy of licensing basis information, the condition may be added to the operating license (license conditions are located in Section 2.C of most operating licenses).

For the time being, the staff should continue imposing conditions on license amendments that involve, as a vital element of the staff's approval, the subsequent placement of information in a particular mandated licensing-basis document. Commonly, this type of amendment relocates requirements from a facility's technical specifications to its UFSAR. The condition will be imposed along with other legally binding aspects of the amendment (e.g., when the amendment is effective and when the amendment must be implemented) on the amendment page (usually listed as item 3) that is signed by an authorized member of the NRR staff. These conditions are generally not added to the operating license (i.e., Section 2.C).

4.5 Safety Evaluation Format

There are several sections of a typical SE, which are described below. Attachment 1, "License Amendment Worksheet," provides additional guidance, in a checklist form, for the content of some of the key sections of an SE. Attachment 3, "Safety Evaluation Template," provides a template for a typical SE. These should be used by PMs and TB staff to quickly assess the completeness of key sections of the SE. Additional questions or surveys regarding the content of SEs may be requested as part of the NRR Integrated Quality Initiative (IQI). In addition, while generally consistent with this guidance, SEs prepared for some license amendments such as power uprates and risk-informed amendments, may differ somewhat from the checklist. The staff should consult applicable guidance (e.g., Review Standard-001 and RG 1.174) and/or recent precedents to identify special features for these types of SEs. The SE (and the licensee's submittal) must document the regulatory decisions associated with a specific license amendment application. On August 24, 2001, the Nuclear Energy Institute (NEI) issued a white paper entitled "Standard Format for Operating License Amendment Requests from Commercial Reactor Licensees" (ML013390222). The standard format for licensee amendment applications provides sections which correlate to certain sections in the SE format specified here. When technical branches are providing input to the PM for use in an SE, they need only provide the Regulatory Evaluation and Technical Evaluation sections. The staff should prepare SEs using the format and content guidance discussed below and in Attachment 1. An exception to this is those SEs prepared using previously issued SEs as a precedent. The staff should use their judgment regarding the benefits of using the precedent (e.g., efficiency, consistency) versus the benefits of the standardized format.

4.5.1 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 in parentheses immediately following the reference (would usually be used for SEs with reference to a small number of agency records) or may be provided in the optional reference section.

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.

4.5.2 Regulatory Evaluation

The regulatory evaluation section [provided by the primary reviewer(s)] provides the regulatory framework for the licensing action. The following structure is recommended:

- A short description of the purpose of the system, function, or program that is the primary subject(s) of the application. The functional level or programmatic level description should be followed by a description of the particular feature, subsystem, component, or program element addressed by the subject specification(s). This information can usually be found in the licensee's application, the associated TS Bases, the FSAR, or other general references. An example would be to describe (in a general manner) how the emergency core cooling system is intended to mitigate an accident and then describe the role of the subject subsystem.
- A short description of the purpose or bases for the requirement(s) that are affected by the proposed change. An example would be how a required completion time limits the unavailability of the subject subsystem. This information can usually be found in the associated Bases section of plant-specific TS or corresponding STS.
- A short description of the regulatory background of the requirement(s) associated with the current design or program. This may include reference to the appropriate review criteria in a regulatory guide, standard review plan, or industry standard. If useful, the relationship to NRC regulations may be provided. Additional background information regarding the regulatory context for the requirement(s) may include reference to generic communications, event reports, or previous license amendments. This discussion is simply intended to provide sufficient background for a reader of the SE to put the matter in the appropriate

regulatory context and understand the subsequent technical evaluation. The staff should avoid adding references to regulations or other documents that are not directly related to the subsequent technical evaluation. For example, 10 CFR 50.36, "Technical specifications," should not be referenced for most TS changes (e.g., change in a completion time or surveillance test interval) since the rule and related guidance will not be relevant to the technical decision regarding the details of a proposed TS requirement. A reference to 10 CFR 50.36 and related documents may, however, be appropriate for a change involving the relocation of a requirement to a Technical Requirements Manual since the change would directly involve the regulatory requirements for the content of TS.

- I. A short description of important precedents associated with the amendment application. This may include reference to previously issued amendments for other facilities, topical reports, TSTFs, or other documents that establish a precedent for a proposed change. As discussed in Section 4.2, staff decisions to not apply specific precedents, especially precedents cited by a licensee, should be clearly explained.

4.5.3 Technical Evaluation

The technical evaluation section [provided by the primary reviewer(s)] documents the staff's evaluation of a proposed change against the relevant regulatory criteria. The evaluation should include a description of the proposed changes and an analysis of the proposal in terms of

regulatory requirements, established staff positions, industry standards, or other relevant criteria. 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). The safety evaluation should be specific as to what information is relied on to form the basis for approving or denying the amendment request. The evaluation should also contain the staff's specific conclusion that the proposed change is acceptable in terms of public health and safety. Very broad statements such as "the staff evaluated the changes and found them acceptable" do not provide sufficient justification for a licensing action. Information contained in the SE should be consistent with the licensee's submittal(s), should not contradict the submittal(s), and should not impose any commitments not agreed upon by the licensee in the submittal(s).

If the staff does not agree with some significant information included in a licensee's application, the staff should discuss the issue with the licensee and either have the licensee revise their application or discuss the issue in the safety evaluation. The staff may also state in an SE that certain information provided by a licensee in an application was not considered essential to the staff's review and was not reviewed by the staff. See Attachment 1, "License Amendment Worksheet," and Attachment 3, "Safety Evaluation Template," for more information.

4.5.4 Other

In addition to the technical considerations of the SE, the issued amendment may include the following sections.

- **Regulatory Commitments** - [to be developed jointly by PM and primary reviewer(s)] Safety evaluations for amendment requests containing regulatory commitments should discuss the commitments and should explicitly state that the staff finds that the subject matter is adequately controlled by the licensee's administrative programs. If an amendment includes numerous regulatory commitments, a separate section in the SE may be used to list the commitments and state the staff's finding regarding classification of the information as regulatory commitments. Typical wording regarding regulatory commitments is as follows:

[Statement of Regulatory Commitment(s)...] The NRC staff finds that reasonable controls for the implementation and for subsequent evaluation of proposed changes pertaining to the above regulatory commitment(s) are best provided by the licensee's administrative processes, including its commitment management program(See Regulatory Issue Summary 2000-017, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff"). The above regulatory commitments do not warrant the creation of regulatory requirements (items requiring prior NRC approval of subsequent changes).

- **Emergency/Exigent Provisions** - [provided by PM] Safety evaluations for amendments processed using the emergency or exigent provisions of 10 CFR 50.91 must include a section that supports a finding that the licensee has used its best efforts to make a timely application.

- **Final No Significant Hazards Consideration Determination** - [provided by PM] Safety evaluations for amendments issued using the emergency or exigent provisions or for amendments for which a hearing has been requested must include a final NSHCD.⁽⁹⁾
- **State Consultation** - [provided by PM] This section states that the NRC has consulted with the appropriate State official in accordance with 10 CFR 50.91. 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 SE.
- **Environmental Considerations** - [provided by PM] This section lists the appropriate categorical exclusion from 10 CFR 51.22 to explain why the staff did not prepare an EA. The PM determines if the amendment meets a categorical exclusion or not. For those amendments involving an EA, this section will reference the assessment's publication in the *Federal Register*. Note that PMs should plan for the fact that the EA and finding of no significant impact must be published in the *Federal Register* prior to the issuance of the amendment.
- **Conclusion** - [provided by PM] This section states the staff's conclusion that the amendment will not endanger public health and safety.
- **References** - [to be developed jointly by PM and primary reviewer(s)] All documents referenced in the SE should be readily available for public inspection (if not proprietary) in the NRC PDR or available for purchase from other sources in the public domain such as Government Printing Office, the National Technical Information Services, university or special technical libraries, or the originating organizations. Documents in ADAMS should include the ADAMS accession number.

(9) After the rulemaking associated with NRC hearing processes becomes effective in early 2004, amendments issued before the expiration of the 60-day period providing opportunity to request a hearing must include a final NSHCD, even if the amendment did not need to be treated as exigent because the amendment is issued after the 30-day comment period.

5.0 Review and 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. When the concurrence chain is determined, the name, title, and organization of each individual should be entered on an amendment routing form (Attachment 2). 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 under the consolidated line item improvement process). PMs should review the responses to the work planning and characterization forms (green forms) to determine those organizations that have requested concurrence. Any questions regarding the required concurrences should be resolved between the PM and technical branches and reported to the appropriate WPC staff.

Licensing Assistants concurrence is intended to ensure uniformity and consistency and to ensure that the package is complete, in the correct format for text and graphics, and all the required steps have been completed.

When the SE is prepared by the TBs, the PM has the responsibility for integrating it into the overall amendment package. If, during this integration, the PM makes substantial changes to the SE, the TB individual involved in the preparation of the original SE should be an early reviewer in the concurrence chain to ensure that there is no change in technical content or original intent. In any case, the concurrence page should indicate the TB originator of the SE. SE input from a TB that is used with only minor editorial changes does not need additional concurrence by that TB. When TB concurrence is not necessary, include the appropriate TB in a concurrence block and note that SE input dated [].

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

The staff should seek out and fully consider whatever information may help ensure that our activities serve to maintain the public health and safety. An issue identified during the review of the possible contributions to the reactor vessel head degradation at Davis Besse was that information available to the licensee and regional inspectors may not have been appropriately considered during licensing action reviews performed by NRR. The staff should consider whether current system conditions, equipment reliability, human performance data, industry experience, or other information could be relevant to a specific regulatory decision. Informal inquiries can be made through routine interactions with licensees, regional NRC staff, or other contacts. When information is deemed important to support the regulatory decision, the staff should follow established procedures and protocols to ensure that the information is appropriately placed into the agency's recordkeeping system.

In limited cases, it may be appropriate to get input from or request verification of facts by resident inspectors or other inspection staff assigned to a regional office (e.g., the staff's findings are based on assumed operator actions, specific plant configurations, or other

considerations where insights from inspection staff would be useful). Any requests for assistance from a regional office should follow appropriate procedures and protocols (e.g., Inspection Procedure 71005, "Inspector Review of Licensing-related Information"). Significant resource requests from regional staff may also require coordination with the Inspection Program Branch in NRR. Visits to sites by NRC headquarters personnel to support licensing reviews should also be coordinated with regional offices to minimize conflicts and unnecessary burdens on the licensee.

If all concurrences cannot be achieved due to differences of opinion within the staff, additional meetings or conference calls with the licensee may be necessary to resolve the issue. Due consideration should be given to the level of involvement of the licensee in the resolution process and, in any case, the licensee should be kept informed of the status of the resolution. Licensee involvement may not be appropriate for purely internal issue resolution such as discussions concerning staff policy. If resolution cannot be achieved or the staff otherwise plans to deny an amendment application, the licensee should be informed prior to forwarding the official denial. The licensee should be given a reasonable time to decide whether to withdraw the application or request a meeting with NRR staff and management.

LIC-203 provides guidance related to RLEP concurrence on EAs.

OGC must concur on all license amendments except under previously agreed upon conditions (e.g., the process described in Section 8.0 for the consolidated line item improvement process (CLIIP)). OGC reviews the amendment package for legal defensibility and completeness. The information and justifications required for OGC concurrence are addressed directly in the various sections of this instruction, directions to the staff regarding the use of plain language, and in other staff procedures and guidance documents.

To assist those requested to concur, amendment packages should include:

- copy of the license amendment
- copy of the SE
- copy of the incoming license amendment request, including all related docketed correspondence
- copy of the *Federal Register* notice (or the forwarding memorandum)
- copy of any relevant background information, including similar evaluations used in preparing the SE, related internal documents, and easily attached reference material
- memorandum forwarding the *Federal Register* notice of issuance
- routing form, including the applicable SRP section number

- 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. Section Chiefs or their designees (possibly the PMs must provide final concurrence for all amendments processed, or must confirm and document amendment package correctness by their signature on the amendment cover letter and amended license.

NRR Office Director concurrence and Commission notification at least 5 days prior to issuance is required for any license amendment for which:

1. the staff has made a final no significant hazards consideration determination, and
2. a hearing has been requested, which will not be concluded prior to issuance of the amendment.

6.0 Amendment Preparation and Issuance

After the required concurrence signatures are obtained, the amendment package is issued to the licensee and the notice of issuance (or denial) is sent to the Rules and Directives Branch (ADM) for transmittal to the *Federal Register*. The State contact person must be called for comments, especially with respect to the no significant hazards consideration (NSHC), prior to issuance of an amendment. The Office of Administration and the Office of the Secretary are contacted prior to issuance to determine if comments from the public or petitions to intervene were received on the proposed amendment. The final package should include:

- a letter transmitting the amendment to the licensee for signature by PM
- a standard distribution or "cc:" list
- the license amendment for final signature by the appropriate level of management (consult ADM-200 for the current practices regarding the delegation of signature authority)
- the revised TS or license pages
- the SE, with reference to an EA if appropriate (the EA is issued as a separate document)
- input to the biweekly *Federal Register* notice or a separate *Federal Register* notice of issuance
- listing for internal distribution to TB, IROP, Regions, etc.

The staff should ensure that the issuance of the amendment package and related documents addresses the recordkeeping requirements of the agency. See Section 9, "Official Agency Records (OARs)," for additional guidance.

7.0 Risk-informed Licensing Action Guidance

7.1 Introduction

Risk-informed regulation is the use of insights and results derived from Probabilistic Risk Assessments (PRAs) in combination with traditional engineering (deterministic) analyses to focus licensee and regulatory attention on issues commensurate with their importance to safety.

It is the Commission's desire that the NRC and the industry make appropriate use of risk-informed regulation in their daily work. The objectives of risk-informed regulation are to enhance safety decisions and make more efficient use of industry and NRC resources. This section provides guidance for processing risk-informed license amendment requests, as well as non-risk-informed amendment requests.

7.2 Responsibilities

7.2.1 Definitions

Risk-Informed Licensing Action (RILA)

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. Mere mention of quantitative or qualitative risk insights does not in itself make a licensing action risk-informed.

Risk-Informed Licensing Panel (RILP)

The Risk Informed Licensing Panel is made up of Division Directors in NRR that participate in licensing reviews, as well as representatives from the Office of General Counsel (OGC) and the Office of Nuclear Regulatory Research (RES). One of the main purposes of the panel is to streamline the review of risk-informed licensing actions by serving as a focal point for resolution of technical issues and for guidance on policy implementation to the NRR staff. This panel will provide a forum for the staff, licensee, owners groups, and the public to receive management attention on risk-informed issues. The panel will also monitor the overall implementation of risk-informed licensing actions.

Very low risk significance

An issue in which risk is expressed numerically is of very low risk significance if it results in a risk decrease, is risk neutral (i.e., it has no effect on risk or the change is too small to measure accurately), or results in an increase of less than $\sim 1\text{E-}6$ per reactor year (mean value) to core damage frequency (CDF) estimates, or an increase in large early release frequency (LERF) of less than $\sim 1\text{E-}7$ per reactor year.

Low to moderate risk significance

An issue in which risk is expressed numerically is of low risk significance if it results in an increase to CDF estimates in the range of $\sim 1E-6$ to $\sim 1E-5$ per reactor year (mean value) or an increase in LERF in the range of $\sim 1E-7$ to $\sim 1E-6$ per reactor year.

Substantial risk significance

An issue in which risk is expressed numerically is of substantial risk significance if it results in an increase to CDF estimates greater than $\sim 1E-5$ per reactor year (mean value) or an increase in LERF greater than $\sim 1E-6$ per reactor year. Note that a “substantial risk increase” should not normally be approved. In fact, approving a change that allows such a risk increase would result in a risk contribution meeting the criteria for consideration of a backfit analysis and possible action to correct the very situation. Guidance that would allow such a circular “approval” and “consideration for backfit” cycle would be inappropriate.

Special circumstances

Conditions or situations that raise concerns about whether there is adequate protection, and that could rebut the normal presumption that compliance with existing regulations provides adequate protection. In such situations, undue risk may exist even when all regulatory requirements are satisfied.

7.2.2 Division of Licensing Project Management

PMs should apply the guidance contained in this Office Instruction in determining the involvement of the Probabilistic Safety Assessment Branch (SPSB) in the review of the submittal. PMs should consult SPSB when any questions arise concerning the submittal review.

The PM should:

- (1) Determine if the submittal is risk-informed (using the above definition and guidance).
- (2) Identify a lead review branch, with SPSB marked for PRA review support.
- (3) Discuss the scope of the review required with the responsible technical branches.
- (4) Send a copy of the submittal to SPSB.
- (5) Ensure that RAIs are focused and are seeking a scope and depth of information in line with the risk significance of the licensing action
- (6) Assess all non-risk-informed licensing action and activity submittals to seek to identify if 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 reviewer suspects that there is such a potential, the nature of the concern should be documented and forwarded along with the submittal to SPSB for joint review and consultation.

- (7) Bring conflicts between branches, divisions, or offices regarding the risk-informed submittals to the RILP by contacting SPSB.

7.2.3 The Lead Technical Review Branch

The branch chief should:

- (1) Ensure that RAIs dealing with a risk-informed submittal are sent to SPSB for review and concurrence. Note that review of RAIs is frequently delegated to section chiefs.
- (2) Ensure that potentially significant risk impacts of all non-risk-informed licensing actions are considered in the staff's review, and that SPSB has been consulted as appropriate.

The NRR lead branch reviewer should:

- (1) Coordinate or consult with SPSB regarding determination of the risk significance of the issue.
- (2) Work with SPSB to identify strengths and limitations of a licensee's risk evaluation.
- (3) Follow the guidance of SRP 19. Note it is expected that the lead reviewer will use good judgment in developing a scope of review commensurate with the risk importance of the issue.
- (4) Work with SPSB to determine an appropriate balance between traditional engineering (deterministic) and probabilistic review, based on the risk significance of the licensee's request.
- (5) Assess all non-risk-informed licensing action and activity submittals to seek to identify if 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 reviewer suspects that there is such a potential, the nature of the concern should be documented and forwarded to the PM for joint review and consultation with SPSB.

7.2.4 SPSB

The branch chief should

- (1) Be responsible for the timeliness of the SPSB review of the risk-informed submittal.
- (2) Ensure that RAIs generated by SPSB are appropriate for the risk significance of the issue.

- (3) Concur in the appropriate level of traditional engineering (deterministic) and probabilistic review. This function is normally delegated to section chiefs.
- (4) Concur in any staff determination regarding the existence of “special circumstances,” and elevate the issue for review by the RILP as appropriate.

The SPSB reviewer should

- (1) Help the lead reviewer determine the risk significance of the risk-informed submittal, or the risk-related issues associated with a non-risk-informed submittal.
- (2) Help the lead reviewer determine the level of traditional engineering (deterministic) and risk review needed for the submittal, based on the risk significance of the issues involved.
- (3) Provide a detailed review or audit of the risk-informed submittal, including a description of the depth and scope of the review performed.

7.3 Guidelines for Using Risk Information in Regulatory Decisionmaking

Use of risk information should be considered in the staff review of both licensee-initiated risk informed license action requests, as well as license action requests in which the licensee chooses to not submit risk information.

The requested changes, and the need for and effectiveness of any compensatory measures that might be warranted because of risk considerations, should be addressed by evaluating the changes relative to the safety principles and integrated decisionmaking process defined in RG 1.174. The following safety principles, which are articulated in the regulatory guide, should be met: (1) the proposed change meets current regulations unless it is explicitly related 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 result in an increase in risk, the increases should be small and consistent with the intent of the Commission’s Safety Goal Policy Statement, and (5) the impact of the proposed change should be monitored using performance measurement strategies. The risk acceptance guidelines (Sections 2.2.4 and 2.2.5 of RG 1.174) describe acceptable levels of risk increase as a function of total core damage frequency (CDF) and large early release frequency (LERF) and the manner in which the acceptance guidelines should be applied in the review and decisionmaking process. The guidelines serve as a point of reference for gauging risk impact but are not legally binding requirements.

The final acceptability of the proposed change would be based on a consideration of current regulatory requirements, as well as on adherence to the safety principles, and not solely on the basis of a comparison of quantitative PRA results with numerical acceptance guidelines.

Situations that exceed RG 1.174 guidance could constitute a trigger point at which questions

are raised as to whether the proposed change provides reasonable assurance of adequate protection. Examples include amendment requests that have a substantial risk increase (exceeding the risk acceptance guideline), are not effectively abated by compensatory measures, and do not meet other safety principles. A more in-depth assessment of the special circumstances, the safety principles, and the issues identified for management attention in Section 2.2.6 of RG 1.174 would then be made in order to reach a conclusion regarding the level of safety associated with the requested change. The authority provided by the Atomic Energy Act and current regulations requires rejection of a license amendment request if the NRC finds that adequate protection is not provided.

7.4 SPSB Involvement in Licensing Action Reviews

The general approach to determining the character of SPSB's role depends more on the technical content of the submittal than on the submittal type, although some generalities may be drawn based on historical analysis. Only a fraction of submittals need to be seen by SPSB, even in today's risk-informed environment. This results from several factors:

The general approach to determining the character of SPSB's role depends more on the technical content of the submittal than on the submittal type, although some generalities may be drawn based on historical analysis. Only a fraction of submittals need to be seen by SPSB, even in today's risk-informed environment. This results from several factors:

- ▶ Many submittals deal with legal or administrative changes, or simple inconsistencies in technical specifications, rather than substantive safety issues.
- ▶ Many submittals deal with technical issues whose resolution take place at a level of detail that lies below the level at which risk models are applied.
- ▶ Many submittals deal with licensing issues that are driven by safety concerns other than major core damage or large release.
- ▶ Many submittals are related to wholesale conversion of technical specifications, or to changes with such clear precedence that resources to review them in-depth cannot be justified.

A set of rules has been established, based on historical analysis of SPSB involvement in previous submittal reviews, that seeks to identify licensing action requests that need to be examined at the level of the integrated risk model, which requires SPSB involvement. Such changes either qualitatively affect the set of possible scenarios, or affect the frequency at which existing scenarios occur, meaning that time, frequency, or probability parameters are changing. Changes that qualitatively affect the scenario are termed "configurational."

In order to apply these rules, the overall submittal must be summarized in terms of an issue or issues whose joint resolution are required for approval/disapproval of the submittal. A determination should be made as to SPSB involvement at each issue level. For example, a submittal may raise only an allowed outage time (AOT) issue; a complex submittal may argue that less redundancy is necessary in a particular system based on a thermal hydraulic (T/H) analysis. The latter submittal should be broken down into the following two issues: the validity

of the T/H analysis and the risk implications of the proposed LCOs, given that the T/H analysis is valid. The former issue is called a “specialty topic” and needs to be resolved by the cognizant TB, while the latter issue may need to be resolved at the risk model level by SPSB, depending upon the details of the change requested. The decomposition of the submittal into discrete issues should be performed by the PM with assistance from SPSB, if required.

In rare situations, a license amendment request could introduce significant and unanticipated risks even when all regulatory requirements are satisfied. These situations, termed “special circumstances” represent conditions or situations that raise questions about whether there is adequate protection, and that could rebut the normal presumption of adequate protection from compliance with existing regulations. In general, a special circumstance may exist if: (1) the situation was not identified or specifically addressed in the development of the current set of regulations, and could be important enough to warrant a new regulation (e.g., a risk-informed regulation) if such situations were encountered on a widespread basis, and (2) the reviewer has knowledge that the risk impact is not reflected by the licensing basis analysis, and reason to believe that the risk increase would warrant denial or attaching conditions to the staff’s approval, if the request were evaluated as a risk-informed application. Examples include license amendment requests which, if approved, could substantially increase the likelihood or consequences of accidents that are risk-significant but beyond the design and licensing basis of the plant, or degrade multiple levels of defense or cornerstones in the reactor oversight process through plant operations or situations not explicitly considered in the development of the regulations. The process and controls for evaluating the existence of special circumstances, requesting risk information from the licensee, and using risk information in judging the acceptability of non-risk-informed license amendment requests are provided in Appendix D of SRP 19.

Identification of a special circumstance would impact the “no significant hazards consideration” finding under 10 CFR 50.91. If identified as a potential special circumstance during initial processing, the amendment request should be noticed without a proposed NSHCD (see Section 3.3). These amendments would not meet the categorical exclusion criteria from 10 CFR 51.22 and require an Environmental Assessment. If determined to be a special circumstance after the staff has noticed the amendment request with a determination that no significant hazards consideration is involved, the amendment request should be re-noticed.

Table 1 provides general guidance to determine SPSB’s role in review of the license action request. If any questions exist, SPSB should be consulted. Please consult SPSB with any questions concerning phenomenological basis, special circumstances, etc.

Table 1 - Guidance on SPSB 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, et al.?	Consult with SPSB
	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?	Consult with SPSB
	Significantly changes functional requirements or redundancy?	Consult with SPSB
	Significantly changes operations that affect the likelihood of undiscovered failures?	Consult with SPSB
	Significantly affects the basis for successful safety function?	Consult with SPSB
	Could create "special circumstances" under which compliance with existing regulations may not produce the intended level of safety, and plant operation may pose an undue risk?	Consult with SPSB
	Completely consistent with deterministic requirements?	Conventional review.

8.0 Consolidated Line Item Improvement Process (CLIP)

8.1 Introduction

As described in NRC Regulatory Issue Summary 2000-06, "Consolidated Line Item Improvement Process for Adopting Standard Technical Specifications Changes for Power Reactors," licensees may request license amendments that have been previously assessed by the staff as part of the CLIP. Under the CLIP, the NRC staff reviews a proposed change to TSs that is expected to be requested for multiple plants. The standard process for proposing such generic changes is associated with the Technical Specification Task Force (TSTF) and their proposals to revise the Standard Technical Specifications.

The purpose of the CLIP is to streamline the license amendment review process involving TSTF changes applicable to multiple plants. By using a standardized process such as the CLIP, the burden on an individual licensee would be reduced by saving resources in preparing license amendment applications and, at the same time, the NRC staff review process would become more efficient. The flow chart provided in Figure 1 details the process flow for the CLIP. There are three required participants in the process flow map: the NEI TSTF, the NRC staff, and the licensees. In addition, all NRC stakeholders are provided an opportunity to comment on a proposed TSTF change before NRC acceptance of the change, as well as to participate in the licensing process for each license amendment application.

Figure 1
Consolidated Line Item Improvement Process (CLIP)

TSTF | NRC Staff | Licensee

The CLIP will improve the efficient adoption of NRC-accepted TSTF changes by having the

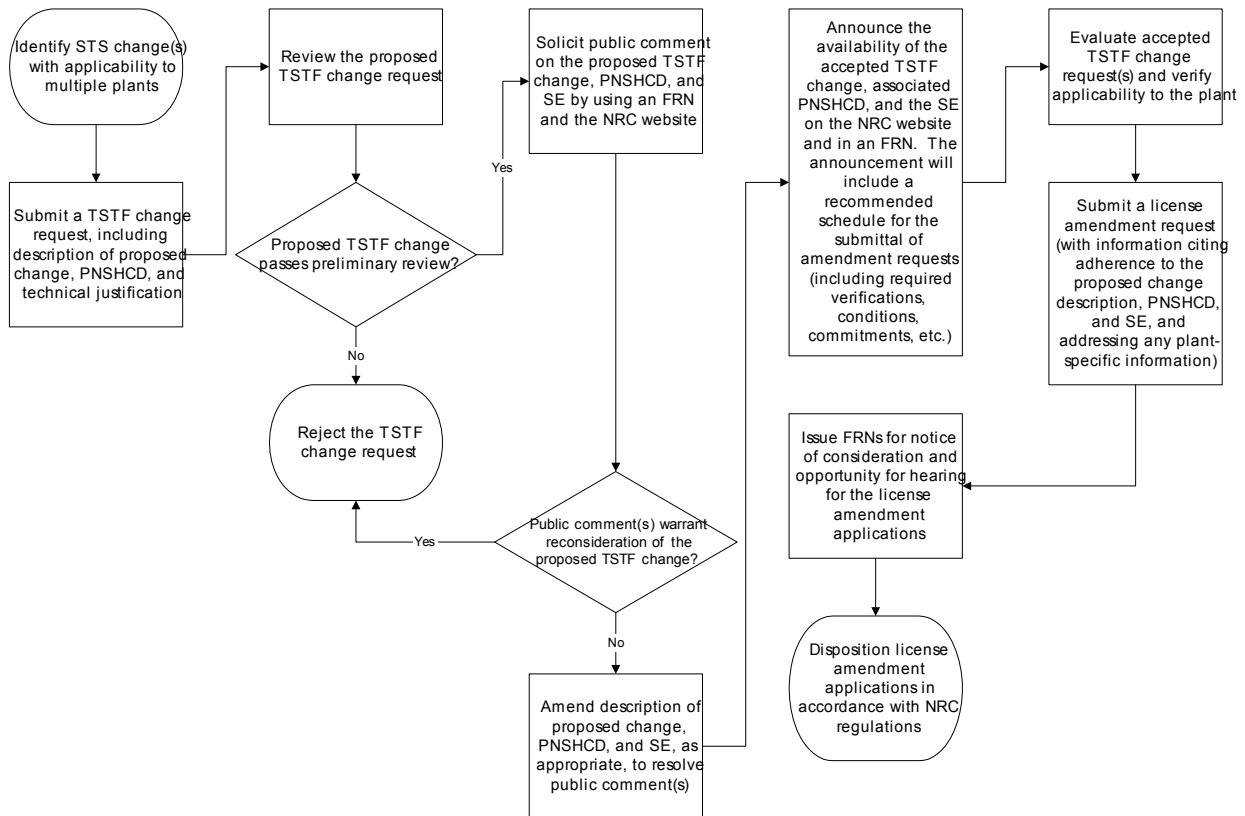
staff prepare and publish a safety evaluation (SE). A TSTF change request from the NEI TSTF will include a technical justification and a proposed NSHC determination as part of the proposal. The TSTF change process supports subsequent license amendment applications.

Following its preliminary review, the NRC staff (RORP and a lead PM from DLPM) will prepare a *Federal Register* notice (FRN) and update the NRC web site to inform and solicit comments from NRC stakeholders regarding the proposed TSTF changes that will be incorporated into the CLIP. The stakeholders will be provided with a description of the TSTF change, the staff's preliminary safety evaluation, and a preliminary NSHCD. After the NRC staff resolves the public comments, another FRN and the NRC web site will be used to notify NRC stakeholders if the TSTF change has been accepted by the NRC staff and, if accepted, that the TSTF change is available for adoption in proposed plant-specific license amendment applications.

The licensees desiring to adopt a specific TSTF change using the CLIP will need to verify that the proposed change is applicable to their facilities. The NRC announcement and the staff's SE will specify any plant-specific verification or other information required in licensees' applications. The licensees may apply for license amendments by citing the applicability of the NSHCD and SE for the accepted TSTF change and addressing any plant-specific information needed to support the staff's review. In order to obtain the maximum efficiency gains from the CLIP, the NRC will recommend that the licensees submit their applications within a specified time following the FRN announcing that the TSTF change has been accepted.

Each amendment application made as part of the CLIP will be processed and noticed in accordance with applicable rules and NRC procedures. When a PM receives an application submitted using the CLIP, the PM should open a TAC describing the amendment as follows -

Title: [Subject (e.g., "Deletion of Post Accident Sampling Requirements")] Using



CLIIP

PA Code/Activity Type for a license amendment
Review Method: PM

Upon receiving a TAC number, the plant-specific PM should take a copy of the application to the lead PM for the CLIIP item. The lead PM for the CLIIP item will in turn prepare the plant specific biweekly notice with the NSHCD and the plant specific license amendment package(s). The lead PM will complete or help complete the WPC blue form indicating the review will be completed within DLPM. The lead PM will likewise determine the need for input or concurrence from the TS Section or other technical branches. The WPC green forms completed by technical branches should generally assume no input or concurrence is required for plant-specific adoption of a CLIIP item noticed for availability.⁽¹⁰⁾

(10) Some generic changes approved through the TSTF process have not been prepared and noticed as available for adoption using the CLIIP. Most of these changes were approved before the CLIIP was developed. In order to gain the efficiencies envisioned for the TSTF process, work planning associated with plant-specific adoption of TSTF changes not processed using CLIIP should focus on the TS Section in DIPM/IROB (i.e., reviews and concurrences from the TS Section will usually suffice since the needed technical agreement was reached during the TSTF review). The TS Section will determine if there is a need for additional technical support for a particular plant-specific request for an approved TSTF.

Concurrence on the amendment package generally includes only the lead PM, the plant-specific PM, the licensing assistant, OGC, and the section chief (for the section containing the plant specific PM). The review and documentation of the lead PM should ensure that the CLIIP item applies to a specific facility, that the licensee has provided the requested verifications and commitments, and that the model SE and model NSHCD may be used for the requested amendment. Concurrences by the PM and LA normally assigned to a specific facility affirms that the CLIIP item applies to the subject facility, that the SE and NSHCD accurately reflect any plant-specific design features or operating practices, and the affected TS are revised. Concurrences by technical branches, including RORP, may be appropriate for some CLIIP items but these branches would generally concur on the models published in the FRN and not on specific license amendment packages. After several amendments are issued for a particular CLIIP item, OGC may inform the lead PM that OGC concurrence is not required for subsequent amendment packages. The lead PM should ensure that when OGC provides notification that their review is no longer required for a particular CLIIP item, this decision is documented as an Official Agency Record in ADAMS.

9.0 Official Agency Records (OARs)

9.1 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. Some records which have historical significance, such as records of the TMI-2 accident, are to be retained permanently. The retention requirement is met by adding the OAR to ADAMS. Some OARS can not be added to ADAMS, such as voluminous license renewal applications, and in these cases a hard copy or electronic copy should be retained in the NRC File Center. For more information on ADAMS and OARs, refer to NUREG/BR-0273, "ADAMS Desk Reference Guide".

9.2 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 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 (see Section 4.3)
- licensee responses to requests for additional information
- NRC letters and memos transmitting notices for publication in the *Federal Register*
- safety evaluations written by NRC staff and officially transmitted from TB to DLPM
- 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

These records shall be entered in ADAMS as Official Records.

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, 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 safety evaluation issued with the license amendment.

9.3 Responsibilities

9.3.1 Division of Licensing Project Management

PMs should ensure that the OARs noted in section 9.2 are retained as OARs, usually by entry into ADAMS.

9.3.2 Technical Review Branches

Section chiefs should ensure that the safety evaluations authored by their sections in support of license amendments are entered in ADAMS as Official Records.

Attachment 1 - License Amendment Worksheet and Instructions

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

Additional information for each item on the form is provided below.

Work Planning - record the date each item is completed and the outcome of that item. Refer to section 2.0 of this guide for detailed information.

Public Notice - record the date each item is completed, if applicable to the amendment. Refer to section 3.0 of this guide for detailed information.

Environmental Assessment - check which category applies. See LIC-203 for detailed information. See 10 CFR 51.22 for categorical exclusions.

Proprietary Information - check if the application includes proprietary information. See LIC-204 for detailed information.

Review and Safety Evaluation Content - check that each section of the safety evaluation includes the appropriate content. Note if changes are needed. Refer to section 4.0 of this guide for detailed information.

Amendment Package, Concurrences & Issuances - record the dates that each item is completed. Refer to section 5.0, 6.0 and 9.0 of this guide for detailed information.

LIC-101, Attachment 1
License Amendment Worksheet



Work Planning

	TAC Number _____
	Acceptance Review _____
	Precedence Review _____
	Technical Complexity Assessment _____
	Risk-Significance Estimate _____
	Review Method _____
	Schedules (Target and Absolute Need Date) _____
	WPC Planning Forms - Blue Form _____
	Green Forms _____

Public Notice

	Proposed NSHCD <input type="checkbox"/> Biweekly <input type="checkbox"/> Individual <input type="checkbox"/> Exigent (Final NSHCD)
	Emergency (Final NSHCD) _____
	Notice for Opportunity for Hearing Without Proposed NSHCD _____
	Hybrid Hearing for Spent Fuel Pool Amendments _____
	Notice of Withdrawal or Denial _____

Environmental Assessment (See LIC-203)

Categorical Exclusion: Yes [Number -] No

Environmental Assessment: Yes No
(check environmental references for power levels, enrichments, burnup, etc.)

Application Includes proprietary information: **Yes (See LIC-204)** **No**

Note - Tech Staff and PMs should ensure that RAIs and SEs do not include proprietary information or should issue documents in accordance with procedure for sensitive information

Review and Safety Evaluation Content

INTRODUCTION

- Reference to licensee's amendment request?
 - Brief description of proposed change?
 - Reference to any supplemental submittals and impact on the no significant hazards consideration determination?
 - Reference to any related NRC activities (e.g., generic letters)?
-
-

REGULATORY EVALUATION

- Description of purpose of system, function or program followed by description of the particular feature, subsystem, component, or program element addressed by the subject specification(s)
 - Description of purpose or basis of the requirement being changed
 - Description of the regulatory background of the requirement(s) associated with the current design or program (e.g., reg guide, SRP, industry standard, regulation)
 - Description of important precedents
-
-

TECHNICAL EVALUATION

- Detailed description of the proposed change included?
 - Method of staff review described?
 - Key information used in the review (from licensee or general knowledge) included?
 - Comparison of change to regulatory criteria included?
 - Regulatory commitment(s) & related finding(s)?
 - Findings/conclusions included?
-
-

REGULATORY COMMITMENTS

- If necessary, is there a discussion of regulatory commitments (may be within evaluation section). Reference to regulatory commitment to include finding that licensee's administrative processes provide adequate controls.
-
-

EXIGENT/EMERGENCY CIRCUMSTANCES

- If necessary, is there a discussion of circumstances and staff's findings?

FINAL NO SIGNIFICANT HAZARDS CONSIDERATION DETERMINATION

- If necessary, is there a final NSHCD?

STATE CONSULTATION

- State consultation conducted and comments addressed?

ENVIRONMENTAL CONSIDERATIONS

- Is the required categorical exclusion or reference to a published environmental assessment included?

CONCLUSION

- Is there a Staff conclusion that the action does not endanger public health and safety?

REFERENCES

- All applicable utility correspondence, UFSAR sections, regulatory requirements/guidance, and industry standard/guides included (in reference section or within SE text)? ADAMS accession numbers included for all agency records referenced?

Amendment Package, Concurrences & Issuances

<input type="checkbox"/>	Concurrences or SE inputs from appropriate technical branches & OGC _____
<input type="checkbox"/>	See ADM-200 for signature authority (e.g., power updates, denials)_____
<input type="checkbox"/>	Notice of Issuance or denial _____
<input type="checkbox"/>	Considered special stakeholder interest _____
<input type="checkbox"/>	Contacts (ADM, SECY, State Official) _____
<input type="checkbox"/>	Final Review, Amendment Numbers_____
<input type="checkbox"/>	Expedited Copy to Licensee _____

Attachment 2 - Amendment Routing Form

Licensing Assistants have developed fairly standard routing forms that address slight Project Directorate variances related to LA/PM/SC concurrences and responsibilities for various duties such as consultations and notifications. Each routing form is expected to include, at least, the following items:

BACKGROUND INFORMATION

- Plant name and affected unit(s)
- TAC number(s)
- Application Date
- Subject or description
- Amendment package contact, phone number, and mail stop
- Amendment number(s) and issuance date (at issuance)

CONCURRENCE ROUTING/PACKAGE PREPARATION

- Concurrence Chain including:
 - LA, PM, TBs, OGC, Management (per ADM-xxx)
- Technical Branches providing SE inputs
- SRP Section (for OGC assignment of staff attorney)
- Check for Final Package Review (PM) and PM/SC signatures (in accordance with PD specific delegations)
- Check for Final Package Review (LA) and assignment of Amendment number(s)
- Dispatch directions

PUBLIC NOTIFICATION/STATE CONSULTATION

- Initial No Significant Hazards Consideration Determination Results
- Federal Register* Publication Information (type, date, citation)
- Notice period and expiration date
- Check for need for final NSHCD
- Check for use of emergency/exigent provisions
- Check for environmental assessment requirements
- Check for inclusion of notice of issuance
- Check for concurrences/notifications if hearing requested
- Check for impact on stakeholders (petitioners, etc.)
- Date and findings from checks with:
 - State contact for comments
 - SECY for petitions to intervene
 - ADM for public comments

Attachment 3 - Safety Evaluation Template

NOTES: (1) *The first page of this safety evaluation should be printed on NRC letterhead paper.*
(2) *template with macros to assist in preparing the SE is available on a common network drive (S:\macros) for DE and DSSA*

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

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

AND AMENDMENT NO. _____ TO FACILITY OPERATING LICENSE NO. [NPF-YY]

[NAME OF LICENSEE]

[NAME OF FACILITY]

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

Directions:

Fill in the **bolded** bracketed information. The *italicized* wording provides guidance on what should be included in each section. Delete the *italicized* wording from the completed safety evaluation (SE).

1.0 INTRODUCTION

Provide the date of the application and any supplements, the name of the licensee, the name of the facility, and the associated docket number(s), license number(s) and the federal register notice. Describe the requested licensing action. Although not required, a statement of why the change is being requested is helpful.

By application dated [] as supplemented by letters dated [] and [], **[Name of Licensee]** (the licensee) requested changes to the Technical Specifications (TSs) for the **[Name of Facility]**. The supplements dated [] and [], provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the *Federal Register* on **[Date (PM/LA will fill in FR information)]** (XX FR XXXX).

The proposed changes would revise **[give general description, which can often be copied from licensee's submittal]**.

2.0 REGULATORY EVALUATION

Define the regulatory framework for the requested licensing action, including a summary of regulations, regulatory guides, SRP sections, generic letters, or NRC staff positions that are directly related to the proposed change. This should be provided by the licensee under the regulatory analysis section of the license amendment request (LAR) and may also be found in

reference documents such as the TS (or STS) Bases Sections and plant FSAR. A recommended outline is provided below:

- *short description of the purpose of the system, function, or program that is the primary subject(s) of the application. The functional level or programmatic level description should be followed by a description of the particular feature, subsystem, component, or program element addressed by the subject specification(s).*
- *short description of the purpose or bases for the requirement(s) that are affected by the proposed change.*
- *short description of the regulatory background of the requirement(s) associated with the current design or program. This may include reference to the appropriate review criteria in a regulatory guide, standard review plan, or industry standard. If useful, the relationship to NRC regulations may be provided.⁽¹⁾*
- *short description of important precedents associated with the amendment application (e.g., previously issued amendments, topical reports, TSTFs)*

3.0 TECHNICAL EVALUATION⁽²⁾

- (1) Avoid referring to documents or regulations that have only indirect relationships to the proposed change unless appropriate for background/completeness and identified as not related to the proposed change. For example, while you might mention 10 CFR 50.46 if a request involves a change in a surveillance test interval (STI) for a major ECCS component, you should state that the proposed change does not relate to the ECCS acceptance criteria. A discussion of the basis for the existing STI would likely be drawn from the TS Bases or other document. As a general matter, references to 10 CFR 50.36 should be reserved for proposed structural changes to TS, such as the relocation of an LCO or administrative requirement.
- (2) The following wording included in Rev. 2 is redundant to the conclusions statements and should not be included in the technical evaluation section:
"The detailed evaluation below will support the conclusion 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) 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."

Document the evaluation of the proposed change against the relevant regulatory criteria. The evaluation must support the conclusions that the regulations are met and that there is reasonable assurance that the health and safety of the public will not be endangered. The licensee's justification for the change may include use of approved methodologies, applicable standards, regulatory guides, and a risk-informed evaluation. The staff should state what they did to evaluate the licensee's proposal. The staff's evaluation may include verification that the licensee followed the applicable regulatory guidance (SRP, Reg Guides), performed independent calculations, and validated that the appropriate assumptions were made. The staff may state in an SE that certain information provided by a licensee in an application was not considered essential to the staff's review and was not reviewed by the staff. Attachment 1 includes a check for the following items for this section of the SE:

4.0

- *Method of staff review described?*
- *Key information used in the review (from licensee or general knowledge) included?*
- *Comparison of change to regulatory criteria included?*
- *Regulatory commitment(s) & related finding(s)?*
- *Findings/conclusions included?*

4.0 STATE CONSULTATION

The PM is responsible for contacting the state official and verifying that this statement is correct.

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].**

5.0 ENVIRONMENTAL CONSIDERATION

Caution: The environmental consideration discussed below is written for a categorical exclusion based on 10 CFR 51.22(c)(9). The PM/LA are responsible to ensure that this is accurate for the specific amendment being issued.

The amendments change a requirement with respect to installation or use of a facility component located within the restricted area as defined in 10 CFR Part 20. The NRC staff has determined that the amendments involve 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 amendments involve no significant hazards consideration, and there has been no public comment on such finding (XX FR XXXX). Accordingly, the amendments meet 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 amendments.

6.0 CONCLUSION

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) such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendments will not be inimical to the common defense and security or to the health and safety of the public.

7.0 REFERENCES

Optional section. References can be provided either in the body of the SE or as a separate section. All documents referenced in the SE should be readily available for public inspection (if not proprietary) in the NRC PDR or available from other sources in the public domain. Include ADAMS Accession Number for references in NRC record-keeping system.

Principal Contributor:

Date:

