OFFICE OF NUCLEAR REACTOR REGULATION

LIC-101, Revision 6	License Amendment Review Procedures
Volume 100	Licensing Processes
Approved By:	Gregory F. Suber
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Responsible Organization:	DORL
Primary Contact:	Michael Marshall 301-415-2871 <u>Michael.Marshall@nrc.gov</u>

Summary: This issuance of LIC-101, Revision 6, "License Amendment Review Procedures," includes changes to (1) support the reunification of the Office of Nuclear Reactor Regulation (NRR) and Office of New Reactors (NRO) (including creation and modification of other NRR office instructions), (2) add non-power production and utilization facilities, (3) support implementation of changes in Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," (4) support risk-informed decision-making, (5) account for changes in the fee validation process, (6) update roles and responsibilities, (7) account for changes to the Master Data Management Program, and (8) update the safety evaluation template.

Training: Required reading for technical reviewers, project managers, licensing assistants, and branch chiefs involved in processing requested licensing actions.

ADAMS Accession Number: ML19248C539

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Office Instruction: LIC-101, Revision 6, "License Amendment Review Procedures"

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*concurred via e-mail

OFFICE	NRR/DORL/PM	NRO/DLSE/PM*	NRR/DLP/PM*	Tech Editor*	NRR/DORL/D*	NRO/DLSE/D*
NAME	MMarshall	DHabib	AAdams	SSchwarz	CErlanger	ABradford
DATE	09/16/2019	09/13/2019	09/20/2019	09/11/2019	09/23/2019	09/24/2019
OFFICE	NRR/DLP/D*	NSIR/DPCP/D*	NSIR/DPR/D*	NSIR/DSO/D*	NRR/DE/D*	NRO/DESR/D*
NAME	MJRoss-Lee(A)	SHelton	MScott	MBailey	BWittick(A)	BCaldwell
DATE	09/24/2019	09/25/2019	09/25/2019	09/25/2019	09/25/2019	09/26/2019
OFFICE	NRR/DIRS/D*	NRR/DMLR/D*	NRR/DRA/D*	NRR/DSS/D*	OGC – NLO*,**	NRR/DRMA
NAME	CMiller	JDonoghue	MFranovich	JMarshall(A)	RWeisman	TGorham
DATE	09/24/2019	09/24/2019	09/26/2019	09/25/2019	07/15/2020	07/21/2020
OFFICE	NRR/DORL/DD					
NAME	GSuber					
DATE	07/31/2020					

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^{**}No legal objection based on update of denial *Federal Register* notice template in next update of LIC-101 to address reference to another template (Agencywide Documents Access and Management System (ADAMS Accession No. ML15281A325 (non-publicly available)) that states it cannot be used for a denial under § 2.103(b) or § 2.108.

1. POLICY

Section 103a. of the Atomic Energy Act of 1954, as amended, "Commercial Licenses," states, "The Commission is authorized to issue licenses to persons applying therefor to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import, or export under the terms of an agreement for cooperation arranged pursuant to section 123, utilization or production facilities for industrial or commercial purposes." This provision implicitly authorizes the U.S. Nuclear Regulatory Commission (NRC) to amend such licenses. Regulatory requirements related to the amendment of licenses, including the appended technical specifications, are primarily contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.90, "Application for amendment of license, construction permit, or early site permit"; 10 CFR 50.91, "Notice for public comment; State consultation"; and 10 CFR 50.92, "Issuance of amendment."

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

This guidance is applicable to amendments to licenses for reactors under construction with a combined license, operating power reactors, plants transitioning to decommissioning,¹ and non-power production facilities and utilization facilities (NPUFs). However, portions of this guidance are also applicable to other licensing actions and activities. For example, the guidance on work planning should be utilized for any licensing action (e.g., exemptions, relief requests, etc.).

2. OBJECTIVES

This office instruction, along with the guidance in Appendix B, "Guide for Processing License Amendments for Operating Reactors and Plants Transitioning to Decommissioning," and Appendix C, "Guide for Processing License Amendments for Non-Power Production and Utilization Facilities," provides NRR² staff a basic framework for processing license amendment applications (and other licensing actions, where applicable).

¹Responsibility for operating reactors for which the licensees have submitted 10 CFR 50.82(a)(1)(i) certification has not been transferred from NRR to NMSS.

²The guidance in this office instruction is also applicable to staff in other offices who provide technical support for NRR license amendment reviews. References to NRR technical staff also apply to all staff performing NRR license amendment reviews.

These procedures should enhance efficiency in responding to the needs of the licensees, the public, and other stakeholders. Specific objectives include:

- Ensure the public health and safety is maintained;
- Promote consistency in processing of license amendments;
- Improve internal and external communications;
- Increase technical consistency for similar licensing actions;
- Improve timeliness in the review of license amendment requests (i.e., meet licensing action timeliness goals); and
- Provide staff with an improved framework for processing license amendment applications.

Appendix B, "Guide for Processing License Amendments for Operating Reactors and Plants Transitioning to Decommissioning," and Appendix C, "Guide for Processing License Amendments for Non-Power Production and Utilization Facilities," provide a general description of the process for reviewing license amendment requests.

3. BACKGROUND

The processes for the planned or routine revision of a license is the license amendment process. The review of license amendment requests or applications is one of the primary mechanisms for regulating changes in the licensees' operation of their facilities. The processes and regulatory requirements associated with amending an operating license (e.g., 10 CFR 50.90, 50.91 and 50.92) are relatively straightforward when applied to actual changes to a facility operating license or the technical specifications. If the change exceeds one or more of the criteria in 10 CFR 50.59, then the licensee must submit an application to the NRC in accordance with 10 CFR 50.90 and the NRC must issue a license amendment prior to the implementation of the proposed change. If a change that requires prior approval does not have an established change process, the change should be handled using the license amendment process since it is the most open and well-defined process available.

4. BASIC REQUIREMENTS

Appendices B and C describe a procedure for processing amendments by licensees pursuant to 10 CFR 50.90. The following are the primary activities covered in the procedure:

- work planning;
- public notification and comment resolution;
- technical review, including preparation of the SE; and
- amendment package processing.

5. RESPONSIBILITIES AND AUTHORITIES

All NRR staff who support the license amendment process are responsible for reading, understanding, and applying the guidance contained in Appendix B, "Guide for Processing License Amendments for Operating Reactors and Plants Transitioning to Decommissioning," or Appendix C, "Guide for Processing License Amendments for Non-Power Production and Utilization Facilities." They are also responsible for identifying possible improvements to the guidance and submitting suggestions for such improvements to their management or to the primary contact for this office instruction.

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

A. WORK PLANNING AND ACCEPTANCE REVIEW

Project Managers

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

- PMs will obtain an Enterprise Project Identifier (EPID) for the amendment request through the Reactor Program System (RPS) to ensure fee recovery, when applicable, and allow tracking of the work activities;
- PMs will provide, using RPS, a proposed work plan to the technical branches that may need to review the application. The proposed work plan should include milestone dates and other considerations:
- PMs will review responses from technical branches in RPS. PMs will work with technical staff and management to resolve issues regarding the work plan;
- PMs will perform and coordinate the acceptance review of the amendment request in accordance with NRR Office Instruction LIC-109, "Acceptance Review Procedures for Licensing Basis Changes." PMs of NPUF amendment requests should follow Section 2.3 of Appendix C;
- PMs, in coordination with an environmental reviewer, will determine if an environmental assessment (EA) is needed in accordance with NRR Office Instruction LIC-203, "Procedural Guidance for Categorical Exclusions, Environmental Assessments, and Considering Environmental Issues;"
- During the acceptance review of amendment requests for power reactors, PMs, in coordination with the technical staff, will consider the use of risk insights and the use of an integrated review team (IRT) in accordance with NRR Office Instruction LIC-206, "Integrated Risk-Informed Decision-Making for Licensing Reviews," to perform the review; and

• If the license amendment request is seeking to adopt an approved topical report or the licensee's justification for the license amendment request relies on an approved topical report, the PM will check to determine whether the topical report SE was previously reviewed by the Office of the General Counsel (OGC). The PM can make this determination by checking the concurrence block of the topical report SE. If the topical report SE was not previously reviewed by OGC, the PM should provide to the OGC mailroom a copy of the topical report and the topical report SE for legal review. This review is separate and concurrent to the staff's review of the amendment request. Additionally, the PM will provide to the attorney reviewing the topical report SE the proposed review schedule from RPS for the amendment request. Additional instructions to PMs concerning topical reports that have not received prior OGC review are in Section 4.2 of Appendix B and Section 2.5.3 of NRR Office Instruction LIC-500, Revision 8, "Topical Report Process."

Workload Management Staff

The workload management staff is responsible for the following specific activities with respect to work planning:

- Maintain and update the systems and databases associated with RPS and EPID status tracking; and
- As requested, provide analysis and reporting of database information.

Technical Staff

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

- Technical staff will work with the PM to ensure that the work plan (as described in RPS) is complete and that the scope, resources, and schedule are sufficient to perform the required safety review;
- Technical staff will consider using risk information and risk insights in accordance with LIC-206 during the acceptance review;
- Technical staff in coordination with the PM will consider use of an IRT in accordance with LIC-206 to perform the review; and
- Technical staff reviewers are responsible for providing acceptance review input to the PM for power reactor amendment requests and respective technical staff BCs in accordance with LIC-109. For NPUF amendment requests, technical staff should follow Section 2.3 of Appendix C.

Office of the General Counsel

- OGC will decide whether topical report SEs that have not received prior legal review need a legal review. OGC will review topical report SEs only once. Once a topical report SE has been reviewed by OGC as part of a review of a licensing action, the topical report SE will be considered as having received OGC review and will not need to be reviewed again by OGC if referenced in future licensing actions; and
- If OGC review is necessary, OGC will work with the PM to ensure that the
 concurrent review of a topical report SE that has not received prior legal review is
 completed without delaying the completion of the amendment review.

Management

The branch chiefs (BCs) are responsible for the following specific activities with respect to work planning and acceptance review:

- Technical staff BCs are responsible for completing work requests in RPS, including ensuring that technical reviewers are assigned promptly in order to support the acceptance review schedule;
- Technical staff BCs are responsible for ensuring that the estimated level of effort is reasonable for the requested licensing action; and
- Technical staff BCs are responsible for ensuring that the assigned reviewers
 meet milestone dates agreed to in RPS within the estimated level of effort in RPS.
 In the event a date cannot be met or work cannot be completed within the
 estimated level of effort, technical staff BCs are responsible for notification of the
 PM prior to missing the due date or exceeding the estimated level of effort and
 coordination with the PM to establish a new due date and new estimated level of
 effort.

B. PUBLIC NOTIFICATION AND COMMENT RESOLUTION

Project Managers

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

- Issuance of the public notification regarding the proposed issuance of the amendment. This includes the following actions:
 - o review the licensee's analysis of no significant hazards consideration and determine its adequacy for use in the public notification;
 - o review the proposed amendment, review schedule, and regulatory requirements to determine what type of public notification is required; and

- prepare the notification for review and concurrence by the LA and BC.
- Resolve any public comments on proposed no significant hazards consideration determination.
- Coordinate NRR activities related to the hearing process.
- Prepare and coordinate issuance of any additional public notifications, including those due to licensee changes in the amendment request and the final notification of amendment approval, denial, or withdrawal.

Technical Staff

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

C. TECHNICAL REVIEW

Project Managers

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

- PMs will review and process RAIs in accordance with NRR Office Instruction LIC-115, "Processing Requests for Additional Information." The review of RAIs should include confirming that the questions are necessary to make a regulatory finding and have a clear regulatory basis;
- PMs may perform the technical review, when appropriate, based on the PM's knowledge of the technical area or if sufficient precedent is available. Prior to starting the review, the PM should consult with the responsible technical BC;
- PMs will coordinate assistance from technical staff, as required;
- If contract support is being used for review involving a NPUF, PMs will coordinate
 assistance from contractors, including revisions to contracts because of changes
 in scope, resources, or due dates;
- PMs will coordinate with technical staff if scope, resources, or due dates need to be changed for any reason and inform all affected parties of changes to the previously established work plan;
- PMs, in coordination with the technical BCs, will ensure that technical staff hours charged are reasonable when compared to the status of the review, the level of

effort (hours) estimates in RPS, experience with similar reviews, and possible efficiency gains anticipated from precedent reviews. PMs will work with appropriate staff and management to resolve any issues;

- PMs will perform fee validation reviews in accordance with NRR Office Instruction, ADM-203, "License Fees Certification Process," and DORL "Job Aid for Fee Billing Validation Review" (ADAMS Accession No. ML19274B076 (non-publicly available);
- For reviews involving NPUF and contractor support, PMs will review the
 contractor's monthly status report and recommend approving or not approving
 payment of the contractor's bill. The review should include verification that the
 contractor's effort is what was expected, consistent with the monthly status
 report, and is reasonable. PMs will resolve any issues in accordance with the
 contracting process;
- If an IRT is being used to conduct the review, the PM will follow the guidance in LIC-206 for a consolidated SE;
- If an IRT is not being used to conduct the review, the PM will consolidate all SE inputs into a single SE;
- If an IRT is not being used to conduct the review, the PM is responsible for writing all sections of the SE, except for regulatory evaluation, technical evaluation, and reference sections;
- PMs will ensure that the regulatory basis and technical basis for the staff's regulatory findings and technical conclusions are clearly articulated in the SE;
- PMs will follow the format and content guidance for SEs that are described in Section 4.0 of Appendix B and the SE template for power reactors³ and SE content guide (see ADAMS Package Accession No. ML20136A161) or Section 4.0 of Appendix C and the SE template for NPUFs (see ADAMS Accession No. ML19289C384), except if the SE is based on a model SE. If the SE is based on a model SE, then PMs should ensure the model SE is followed; and
- If an EA is needed, the PM, in coordination with an environmental reviewer, determines whether the PM or environmental reviewer will prepare the EA.

³A separate SE template is available for Vogtle 3 and 4 at ADAMS Accession No. ML16290E857.

Technical Staff

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

- If any sensitive unclassified non-safeguards information (SUNSI) (e.g., proprietary or security-related information) is included in a document (e.g., RAIs, SEs, audit plans, summaries) prepared by the technical staff, the technical staff will ensure that any SUNSI (e.g., proprietary or security-related information) is clearly marked in the document within double brackets (i.e., [[......]]). The transmittal document or e-mail from the technical organization to the project organization should clearly note that the document contains SUNSI as marked;
- Technical reviewers will prepare and process RAIs in accordance with LIC-115;
- Technical reviewers will perform the technical review as assigned in RPS;
- Technical reviewers will update the status of assigned milestones in RPS;
- Technical reviewers will coordinate with the PM if scope, resources, or schedule (i.e., milestones) need to be changed for any reason prior to making changes in RPS:
- Technical reviewers will ensure that the regulatory basis and technical basis for the staff's regulatory findings and technical conclusions are clearly articulated in the SE;
- Technical reviewers will follow the format and content guidance for SEs described in Section 4.0 of Appendix B and the SE template and SE content guide (see ADAMS Package Accession No. ML20136A161) for power reactors, Section 4.0 of Appendix C and the SE template for NPUFs (see ADAMS Accession No. ML19289C384) or model SE, if available (e.g., Technical Specification Task Force (TSTF) Travelers);
- If an IRT is being used to conduct the review, the technical reviewer will follow the guidance in LIC-206 for a consolidated SE; and
- If an IRT is not being used to conduct the review, the technical reviewer is responsible for writing the regulatory evaluation technical evaluations and reference sections of the SE.

Management

BCs and executives are responsible for the following areas associated with the technical review:

- Technical BCs will ensure documents (e.g., RAIs, SEs, audit plans, summaries) are provided to the project organization in accordance with the work plan (i.e., estimated level of effort and schedule) in RPS;
- Technical BCs will ensure that technical staff hours charged are reasonable when compared to the status of the review, the level of effort (hours) estimates in RPS, experience with similar reviews, and possible efficiency gains anticipated from precedent reviews;
- Project and technical BCs will ensure hours charged by their staff to a review are reasonable and within the normal limits required to complete any particular activity on the review in accordance with ADM-203;
- Technical BCs will ensure documents (e.g., RAIs, SEs, audit plans, summaries) prepared in their branch are developed and processed in accordance with applicable office instructions;
- Technical BCs should ensure that SEs authored by their branches in support of license amendments are entered in ADAMS as official agency records;
- Project and technical BCs will ensure RAIs and SEs meet applicable content and quality expectations; and
- Executive management will assist in resolving staff issues related to preparation of RAIs and SEs (e.g., scope, resources, schedule, technical issues).

D. AMENDMENT PACKAGE PROCESSING

Project Managers

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

- PMs will assemble the package for review and concurrence consistent with the latest plant-specific boilerplates;
- PMs will ensure that the concurrence chain includes all of the technical (i.e., all the branches identified in RPS providing input or concurrence), legal, administrative, and management positions necessary for adequate review of the amendment and is consistent with the requirements in NRR Office Instruction ADM-200, "Delegation of Signature Authority;"

- PMs will verify changes to technical specifications and the license. Changes should be verified against the application, supplements, and current version in the authority file (i.e., the official copy of the license and technical specifications for each plant maintained by the NRC);
- PMs will contact the State official, in accordance with the requirements in 10 CFR 50.91(b). For NPUF, the State official only needs to be contacted for an amendment involving a testing facility or NPUF licensed under 10 CFR 50.22;
- PMs will track the status of the amendment package as it moves through the review and concurrence process; and
- After amendment issuance, PMs, in coordination with the LA, will ensure that the changes, if any, to the technical specifications and license have been incorporated into the authority file.

Licensing Assistants

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

- LAs will review the package for correct spelling, punctuation, format, distribution, etc., and accuracy of all quoted material (including license conditions quoted on the amendment authorization page or repeated in the SE), consistent with relevant administrative requirements (e.g., management directives, NRC Style Guide);
- LAs will review the package to ensure consistency with latest plant-specific boilerplates and verify that the boilerplates are current and up to date (e.g., main addressee, licensee name(s));
- LAs will verify changes to technical specifications and licenses. Changes should be verified against the application, supplements, and current version in the authority file;
- If an EA was not prepared, LAs will confirm that the correct categorical exclusion is cited in the SE;
- LAs will verify that the amendment has been properly noticed;
- LAs will verify whether there were any public comments on the proposed no significant hazards consideration determination and whether a hearing was requested;
- LAs will complete an amendment routing sheet (ADAMS Accession No. ML081980829 (non-publicly available) and place on top of the concurrence package prior to returning to the PM;

- LAs will assign amendment numbers to the package and perform a final quality assurance check before issuance; and
- After amendment issuance, LAs will ensure that the changes to the technical specifications and license have been incorporated into the authority file.

Technical Staff

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

- Technical reviewers will review amendment packages if the SE was prepared by the PM or the technical branch response to the work request was "concurrence only; and"
- Technical reviewers will review amendment packages if SE input was prepared by technical staff and substantial changes were made to the SE input (i.e., changes are more than editorial and change technical content or original intent).

Office of the General Counsel

 OGC will review all amendment packages for legal adequacy and defensibility unless an agreement is reached that specific amendments do not require OGC concurrence (e.g., see Section 8.2.2 of Appendix B regarding the Consolidated Line Item Improvement Process). Refer to NRR Office Instruction COM-109, "NRR Interfaces with the Office of the General Counsel," for further details regarding OGC review.

Management

- Technical BCs will concur on amendment packages if the SE was prepared by the PM or if the technical branch response to the work request was "concurrence only;"
- Technical BCs will concur on amendment packages if the SE input was prepared by technical staff and substantial changes were made to the SE input (i.e., changes are more than editorial and change technical content or original intent);
- Project and technical BCs should verify that the concurrence chain includes all the technical, legal, administrative, and management positions necessary for adequate review of the amendment and signature authority are in accordance with ADM-200 and other applicable office instructions; and
- NRR executive management will, as necessary, resolve staff concerns regarding
 the issuance or denial of a license amendment, the scope of review, resources or
 schedules for a review, or other matters related to the NRC disposition of a
 license amendment application.

6. PERFORMANCE MEASURES

For licensing actions (e.g., license amendments) related to operating power reactors and plants transitioning to decommissioning, the goal is for at least 95 percent to be less than 1 year old and for 100 percent to be less than 2 years old. When these metrics are not met, an explanation must be provided to Congress. These metrics are referred to as the Congressional Budget Justification (CBJ) metrics. However, the NRC is permitted to exclude certain licensing actions from the CBJ metrics as described in the annual CBJ (NUREG-1100). Guidance on the circumstances and the methods for excluding licensing actions from the timeliness metrics is described in a memorandum dated March 2, 2020 (ADAMS Accession No. ML19275F040 (non-publicly available)). See ADAMS Accession No. ML15334A189 (non-publicly available) for the exclusion memorandum template.

For licensing actions associated with operating reactors, plants transitioning to decommissioning, and non-power production and utilization facilities licensing actions that result in an SE (e.g., license amendments), the goal is for all actions to be completed within 2 years. This metric is referred to as the Nuclear Energy Innovation and Modernization Act (NEIMA) metric.

Additionally, for operating power reactors and plants transitioning to decommissioning, to monitor the accuracy of level of effort and completion estimates provided to licensees, the following performance measure goals, which are QPR metrics, will be reported quarterly to the Office of the Executive Director for Operations:

- Percentage of licensing actions completed within forecasted hours, plus 25 percent, shall be greater than or equal to 90 percent.
- Percentage of licensing actions completed within forecasted schedule, plus 1 month, shall be greater than or equal to 90 percent.

7. **PRIMARY CONTACT**

Michael Marshall NRR/DORL 301-415-2871 Michael.Marshall@nrc.gov

8. **RESPONSIBLE ORGANIZATION**

NRR/DORL

⁴For licensing actions with an RPS – Licensing/WM software "Date Available in ADAMS" of October 1, 2016, or later, the age of the licensing action will be measured starting when the acceptance review is complete. Previously, the age of a licensing action was measured starting at the application date.

9. <u>EFFECTIVE DATE</u>

August 3, 2020

10. CERTIFICATION DATE

August 3, 2025

11. REFERENCES

- 1. DORL "Job Aid for Fee Billing Validation Review" (ADAMS Accession No. ML19274B076 (non-publicly available)
- 2. Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," https://drupal.nrc.gov/policy/directives/toc/md8004.htm
- 3. NRR Memorandum to Division Directors, Office of Nuclear Reactor Regulation, from Craig G. Erlanger, Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, "Guidance for Documenting Unusually Complex Licensing Actions and Other Licensing Tasks Excluded from the Timeliness Metrics, Revision 1," dated March 2, 2020 (ADAMS Accession No. ML19275F040 (non-publicly available))
- 4. NRR Template, "Decision to Classify CAC as Unusually Complex Licensing Action/Task (Memo) (ADAMS Accession No. ML15334A189 (non-publicly available))
- 5. NRR Office Instruction ADM-200, Revision 13, "Delegation of Signature Authority," dated January 17, 2020 (ADAMS Accession No. ML19240B408 (non-publicly available))
- 6. NRR Office Instruction, ADM-203, Revision 4, "License Fees Certification Process," dated October 9, 2019 (ADAMS Accession No. ML19261A173 (non-publicly available))
- 7. NRR Office Instruction COM-109, Revision 3, "NRR Interfaces with the Office of the General Counsel," dated October 10, 2019 (ADAMS Accession No. ML19177A013 (non-publicly available))
- 8. NRR Office Instruction LIC-203, Revision 4, "Procedural Guidance for Categorical Exclusions, Environmental Assessments, and Considering Environmental Issues," dated July 7, 2020 (ADAMS Accession No. ML20016A379)
- 9. NRR Office Instruction LIC-109, "Acceptance Review Procedures for Licensing Basis Changes" (ADAMS Accession No. ML20036C829)
- 10. NRR Office Instruction LIC-115, "Processing Requests for Additional Information," dated November 6, 2019 (ADAMS Accession No. ML19242B237)

- 11. NRR Office Instruction LIC-206, Revision 1, "Integrated Risk-Informed Decision-Making for Licensing Reviews," dated June 26, 2020 (ADAMS Accession No. ML19263A645)
- 12. NRR Office Instruction LIC-500, Revision 8, "Topical Report Process," dated February 6, 2020 (ADAMS Accession No. ML19123A252)

Enclosures:

- 1. Appendix A: Change History
- 2. Appendix B: Guide for Processing Licensing Amendments for Operating Reactors and Plants Transitioning to Decommissioning
- 3. Appendix C: Guide for Processing Licensing Amendments for Non-Power Production and Utilization Facilities

Appendix A - Change History

Office Instruction LIC-101, Revision 5 License Amendment Review Procedures

LIC-101 Change History				
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) expanding 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 for DLPM Training presentation to be developed	
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	for NRR Web page 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				
Revision Date	Description of Changes	Method Used to 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 percent 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	Recommended reading for technical staff supporting license amendments Required reading and training session for DLPM Emphasize change regarding use of topical reports (YT020020177)	
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	Training sessions to be offered to NRR staff Required reading and training session for DLPM	

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LIC-101 Change History				
Revision Date	Description of Changes	Method Used to Announce & Distribute	Training	
05/22/2012	Changes in Revision 4 include: (1) overall streamlining and removal of unnecessary detail; (2) revisions to reflect NRR organizational name changes; (3) updates to discussion of work planning based on current Blue/Green sheet process; (4) updates to discussion on acceptance reviews based on Office Instruction LIC-109; (5) addition of specific regulatory requirements associated with each step in the amendment review process; (6) addition of references to ADAMS Accession Nos. for templates of each type of public notification; (7) further detail regarding when a commitment should be elevated into an obligation; (8) removal of detail on content of safety evaluations from Section 4.0 of the guide and addition of detail to the safety evaluation template attached to the guide; (9) addition of new discussion on amendment withdrawals, denials, and corrections; (10) removal of details in risk-informed licensing action guidance that is either covered in other documents (e.g., SRP, RGs) or is not needed for proper coordination with APLA; (11) removal of details on development of Technical Specifications Task Force travelers and consolidated line item improvement process models based on issuance of Office Instruction LIC-600; (12) update of license amendment worksheet (Attachment 1) to allow for better tracking of review status; (13) deletion of Attachment 2 (Amendment Routing Form) and addition of discussion about the form in Section 5.0 of the guide; (14) renumbering of Attachment 3 to Attachment 2 (safety evaluation template); (15) renumbering Section 9.0 regarding OARs as Section 10.0 and adding new Section 9.0 regarding emergency plan changes; and (16) miscellaneous editorial changes to better describe current practices.	E-mail to NRR staff	Required reading for NRR staff supporting license amendment reviews Training sessions to be offered to NRR staff	

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01/09/17 Changes in Revision 5 include: (1) added further information on sensitive unclassified non-safeguards information (SUNSI) marking and processing of requests for additional information (RAIs) and safety evaluations (SEs); (2) revised Performance Measures section to address the Office of Nuclear Reactor Regulation (NRR) operating plan goals and to reference memo on excluding Cost Activity Codes (CACs) from the timeliness metrics; (3) changed references to Task Assignment Control (TAC) numbers to CACs: (4) added discussion that SEs may be transmitted to the Division of Operating Reactor Licensing (DORL) via e-mail or memoranda; (5) added boilerplate SE words to use to address when re-noticing is required due to supplements expanding the scope of the application as originally noticed; (6) updated references to latest Agencywide Documents Access and Management System (ADAMS) accession numbers for Federal Register notice templates; (7) revised a number of sections to address recommendations in the LIC-101 Working Group report (ML16043A039): (8) revised a number of sections to address changes per the Expectations Memo dated April 18, 2016 (ML16202A029); (9) changed references to NRR's Center for Planning and Analysis Branch (CPAB) to NRR's Financial, Human Capital and Analysis Support Branch (FHAB); (10) added further information to discuss reasons for issuing a final no significant hazards consideration determination; (11) added expectation that project manager (PM) is responsible for verifying technical specification authority file after amendment issuance; (12) added expectation of licensing assistant (LA) peer review for amendment packages requiring NRR Office Director review; (13) added further detail regarding LA final quality assurance check of amendment package; (14) changed references to NRR's environmental review branch from RERB to RERP: (15) added guidance regarding whether a new CAC is needed for correction letters; (16) revised process for SUNSI review of incoming emergency preparedness documents; (17) revised work planning discussion based on the replacement of TRIM and Firefly; and

E-mail to NRR Required reading for

Required reading for NRR staff supporting license amendment reviews

Training sessions to be offered to NRR staff

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LIC-101 Change History			
Revision Date	Description of Changes	Method Used to Announce & Distribute	Training
	(18) miscellaneous editorial changes, corrections, and clarifications.		
07/31/20	Changes in Revision 6 include: (1) supporting the reunification of the Office of Nuclear Reactor Regulation and Office of New Reactors (NRO) (including creation and modification of other NRR office instructions), (2) adding non-power production and utilization facilities, (3) supporting implementation of changes in Management Directive 8.4, "Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," (4) supporting risk-informed decision-making, (5) accounting for changes in the fee validation process, (6) updating roles and responsibilities, (7) account for changes to the Master Data Management Program, and (8) updating safety evaluation template.	E-mail to NRR staff	Required reading for NRR staff supporting license amendment reviews

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Appendix B

Guide for Processing License Amendments for Operating Reactors and Plants Transitioning to Decommissioning

Revision 6

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1.0 Introduction

This guide provides staff in the U.S. Nuclear Regulatory Commission (NRC or the Commission) Office of Nuclear Reactor Regulation (NRR)¹ a basic framework for processing license amendment applications.² In addition, some of the guidance contained in this document may be used, where appropriate, for the processing of other licensing actions and activities where specific guidance is not provided in a related office instruction. For example, the guidance on safety evaluations (SEs) and work planning may be utilized for any licensing action or activity.

NRR staff involved in processing license amendments should identify any possible improvements to this guidance and submit suggestions to their management or to the contact listed for LIC-101.

1.1 Objectives

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

1.2 Process Overview

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

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

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¹The guidance in this office instruction is also applicable to staff in other offices who provide technical support for NRR license amendment reviews. References to NRR technical staff also apply to all staff performing NRR license amendment reviews.

²Certain types of license amendments may have additional guidance that supplement the guidance in LIC-101 (e.g., NRR Office Instruction LIC-112 for power uprates, NRR Office Instruction LIC-601 for processing of conversions to the improved Standard Technical Specifications, and Regulatory Guide 1.174 for risk-informed license amendments).

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

- work planning
- public notification and comment resolution
- technical review, including preparation of the SE
- amendment package processing

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

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

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

2.0 Work Planning and Acceptance Review

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

2.1 Initiate a New Project in the Reactor Program System

When a PM receives a licensing action request from a licensee, the PM should initiate a new project in the Reactor Program System (RPS).

Note: In order to meet acceptance review timeliness goals discussed in LIC-109, it is important that the PM initiate the project as soon as possible after the application is received (i.e., generally within 2 working days).

Enterprise Project Identifiers (EPIDs) provide a means of billing the licensee and tracking the work. Each unrelated change in an application should be assigned an individual EPID. For example, if an application includes requests for more than one type of licensing action (e.g., an exemption and an amendment), each type of licensing action must have a separate EPID or if a license amendment request includes unrelated changes such as multiple Technical Specifications Task Force (TSTF) Travelers, each unrelated change needs to be assigned to a separate EPID. Separate EPIDs are needed to ensure accurate tracking of amount and types of licensing actions being reviewed. For most license amendments, the EPID should be coded

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as fee billable and Activity Type "LLA." Some exceptions include license transfers (Activity Type "LLM") and power uprates (Activity Type "LLS").

The PM's initiation of the project creates an assignment in RPS that the technical branch chief (BC) responds to, as discussed below in Section 2.2. At the initiation of the project, the PM provides some of the essential work planning information such as: (1) the technical branches (TBs) being requested to provide input to appropriate project organization for the review; (2) the proposed schedule for the TB's completion of the acceptance review; (3) the proposed schedule for the TB's submittal of the request for additional information (RAI) to DORL; and (4) the proposed schedule for the TB's submittal of SE input to the appropriate project organization. In initiating the project, the PM should review the amendment request in sufficient detail to develop a work plan that defines the scope, depth, resources, and schedule.

Note: For reactors under construction with a combined license, the schedule and resources in the work plan for routine reviews should support issuance of the *Federal Register* notice within 60 days and completion of the review within 180 days of acceptance of the requested licensing action.

The PM should use the "Resource Matrix" in RPS when selecting the TBs that should be involved in the review. Identifying branches involved in precedent reviews may be helpful in identifying branches that should be involved in the review. The PM should be "conservative" in selecting the TBs. In other words, if the PM is not sure if a TB should be included, the PM should make reasonable attempts to communicate with the TB BC to see if the TB needs to be included in the review. If attempts to contact the BC are unsuccessful, then the PM should select the TB in RPS, so the TB can document whether the TB has any scope in the review. Consistent with the NRR Office Instruction LIC-206, the PM should consider whether a risk analyst needs to be assigned to the review.

2.2 TB Responds to RPS Assignment

After the PM initiates the project in RPS (as discussed in Section 2.1), the TB BCs will receive notification from RPS.

The response to the assignment in RPS is for the TB to assign the specific reviewer and to provide the TB's proposed schedule milestone dates.

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

The PM should assess the TB's responses and ensure that the work plan meets schedule goals and covers all appropriate technical areas.

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When the TB enters milestone dates in RPS, the TB should enter dates that are achievable with a high degree of confidence. The TB should carefully review the dates proposed by the PM rather than just accepting the dates without assessing the ability to meet the dates. The TB should take into consideration the assigned technical reviewer's current and expected workload, planned leave, and priority of other tasks they are working. In addition, the TB should consider whether the licensee's requested review schedule is realistic (e.g., licensee requesting review to be completed in a short timeframe). When determining milestone dates in RPS, the TB BC should assess whether the review is a good candidate for contract support. See ADAMS Accession No. ML16211A433 for a flow chart TB BCs may use as a job aid in determining whether contract support should be used.

If circumstances change after the initial schedule is established such that meeting the target dates is in jeopardy, the TB reviewer should update the schedule dates for the impacted milestones after receiving approval from the TB BC. In the event a date cannot be met or work cannot be completed within the estimated level of effort, TB BCs are responsible for notifying the PM prior to missing the due date or exceeding the estimated level of effort and coordinating with the PM to establish a new due date and new estimated level of effort.

2.3 Acceptance Review

As soon as practical following receipt of the application, the task of performing the acceptance review should begin. This review should be completed by the PM and the technical staff in accordance with NRR Office Instruction LIC-109, "Acceptance Review Procedures," and consistent with LIC-206, "Integrated Risk-Informed Decision-Making for Licensing Reviews."

Note: Prior to issuing the results of the acceptance review to the licensee, the PM should communicate with all the reviewers regarding the acceptance review (e.g., via phone call, e-mail, meeting). The purpose of the communication would be to: (1) ensure that all of the proposed changes will be evaluated by one of the identified branches to prevent items from "falling through the cracks"; (2) prevent duplication of reviews of technical specification items; (3) identify other branches that may have been inadvertently omitted; and (4) discuss the reasonableness of the proposed review schedule, need for audit, potential acceptance review issues, etc. For routine, straightforward reviews (e.g., high degree of precedence, limited number of review branches), the PM should use judgement regarding the need for the above communications.

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

requested amendment issuance date

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- requested implementation period³
- discussion of whether the submittal includes any regulatory commitments
- discussion of environmental considerations (e.g., categorical exclusions in 10 CFR 51.22)⁴
- discussion of whether submittal is based on precedent
- inclusion of retyped technical specification pages (i.e., clean pages)
- inclusion of technical specification bases pages

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

3.0 Public Notification

As soon as practicable following completion of the acceptance review (as discussed in Section 2.3), PMs should prepare the appropriate type of public notification regarding the proposed issuance of the amendment. The associated requirements for this public notification are discussed below. The specific types of notices are discussed in Sections 3.1 through 3.7.

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

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

The regulation in 10 CFR 50.91(a)(2)(ii) states that each notice will (1) contain the staff's proposed determination under the standards in 10 CFR 50.92 (i.e., proposed no significant hazards consideration (NSHC) determination); (2) provide a brief description of the amendment and the facility involved; (3) solicit comments on the proposed NSHC determination; and (4) provide for a 30-day comment period. For biweekly notices, item 3 (solicit comments) and item 4 (provide 30-day comment period) are included in the boilerplate language in the *Federal Register* notice (i.e., text preceding the plant-specific notices). Per 10 CFR 50.91(a)(2)(iii), the comment period will begin on the day after the date of the publication of the first notice, and normally, the amendment will not be granted until after this comment period expires.

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³If the licensee does not specify an implementation period in the application, it is suggested that the PM contact the licensee to determine the desired implementation period.

⁴Although licensees are not required to discuss environmental considerations in their license amendment applications, the NRC may require the licensee to subsequently submit environmental information pursuant to 10 CFR 51.41 (aids the Commission to comply with National Environmental Policy Act (NEPA) requirements).

Although 10 CFR 50.91 requires that the NRC solicit comments only on the proposed NSHC determination, the NRC staff has routinely addressed comments related to any aspect of the application. See Section 6.0 of notices and environmental findings template (ADAMS Accession No. ML20136A156) for further details.

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

The regulations in 10 CFR 50.91(a)(3) state:

The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of Federal Register notices. In either event, it will not make and will not publish a final determination on no significant hazards consideration, unless it receives a request for a hearing on that amendment request.

As such, the NRC staff must make and publish a final determination on NSHC if a hearing is requested and the staff issues the amendment before the requested hearing is concluded. In addition, the NRC staff's practice is to include a final NSHC determination in the SE if the amendment is issued prior to expiration of the 60-day period to request a hearing (i.e., in case a hearing is requested after the amendment is issued but before the expiration of the hearing period).⁵

The regulations in 10 CFR 50.91(a)(4) state:

Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is

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⁵Preparing a final NSHC determination for amendments issued prior to expiration of the period for requesting a hearing has been the NRR practice based on guidance issued in 1983. Under this guidance, final NSHC determinations were prepared for emergency and exigent amendments, which were then the only amendments contemplated to be issued before expiration of the opportunity to request a hearing, which then was only 30 days. This guidance, Division of Licensing Operating Procedure (DLOP) 228, Revision 1, "Revised Procedures for Processing License Amendments for Power Reactors and Testing Facilities (the "Sholly" Legislation) - No Significant Hazards Consideration, Noticing and State Consultation" (ADAMS Accession No. ML16077A090), was issued to implement an Interim Final Rule, "Standards for Determining Whether License Amendments Involve No Significant Hazards Considerations," dated April 6, 1983 (48 FR 14864). The Final Rule (also known as the "Sholly rule") was issued on March 6, 1986 (51 FR 7744), "Final Procedures and Standards on No Significant Hazards Considerations."

involved, in which case the Commission will provide an opportunity for a prior hearing.

If the NRC staff intends to issue an amendment for which a hearing has been requested, the staff needs to notify the Commission via issuance of a "Notification of Significant Licensing Action," in accordance with the guidance in an NRR memorandum dated December 13, 2000 (ADAMS Accession No. ML003779315). The regulation in 10 CFR 50.58(b)(5) states that the Commission may make the amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that NSHC is involved.

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

- 10 CFR 50.58(b)(3) states that if the NRC finds that exigent circumstances exist, as defined in 10 CFR 50.91, the NRC may reduce the period provided for public notice and comment.
- 10 CFR 50.58(b)(3) states that if the NRC finds, in an emergency situation, as defined in 10 CFR 50.91, that the amendment involves NSHC determination, the NRC may dispense with public notice and comment and issue the amendment.
- 10 CFR 50.91(a)(7) states that, where the NRC finds that significant hazards considerations are involved, it will issue a *Federal Register* notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR Part 2.
- Consistent with 10 CFR 2.307(c), for applications containing either sensitive unclassified non-safeguards information (SUNSI) or safeguards information (SGI), the *Federal Register* notice also contains an order, signed by the Secretary of the Commission, which establishes procedures to allow potential parties to request access to the SUNSI or SGI documents.
- In accordance with Subpart K of 10 CFR Part 2 (10 CFR 2.1101 through 10 CFR 2.1119), hybrid hearing procedures apply to proposed amendments regarding expansion of spent fuel storage capacity at the site of a civilian nuclear power plant. The regulation in 10 CFR 2.1107 provides requirements regarding noticing of proposed amendments of this type and requirements that the *Federal Register* notice identify the availability of the hybrid hearing procedures.

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

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

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

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

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

If the supplemental information expanded the scope of the proposed amendment beyond the description on the NRC staff's original notice, then the proposed amendment should be re-noticed (see Section 3.8 for guidance on re-noticing). As such, it is recommended that, for the original notice, the description of the amendment should be brief and should broadly characterize the aspects of the license amendment in a form such that the general public can readily understand the purpose of the amendment. The notice should not be prescriptive as to a precise section number, technical specification, wording, or specific engineering parameter values unless necessary for the public to understand the purpose of the amendment. The NRC staff should add the following statement to Section 1.0, "Introduction," of the SE for the amendment if re-noticing was required due to supplemental information causing an expansion in scope:

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On **[enter date]**, the Nuclear Regulatory Commission (NRC or the Commission) staff published a proposed no significant hazards consideration (NSHC) determination in the *Federal Register* **[(XX FR XXXX)]** for the proposed amendment. Subsequently, by letters dated **[enter dates]**, the licensee provided additional information that expanded the scope of the amendment request as originally noticed in the *Federal Register*. Accordingly, the NRC published a second proposed NSHC determination in the *Federal Register* on **[enter date (XX FR XXXX)]**, which superseded the original notice in its entirety.

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

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

The most common form of public notification is for the NRC staff to issue a proposed NSHC determination in the *Federal Register* as part of a biweekly collection (i.e., the Biweekly Report) of notices in the *Federal Register*. This type of notice (typically called a biweekly notice) provides a 30-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is prepared using the Routine Biweekly *Federal Register Notice* Process Instructions (ADAMS Accession No. ML20069B723).

PMs should consult the biweekly schedule⁶ or coordinate with the DORL licensing assistant (LA) regarding the schedule for publication of the biweekly notices to ensure that the time period for comments and hearing requests is compatible with the schedule for proposed issuance of the amendment. If the biweekly schedule is not compatible, the PM should consider issuing the notice as an individual notice as discussed below in Section 3.2. The biweekly schedule is maintained in ADAMS at Accession No. ML092240166.

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

If the required schedule for issuance of an amendment cannot be accommodated by the normal biweekly publication of the notice, an individual notice can be published in the *Federal Register*. This type of notice (typically called an individual notice) provides a 30-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee. The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML14037A053 and ML082130341 for templates of the notice and transmittal letter, respectively.

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⁶The noticing schedule for license amendment requests involving SUNSI or SGI is monthly (see Section 3.7).

NOTE: For reactors under construction with a combined license, templates for individual notices are available (see ADAMS Accession Nos. ML19290F002 and ML19290E984 for a template of the notice). If these templates are followed, the *Federal Register Notice* does not have to be reviewed by OGC. If it is a controversial issue or any change other than editorial style, the notice is required to be reviewed by OGC.

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

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

For those amendments for which the PM does not find that the criteria for an NSHC determination have clearly been satisfied, an individual notice can be published in the *Federal Register* that describes the amendment request and provides neither a proposed NSHC determination nor a definitive finding that the subject amendment involves a significant hazards consideration. In previous NRR procedures for processing license amendments, these notices are sometimes referred to as "Category 3" notices. This type of notice does not solicit any comments (i.e., since an NSHC determination is not included) but provides a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee. The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML14045A192 and ML082130323 for templates of the notice and transmittal letter, respectively.

If a hearing is requested for an amendment that was noticed using a Category 3 notice, and the staff plans to issue the amendment prior to the completion of any hearing, the PM should issue a notice with a proposed NSHC determination (allowing 30 days for public comment) and include a final NSHC determination in the SE. Consistent with the requirements in 10 CFR 50.58(b)(5), the amendment may be made immediately effective in advance of the holding and completion of any required hearing.⁷ Note, the notice with the proposed NSHC determination should not include an opportunity for a hearing since the opportunity for a hearing

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⁷The authority and role of the staff, and the hearing-related additional steps that must be completed, are stated in applicable regulations (usually 10 CFR 2.1202) and may be further limited via Staff Requirements Memoranda and Commission policy statements.

was already provided in the original Category 3 notice. See ADAMS Accession No. ML053490030 for an example of a notice with a proposed NSHC determination that was issued following issuance of a Category 3 type notice.

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

If a licensee believes that a proposed amendment is needed in a timeframe that does not permit the NRC staff to publish a *Federal Register* notice allowing for the normal 30-day period for public comment on the proposed NSHC determination, the licensee may apply for the amendment under exigent circumstances using the provisions of 10 CFR 50.91(a)(6). Processing a license amendment under exigent circumstances allows a reduced period for public comment. In addition, due to the shortened timeframe for issuance of the amendment, the hearing request period will end after the amendment is issued. Although 10 CFR 50.58(b)(4) states that the NRC will provide a 30 day-notice of opportunity for a hearing in exigent circumstances, the staff's practice has been to allow a hearing request period of 60 days (i.e., consistent with 10 CFR 2.309(b)(3)).

Since the amendment will be issued prior to expiration of the period to request a hearing, the SE must include a final NSHC determination. The NRC staff must also justify the issuance of the amendment under exigent circumstances. See Sections 2.0 and 4.0 of the notices and environmental findings template (see ADAMS Accession No. ML20136A156) for further discussion on the SE content.

The regulation provides two methods of public notification under exigent circumstances (assuming the NRC staff determines the amendment involves NSHC): (1) via issuance of a *Federal Register* notice; or (2) via use of local media. Each of these methods is discussed below. The notice should be written at a high enough level of detail that the risk of needing to re-notice it if the licensee changes a minor element of its request is small, and the high-level description of proposed changes should allow the reader to understand what's changing and determine if they want a hearing.

Method 1 - Federal Register Notice

The first method provides a 14-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee (i.e., as an individual notice). The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML14037A053 and ML082130369 for templates of the notice and transmittal letter, respectively.

The regulation in 10 CFR 50.91(a)(2)(i) states that under 10 CFR 2.105, the NRC may provide notification of the proposed issuance of an amendment: (1) through an individual notice in the *Federal Register*, or (2) by inclusion of a notice in the periodic *Federal Register* notice of proposed actions; or (3) by publishing both such notices. Although not required by this regulation, NRC standard practice is to publish what is typically called a "repeat notice" in the "periodic *Federal Register* notice of proposed actions" (i.e., biweekly notice). The repeat notice

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is a brief abstract of the information provided in the individual notice. Similar to the discussion above in Section 3.1, this type of notice is first issued as an internal non-public memorandum from the PM to the Biweekly Notice Coordinator. See ADAMS Accession No. ML082250714 for a template of the memorandum.

Method 2 - Local Media

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

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

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

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

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

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

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

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publish a notice of proposed determination on no significant hazards consideration but will publish a notice of issuance under § 2.106 of this chapter, providing for opportunity for a hearing and for public comment after issuance.

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

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

As noted above, 10 CFR 50.91(a)(5) requires that the staff provide an opportunity for public comment after issuance of an emergency amendment. For amendments not issued in an emergency situation, the solicitation of public comment pertains to comments on the NRC staff's proposed NSHC determination in accordance with 10 CFR 50.91(a)(2)(ii). As noted in Section 3.0, comments received are normally addressed in the SE. However, for an emergency amendment, a proposed NSHC determination is not issued and any comments received will likely be after amendment issuance (i.e., staff will not be able to address comments in the SE). As such, it is recommended that any significant comments received be treated as controlled correspondence and processed in accordance with NRR Office Instruction ADM-311, "Controlled Correspondence Process."

Since the amendment will be issued prior to expiration of the hearing request period, the SE must include a final NSHC determination. The NRC staff must also justify the issuance of the amendment under emergency circumstances. See Sections 3.0 and 4.0 of the notices and environmental findings template (see ADAMS Accession No. ML20136A156) for further discussion on the SE content.

3.6 Notices for Spent Fuel Storage Capacity Expansion

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

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

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3.7 Guidance for Noticing Amendments Containing SUNSI or SGI

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

Notices for applications containing SUNSI or SGI can either be issued as part of a monthly report that is issued in the *Federal Register* (via a memorandum to the SUNSI/SGI Notice Coordinator) or as an individual notice. PMs should coordinate with the LA regarding the schedule for publication of the monthly report to ensure the time period for public comments and hearing requests are compatible with the schedule for proposed issuance of the amendment. The monthly SUNSI/SGI noticing schedule is maintained in ADAMS at Accession No. ML092640510.

For a notice to be included in the monthly report, see ADAMS Accession No. ML082660487 for a template of the Memo to the SUNSI/SGI Notice Coordinator. For an individual notice, see ADAMS Accession Nos. ML15023A473 and ML101270178 for templates of the notice and transmittal letter, respectively. Further information regarding noticing amendments containing SUNSI or SGI is contained in NRR Office Instruction LIC-201, "NRR Support to the Hearing Process."

3.8 Guidance on Re-noticing

As discussed in Section 3.0, licensees often supplement applications with additional information and may make changes to the original application. If the supplemental information expanded the scope of the proposed amendment beyond the description in the NRC staff's original notice, then the proposed amendment should be re-noticed. As an example, the description of the amendment request in the notice could read as follows:

The license amendment request was originally noticed in the *Federal Register* on [enter date and *Federal Register* citation]. The notice is being reissued in its entirety to include the revised scope, description of the amendment request, and proposed no significant hazards consideration determination.

Re-noticing could potentially impact the project schedule since the new notice will allow a second comment period and hearing request period.

3.9 Guidance on Correction Notices

If minor errors are discovered following issuance of a *Federal Register* notice (e.g., editorial, typographical type errors), a correction notice can be issued. This type of notice would not impact the original time period for public comment or to request a hearing. See ADAMS Accession No. ML14223A016 for a template for a correction notice.

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In addition to correction notices, the NRC staff can also issue notices to extend a public comment period or to re-open a public comment period. See ADAMS Accession No. ML14317A293 for a template to extend the comment period and ADAMS Accession No. ML14316A365 for a template to re-open a comment period.

4.0 Safety Evaluation

The NRC staff is required by the Atomic Energy Act and the Administrative Procedure Act to provide a basis for its licensing actions. Agency actions can be overturned if found to be "arbitrary and capricious"; in other words, the agency must be able to justify why it took the action. Moreover, licensing actions typically require findings of reasonable assurance that operation of the facility can be conducted without endangering the health and safety of the public and will not be inimical to the health and safety of the public (e.g., 10 CFR 50.57(a)). An SE is one way to provide this required basis and to document the required findings. Moreover, the Nuclear Energy Innovation and Modernization Act of 2019 ties NRC schedule requirements to the issuance of SEs, and in accordance with 10 CFR 2.337(g), any SEs will be offered into evidence in proceedings involving licensing applications. The length and level of detail of an SE may vary according to the specifics of the action in question.

In addition, staff must follow NRC Management Directive (MD) 3.53, "NRC Records and Document Management Program," Handbook 1, Part I, "Recordkeeping Requirements." Specifically, MD 3.53 requires that, in order to provide adequate documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the NRC, records shall be created and maintained that are sufficient to document the formulation and execution of basic policies and decisions and necessary actions taken, including all significant decisions and commitments reached orally (person to person, by telecommunications, or in conference). MD 3.53 provides the Commission's interpretation of its obligations under the Federal Records Act (which is codified in Title 44 of the United States Code, Chapters 21, 29, 31, and 33) and regulations promulgated by the National Archives and Records Administration (36 CFR Part 1220).

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

NRC staff SEs are not part of a plant's licensing basis. As discussed in NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," dated January 7, 2004 (ADAMS

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Accession No. ML033530249), the NRC staff should not attempt to establish licensing bases information in SEs. It is important that licensees provide the licensing bases information so that there is no confusion following the licensing action and to avoid a perception of staff-imposed backfits (see 10 CFR 50.109). A useful application of the staff's SEs, by both licensees and the staff, can be in assessing what information should be incorporated into mandated licensing bases documents following issuance of the amendment (e.g., revision to the Updated Final Safety Analysis Report (UFSAR)).

PMs and TB reviewers should establish the appropriate scope and depth for the review as part of the work planning discussed in Section 2.0 (giving due consideration to the technical complexity of the proposed change, availability of applicable precedent, timeliness goals, and guidance such as the Standard Review Plan). General guidance regarding SE planning and control, the use of precedent, and proper use of regulatory commitments is provided below. A template for a typical SE and instructions for preparing an SE is provided in the DORL boilerplates under ADAMS Package Accession No. ML20136A1618.

4.1 SE Planning and Control

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

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

The transmittal of SEs from TBs to the appropriate project organization should follow NRR Office Instruction ADM-200, "Delegation of Signature Authority." Specifically, for internal correspondence between divisions, the signature authority lies with the technical staff BC (or re-delegated to a staff member qualified in accordance with NRR Office Instruction ADM-504, "Qualification Program"). The SEs may be signed and transmitted from the technical staff BC to the appropriate project organization electronically (using an appropriate electronic signature process, such as e-mailing the SE input, which is preferred) or in hard copy, as long as the SE input transmittals are appropriately preserved by the technical staff as official agency records (OARs) in ADAMS (see Section 10.0 for additional guidance for when an internal document may warrant preservation as an OAR). The SE input prepared by the TB and the transmittal e-mail or memo needs to be placed in ADAMS by the TB as non-publicly available.

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⁸A separate SE template is available for Vogtle 3 and 4 at ADAMS Accession No. ML16290E857.

4.2 Use of Precedent and References to Approved Topical Reports

While precedents can help achieve efficiency and consistency, there are a number of considerations and cautions regarding the use of a precedent SE by staff. These include, but are not limited to, the following:

- Ensure that the precedent is appropriate for use with the intended amendment.
- Ensure that the precedent meets current expectations for format, findings, internal NRR guidance for the item, NRR guidance to industry, and technical content.
- Ensure that previous plant-specific information is replaced with information relevant to the current plant.
- Obtain TB concurrence, unless formal guidance has been issued that provides an alternative concurrence process.
- Ensure that the precedent being used corresponds to the issued SE and not to intermediate versions or drafts. Use of the final SE (as issued) for the precedent will ensure that the staff is consistent and will improve efficiency by incorporating changes made by NRR and OGC as part of the concurrence process for the precedent SE. Significant feedback received during the concurrence process from other organizations, managers, or OGC should be provided to the primary authors of the SE for consideration and incorporation into ongoing and future work products.
- Decisions to not apply specific precedents, especially precedents cited by a licensee, should be clearly explained in the SE (to avoid the appearance of being arbitrary and/or inconsistent). The staff should assess any change in a prior staff position to ensure that the safety or regulatory issue is consistent with the NRC principles of good regulation (e.g., efficiency, clarity, and reliability). The staff should also ensure that changes in staff position are assessed to determine whether the change could constitute a plant-specific or generic backfit or forward fit.

<u>Caution:</u> Changes in staff position (including a new position) may be a backfit or a forward fit per MD 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests." The direction in MD 8.4 will be used to assess whether a change in staff position is or is not a backfit or forward fit. If the change in staff position is a backfit or forward fit, the direction in MD 8.4 must be followed, including direction on communication with the licensee.

Referencing approved 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 NRR Office Instruction LIC--500, "Topical Report

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

If a licensee in its application or the NRC staff during its review identifies a deviation from the process or limitations associated with an approved 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).

Note: If an unapproved topical report that is being reviewed by the NRC staff is included in a LAR, the NRC staff should follow the guidance in NRR Office Instruction LIC-109, Revision 2, "Acceptance Review Procedures," for LARs that reference unapproved topical reports.

OGC may conduct a legal review of a topical report SE that did not receive a legal review prior to or after the NRC issues its approval of the topical report. If OGC has any amendment-specific concerns or comments arising from the legal review of the topical report SE, PMs should immediately seek direction from their BCs on the most appropriate manner to disposition OGC's amendment-specific concerns or comments. The reviewing attorney, with support from the PM, will determine whether addressing OGC's amendment-specific concerns or comments after approval of a topical report would result in a change in staff position. The reviewing attorney, with support from the PM, should ensure that any change in staff position is assessed to determine whether the change could constitute a plant-specific or generic backfit or forward fit. If OGC has any generic concerns or comments on the topical report SE, the PMs, with assistance from their BCs, should hand over the concerns or comments to the BC responsible for topical report reviews for disposition. Once OGC has reviewed a topical report SE as part of a review of a licensing action, the topical report SE is considered to be "reviewed by OGC" and will not require OGC review if referenced in future licensing actions.

4.3 Requests for Additional Information

The guidance for developing and processing RAIs is provided in NRR Office Instruction LIC-115, "Processing Requests for Additional Information." The technical and project staff will follow the direction in NRR Office Instruction LIC-115.

It is expected that a draft SE input be developed before preparing RAIs such that any "holes" (i.e., missing information) in the SE input would inform the staff's determination of the additional information that is required. Developing draft SEs at the RAI stage enhances our safety focus

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by ensuring we obtain the necessary information to complete the review, while providing greater clarity and discipline in the RAI process. The TB should be able to correlate each RAI to a hole in the draft SE input that the licensee response is expected to fill. The expectation that a draft SE input be prepared may be waived with agreement between the technical and project BCs. Applying this waiver should be the exception and not the rule and is anticipated to be used primarily in cases where expediency is necessary (e.g., exigent and emergency amendments) or where development of the draft SE would have an overwhelmingly negative impact on the schedule not commensurate with the benefit.

Note, although "holes" in a draft SE inform the need for any RAIs, the final SE should not explicitly cite RAIs and RAI responses. The information contained within an RAI response may be included in the SE, if it is material to the regulatory finding. Simple clarifications do not rise to the threshold of documentation in the SE. Additionally, the fact that an RAI was issued should not be discussed. Information contained within an RAI response may be described in an SE only when it:

- Provides information that is new or supersedes existing information;
- Addresses a significant or generic technical concern that would have affected whether the request would be approved;
- Supports the response to a related enforcement issue; and/or
- Documents a response to an external stakeholder issue raised during administrative related activities such as hearings, petitions, etc.

The scope of the discussion should appropriately describe the technical concern, identify which document the response information was provided in, and discuss how the information resolved the concern without detailing the asked questions. The SE need only address the technical areas under review.

Note: In the transmittal of RAIs to the appropriate project organization, the TB BC should acknowledge the review of the draft SE, confirming that "holes" in the draft SE line up with the RAIs being asked.

If a licensee does not respond to the RAI by the date specified and the NRC staff plans to deny the application consistent with 10 CFR 2.108, "Denial of application for failure to supply information," then the PM should follow the process described in Section 6.3 of this Appendix. It should be noted that denial based on failure to supply information does not require a denial SE.

4.4 Regulatory Commitments and License Conditions

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

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4.4.1 Regulatory Commitments

LIC-100 states, "The licensing bases for a nuclear power reactor can be represented by a few categories of information that form a hierarchy structure in terms of associated change controls and reporting requirements." LIC-100 lists obligations, mandated licensing bases documents, and regulatory commitments as the categories in this hierarchy and defines these categories as follows:

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

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

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

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

<u>Caution:</u> Escalating commitments into obligations or into a mandated licensing basis document may be a backfit or forward fit per MD 8.4. MD 8.4 will be used to assess whether the escalation is or is not a backfit or forward fit. If the escalation is a backfit or forward fit, the direction in MD 8.4 must be followed, including direction on communication with the licensee.

For those regulatory commitments that don't warrant escalation into an obligation but are relied on by the staff as an element of the staff's approval of the proposed amendment, the staff's SE can rely on the commitment if the commitment is subsequently incorporated into a mandated licensing basis document (e.g., UFSAR). For example, many amendments involve relocation of

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information from the technical specifications to a licensee-controlled document (e.g., UFSAR, technical requirements manual). Relocation of this information is typically identified as a commitment in the licensee's application. For these types of amendments, the staff's SE will usually need to make a conclusion that future changes to the relocated material will be adequately controlled under the provisions of 10 CFR 50.59. In order to ensure that the provisions of 10 CFR 50.59 apply to the information removed from the technical specifications when the licensee implements the amendment, the PM should add language to the implementation statement on the amendment page similar to the following:

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

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

4.4.2 NRC-Proposed License Conditions

Per 10 CFR 50.10(b), a power plant may only be used as authorized by a license issued by the Commission. As stated in 10 CFR 50.50, when the Commission issues a license, it will include such conditions as the Commission deems appropriate and necessary. License conditions are a form of obligation (i.e., legally binding condition or action) and are formal statements included in the license necessary to establish, implement, or maintain applicable rules, regulations, or licensing bases.

In accordance with 10 CFR 50.54, all power reactor licenses include certain conditions. Specifically, 10 CFR 50.54(a) to 50.54(ii) are, with certain exceptions, conditions in every nuclear power reactor operating license issued under 10 CFR Part 50 and every combined license issued under 10 CFR Part 52.

License conditions should:

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

License conditions should not:

- address issues already addressed by an existing rule, requirement, order, or regulation;
- require NRC action to complete;
- be open-ended;

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- address a facility not controlled by the license; or
- address voluntary requests.

The NRC staff may impose license conditions without agreement from the licensee. However, to ensure no unintended consequences, it is strongly recommended that the NRC staff seek the licensee's views on the language of NRC-proposed license conditions. The NRC staff's request to the licensee should fully describe the proposed license condition, and the request should be sent from the responsible project division director or above. The NRC staff request can be done through the RAI process or a separate letter to the licensee. Licensee comments on the proposed license condition (i.e., response) should be documented via a formal docketed submittal (under oath or affirmation).

<u>Caution:</u> Imposing a license condition on a licensee may be a backfit or forward fit per MD 8.4. The direction in MD 8.4 will be used to assess whether the NRC-proposed license condition is or is not a backfit or forward fit. If the NRC-proposed license condition is a backfit or forward fit, the direction in MD 8.4 must be followed, including direction on communication with the licensee.

<u>Caution:</u> Imposing an NRC-proposed license condition on a licensee could be construed as a partial denial of an amendment request, requiring the NRC to issue a *Federal Register* notice that offers the licensee an opportunity to request a hearing (see 10 CFR 2.103). See section 6.3, below.

4.5 Environmental Considerations

Most proposed amendments fit under one of the categorical exclusions in 10 CFR 51.22(c) and, as such, do not require an environmental assessment (EA). However, it is a good practice for the PM to determine if an EA is needed early during the license amendment review. As needed, the PM should coordinate with the environmental reviewer and OGC to determine the need for an EA. Further guidance on whether an EA is required is contained in the Section 7.0 of the attached notices and environmental findings template (see ADAMS Accession No. ML20136A156). Specific guidance on preparing EAs and considering environmental issues is contained in NRR Office Instruction LIC-203, "Procedural Guidance for Preparing Categorical Exclusions, Environmental Assessments, and Considering Environmental Issues."

5.0 Amendment Package Preparation and Concurrence

5.1 Amendment Package Preparation

After the PM has received all the required SE inputs (or the PM has prepared the SE), the PM should begin assembly of the amendment package, so it is ready for review and concurrence.

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SE inputs should be integrated into a single SE using the guidance in Safety Evaluation Template (ADAMS Package Accession No. ML20136A161).

After the PM integrates all the SE inputs, if the draft SE contains SUNSI (e.g., proprietary or security-related information) or potentially contains SUNSI, the PM should send the draft version of the SE to the licensee to determine if it appropriately identifies information which is considered to contain SUNSI. Any information considered by the NRC staff to contain SUNSI should be marked within double brackets (i.e., [[......]]). The draft version of the SE can be provided by letter or electronically using the BOX - Enterprise File Synchronization and Sharing (EFSS) Solution.

The transmittal letter to the licensee should clearly state that the requested review is in regard to whether the information is properly marked as SUNSI only. The transmittal letter should be made available to the public, and the enclosed SE should be withheld from the public until the submitter confirms that there is no proprietary information in the SE. When an SE or other staff report contains proprietary information, a non-proprietary version should also be prepared by the staff, if practicable, to be placed in the public domain.

The following are examples of letters transmitting draft SEs for licensee review: (1) letter transmitting SE potentially containing proprietary information (ADAMS Accession No. ML112430591); and (2) letter transmitting SE containing proprietary information (ADAMS Accession No. ML102710032). Additional sample letters for transmitting draft SEs can be found in ADAMS at Package Accession No. ML062080003. See ADAMS Accession No. ML062080129 for the template draft safety evaluation letter.

To use BOX – EFSS, the PM will need to request a folder be created by one of the NRC Box Administrators or via the NRC Service Catalog. After a folder has been created for the project manager, an electronic copy of the draft SE should be placed in the folder. Then the project manager will provide a link to the folder to the licensee. Note that the licensee must create a BOX account, which is free, to access the draft SE. More detailed information on the use of the BOX – EFSS Solution is available in the NRC Box – EFSS User Guide.

Following receipt of the response from the licensee, the PM should revise the draft SE, as required, to correctly denote the information considered to contain SUNSI. At this time, the PM should also prepare a redacted version of the SE, which can be made publicly available if the amendment is approved for issuance. See ADAMS Package Accession No. ML102700263 for an example of an amendment that transmitted proprietary and non-proprietary versions of the SE.

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Further guidance on transmittal of proprietary information is provided in NRR Office Instruction LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure."

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

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

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

- Transmittal letter.
- License amendment pages.
- List of revised license and technical specification pages (and other appendices to the license, as applicable).
- Revised license and technical specification pages (and other appendices to the license, as applicable).
- SE.
- Notice of Issuance.
- For plants with a COL that both an amendment and exemption requests are being processed, the exemption should be added to the package.

All documents in the package except for the notice of issuance should be assembled into an ADAMS package. To assist those requested to concur (discussed further below in Section 5.2), the PM should include the following in the amendment package (in addition to items listed above):

- copy of the incoming license amendment application and all licensee supplements
- copy of the *Federal Register* notice that provided public notification regarding the proposed issuance of the amendment
- copy of TB SE inputs

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 copy of any relevant background information, including information used in preparing the SE (e.g., UFSAR sections, guidance documents) and documents referenced in the SE (if not readily available in ADAMS or on the NRC Web site)

5.2 Concurrence

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

LA concurrence is required for all license amendments. See LIC-101, Section 5.0, "Responsibilities and Authorities," Sub-section D, "Amendment Package Processing," for specific LA responsibilities related to review and concurrence. Further guidance for LA review of the amendment package is contained in the "DORL Licensing Assistant Review (for Most Documents)" checklist (ADAMS Accession No. ML15352A155).

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

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

OGC must review all license amendments except under previously agreed upon conditions (e.g., see Section 8.2.2 regarding the CLIIP). OGC reviews the amendment package for "no legal objection."

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

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

<u>Caution</u>: If the amendment package will be forwarded to the NRR Office Director for signature, it is expected that a second LA perform a peer review of the amendment package before the package is sent to the NRR Office Director. It is recommended that this step be performed after the project division director review so that all changes made during the concurrence process are reviewed. The PM should request the LA peer review through their respective BC.

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

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

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

- (1) the LA check <u>www.regulations.gov</u> to determine if there are any public comments on the proposed NSHC;
- (2) the LA contact the Office of the Secretary to determine whether a hearing has been requested; and
- (3) the PM contact the State official in accordance with the requirements in 10 CFR 50.91(b).

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

6.0 Amendment Issuance, Denial, Withdrawal, and Corrections

6.1 Regulatory Background

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

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

- A. The application for amendment filed by [licensee] dated [insert date] complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I;
- B. The facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission;

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- C. There is reasonable assurance: (i) that the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the Commission's regulations set forth in 10 CFR Chapter I;
- D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public; and
- E. The issuance of this amendment is in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

The regulations concerning withdrawal are addressed primarily in 10 CFR 2.107, which states, in part, that the Commission may permit an applicant to withdraw an application prior to the issuance of a notice of hearing on such terms and conditions as it may prescribe, or may, on receiving a request for withdrawal of an application, deny the application or dismiss it with prejudice. If the application is withdrawn prior to issuance of a notice of hearing, the Commission shall dismiss the proceeding. Withdrawal of an application after the issuance of a notice of hearing shall be on such terms as the presiding officer may prescribe.

6.2 Amendment Issuance

After the required concurrence signatures are obtained, and the NRC staff determines that the proposed amendment is acceptable and should be issued, the PM should forward the original amendment package to the administrative assistant for processing and scanning in preparation for dispatch. If amendment numbers had not previously been added to the package, the PM should ensure that the LA has assigned amendment numbers on the amendment routing sheet. The PM should give the package to the administrative assistant organized in the following order:

- Transmittal letter.
- License amendment pages.
- List of revised license and technical specification pages (and other appendices to the license, as applicable).
- Revised license and technical specification pages (and other appendices to the license, as applicable).
- SE.
- Notice of Issuance.

Following processing and scanning of the package, the administrative assistant will e-mail a copy to the LA for a final quality assurance check. This LA check should be a cursory review to ensure that the concurrence blocks are complete, all pages are properly dated, amendment

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numbers have been properly added, and that pages are in the proper order with no pages missing. The purpose is not to do a new LA review. However, if errors are noted beyond any scanning or document processing errors, the LA should coordinate with the PM to discuss the need for any other corrections before the amendment is sent out via Listserv.

6.3 Amendment Denial or Withdrawal

Early and enhanced management attention and engagement should be provided whenever staff is considering denial of a license amendment for technical or safety reasons. Some licensing requests may not satisfy NRC safety regulations and warrant a denial. Whenever a denial is being considered, a BC-level meeting between the technical and project branches should be held at the earliest opportunity. If the outcome of that meeting is anything other than alignment to continue the staff's review, the respective division-level management should be briefed expeditiously. The technical and project BCs should collaborate to prepare a joint briefing with options and recommendations, even if differing views exist. If the division-level management support a denial recommendation, a denial SE shall be prepared and processed as discussed below.

If the NRC staff's review of the proposed amendment determines that the amendment should be denied, the staff must prepare an SE documenting the basis for the denial. The denial SE does not need to address aspects of the request that are acceptable, but it should address all aspects of the request that are not acceptable to the staff, and the evaluation should be sufficient to support a conclusion that the amendment is not acceptable. The PM should also prepare a denial transmittal letter (see ADAMS Accession No. ML082040984 for a template) and a Federal Register Notice of Denial (see ADAMS Accession No. ML14013A013 for a template). Consistent with NRR Office Instruction ADM-200, the project division director is added to the concurrence block and is the signature authority for the denial transmittal letter.

The PM should obtain concurrences from the LA, applicable technical BCs, OGC, and the project BC. However, the project division director concurrence and signature will initially be left blank. Following receipt of the project BC concurrence to deny the amendment, the PM and BC will brief the project division-level management regarding the intent to deny the amendment. Assuming the division-level management agrees with this path going forward, the PM will contact the licensee to arrange for a call with the project division-level management. During the initial contact, the PM should inform the licensee that the staff plans to deny the amendment. The PM should also coordinate with the applicable TB reviewers to arrange for them to be available during the call between the project division-level management and the licensee. TB reviewers should be prepared to discuss their regulatory findings during the call.

During the call, the project division-level management will inform the licensee of the staff plans to deny the amendment and offer the licensee an opportunity to withdraw the amendment or to request a public meeting for further discussion of the issues. To ensure that the licensee has a meaningful opportunity to make an informed business decision on denial or withdrawal, the project division-level management (with assistance from TB reviewers as necessary) will provide the basis for the staff's plan to deny the amendment. The project division-level management should make clear that if the licensee does not either submit a formal withdrawal

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in writing by a specific date (e.g., 2 or 3 days from the call) or request a public meeting by the same date, the staff will issue the denial.

If the licensee submits a request to withdraw the amendment, the PM should prepare a transmittal letter documenting the withdrawal (see ADAMS Accession No. ML082260953 for a template) and a *Federal Register* Notice of Withdrawal (see ADAMS Accession No. ML14013A020 for a template). If a hearing on the amendment has been granted, the terms of the withdrawal must be consistent with the withdrawal terms, if any, set by the presiding officer. Following issuance of the transmittal letter and Notice of Withdrawal, the PM should prepare an internal non-public memorandum to the project BC, which documents the call with the licensee and the decision by the licensee to withdraw the proposed amendment. The draft SE documenting the basis for the planned denial of the amendment should be included as an enclosure to the memorandum to ensure that an adequate record of the staff's decision-making process is captured as an OAR (i.e., consistent with MD 3.53 as discussed in Section 10.0 of this office instruction).

If the licensee does not withdraw the amendment or request a public meeting by the date set during the project division-level management call, the PM should obtain the division director's concurrence and signature on the denial package and formally issue the denial.

6.4 Amendment Corrections

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

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

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license. The limitation on tracing the introduction of a typographical error to a specific amendment application is necessary to establish that the change introduced by the error was in fact improperly made.

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

The amendment itself (i.e., the two-page document usually signed by the project BC) is legally binding. Amendments often change operating license pages. Operating license pages are legally binding. The issue of errors in the two-page document or the operating license pages is not addressed by SECY-96-238. In the absence of a policy, the staff should follow the same principle set forth in SECY-96-238 (for correction to the TSs) for the correction of errors in the amendment itself or in operating license pages.

In general, correction letters will not involve a significant amount of time or schedule to complete and the effort will usually just involve the PM, LA, and BC. For cases such as this, the PM does not need to take out a new EPID (i.e., PM should use the plant PM EPID for time spent on this effort). For more complicated correction letters (e.g., involving use of staff outside of the project organization), the PM should request a new EPID as a fee-billable, other licensing activity (i.e., activity code "RO").

7.0 Preliminary Amendment Request (PAR)

Use of the PAR process is limited to reactors under construction in accordance with a combined license. For changes during construction arising after the issuance of the COL and before the 10 CFR 52.103(g) finding, the licensee has the option of using the PAR process in accordance with the specific terms in the plant's license for changes during construction. The licensee may use the PAR process for license amendments at any time before the 10 CFR 52.103(g) finding.

The result of the PAR process is a determination of whether the NRC has any objection to a licensee proceeding with the construction and testing of a proposed plant change or proposed modification requiring a license amendment or exemption while the NRC is conducting the detailed technical review of the related LAR. A licensee may proceed with construction and testing only upon receipt of the no objection PAR determination notification. The NRC "No Objection" determination of the PAR is not a pre-approval of the LAR on its technical merits, nor does it imply any NRC approval of the LAR. If the LAR is subsequently approved, the licensee would change the licensing basis in its updated final safety analysis report (UFSAR). If the LAR is subsequently denied, the licensee must return the facility to its current licensing basis. In all cases, the licensee must obtain the NRC LAR determination for the changed or modified structures, systems or components (SSCs) prior to the completion of its inspections, tests, analyses and acceptance criteria (ITAAC) and the related ITAAC Closure Notification submittal to the NRC.

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To use the PAR process, the licensee should submit a written request to the NRC in accordance with NRC interim staff guidance COL-ISG-025, "Changes during Construction Under Title 10 of the Code of Federal Regulations Part 52," consistent with the plant's license condition related to changes during construction.

The activities supporting PAR review should be charged to the same EPID as the corresponding license amendment request. The PM should include completion of the PAR review as a milestone in the amendment review schedule in RPS. The NRC staff will conduct the review of the PAR consistent with the direction in COL-ISG-025.

The PAR determination is not pre-approval of the LAR, nor does it imply any NRC approval of the LAR. As noted in COL-ISG-025, related to the "Preliminary Amendment Request Process," the NRC will not issue a determination on the PAR until, (1) the licensee submits the LAR and (2) the NRC has accepted the related LAR for review. As noted, the LAR acceptance process must confirm two conditions: first, the staff must verify that the requested amendment involves NSHC, and second, the staff must verify that a categorical exclusion in 10 CFR 51.22 applies to the requested amendment. If the licensee elects to proceed with construction after receiving the NRC's PAR determination of "No Objection," and the LAR is subsequently withdrawn or denied, the licensee must return the facility to its CLB. The timeframe for issuance of the PAR determination notification will be established with consideration of the licensee's construction schedules and NRC resources.

After (1) the licensee submits the related LAR and (2) the NRC has accepted the related LAR for detailed technical review, the PM will prepare the PAR determination (i.e., notification) letter for internal concurrence and transmittal to the licensee. The NRC's PAR determination letter will state whether the licensee may proceed in accordance with the PAR, LAR, and COL-ISG-025. The respective technical divisions that were consulted in the PAR review will be included on concurrence.

8.0 Technical Specifications Task Force (TSTF) Travelers

8.1 Background

The Standard Technical Specifications (STS) for the six vendor designs include Babcock & Wilcox (NUREG-1430), Westinghouse (NUREG-1431), Combustion Engineering (NUREG-1432), General Electric Boiling Water Reactor (BWR)/4 (NUREG-1433), General Electric BWR/6 (NUREG-1434), and Advanced Passive 1000 (AP1000) Plants (NUREG-2194).

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

Using the Traveler process to change the STS improves the efficiency of the licensing process by allowing the NRC staff to review and approve a proposed change that will be used and

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referenced in the preparation of license amendment requests by multiple licensees following approval of the Traveler. The Traveler provides the model technical and regulatory bases for the license amendment request.

Additionally, selected TSTF Travelers are approved as part of the Consolidated Line Item Improvement Process (CLIIP). When TSTF Travelers are "CLIIPed," additional efficiencies are gained. CLIIP Travelers, when adopted by a licensee, require minimal plant-specific information or justification for use—such staff need only verify that the facility design and operational conditions fall within those postulated in the CLIIP. Therefore, the NRC staff can review a CLIIP license amendment request in less time than that of a non-CLIIP request. CLIIP license amendment requests typically do not require review by the TBs. Only the branch responsible for technical specification and the plant PM typically need to review a CLIIP license amendment request, unless it is a risk-informed CLIIP license amendment request, which would also need to be reviewed by risk analyst.

Model SEs are prepared for all approved Travelers, whether or not they are part of the CLIIP.⁹ A model application is submitted by the TSTF as an attachment to the Traveler. Approved Travelers ("non-CLIIPed" and "CLIIPed") may be adopted by licensees that have converted to the STS, as well as licensees that have not converted to the STS but have determined that the technical specification changes are applicable to their facilities. The model application will cite any plant-specific verification or other information needed in a licensee's application. The process for review of TSTF Travelers is described in detail in NRR Office Instruction LIC-600.

8.2 Processing of Amendment Requests Based on Approved Travelers

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

During the acceptance review, the NRC staff should review the licensee's application to ensure that it is consistent with the model application for the approved Traveler. The NRC staff should follow as closely as possible the model SE when preparing the plant-specific SE. The model SE approving a Traveler has been approved by OGC, the branch responsible for technical specification, and other appropriate TBs. If the model SE is not followed closely, then the efficiency gains are lost and the plant-specific SE may receive additional OGC comments and need to be reviewed by the TBs.

8.2.1 Amendments to Adopt Approved Travelers Not Part of the CLIIP

The PM should consult with the branch responsible for technical specifications to determine which TBs need to review or concur on any amendment request to adopt approved Travelers

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⁹In the past, model SEs were not prepared for all approved Travelers; the NRC staff would prepare a model application. However, that is no longer the case.

that are not part of the CLIIP. These amendment requests will be treated as normal license amendments and, as such, will be subject to the normal licensing action review timeliness metrics. The licensee's application should follow the model application as closely as possible and provide any needed plant-specific information.

8.2.2 Amendments to Adopt Approved Travelers as Part of the CLIIP

When the PM receives an application submitted based on an approved Traveler as part of the CLIIP, before the EPID is requested the PM in coordination with the technical staff from the branch responsible for technical specifications should review the application to assess whether the licensee provided the necessary plant-specific verifications and other information as cited in and model application. The PM should also make note of any exceptions or deviations discussed in the licensee's application. The level of conformity to the model application (including differences between the plant-specific TSs and the STS) will determine whether the amendment will be reviewed as a CLIIP amendment (with an accelerated review schedule) or as a normal license amendment (with a review schedule consistent with the normal timeliness goals). As needed, the PM should coordinate with the branch responsible for technical specifications in making the determination.

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

[Plant Name including unit numbers] [TSTF Traveler Title] Using CLIIP (TSTF-[number])

When filling out RPS (discussed in Section 2.1), the PM should identify the branch responsible for technical specifications as the recommended lead branch. The PM should consult with the branch responsible for technical specifications to determine the need for input or concurrence from other TBs.

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

9.0 Amendments for Emergency Plan Changes

9.1 Background and Regulatory Requirements

In a final rule dated November 23, 2011 (76 FR 72560), the NRC amended its regulations pertaining to emergency preparedness. The final rule, in part, revised the regulatory process for NRC approval of emergency plan changes. This section describes the regulatory requirements

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associated with emergency plan changes including those changes made by the final rule. Section 9.2 provides guidance on processing of emergency plan changes consistent with the final rule.

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

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

9.1.1 Emergency Plan Changes

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

As defined in 10 CFR 50.54(q)(1), a "reduction in effectiveness" means a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency. As also defined in 10 CFR 50.54(q)(1), an:

"emergency planning function" means a capability or resource necessary to prepare for and respond to a radiological emergency, as set forth in the elements of Section IV of Appendix E to 10 CFR Part 50, and, for nuclear power reactor licensees, the planning standards of 10 CFR 50.47(b).

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

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

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

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

If a licensee's analysis of a proposed change determines that the change would result in a reduction of effectiveness of the emergency plan, and the plan, as changed would not meet the requirements in Appendix E to 10 CFR Part 50 and the planning standards of 10 CFR 50.47(b), the licensee would need to request an exemption from the affected requirements in accordance with 10 CFR 50.12.

Consistent with the requirements in 10 CFR 50.54(s)(3), the NRC will base its finding that adequate protective measures can and will be taken in the event of a radiological emergency based on a review of Federal Emergency Management Agency (FEMA) findings and determinations as to whether State and local emergency plans are adequate and capable of being implemented, and on the NRC assessment as to whether the licensee's emergency plans are adequate and capable of being implemented. As such, a proposed change to a licensee's emergency plan that has the potential, based on NRC staff's review, or as determined by the licensee, of impacting the requirements of FEMA-approved State and local emergency plans, will be referred to FEMA for evaluation and FEMA's input will be considered in the staff's technical review in determining the acceptability of a proposed change. A discussion of interagency roles and responsibilities is provided in the "Memorandum of Understanding between the Department of Homeland Security / Federal Emergency Management Agency and Nuclear Regulatory Commission Regarding Radiological Emergency Response, Planning, and Preparedness" (ADAMS Accession No. ML15344A371).

Appendix A to NRC Regulatory Guide (RG) 1.219, "Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors," dated November 2011 (ADAMS Accession No. ML102510626), provides a flowchart of an acceptable licensee decision-making process for whether a proposed emergency plan change requires NRC prior approval. A detailed discussion of this process is included in Section C.5, "Review Process" of the RG. Section C.4, "Emergency Planning Functions," of the RG provides examples of changes that are expected to result in a reduction of effectiveness of the emergency plan and examples of changes that would likely not result in a reduction in effectiveness of the emergency plan. As explained in

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Section C.4.a, these examples are not all inclusive or exclusive, and site-specific situations may possibly make a particular example inapplicable to that site. Even if a particular example completely encompasses the change under consideration, the licensee's evaluation must explain why the site-specific implementation of the change would not reduce the effectiveness of the emergency plan for that particular site. Such an analysis cannot simply cross-reference an example in the RG.

9.1.2 Emergency Action Level (EAL) Changes

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

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

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

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

In addition to the above documents:

- Revision 5 of NEI 99-01, "Methodology for Development of Emergency Action Levels," dated February 2008 (ADAMS Accession No. ML080450149), was endorsed as an acceptable method for EAL scheme development as discussed in an NRC letter dated February 22, 2008 (ADAMS Accession No. ML080430535).
- Revision 6 of NEI 99-01, "Development of Emergency Action Levels for Non-Passive Reactors," dated November 2012 (ADAMS Accession No. ML12326A805), was endorsed as an acceptable method for EAL scheme development as discussed in an NRC letter dated March 28, 2013 (ADAMS Accession No. ML12346A463).

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 Revision 0 of NEI 07-01 dated July 2009, "Methodology for the Development of Emergency Action Levels, Advanced Passive Light Water Reactors" (ADAMS Accession No. ML092030210), was endorsed for use by current and prospective applicants as a reference in the development of their new reactor applications using the AP1000 or Economic Simplified Boiling Water Reactor (ESBWR) designs as discussed in an NRC letter dated August 12, 2009 (ADAMS Accession No. ML092190035).

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

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

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

9.2 Processing of Emergency Plan Changes

Consistent with the requirements stated in 10 CFR 50.54(q)(4), the proposed changes to emergency plans and individual EALs that would reduce the effectiveness of the emergency plan must be submitted to the NRC as license amendment requests. In addition, proposed EAL scheme changes need to be submitted to the NRC as license amendment requests, as stated in Section IV.B.2 of Appendix E to 10 CFR Part 50.

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

9.2.1 Work Request

Proposed emergency plan changes, for which the licensee has requested prior NRC approval, should be forwarded with the licensee's application to the Office of Nuclear Security and Incident Response (NSIR), Division of Preparedness and Response (DPR), Reactor Licensing Branch (RLB), using the standard RPS process described above in Sections 2.1 and 2.2.

In addition to proposed changes to emergency plans, for which the licensee has requested prior NRC approval, the emergency preparedness regulations require certain submittals to the NRC

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pursuant to the requirements in 10 CFR 50.4 (e.g., emergency plan changes that have been evaluated by the licensee as not representing a reduction in effectiveness, updates to the licensee's evacuation time estimates, and biennial exercise scenarios). For submittals that do not request NRC prior approval, EPID are not required unless specifically requested by NSIR. In addition, since NSIR staff receives these submittals via e-mail distribution from the NRC's Document Control Desk (DCD), the PM does not need to forward these types of incoming documents to NSIR.

9.2.2 SUNSI Review

In accordance with the SRM for SECY-15-0032, "Reviewing Documents for Public Release under Sensitive Unclassified Non-Safeguards Information Guidance," dated June 15, 2015 (ADAMS Accession No. ML15167A090), the NRC staff will apply the SUNSI policy to review, release, and withhold emergency preparedness documents. Prior to this SRM, these documents were initially profiled by the NRC's DCD as non-publicly available and the staff was not requested to perform a SUNSI review. In response to the SRM, the documents will still be initially profiled as non-publicly available; however, the staff will be requested to perform a SUNSI review.

SUNSI reviews of incoming emergency preparedness documents will be performed in accordance with the guidance in NSIR Office Procedure EP-200, "NSIR Process for the Review of Sensitive Unclassified Non-Safeguards Information in Emergency Preparedness Documents" (ADAMS Accession No. ML16029A366). To address ADAMS public release timeliness report concerns, the PM will conduct a SUNSI review of the cover letters of incoming emergency preparedness documents that are added to ADAMS as "Non-Public Pending Review" within 5 working days. NSIR staff will be responsible for performing the SUNSI review of the attachments to the cover letter at a later time. If the PM determines that the cover letter does not contain SUNSI, the PM should send an e-mail addressed to ADAMS IM requesting that the cover letter be made publicly available. In general, the easiest way to do this is to forward the ERIDs e-mail for the subject document to ADAMS IM with a message such as the following:

ADAMS IM,

I have reviewed the cover letter for the document below and determined that it does not contain SUNSI and can be made publicly available. However, I have not reviewed the rest of the document. The rest of the document will be reviewed at a later time by NSIR.

In accordance with the guidance in Section 5.1 of NSIR Office Procedure EP-200 (ML16029A366), please create a package with the cover letter designated "Publicly Available" and the remainder of the document designated "Non-Public Pending Review."

Thanks,

[Project Manager Name]

Project Manager for [Plant Name]

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The PM should copy the NSIRDPR-ORLT Resource mailbox on the e-mail to ADAMS IM. In addition, the PM should forward the response from ADAMS IM to the NSIRDPR-ORLT Resource mailbox so NSIR is aware of the package accession number.

See NSIR Office Procedure EP-200 for further guidance for performance of the SUNSI reviews.

9.2.3 Safety Evaluation

The SE for all emergency plan changes, including EAL changes, should include a conclusion regarding whether the emergency plan as revised by the proposed change: (1) continues to meet the planning standards in 10 CFR 50.47(b) and the requirements in Appendix E to 10 CFR Part 50; and (2) continues to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

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

9.2.4 Environmental Considerations

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

9.2.5 Amendment Page Wording

The amendment page for a typical amendment affecting the technical specifications would include wording such as the following on the amendment page (plant-specific boilerplates may be slightly different depending on the actual license condition wording):

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

Technical Specifications and Environmental Protection Plan

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

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with the Technical Specifications and the Environmental Protection Plan.

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

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

2. Accordingly, by Amendment No. , Facility Operating License No. [license number] is hereby amended to authorize revision to the [name of emergency plan] as set forth in [Licensee Name]'s application dated [enter date], as supplemented by letters dated [enter dates], and evaluated in the NRC staff's safety evaluation dated [enter date of safety evaluation]. The license amendment is effective as of its date of issuance and shall be implemented within [insert per application] days.

9.2.6 Signature Authority

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

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

All three items above require review by OGC.

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

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10.0 Official Agency Records

10.1 Introduction

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

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

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

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

10.2 Identification of OARs

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

- licensee amendment submittals
- NRC letters and e-mails documenting the acceptance review
- requests for additional information to licensee
- licensee responses to requests for additional information
- NRC letters and memoranda transmitting notices for publication in the Federal Register

SEs written by NRC staff

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

The above records shall be entered in ADAMS as OARs.

In some cases, working files may meet criteria to be considered OARs. However, NRR has determined that working files associated with the license amendment process (such as work requests, cover sheets, 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 SE issued with the license amendment.

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Appendix C

Guide for Processing License Amendments For Non-Power Production and Utilization Facilities Revision 0

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1.0 Introduction

This guide provides staff in the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Reactor Regulation (NRR), Division of Advanced Reactors and Non-Power Production and Utilization Facilities (DANU) a basic framework for processing license amendment applications for non-power production and utilization facilities (NPUFs). NPUFs are non-power reactors (research reactors and testing facilities) and utilization and production facilities used in the production of medical radioisotopes. NPUFs are licensed under Section 104 or 103 of the Atomic Energy Act of 1954, as amended (AEA). In the regulations, this corresponds to facilities licensed under Title 10 of the Code of Federal Regulations (10 CFR) Section 50.21(a) or (c), or both Section 50.21(a) and (c), for AEA Section 104 facilities or 10 CFR 50.22 for AEA Section 103 facilities. The regulations in 10 CFR 50.91 and 10 CFR 50.92(c) only apply to facilities licensed under 10 CFR 50.22 and testing facilities. In addition, NPUFs licensed under Section 104 of the AEA are subject to "minimum regulation." The AEA states that "the Commission is directed to impose only such minimum amount of regulation of the licensee as the Commission finds will permit the Commission to fulfill its obligations under this Act to promote the common defense and security and to protect the health and safety of the public and will permit the conduct of widespread and diverse research and development." The application of minimum regulation is reflected in differences between the process for the issuance of license amendments for AEA Section 104a, and 104c, facilities (i.e., non-testing facilities) and the process for testing and other facilities under AEA Section 103.

Some of the guidance contained in this document may be used, where appropriate, for the processing of other licensing actions and activities where specific guidance is not provided in a related office instruction. For example, the guidance on requests for additional information (RAIs) may be utilized for any licensing action or activity for which the NRC staff asks the licensee for additional information.

NRR staff involved in processing license amendments should identify any possible improvements to this guidance and submit suggestions to their management or to the contact listed for LIC-101.

1.1 Objectives

The primary objective of this guide is to provide NRR staff a basic framework to process license amendment applications for NPUFs, thereby improving NRR's efficiency and consistency in performing these reviews. This procedure should enhance NRR's efficiency in responding to the needs of the licensees, the public, and other stakeholders. Specific objectives include the following:

- Promote consistency in processing of license amendments.
- Improve internal and external communications.
- Increase technical consistency for similar licensing actions.

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- Minimize delays in reviewing license amendments (i.e., meet licensing action timeliness goals).
- Provide staff with an improved framework for processing license amendment requests.

1.2 Process Overview

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

The role of the project manager (PM) in the license amendment process is to manage the NRC's review of the application, either by performing the review or by overseeing the review performed by technical staff or contractors. The PM ensures that the guidelines in Office Instruction LIC-101 and the NRC's Principles of Good Regulation are adhered to throughout the process. PMs and technical staff are jointly responsible for ensuring that NRR meets the goals established in the agency's operating and performance plans. The process employed for license amendment reviews can be characterized by the following sub-processes:

- work planning and acceptance review
- public notification and comment resolution
- technical review, including preparation the safety evaluation (SE)
- amendment package processing

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

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

2.0 Work Planning and Acceptance Review

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

PMs are responsible for the general oversight and coordination of activities related to processing NPUF license amendments. NPUF technical reviews may be performed by

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contractors, NRR technical staff, DANU staff, and/or the NPUF PM. Projects are tracked in the Reactor Program System (RPS). If a contractor is to be used for technical review, the contracting process needs to be completed before contractor review activities can begin. Office of Nuclear Regulatory Research (RES) technical review services for NPUF amendment reviews are requested using RES work request procedures. COM-100, "NRR Interfaces With RES" (ADAMS Accession No. ML062280401), and RES Office Instruction PRM-001, Revision 2, "Process for Responding to Work Requests: Informal Assistance Requests, Feasibility Study Requests, Research Assistance Requests, User Need Requests, and Research Plans" (ADAMS Accession No. ML17040A032), contain additional details. NPUF PMs are responsible for the following specific activities with respect to work planning and acceptance review.

2.1 Initiate a New Project in RPS

After the PM receives the license amendment application from the licensee, the NPUF PM should create a new project using the RPS software. The project should be created without significant delay after the NPUF PM receives the application.

The PM will obtain a labor cost string (i.e., enterprise project identifier (EPID)) for the license amendment application using RPS, to ensure fee recovery, if applicable, and allow tracking of the work activities. Note that most NPUF amendment reviews are exempt from fees.

The NPUF PM should review the amendment request in sufficient detail to develop a work plan that defines the scope, depth, resources, and schedule of the review. Use RPS to propose the NRR technical branches or PRLB staff that should be involved in the review, the requested milestone dates, and other work planning considerations. If a technical branch is proposed to conduct the review, the PM should contact the technical BC to confirm that the scope of the requested work is within that branch's responsibility before requesting the branch in RPS. For RES, follow RES procedures to request assistance. For reviews performed by contractors, initiate an advanced procurement plan followed by a Strategic Acquisition System requisition request. Scheduling information is entered into RPS by the NPUF PM.

The PM will review responses from technical branches (TBs) or DANU staff in RPS and resolve any issues regarding review coordination, review characterization, and proposed milestone dates. For reviews conducted by RES, refer to the RES response to the request for assistance. Because contractors are conducting their review in accordance with the contract statement of work, this step is not necessary for contractor reviews.

2.2 PM and TBs Finalize Work Plan

After the PM creates the work plan in RPS (as discussed in Section 2.1), the BCs of the TBs, if requested by the PM for support in performing the review, will receive notification from the RPS and will respond to the PM and assign reviewers as needed. The technical staff will work with the PM to ensure that the work plan is complete and that the scope, resources, and schedule are sufficient to perform the required safety review.

The technical BCs are responsible for responding to requests in RPS, including ensuring that technical reviewers are assigned promptly to support the acceptance review schedule

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established by the NPUF PM. Also, the technical BCs are responsible for ensuring that the assigned reviewers meet milestone dates agreed upon with the NPUF PM. In the event a date cannot be met, technical staff BCs are responsible for notification of the NPUF PM prior to missing the due date and coordination with the NPUF PM to establish a new due date.

The PM will review responses from licensing or TBs in RPS and resolve any issues regarding review coordination, review characterization, and proposed milestone dates. For reviews conducted by RES, the PM will refer to the RES response to the request for assistance. Because contractors are conducting their review in accordance with the contract statement of work, the schedule is that given in the statement of work. The PM should assess the responses and ensure that the work plan meets schedule goals and covers all appropriate technical areas.

Technical staff are responsible for providing acceptance review input to the PM and respective technical staff BCs. When the licensing or TB enters milestone dates into RPS, they should enter dates that they believe with a high degree of confidence can be met. The licensing or TB should carefully review the dates proposed by the PM, rather than just accepting the dates without assessing the ability to meet the dates. The licensing or TB should take into consideration the assigned technical reviewers' current/expected workload, planned leave, and priority of other tasks they are working on. In addition, the licensing or TB should consider whether the licensee's requested review schedule is realistic (e.g., licensee requesting review to be completed in a short timeframe). Furthermore, if circumstances change after the initial schedule is established such that meeting the target dates is in jeopardy, the licensing or TB reviewer should update the schedule dates for the impacted milestones after receiving approval from the licensing or TB BC and the PM.

2.3 Acceptance Review

As soon as practical following receipt of the application, the task of performing the acceptance review should begin. This review should be completed by the PM and technical reviewers (with contractor assistance, only if needed), considering the guidance in LIC-109, "Acceptance Review Procedures."

Acceptance reviews for amendment requests should be performed utilizing the general process of LIC-109. Typically, acceptance review processes for amendments should not exceed 60 calendar days. Rare cases may occur where additional acceptance review time may be appropriate (i.e., necessary use of contractors for complex amendment). The primary difference is that the periods of time for actions given in LIC 109 can be adjusted by the NPUF PM to reflect the complexity of the amendment and the resources available to the licensee to address issues identified during the acceptance review. In addition to the process in LIC-109, the NPUF

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¹LIC-109 states that research and test reactor reviews are not within its scope. However, acceptance reviews for NPUF amendment requests should be performed utilizing the applicable elements of LIC-109. This means that the process is generally the same, but deadlines are established by the NPUF PM.

PMs should review the licensee's application to ensure it contains information that addresses the following regulatory requirements:

- (a) 10 CFR 50.90 requires that the application be submitted as specified in 10 CFR 50.4, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications.
- (b) 10 CFR 50.4 specifies that the application must be addressed to the Document Control Desk (DCD). The application can also be submitted electronically (with certain restrictions as specified in 10 CFR 50.4(a)). The above requirements also apply to supplements to the application (e.g., responses to RAIs). The licensee may submit a separate electronic copy to the NPUF PM to facilitate the review process.
- (c) 10 CFR 50.30(b) requires that the application (and associated supplements) be submitted under oath or affirmation. NRC Regulatory Issue Summary 2001-18 (ADAMS Accession No. ML010990211) discusses acceptable means of meeting the oath or affirmation requirements in 10 CFR 50.30(b).
- (d) For amendment applications from testing facilities and NPUFs licensed under 10 CFR 50.22, 10 CFR 50.91(a)(1) requires that the licensee provide its analysis of the issue of no significant hazards consideration (NSHC) using the standards in 10 CFR 50.92. NRC Regulatory Issue Summary 2001-22 (ADAMS Accession No. ML011860215) provides guidance to licensees on preparing an NSHC analysis.
- (e) 10 CFR 50.91(a)(5) discusses the requirements for the issuance of an emergency amendment and licensee must explain why the emergency situation occurred and why it could not avoid this situation. Because the wording of this regulation indicates that it only applies to power reactors, consult with the Office of the General Counsel (OGC) if a licensee indicates it will request an emergency amendment.
- (f) For amendment applications from testing facilities and NPUFs licensed under 10 CFR 50.22, 10 CFR 50.91(a)(6)(vi) requires that, for exigent amendments, the license must explain the exigency and why the licensee cannot avoid it.
- (g) For amendment applications from testing facilities and NPUFs licensed under 10 CFR 50.22, 10 CFR 50.91(b)(1) requires that the licensee provide a copy of the application to the State.
- (h) If the application contains proprietary information, the requirements in 10 CFR 2.390(b)(1) must be followed by the licensee. The NRC staff is required by 10 CFR 2.390(b)(3) to determine whether information sought to be withheld from public disclosure is a trade secret or confidential or privileged commercial or financial information (i.e., proprietary information) and, if so, whether it should be withheld from public disclosure. Specific

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guidance on proprietary reviews is contained in NRR Office Instruction LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure."

Note: For reviews performed by the TBs, within 10 days of receiving confirmation from TBs of assigned reviewers for a given license amendment application, the PM should communicate with all the reviewers regarding the acceptance review (e.g., by phone call, e-mail, meeting). The purpose of the communication would be to: (1) ensure that all of the proposed changes will be evaluated by one of the identified branches to prevent items from "falling through the cracks"; (2) prevent duplication of reviews of technical specification items; (3) identify other branches that may have been inadvertently omitted during the preparation of the project; and (4) discuss the reasonableness of the proposed review schedule, need for audit, potential acceptance review issues, etc. For routine, straightforward reviews (e.g., high degree of precedence, limited number of review branches), the PM should use judgement regarding the need for the above communications.

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

- requested amendment issuance date
- requested implementation period²
- discussion of whether the submittal includes any regulatory commitments
- discussion of environmental considerations (e.g., categorical exclusions in 10 CFR 51.22)³
- discussion of whether submittal is based on precedent
- inclusion of retyped technical specification pages (i.e., clean pages)

3.0 Public Notification

As soon as practicable following completion of the acceptance review (as discussed in Section 2.3), NPUF PMs should determine the need for public notification of the amendment. If public notification is needed, the NPUF PM should prepare the appropriate type of public notification regarding the proposed issuance of the amendment. The associated requirements for this public notification are discussed below. The specific types of notices are discussed in

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²If the licensee does not specify an implementation period in the application, it is suggested that the NPUF PM contact the licensee to determine the desired implementation period.

³Although licensees are not required to discuss environmental considerations in their license amendment applications, the NRC may require the licensee to subsequently submit environmental information pursuant to 10 CFR 51.41 (aids the Commission to comply with National Environmental Policy Act (NEPA) requirements).

Sections 3.1 through 3.3. The responsibilities of the NPUF PM and technical and, if appropriate, contractor staff are discussed below.

Project Manager

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

- Issuance of the public notification regarding the proposed issuance of the amendment for testing facilities under 10 CFR 50.21(c) and NPUF facilities licensed under 10 CFR 50.22 (which includes testing facilities). This includes the following actions:
 - o review the licensee's analysis of no significant hazards consideration and determine its adequacy for use in the public notification;
 - o review the proposed amendment, review schedule, and regulatory requirements and determine what type of public notification is required; and
 - o prepare the notification for review and concurrence by the licensing assistant (LA) and the BC.
- Resolve any public comments on NSHC.
- Coordinate NRR activities related to the hearing process.
- Prepare and coordinate issuance of any additional public notifications, including those due to licensee changes in the amendment request and the final notification of amendment approval, denial, or withdrawal.

Technical and Contractor Staff

If requested by the NPUF PM, the contractor (if part of the contract statement of work) or technical staff, as appropriate, shall assist in evaluating the licensee's analysis of issues related to NSHC, resolving public comments, and participating in the hearing process. Technical staff BCs will work with the NPUF PMs to set expectations for technical staff support based on resource availability.

3.1 Amendments for Testing Facilities and NPUFs Licensed Under 10 CFR 50.22

For amendments for testing facilities under 10 CFR 50.21(c) and NPUF facilities licensed under 10 CFR 50.22 (including testing facilities), 10 CFR 50.91(a)(2)(i) states that under 10 CFR 2.105, the NRC may provide notification of the proposed issuance of an amendment: (1) through an individual notice in the *Federal Register*, or (2) by inclusion of a notice in the periodic *Federal Register* notice of proposed actions; or (3) by publishing both such notices.

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Although the NRC staff publishes the periodic *Federal Register* notice for proposed amendments on a biweekly basis (except for the notices discussed below in Section 3.3), 10 CFR 50.91(a)(2)(i) requires that the periodic *Federal Register* notice of proposed actions be published only at least once every 30 days.

The regulation in 10 CFR 50.91(a)(2)(ii) states that each notice will: (1) contain the staff's proposed determination under the standards in 10 CFR 50.92 (i.e., proposed NSHC determination); (2) provide a brief description of the amendment and the facility involved; (3) solicit comments on the proposed NSHC determination; and (4) provide for a 30-day comment period. For biweekly notices, item 3 (solicit comments) and item 4 (provide 30-day comment period) are included in the boilerplate language in the *Federal Register* notice (i.e., text preceding the plant-specific notices). Per 10 CFR 50.91(a)(2)(iii), the comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

Although 10 CFR 50.91 requires that the NRC solicit comments only on the proposed NSHC determination, the NRC staff has routinely addressed comments related to any aspect of the application. Comments received are normally addressed in the SE. See Section 7.0 of Safety Evaluation Template (ADAMS Accession No. ML19289C384) for further details.

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

The regulation in 10 CFR 50.91(a)(3) states:

The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of Federal Register notices. In either event, it will not make and will not publish a final determination on no significant hazards consideration, unless it receives a request for a hearing on that amendment request.

As such, the NRC staff must make and publish a final determination on NSHC if a hearing is requested and the staff issues the amendment before the requested hearing is concluded. In addition, the NRC staff's practice is to include a final NSHC determination in the SE if the amendment is issued prior to expiration of the 60-day period to request a hearing (i.e., in case a hearing is requested after the amendment is issued but before the expiration of the hearing period).⁴

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⁴Preparing a final NSHC determination, for amendments issued prior to expiration of the period for requesting a hearing, has been the NRR practice based on guidance issued in 1983. Under this guidance, final NSHC determinations were prepared for emergency and exigent amendments, which were then the only amendments contemplated to be issued before expiration of the opportunity to request a hearing, which then was only 30 days. This guidance, Division of Licensing Operating Procedure (DLOP) 228, Revision 1, "Revised Procedures for Processing License Amendments for Power Reactors and Testing Facilities (the "Sholly" Legislation) - No Significant

The regulation in 10 CFR 50.91(a)(4) states:

Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is involved, in which case the Commission will provide an opportunity for a prior hearing.

If the NRC staff intends to issue an amendment for which a hearing has been requested, the staff needs to notify the Commission via issuance of a "Notification of Significant Licensing Action," in accordance with the guidance in an NRR memorandum dated December 13, 2000 (ADAMS Accession No. ML003779315). 10 CFR 50.58(b)(5) states that the Commission may make the amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing where it has determined that NSHC is involved.

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

- 10 CFR 50.58(b)(3) states that if the NRC finds that exigent circumstances exist, as
 defined in 10 CFR 50.91, the NRC may reduce the period provided for public notice and
 comment.
- 10 CFR 50.91(a)(7) states that, where the NRC finds that significant hazards
 considerations are involved, it will issue a Federal Register notice providing an
 opportunity for a prior hearing, unless it finds an imminent danger to the health or safety
 of the public, in which case it will issue an appropriate order or rule under 10 CFR Part 2.
- Consistent with 10 CFR 2.307(c), for applications containing either sensitive unclassified non-safeguards information (SUNSI) or safeguards information (SGI), the *Federal Register* notice also contains an order, signed by the Secretary of the Commission, which establishes procedures to allow potential parties to request access to the SUNSI or SGI documents.

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

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Hazards Consideration, Noticing and State Consultation" (ADAMS Accession No. ML16077A090), was issued to implement an Interim Final Rule, "Standards for Determining Whether License Amendments Involve No Significant Hazards Considerations," dated April 6, 1983 (48 FR 14864). The Final Rule (also known as the "Sholly rule") was issued on March 6, 1986 (51 FR 7744), "Final Procedures and Standards on No Significant Hazards Considerations."

The regulation in 10 CFR 50.91(a)(1) requires that the licensee provide its analysis of the issue of NSHC using the standards in 10 CFR 50.92. NRC Regulatory Issue Summary 2001-22 (ADAMS Accession No. ML011860215) provides guidance to licensees on preparing an NSHC analysis. As part of the process in preparing the public notification regarding the proposed issuance of the amendment, the PM should review the licensee's analysis to determine if it adequately supports a proposed determination that all three of the NSHC standards are satisfied. If the review determines that it appears that the three standards in 10 CFR 50.92 are satisfied, the PM should use the licensee's analysis in the public notification. If the review determines that the licensee's analysis does not appear to satisfy the three standards in 10 CFR 50.92, the PM may prepare a public notification containing the NRC's NSHC analysis or request the licensee to resubmit a revised NSHC analysis. Alternatively, the PM can prepare a notice without a proposed NSHC determination (see Section 3.1.3 below).

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

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

If the supplemental information expanded the scope of the proposed amendment beyond the description on the NRC staff's original notice, then the proposed amendment should be re-noticed (see Section 3.4 for guidance on re-noticing). As such, it is recommended that, for the original notice, the description of the amendment should be brief and broadly characterize the aspects of the license amendment in a form such that the general public can readily understand the purpose of the amendment. The notice should not be prescriptive as to a precise section number, technical specification, wording, or specific engineering parameter values unless necessary for the public to understand the purpose of the amendment. The NRC staff should add the following statement to Section 1.0, "Introduction," of the SE for the amendment if re-noticing was required due to supplemental information causing an expansion in scope:

On **[enter date]**, the Nuclear Regulatory Commission (NRC or the Commission) staff published a proposed no significant hazards consideration (NSHC) determination in the *Federal Register* **[(XX FR XXXX)]** for the proposed amendment. Subsequently, by letters dated **[enter dates]**, the licensee provided additional information that expanded the scope of the amendment request as originally noticed in the *Federal Register*. Accordingly, the NRC published a second proposed NSHC determination in the *Federal Register* on **[enter date (XX FR XXXX)]**, which superseded the original notice in its entirety.

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

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

The most common form of public notification is for the NRC staff to issue a proposed NSHC determination in the *Federal Register* as part of a biweekly collection (i.e., the Biweekly Report) of notices in the *Federal Register*. This type of notice (typically called a biweekly notice) provides a 30-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is prepared using the Routine Biweekly *Federal Register Notice* Process Instructions (ADAMS Accession No. ML20069B723).

PMs should consult the biweekly schedule for publication of the biweekly notices to ensure that the time period for comments and hearing requests are compatible with the schedule for proposed issuance of the amendment. If the biweekly schedule is not compatible, the PM should consider issuing the notice as an individual notice as discussed below in Section 3.1.2. The biweekly schedule is maintained in ADAMS at Accession No. ML092240166.

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

If the required schedule for issuance of an amendment cannot be accommodated by the normal biweekly publication of the notice, an individual notice can be published in the *Federal Register*. This type of notice (typically called an individual notice) provides a 30-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee. The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML14037A053 and ML082130341 for templates of the notice and transmittal letter, respectively.

10 CFR 50.91(a)(2)(i) states that under 10 CFR 2.105, the NRC may provide notification of the proposed issuance of an amendment: (1) through an individual notice in the *Federal Register*, or (2) by inclusion of a notice in the periodic *Federal Register* notice of proposed actions; or (3) by publishing both such notices. Although not required by this regulation, NRC standard practice is to publish what is typically called a "repeat notice" in the "periodic *Federal Register* notice of proposed actions" (i.e., biweekly notice). The repeat notice is a brief abstract of the information provided in the individual notice. Similar to the discussion above in Section 3.1.1, this type of notice is first issued as an internal non-public memorandum from the PM to the Biweekly Notice Coordinator. See ADAMS Accession No. ML082250714 for a template of the memorandum.

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

For those amendments for which the PM does not find that the criteria for an NSHC determination have clearly been satisfied, an individual notice can be published in the *Federal Register* that describes the amendment request and provides neither a proposed NSHC determination nor a definitive finding that the subject amendment involves a significant hazards

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consideration. In previous NRR procedures for processing license amendments, these notices are sometimes referred to as "Category 3" notices. This type of notice does not solicit any comments (i.e., since an NSHC determination is not included) but provides a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee. The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML14045A192 and ML082130323 for templates of the notice and transmittal letter, respectively.

If a hearing is requested for an amendment that was noticed using a Category 3 notice, and the staff plans to issue the amendment prior to the completion of any hearing, the PM should issue a notice with a proposed NSHC determination (allowing 30 days for public comment) and include a final NSHC determination in the SE. Consistent with the requirements in 10 CFR 50.58(b)(5), the amendment may be made immediately effective in advance of the holding and completion of any required hearing⁵. Note, the notice with the proposed NSHC determination should not include an opportunity for a hearing since the opportunity for a hearing was already provided in the original Category 3 notice. See ADAMS Accession No. ML053490030 for an example of a notice with a proposed NSHC determination that was issued following issuance of a Category 3 type notice.

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

If a licensee believes that a proposed amendment is needed in a timeframe that does not permit the NRC staff to publish a *Federal Register* notice allowing for the normal 30-day period for public comment on the proposed NSHC determination, the licensee may apply for the amendment under exigent circumstances using the provisions of 10 CFR 50.91(a)(6). Processing a license amendment under exigent circumstances allows a reduced period for public comment. In addition, due to the shortened timeframe for issuance of the amendment, the hearing request period will end after the amendment is issued. Although 10 CFR 50.58(b)(4) states that the NRC will provide a 30-day notice of opportunity for a hearing in exigent circumstances, the staff's practice has been to allow a hearing request period of 60 days (i.e., consistent with 10 CFR 2.309(b)(3)).

Since the amendment will be issued prior to expiration of the period to request a hearing, the SE must include a final NSHC determination. The SE must also justify the issuance of the amendment under exigent circumstances. See Sections 4.0 and 6.0 of the SE template (see ADAMS Accession No. ML19289C384) for further discussion on the SE content.

The regulation provides two methods of public notification under exigent circumstances (assuming the NRC staff determines the amendment involves NSHC): (1) via issuance of a *Federal Register* notice; or (2) via use of local media. Each of these methods is discussed below. The notice should be written at a high enough level of detail that the risk of needing to re-notice it if the licensee changes a minor element of its request is small, and the high-level

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⁵The authority and role of the staff, and the hearing-related additional steps that must be completed, are stated in applicable regulations (usually 10 CFR 2.1202) and may be further limited via Staff Requirements Memoranda and Commission policy statements.

description of proposed changes should allow the reader to understand what's changing and determine if they want a hearing.

Method 1 - Federal Register Notice

The first method provides a 14-day period for comments on the proposed NSHC determination and a 60-day period to request a hearing. This type of notice is first issued as an enclosure to a letter from the PM to the licensee (i.e., as an individual notice). The notice is then published in the *Federal Register*. See ADAMS Accession Nos. ML14037A053 and ML082130369 for templates of the notice and transmittal letter, respectively.

10 CFR 50.91(a)(2)(i) states that under 10 CFR 2.105, the NRC may provide notification of the proposed issuance of an amendment: (1) through an individual notice in the *Federal Register*, or (2) by inclusion of a notice in the periodic *Federal Register* notice of proposed actions; or (3) by publishing both such notices. Although not required by this regulation, NRC standard practice is to publish what is typically called a "repeat notice" in the "periodic *Federal Register* notice of proposed actions" (i.e., biweekly notice). The repeat notice is a brief abstract of the information provided in the individual notice. Similar to the discussion above in Section 3.1.1, this type of notice is first issued as an internal non-public memorandum from the PM to the Biweekly Notice Coordinator. See ADAMS Accession No. ML082250714 for a template of the memorandum.

Method 2 - Local Media

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

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

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

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

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3.2 Amendments for NPUFs Licensed Under 10 CFR 50.21(a) and (c) That are Not Testing Facilities

For most amendments to operating licenses for NPUFs under 10 CFR 50.21(a) and (c) that are not testing facilities, notices are not required of proposed action before issuance of license amendments. Hearings are not required (i.e., mandatory hearings) by the AEA or the regulations for license amendments for NPUFs licensed under 10 CFR 50.21(a) and (c) that are not testing facilities.

As discussed in 10 CFR 2.105, if the Commission has not found that a hearing for an amendment is in the public interest, a notice of proposed action will be published for certain licensing actions. 10 CFR 2.105(a)(3) requires a notice of proposed action for an amendment of a license for a facility that involves a significant hazards consideration. What constitutes an amendment with a significant hazards consideration is given in 10 CFR 50.92(c) as a proposed amendment that would:

- (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or
- (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or
- (3) Involve a significant reduction in a margin of safety.

The determination of whether a significant hazards consideration exists is a screening process for deciding whether to notice and provide opportunity for hearing before an amendment is issued. The determination is not a substitute for the evaluation of the amendment request, the NRC's public health and safety decision, or decision to issue or deny the amendment. While testing facilities and facilities licensed under 10 CFR 50.22 are required by 10 CFR 50.91(a) to provide their analysis about the issue of NSHC at the time the licensee requests a license amendment, no such requirement exists for NPUFs licensed under 10 CFR 50.21(a) and (c) that are not testing facilities. The PM must decide if the requested amendment constitutes a significant hazards consideration.

Over the last 30 years, there has not been a NPUF amendment request that involves a significant hazards consideration. Because of this, there is limited guidance on what constitutes a significant hazards consideration for a NPUF. The NPUF PM can gain some insights from NRC Regulatory Issue Summary 2001-22 (ADAMS Accession No. ML011860215), which provides guidance to licensees on preparing an NSHC analysis. The statement of considerations published with the final rule, "Final Procedures and Standards on No Significant Hazards Considerations" (51 FR 7744), contains examples of amendments that are considered likely and not likely to involve significant hazards considerations. Examples of amendments from the statement of considerations applicable to NPUFs, that are considered likely to involve significant hazards considerations, are:

(i) A significant relaxation of the criteria used to establish safety limits.

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- (ii) A significant relaxation of the bases for limiting safety system settings or limiting conditions for operation.
- (iii) A significant relaxation in limiting conditions for operation not accompanied by compensatory changes, conditions, or actions that maintain a commensurate level of safety (such as allowing a plant to operate at full power during a period in which one or more safety systems are not operable).
- (iv) Renewal of an operating license.
- (v) A change to technical specifications or other NRC approval involving a significant unreviewed safety question.
- (vi) A change in plant operation designed to improve safety but which, due to other factors, in fact allows plant operation with safety margins significantly reduced from those believed to have been present when the license was issued.

Examples of amendments from the statement of considerations applicable to NPUFs, that are considered not likely to involve significant hazards considerations, are:

- (i) A purely administrative change to technical specifications: for example, a change to achieve consistency throughout the technical specifications, correction of an error, or a change in nomenclature.
- (ii) A change that constitutes an additional limitation, restriction, or control not presently included in the technical specifications: for example, a more stringent surveillance requirement.
- (iii) For a nuclear power reactor, a change resulting from a nuclear reactor core reloading, if no fuel assemblies significantly different from those found previously acceptable to the NRC for a previous core at the facility in question are involved. This assumes that no significant changes are made to the acceptance criteria for the technical specifications, that the analytical methods used to demonstrate conformance with the technical specifications and regulations are not significantly changed, and that NRC has previously found such methods acceptable.
- (iv) A relief granted upon demonstration of acceptable operation from an operating restriction that was imposed because acceptable operation was not yet demonstrated. This assumes that the operating restriction and the criteria to be applied to a request for relief have been established in a prior review and that it is justified in a satisfactory way that the criteria have been met.
- (v) Upon satisfactory completion of construction in connection with an operating facility, a relief granted from an operating restriction that was imposed because the construction was not yet completed satisfactorily. This is intended to involve only restrictions where it is justified that construction has been completed satisfactorily.
- (vi) A change which either may result in some increase to the probability or consequences of a previously analyzed accident or may reduce in some way a

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safety margin, but where the results of the change are clearly within all acceptable criteria with respect to the system or component specified in the Standard Review Plan. For example, a change resulting from the application of a small refinement of a previously used calculational model or design method.

- (vii) A change to make a license conform to changes in the regulations where the license change results in very minor changes to facility operations clearly in keeping with the regulations.
- (viii) A change to a license to reflect a minor adjustment in ownership shares among coowners already shown in the license.
- (ix) A repair or replacement of a major component or system important to safety, if the following conditions are met: (1) The repair or replacement process involves practices which have been successfully implemented at least once on similar components or systems elsewhere in the nuclear industry or in other industries and does not involve a significant increase in the probability or consequences of an accident previously evaluated or create the possibility of a new or different kind of accident from any accident previously evaluated; and (2) The repaired or replacement component or system does not result in a significant change in its safety function or a significant reduction in any safety limit (or limiting condition of operation) associated with the component or system.
- (x) An expansion of the storage capacity of a spent fuel pool when all of the following are satisfied: (1) The storage expansion method consists of either replacing existing racks with a design which allows closer spacing between stored spent fuel assemblies or placing additional racks of the original design on the pool floor if space permits; (2) The storage expansion method does not involve rod consolidation or double tiering; (3) The Keff of the pool is maintained less than or equal to 0.95; and (4) No new technology or unproven technology is utilized in either the construction process or the analytical techniques necessary to justify the expansion.

Although the third item on this list refers to power reactors, it provides insight to core changes in research reactors. Changes to the limiting core configuration should be carefully considered in determining if a significant hazards consideration exists. The impact of the core change on the accident analysis should be included in the considerations.

The PM may consider the following discussion when determining whether a proposed amendment contains a significant hazards consideration. The entirety of the amendment request needs to be considered. This discussion can also be used by the PM when evaluating a NSHC discussion submitted by a testing facility licensee or a licensee licensed under 10 CFR 50.22.

The first significant hazards consideration test is, "Does the amendment involve a significant increase in the probability or consequences of an accident previously evaluated?" Accidents considered for NPUFs are discussed in Chapter 13 of the non-power format guidance and reactor standard review plan, NUREG-1537, Parts 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" (ADAMS Accession

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Nos. ML042430055 and ML042430048). Accidents or malfunctions involving experiments are normally limited by the facility technical specifications to consequences bound by 10 CFR Part 20.

Except for external events at some facilities (e.g., aircraft impact or tornado strike), NPUFs do not perform probabilistic evaluations of accidents. It is assumed that the occurrence of accident initiating events is very low, such that these events are not expected to occur during a facility's lifetime. If this assumption would not continue to be valid under a proposed amendment request, then this could be a significant increase in the probability of an accident previously evaluated and the amendment would involve a significant hazards consideration.

Consequences of accidents at NPUFs are normally low, currently within 10 CFR Part 20 for operating facilities and well within 10 CFR Part 20 for most facilities. The dose to a member of the public for the maximum hypothetical accident, the bounding fission product release accident, is less than 1 millirem for a number of facilities. Because of this, a small increase in actual dose, for example, from 0.1 mrem to 10 mrem, could be seen as significant because it represents two orders of magnitude. However, the dose remains well within 10 CFR Part 20. If a proposed license amendment increases dose but the potential dose from an accident remains within 10 CFR Part 20 and the prior authorization in 10 CFR 20.1301(d) is not needed, the increase may not be considered significant and the proposed amendment would not involve a significant hazards consideration.

The second significant hazards consideration test is, "Does the amendment create the possibility of a new or different kind of accident from any accident previously evaluated?" A different initiating event that leads to an evaluated accident is not considered a new or different kind of accident. However, it could impact the probability or consequence of an accident and could need to be considered under the first test. For example, an increase in power level could result in decay heat levels that could lead to fuel damage. While a loss of coolant accident could have already been evaluated (direct radiation shine from the uncovered core evaluated), the increased power level could lead to the consideration of a new accident (fuel failure) or could change the probability or consequence of an existing accident.

The last significant hazards consideration test is, "Does the amendment involve a significant reduction in a margin of safety?" A margin of safety could be the margin between fuel temperature and the safety limit. An amendment that reduces a margin of safety by greater than 50 percent could be considered significant and involve a significant hazards consideration.

For any amendment request where a notice of proposed action was issued, 10 CFR 2.106(a)(1) requires the issuance of a notice of issuance.

3.3 Guidance for Noticing Amendments Containing SUNSI or SGI

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

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Notices for applications for testing facilities and facilities licensed under 10 CFR 50.22 containing SUNSI or SGI can either be issued as part of a monthly report that is issued in the *Federal Register* (via a memorandum to the SUNSI/SGI Notice Coordinator) or as an individual notice. NPUF PMs should coordinate with the LA regarding the schedule for publication of the monthly report to ensure the time period for public comments and hearing requests is compatible with the schedule for proposed issuance of the amendment. The monthly SUNSI/SGI noticing schedule is maintained in ADAMS at Accession No. ML092640510. For a notice to be included in the monthly report, see ADAMS Accession No. ML082660487 for a template of the Memo to the SUNSI/SGI Notice Coordinator Notices. For an individual notice, see ADAMS Accession Nos. ML15023A473 and ML101270178 for templates of the notice and transmittal letter, respectively. NPUFs licensed under 10 CFR 50.21(a) and (c) that are not testing facilities containing SUNSI or SGI need to be issued as an individual notice.

Further information regarding noticing amendments containing SUNSI or SGI is contained in NRR Office Instruction LIC-201, "NRR Support to the Hearing Process."

3.4 Guidance on Re-Noticing

As discussed in Section 3.1, licensees often supplement applications with additional information and may make changes to the original application. For those license amendment applications where a notice was issued, if the supplemental information expanded the scope of the proposed amendment beyond the description in the NRC staff's original notice, then the proposed amendment should be re-noticed. As an example, the description of the amendment request in the notice could read as follows:

The license amendment request was originally noticed in the *Federal Register* on [enter date and *Federal Register* citation]. The notice is being reissued in its entirety to include the revised scope, description of the amendment request, and proposed no significant hazards consideration determination.⁶

Re-noticing could potentially impact the project schedule since the new notice would allow a second comment period and hearing request period.

3.5 Guidance on Correction Notices

If minor errors are discovered following issuance of a *Federal Register* notice (e.g., editorial, typographical type errors), a correction notice can be issued. This type of notice would not impact the original time period for public comment or to request a hearing. See ADAMS Accession No. ML14223A016 for a template for a correction notice.

In addition to correction notices, the NRC staff can also issue notices to extend a public comment period or to re-open a public comment period. See ADAMS Accession No. ML14317A293 for a template to extend the comment period and ADAMS Accession No. ML14316A365 a template to re-open a comment period.

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⁶The wording about NSHC would only apply to testing facilities and facilities licensed under 10 CFR 50.22.

4.0 Safety Evaluation

The NRC staff is required by the Atomic Energy Act and the Administrative Procedure Act to provide a basis for its licensing actions. Agency actions can be overturned if found to be "arbitrary and capricious;" in other words, the agency must be able to justify why it took the action. Moreover, licensing actions typically require findings of reasonable assurance that operation of the facility can be conducted without endangering the health and safety of the public and will not be inimical to the health and safety of the public (e.g., 10 CFR 50.57(a)). An SE is one way to provide this required basis and to document the required findings. Moreover, the Nuclear Energy Innovation and Modernization Act of 2019 ties NRC's schedule requirements to the issuance of SEs, and, in accordance with 10 CFR 2.337(g), any SEs will be offered into evidence in proceedings involving licensing applications. The length and level of detail of an SE may vary according to the specifics of the action in question.

In addition, staff must follow NRC Management Directive (MD) 3.53, "NRC Records and Document Management Program," Handbook 1, Part I, "Recordkeeping Requirements." Specifically, MD 3.53 requires that, in order to provide adequate documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the NRC, records shall be created and maintained that are sufficient to document the formulation and execution of basic policies and decisions and necessary actions taken, including all significant decisions and commitments reached orally (person to person, by telecommunications, or in conference). MD 3.53 provides the Commission's interpretation of its obligations under the Federal Records Act (which is codified in Title 44 of the United States Code, Chapters 21, 29, 31, and 33) and regulations promulgated by the National Archives and Records Administration (36 CFR Part 1220).

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

NRC staff SEs are not part of a facility's licensing basis. As discussed in NRR Office Instruction LIC-100, "Control of Licensing Bases for Operating Reactors," the NRC staff should not attempt to specifically interpret and/or describe licensing bases information in SEs. It is important that licensees provide the licensing bases information so that there is no confusion following the licensing action. A useful application of the staff's SEs, by both licensees and the staff, can be

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⁷LIC-100 is written for power reactors. However, the specific guidance from the LIC given in this appendix is applicable to NPUF licensees.

in assessing what information should be incorporated into mandated licensing bases documents following issuance of the amendment (e.g., revision to the Safety Analysis Report (SAR)). However, while not part of the technical specifications for NPUFs, each technical specification (except definitions and the administrative sections of the technical specifications) contains a basis section. It is not uncommon for this basis statement to be revised to reflect proposed changes to the technical specification. While not part of the formal review, the reviewer should confirm that the proposed changes to the technical specification basis are consistent with the proposed technical specification. If the proposed changes are not consistent with the proposed basis, the reviewer should ascertain the reason for the inconsistency.

General guidance regarding technical review, SE planning and control, the use of precedent, guidelines on requesting additional information and proper use of regulatory commitments is provided below. A template for a typical SE and guidance for preparing an SE is provided in Safety Evaluation Template (ADAMS Accession No. ML19289C384).

4.1 Technical Review

PMs and technical reviewers should establish the appropriate scope and depth for the review as part of the work planning process (giving due consideration to the technical complexity of the proposed change, availability of applicable precedent, timeliness goals, and guidance such as the NUREG-1537, Part 2, the Standard Review Plan, and acceptance criteria). Perform the technical review, when appropriate, based on the NPUF PM's knowledge of the technical area or precedent, if available.

4.2 Safety Evaluation Planning and Control

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

Occasionally, technical staff will use contractors to assist in performing a review. If this is the case, PMs should treat the SE the same as a technical staff review and communicate with the technical staff member designated as the contractor's technical monitor. If the PM is the technical monitor for the contractor, the PM is responsible for the interactions with the contractor and for ensuring that the contractor's product meets the requirements of the contract.

The transmittal of SEs from TBs to project organization should follow NRR Office Instruction ADM-200, "Delegation of Signature Authority." Specifically, for internal correspondence between divisions, the signature authority lies with the technical staff BC (or re-delegated to a staff member qualified in accordance with ADM-504). The SEs may be signed and transmitted from the technical staff BC to project organization electronically (using an appropriate electronic signature process, such as e-mailing the SE) or in hard copy, as long as the SE transmittals are appropriately preserved by the technical staff as Official Agency Records (OARs) in ADAMS (see Section 10.0 for additional guidance for when an internal document may warrant preservation as an OAR).

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4.3 Use of Precedent and References to Staff-Approved NUREGs or Topical Reports

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

- Use precedents, as applicable, to achieve efficiency and consistency.
- Ensure that the precedent is appropriate for use with the intended amendment.
- Ensure that the precedent meets current expectations for format, findings, internal NRR guidance for the item, NRR guidance to the NPUF community, and technical content.
- Ensure that previous facility-specific information is replaced with information relevant to the current facility.
- Obtain additional concurrences if needed to use precedent, as appropriate, unless formal guidance has been issued that provides an alternative concurrence process.
- Ensure that the precedent being used corresponds to the issued SE and not to
 intermediate versions or drafts. Use of the final SE (as issued) for the precedent will
 ensure that the staff is consistent and will improve efficiency by incorporating changes
 made by NRR and the OGC as part of the concurrence process for the precedent SE.
 Significant feedback received during the concurrence process from other NRR
 organizations, managers, or OGC should be provided to the primary authors of the SE
 for consideration and incorporation into ongoing and future work products.
- Decisions to not apply specific precedents, especially precedents cited by a licensee, should be clearly explained in the SE (to avoid the appearance of being arbitrary and/or inconsistent). The staff should assess any change in a prior staff position to ensure that the safety or regulatory issue is consistent with the NRC principles of good regulation (e.g., efficiency, clarity, and reliability).

There are several NUREG series documents that generically approve the use of low-enriched uranium (LEU) fuel in non-power reactors (referred to as fuel acceptable to the Commission in 10 CFR 50.64). Referencing these NUREGs in license amendment applications and associated NRC SEs improves the efficiency of the licensing process by allowing the staff and multiple affected licensees to use one fuel review in their high-enriched uranium (HEU) to LEU conversion applications. As with the use of precedent amendments, the staff should ensure that a reference in a license amendment application to a staff-approved NUREG report is appropriate for the subject conversion and its supporting analysis. The reviewer should ensure that supporting analyses that refer to a staff-approved NUREG report are performed consistent with the limitations and conditions identified within the NUREG.

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

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a methodology or proposal that will be used by multiple licensees. Guidance for the staff's review of a topical report is provided in NRR Office Instruction LIC-500, "Topical Report Process." As with the use of precedent amendments, the staff should ensure that a reference in a license amendment application to a staff-accepted Approved Version of the topical report is appropriate for the subject change and its supporting analysis. The reviewer should ensure that supporting analyses that refer to a staff-accepted Approved Version of the topical report are performed consistent with the limitations and conditions identified within the topical report and the staff's SE for the topical report. Some SEs for topical reports may include specific guidance for licensees referencing the topical report in a plant-specific application.

If a licensee in its application or the NRC staff during its review identifies a deviation from the bases for determining that the fuel is acceptable to the Commission, the staff should address the deviation in its SE for the facility-specific conversion application. To address deviations from approved fuel NUREGs, 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).

4.4 Requests for Additional Information

The guidance for developing and processing RAIs is provided in NRR Office Instruction LIC-115, "Processing Requests for Additional Information." The technical and project staff will follow the direction in LIC-115.

It is expected that a draft SE be developed before preparing RAIs such that any "holes" in the SE would inform the staff's determination of the additional information that is required. For technical evaluation reports (TER8) developed by contractors, a draft TER with holes should be a deliverable of the contract. Developing draft SEs and TERs at the RAI stage enhances our safety focus by ensuring we obtain the necessary information to complete the review, while providing greater clarity and discipline in the RAI process. The TB or contractor should be able to correlate each RAI to a hole in the draft SE or TER that the licensee response is expected to fill. The expectation that a draft SE be prepared may be waived with agreement between the TB or contractor and project BC. This may require a modification to the contract. Applying this waiver should be the exception and not the rule and is anticipated to be used primarily in cases where expediency is necessary (e.g., exigent amendments) or where development of the draft SE or TER would have an overwhelmingly negative impact on the schedule not commensurate with the benefit. Note, although "holes" in a draft SE or TER inform the need for any RAIs, the final SE or TER need not explicitly cite RAIs and RAI responses. The SE or TER need only address the technical areas under review.

Note: In the transmittal of RAIs to project organization, the TB, BC, or the contractor should acknowledge the review of the draft SE or TER, confirming that "holes" in the draft SE or TER line up with the RAIs being asked.

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⁸TERs are reports from contractors that the NPUF PM develops into SE input.

4.5 Licensing Bases and License Conditions

4.5.1 Licensing Bases

The licensing bases for a NPUF can be represented by a few categories of information that form a hierarchy structure in terms of associated change controls and reporting requirements. Mandated licensing bases documents are discussed below.

- 1. Obligations conditions or actions that are legally binding requirements imposed on licensees through applicable rules, regulations, orders, and licenses (including technical specifications and license conditions). The imposition of obligations (sometimes referred to as regulatory requirements) during routine interactions with licensees should be reserved for matters that satisfy the criteria of 10 CFR 50.36 or are otherwise found to be of high safety or regulatory significance. The major distinction between obligations and other parts of the licensing bases is that changes to obligations generally cannot be made without prior NRC approval.
- 2. Mandated Licensing Bases Documents documents, such as the SAR, the security plan, and the emergency plan, for which the NRC has established requirements for content, change control and reporting. Information that should be included in these documents is specified in applicable regulations and regulatory guides. The change control mechanisms and reporting requirements are defined by regulations such as 10 CFR 50.59, 10 CFR 50.54, and 10 CFR 50.71.

Although not common for NPUF licenses, some amendments involve approving a change in the licensing bases with no accompanying technical specification or license change (e.g., a change to the SAR that cannot be made under 10 CFR 50.59). For these types of amendments, the language for the implementation statement on the amendment page would also authorize revision to the SAR. Suggested wording for the implementation statement (for amendments that approve a change to the SAR, usually Enclosure 1 in the license amendment package) should include wording similar to the following:

Accordingly, by Amendment No, the licen	se is amended to authorize
revision to the Safety Analysis Report (SAR), a	is set forth in the application dated
[]. The licensee shall update the SAR t	o incorporate the [] as
described in the licensee's application dated [] and the NRC staff's safety
evaluation attached to this amendment	

4.5.2 NRC-Proposed License Conditions

Per 10 CFR 50.10(b), a NPUF may only be used as authorized by a license issued by the Commission. As stated in 10 CFR 50.50, when the Commission issues a license, it will include such conditions as the Commission deems appropriate and necessary. License conditions are a form of obligation (i.e., legally binding condition or action) and are formal statements included in the license necessary to establish, implement, or maintain applicable rules, regulations, or licensing bases.

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From its creation in 1956 (21 FR 359), 10 CFR 50.54 was intended to apply to all licenses, including research and test reactors, unless otherwise specified. In 2007, 10 CFR Part 50, including 10 CFR 50.54, was updated to include references to combined licenses under 10 CFR Part 52. There was a question if the wording of the update to 10 CFR 50.54 could be interpreted to say that 10 CFR 50.54 only applies to power reactors. This is not the case. In accordance with 10 CFR 50.54, all NPUF licenses include certain conditions. Not all the conditions in 10 CFR 50.54 apply to NPUFs. Those paragraphs of 10 CFR 50.54 that are not explicitly limited to nuclear power reactors may be applicable to NPUFs. The NPUF PM needs to understand what parts of 10 CFR 50.54 apply to the specific NPUF type under review.

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

License conditions should:

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

License conditions should not:

- address issues already addressed by an existing rule, requirement, order or regulation;
- require NRC action to complete;
- be open-ended;
- address a facility not controlled by the license; or
- address voluntary requests.

<u>Caution:</u> Imposing an NRC-proposed license condition on a licensee could be construed as a partial denial of an amendment request, requiring the NRC to issue a *Federal Register* notice that offers the licensee an opportunity to request a hearing (see 10 CFR 2.103). See section 6.3, below.

4.6 Environmental Considerations

Most proposed amendments fit under one of the categorical exclusions in 10 CFR 51.22(c) and, as such, do not require an environmental assessment (EA). However, it is a good practice for the NPUF PM to determine if an EA is needed early during the license amendment review. As needed, the NPUF PM should coordinate with the environmental reviewer and OGC to determine the need for an EA. Further guidance on whether an EA is required is contained in the Section 8.0 of the attached SE template (see ADAMS Accession No. ML19289C384). Specific guidance on preparing EAs and considering environmental issues is contained in NRR

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Office Instruction LIC-203, "Procedural Guidance for Preparing Categorical Exclusions, Environmental Assessments, and Considering Environmental Issues."

5.0 Amendment Package Preparation and Concurrence

5.1 Amendment Package Preparation

After the PM has received all the required SE inputs (or the PM has prepared the SE), the PM should begin assembly of the amendment package, so it is ready for review and concurrence. SE inputs should be integrated into a single SE using the guidance in Safety Evaluation Template (ADAMS Accession No. ML19289C384).

After the PM integrates all the SE inputs, if the draft SE contains SUNSI (e.g., proprietary or security-related information) or potentially contains SUNSI, the PM should send the draft version of the SE to the licensee to determine if it appropriately identifies information that is considered to contain SUNSI. Any information considered by the NRC staff to contain SUNSI should be marked within double brackets (i.e., [[......]]). The draft version of the SE can be provided by letter or electronically using the BOX - Enterprise File Synchronization and Sharing (EFSS) Solution.

The transmittal letter to the licensee should clearly state that the requested review is in regard to whether the information is properly marked as SUNSI only. The transmittal letter should be made available to the public, and the enclosed SE should be withheld from the public until the submitter confirms that there is no proprietary information in the SE. When an SE or other staff report contains proprietary information, a non-proprietary version should also be prepared by the staff, if practicable, to be placed in the public domain.

The following are examples of letters transmitting draft SEs for licensee review: (1) letter transmitting SE potentially containing proprietary information (ADAMS Accession No. ML112430591); and (2) letter transmitting SE containing proprietary information (ADAMS Accession No. ML102710032). Additional sample letters for transmitting draft SEs can be found in ADAMS at Package Accession No. ML062080003. See ADAMS Accession No. ML062080129 for the template draft SE letter.

To use BOX – EFSS, the PM will need to request a folder be created by one of the NRC Box Administrators or via NRC Service Catalog. After a folder has been created for the project manager, an electronic copy of the draft SE should be placed in the folder. Then the PM will provide a link to the folder to the licensee. Note that the licensee must create a BOX account, which is free, to access the draft SE. More detailed information on the use of the BOX – EFSS Solution is available in the NRC Box – EFSS User Guide.

Following receipt of the response from the licensee, the PM should revise the draft SE, as required, to correctly denote the information considered to contain SUNSI. At this time, the PM should also prepare a redacted version of the SE, which can be made publicly available if the amendment is approved for issuance. See ADAMS Package Accession No. ML102700263 for

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an example of an amendment that transmitted proprietary and non-proprietary versions of the SE.

Further guidance on transmittal of proprietary information is provided in LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure."

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

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

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

- Transmittal letter.
- License amendment pages.
- List of revised license and technical specification pages.
- Revised license and technical specification pages (the package can consist of the list of revised license pages followed by the replacement pages and then the list of revised technical specification pages followed by the replacement pages).
- SE.
- Notice of Issuance for licensing actions that have been pre-noticed.

To assist those requested to concur (discussed further below in Section 5.3), the PM should include the following in the amendment package (in addition to items listed above):

- copy of the incoming license amendment application and all licensee supplements
- copy of the RAIs if the RAIs are not clearly stated in licensee supplements
- copy of the *Federal Register* notice that provided public notification regarding the proposed issuance of the amendment for those actions that were noticed
- copy of TB or contractor SE inputs

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• copy of any relevant background information, including information used in preparing the SE (e.g., SAR sections, guidance documents) and documents referenced in the SE (if not readily available in ADAMS or on the NRC Web site)

5.2 Concurrence

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

LA concurrence is required for all license amendments. See Section 5.1 above for specific LA responsibilities related to review and concurrence.

In instances where the SE was written by the PM or the SE was prepared by the PM using contractor input, there is no need for concurrence from the related TB. The PM may consult with TBs as needed. Depending on the depth and nature of the consultation, the TB may be on concurrence for the licensing action. PMs should review RPS to determine those organizations that have requested concurrence.

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

OGC must review all license amendments except under previously agreed upon conditions. OGC reviews the amendment package for "no legal objection."

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

Additional guidance and signature authority for special categories of amendments such as changes in licensed power level and denial of amendment requests are provided in ADM-200.

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Caution: If the amendment package will be forwarded to the NRR Office Director for signature, it is expected that a second LA perform a peer review of the amendment package before the package is sent to the NRR Office Director. It is recommended that this step be performed after the project division director review so that all changes made during the concurrence process are reviewed. The PM should request the LA peer review through the respective BC.

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

An amendment routing sheet may be placed on top of the amendment concurrence package by the LA (during the LA review) to facilitate the routing and concurrence of the package. The amendment routing sheet also serves as a checklist to help ensure the necessary coordination, regulatory, and administrative tasks have been completed prior to amendment issuance.

For testing facilities and facilities licensed under 10 CFR 50.22, during the early stages of review and concurrence, it is recommended that:

- (1) the LA check <u>www.regulations.gov</u> to determine if there were any public comments on the proposed amendment;
- (2) the LA contact the Office of the Secretary to determine whether a hearing was requested; and
- (3) the PM contact the State official in accordance with the requirements in 10 CFR 50.91(b).

The PM should take any additional actions required (e.g., revision of SE to address comments) as a result of the above actions.

6.0 Amendment Issuance, Denial, Withdrawal, and Corrections

6.1 Regulatory Background

As discussed in 10 CFR 50.92(a), in determining whether an amendment to a license will be issued, the Commission will be guided by the considerations that govern the issuance of initial

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licenses to the extent applicable and appropriate. The specific considerations governing the Commission's decision of whether an operating license will be issued are discussed in 10 CFR 50.40, "Common standards." In addition, 10 CFR 50.57, "Issuance of operating license" lists the specific findings the Commission must make to issue a license. Specifically, consistent with 10 CFR 50.92(a), 10 CFR 50.40, and 10 CFR 50.57, the staff must make the following findings to issue an amendment:

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

- A. The application for amendment to [Renewed (use renewed if applicable)] Facility Operating License No. [license number] filed by [licensee] dated [insert date] complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in Title 10 of the Code of Federal Regulations (10 CFR) Chapter I;
- B. The facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission;
- C. There is reasonable assurance that (i) the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) such activities will be conducted in compliance with the Commission's regulations set forth in 10 CFR Chapter I;
- D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public; and
- E. This amendment is issued in accordance with the regulations of the Commission as stated in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," and all applicable requirements have been satisfied.

Amendments for NPUFs licensed in accordance with 10 CFR 50.21(a) or (c) that are not testing facilities are not noticed as a proposed action unless the amendment involves a significant hazards consideration, or a decision is made that noticing is in the public interest. If an amendment is not noticed, the following finding is added:

F. Prior notice of this amendment was not required by 10 CFR 2.105, "Notice of proposed action," and publication of a notice of issuance for the amendment is not required by 10 CFR 2.106, "Notice of issuance."

The regulations concerning withdrawal are addressed primarily in 10 CFR 2.107, which state, in part, that the Commission may permit an applicant to withdraw an application prior to the issuance of a notice of hearing on such terms and conditions as it may prescribe, or may, on receiving a request for withdrawal of an application, deny the application or dismiss it with prejudice. If the application is withdrawn prior to issuance of a notice of hearing, the Commission shall dismiss the proceeding. Withdrawal of an application after the issuance of a notice of hearing shall be on such terms as the presiding officer may prescribe.

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6.2 Amendment Issuance

After the required concurrence signatures are obtained and the NRC staff determines that the proposed amendment is acceptable and should be issued, the PM should forward the original amendment package to the administrative assistant for processing in preparation for dispatch. If amendment numbers had not previously been added to the package, the PM should ensure that the LA has assigned amendment numbers.

If the technical specifications are being modified by the license amendment, the license condition requiring the licensee to operate the reactor in accordance with the technical specifications is changed to reflect the new amendment. The wording of the license condition is dependent on whether the license has been renewed or reissued. The regulation in 10 CFR 50.51(a) limits the term of a license to 40 years. Several NPUF licenses were issued for terms of less than 40 years, for example, 20 years. These licenses were initially renewed by the issuance of a 20-year license amendment. If the term goes beyond 40 years, the license is renewed by reissuance of the license. Reissuance is in the form of a new license, not an amendment to the license (although the license number is retained). Because it is a new license, reissuance of the license replaced all past amendments to the license. However, a decision was made to continue to number amendments to the reissued license in order and not restart numbering at Amendment No. 1.

The wording in the amendment revising the license condition on technical specifications following this general format:

Accordingly, the license is amended by changes to the Technical Specifications as indicated in Attachment [give attachment number] to this license amendment. Paragraph [give paragraph number] of [Renewed (use renewed if applicable)] Facility Operating License No. [give license number] is hereby amended to read as follows:

[give paragraph number] Technical Specifications

The Technical Specifications contained in Appendix A, as revised by Amendment No. [give amendment number] through [give amendment number], are hereby incorporated in the license. The licensee shall operate the facility in accordance with the Technical Specifications.

If the license has been reissued, amendment numbers continue in order. However, the amendments incorporated into the license are only those issued after the license reissuance.

For example, if amendment Nos. 1 through 14 were issued before the license reissuance, the above paragraph for Amendment No. 14 before license reissuance would read:

[give paragraph number] Technical Specifications

The Technical Specifications contained in Appendix A, as revised by Amendment No. 1 through 14, are hereby incorporated in the license. The

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licensee shall operate the facility in accordance with the Technical Specifications.

This paragraph in the reissued license would replace all past amendments and read:

[give paragraph number] Technical Specifications

The Technical Specifications contained in Appendix A are hereby incorporated in the license. The licensee shall operate the facility in accordance with the Technical Specifications.

If the next amendment, No. 15, changed the technical specifications, the paragraph would read:

[give paragraph number] Technical Specifications

The Technical Specifications contained in Appendix A, as revised by Amendment No. 15, are hereby incorporated in the license. The licensee shall operate the facility in accordance with the Technical Specifications.

So, in this example, Amendment No. 15 is the new starting amendment for technical specification changes. If Amendment No. 16 also changed the technical specifications, the paragraph would read:

[give paragraph number] Technical Specifications

The Technical Specifications contained in Appendix A, as revised by Amendment No. 15 through 16, are hereby incorporated in the license. The licensee shall operate the facility in accordance with the Technical Specifications.

This pattern (next would be Amendment Nos. 15 through 17) would continue until the license was reissued again.

The PM should give the package to the administrative assistant organized in the following order:

- transmittal letter
- license amendment pages
- list of revised license pages
- revised license pages
- list of revised technical specification pages
- revised technical specification pages
- SE
- notice of issuance (only for amendments that were pre-noticed)

Following processing of the package, the administrative assistant will e-mail a scanned copy to the LA for a final quality assurance check. This LA check should be a cursory review to ensure that the concurrence blocks are complete, all pages are properly dated, amendment numbers have been properly added, and that pages are in the proper order with no pages missing. The purpose is not to do a new LA review. However, if errors are noted beyond any document

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processing errors, the LA should coordinate with the PM to discuss the need for any other corrections before the amendment is sent out.

6.3 Amendment Denial or Withdrawal

Early and enhanced management attention and engagement should be provided whenever staff is considering denial of a license amendment for technical or safety reasons. Management recognizes that some licensing requests may not satisfy NRC safety regulations and warrant a denial. Whenever a denial is being considered, a BC-level meeting should be held at the earliest opportunity. If the outcome of that meeting is anything other than alignment to continue the staff's review, the respective deputy directors should be briefed expeditiously. The BCs should collaborate to prepare a joint briefing with options and recommendations, even if differing views exist. If the deputy directors support a denial recommendation, a denial SE shall be prepared and processed as discussed below.

If the NRC staff's review of the proposed amendment determines that the amendment should be denied, the staff must prepare an SE documenting the basis for the denial. The denial SE does not need to address aspects of the request that are acceptable, but it should address all aspects of the request that are not acceptable to the staff, and the evaluation should be sufficient to support a conclusion that the amendment is not acceptable. The PM should also prepare a denial transmittal letter (see ADAMS Accession No. ML082040984 for the template) and a Federal Register Notice of Denial (see ADAMS Accession No. ML14013A013 for the template). Consistent with ADM-200, the project division director is added to the concurrence block and is the signature authority for the denial transmittal letter.

The PM should obtain concurrences from the LA, applicable technical BCs, OGC, and the project BC. However, the project division director concurrence and signature initially will be left blank. Following receipt of the project BC concurrence to deny the amendment, the PM and BC will brief the project division director regarding the intent to deny the amendment. Assuming the division director agrees with this path going forward, the PM will contact the licensee to arrange for a call with the project division director. During the initial contact, the PM should inform the licensee that the staff plans to deny the amendment. The PM should also coordinate with the applicable TB reviewers to arrange for them to be available during the call between the project division director and the licensee. TB reviewers should be prepared to discuss their regulatory findings during the call.

During the call, the project division director will inform the licensee of the staff plans to deny the amendment and offer the licensee an opportunity to withdraw the amendment or to request a public meeting for further discussion of the issues. To ensure that the licensee has a meaningful opportunity to make an informed business decision on denial or withdrawal, the division director (with assistance from technical reviewers as necessary) will provide the basis for the staff's plan to deny the amendment. The project division director should make clear that if the licensee does not either submit a formal withdrawal in writing by a specific date (e.g., 2 or 3 days from the call) or request a public meeting by the same date, the staff will issue the denial.

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If the licensee submits a request to withdraw the amendment, the NPUF PM should prepare a transmittal letter documenting the withdrawal (see ADAMS Accession No. ML082260953 for a template) and a *Federal Register* Notice of Withdrawal (see ADAMS Accession No. ML14013A020 for a template). If a hearing on the amendment has been granted, the terms of the withdrawal must be consistent with the withdrawal terms, if any, set by the presiding officer. The *Federal Register* notice is needed for proposed actions that were noticed (testing facilities and facilities licensed under 10 CFR 50.22). Following issuance of the transmittal letter and Notice of Withdrawal, the PM should prepare an internal non-public memorandum to the project BC, which documents the call with the licensee and the decision by the licensee to withdraw the proposed amendment. The draft SE documenting the basis for the planned denial of the amendment should be included as an enclosure to the memorandum to ensure that an adequate record of the staff's decision-making process is captured as an OAR (i.e., consistent with MD 3.53 as discussed in Section 10.0 of this office instruction).

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

6.4 Amendment Corrections

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

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

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specific amendment application is necessary to establish that the change introduced by the error was in fact improperly made.

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

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

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

In general, correction letters will not involve a significant amount of time or schedule to complete, and the effort will usually just involve the PM, LA, and BC. For cases such as this, the NPUF PM does not need to take out a new a labor cost string (i.e., EPID), instead the PM should use the NPUF PM A11010 CAC for time spent on this effort. For more complicated correction letters, the PM may need to request a new labor cost string (i.e., EPID), if the licensee is fee-billable.

7.0 Amendments for Emergency Plan Changes

7.1 Background and Regulatory Requirements

The EP requirements applicable to a particular licensee or applicant can vary depending on the type of facility. In the August 19, 1980, EP final rule, "Emergency Planning" (45 FR 55402), the NRC established in Appendix E to 10 CFR Part 50 emergency planning requirements for RTRs that reflected the lower potential radiological hazards associated with these facilities. While NPUFs must meet the emergency planning requirements of 10 CFR 50.34(a)(10) and (b)(6)(v) and 10 CFR 50.54(q) and Appendix E to 10 CFR Part 50, the requirements of 10 CFR 50.47 do not apply to these facilities. Additionally, in section I.3. of Appendix E to 10 CFR Part 50, the NRC differentiates between emergency planning requirements for nuclear power reactors and other facilities, stating that the size of emergency planning zones (EPZs) and the degree of compliance with sections I-V of Appendix E to 10 CFR Part 50 will be determined on a case-by-case basis for facilities other than power reactors.

Further, footnote 2 of Appendix E to 10 CFR Part 50 allows the use of RG 2.6, "Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities," Revision 2, issued September 2017, for the development and evaluation of emergency response plans at NPUFs (ADAMS Accession No. ML17263A472). Consistent with the radiological risks associated with operating power levels between 5 watts thermal

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and 20 megawatts thermal (MWt) for currently operating RTRs, RG 2.6, Revision 2, endorses the use of the source term and power-level based emergency planning guidance contained in American National Standards Institute (ANSI) and /American Nuclear Society (ANS) standard ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors." Similarly, RG 2.6, Revision 2, endorses the use of ANSI/ANS-15.16-2015 for other NPUFs. Standard ANSI/ANS-15.16, originally developed in 1982, and updated in 2008 and 2015, provides specific criteria and guidance for RTRs to comply with the applicable requirements set forth in 10 CFR 50.34, 10 CFR 50.54, and Appendix E to 10 CFR Part 50.

In October 1983, the NRC issued NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors" (ADAMS Accession No. ML062190191), as a standard review plan for evaluating emergency plans submitted by RTR licensees. Consistent with ANSI/ANS-15.16, NUREG-0849 provides areas of review, planning standards, and evaluation items for the NRC to evaluate a licensee's compliance with the applicable emergency planning requirements. Notably, the guidance contained in both ANSI/ANI-15.16 and NUREG-0849 addresses EPZs for RTRs ranging from the operations boundary to 800 meters from the operations boundary for facilities up to 50 MWt. Both guidance documents state that the EPZs for facilities operating above 50 MWt are to be considered on a case-by-case basis. In addition to NUREG-0849 and ANSI/ANS-15.16, Section 12.7, "Emergency Planning," of the non-power format guidance and reactor standard review plan, NUREG-1537, Parts 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" (ADAMS Accession Nos. ML042430055 and ML042430048) and the Interim Staff Guidance augmenting NUREG-1537, Parts 1 and 2, for the licensing of radioisotope production facilities and aqueous homogeneous reactors (ADAMS Accession Nos. ML12156A069 and ML12156A075) provide additional emergency planning considerations for NPUFs. These criteria and guidance provide a basis for NPUF applicants and licensees to develop acceptable emergency response plans for their facilities.

In a final rule for emergency preparedness dated November 23, 2011 (76 FR 72560), the NRC amended its regulations pertaining to emergency preparedness. The final rule, in part, revised the regulatory process for NRC approval of emergency plan changes. This section describes the regulatory requirements associated with emergency plan changes including those changes made by the final rule. Section 7.2 provides guidance on processing of emergency plan changes consistent with the final rule.

The requirements associated with changes to emergency plans, including changes to emergency action levels (EALs), are contained in 10 CFR 50.54(q) and in Section IV.B.2 of Appendix E to 10 CFR Part 50. In accordance with the requirements in 10 CFR 50.54(q)(2), once an operating license is issued, the licensee is required to follow and maintain the effectiveness of its emergency plan.

7.1.1 Emergency Plan Changes

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

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As defined in 10 CFR 50.54(q)(1), a "reduction in effectiveness" means a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency. Also, as defined in 10 CFR 50.54(q)(1):

emergency planning function" means a capability or resource necessary to prepare for and respond to a radiological emergency, as set forth in the elements of Section IV of Appendix E to 10 CFR Part 50.

The requirements in 10 CFR 50.54(q)(4) applicable to NPUFs state the following:

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

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

In accordance with 10 CFR 50.54(q)(4), proposed changes to the emergency plan are submitted to the NRC for prior approval as a license amendment request pursuant to 10 CFR 50.90, if the licensee has determined that the changed emergency plan would represent a reduction in effectiveness and would continue to meet the requirements in Appendix E to 10 CFR Part 50. The NRC staff acceptance criteria for these types of amendment requests relate to whether emergency plan as revised by the proposed change: (1) continues to meet the requirements in Appendix E to 10 CFR Part 50; and (2) continues to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

If a licensee's analysis of a proposed change determines that the change would result in a reduction of effectiveness of the emergency plan, and the plan, as changed would not meet the requirements in Appendix E to 10 CFR Part 50, the licensee would need to request an exemption from the affected requirements in accordance with 10 CFR 50.12.

Emergencies at existing research reactors do not lead to consequences greater than U.S. Environmental Protection Agency (EPA) early phase Protective Action Guidelines (PAGs) at the facility's site boundary; therefore, FEMA findings and State and local plans are not needed for the Commission's reasonable assurance determination. However, per the "Memorandum of Understanding between the Department of Homeland Security/Federal

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Emergency Management Agency [FEMA] and Nuclear Regulatory Commission Regarding Radiological Emergency Response, Planning, and Preparedness" (ADAMS Accession No. ML15344A371), the NRC would consult with FEMA to determine the adequacy of offsite plans and preparedness as part of its overall reasonable assurance determination for utilization facilities as defined in public Law 96-295,9 if offsite radiological consequences for applicable design basis accidents would be expected to exceed the EPA early phase PAGs at the facility's site boundary.

7.1.2 Emergency Action Level (EAL) Changes

The emergency plan must provide for a standard emergency classification scheme (e.g., notification of unusual event, alert, site area emergency, general emergency). An EAL is a pre-determined, site-specific, observable threshold for a facility condition that places the facility in an emergency class. Each emergency plan shall include only those standard classes appropriate for dealing with accident consequences determined to be credible for the specific facility. A general emergency is not credible for most research reactors and, therefore, most research reactors would not include this class as part of their emergency plans.

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

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

Consistent with the discussion in Section 7.1.1, the NRC staff acceptance criteria for these types of amendment requests relate to whether the emergency plan as revised by proposed change: (1) continues to meet the requirements in Appendix E to 10 CFR Part 50; and (2) continues to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

7.2 Processing of Emergency Plan Changes

Consistent with the requirements stated in 10 CFR 50.54(q)(4), proposed changes to emergency plans and individual EALs that would reduce the effectiveness of the emergency plan must be submitted to the NRC as license amendment applications. In addition, proposed EAL scheme changes need to be submitted to the NRC as license amendment requests, as stated in Section IV.B.2 of Appendix E to 10 CFR Part 50.

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⁹Title 1, Section 108(a) of Public Law 96-295 (June 30, 1980) defines the term "utilization facility" as meaning a facility licensed under section 103, "Commercial Licenses," and 104(b), "Medical Therapy and Research and Development," of the Atomic Energy Act of 1954.

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

7.2.1 Work Request

Proposed emergency plan changes, for which the licensee has requested prior NRC approval, should be forwarded with the licensee's application to the Office of Nuclear Security and Incident Response (NSIR), Division of Preparedness and Response, Reactor Licensing Branch.

In addition to proposed changes to emergency plans, for which the licensee has requested prior NRC approval, the emergency preparedness regulations require certain submittals to the NRC pursuant to the requirements in 10 CFR 50.4 (e.g., emergency plan changes that have been evaluated by the licensee as not representing a reduction in effectiveness). For submittals that do not request NRC prior approval, a labor cost string (i.e., EPID) is not required unless specifically requested by NSIR. In addition, since NSIR staff receive these submittals via e-mail distribution from the NRC's DCD, the PM does not need to forward these types of incoming documents to NSIR but should confirm that NSIR has received them.

7.2.2 SUNSI Review

In accordance with the SRM for SECY-15-0032, "Reviewing Documents for Public Release under Sensitive Unclassified Non-Safeguards Information Guidance," dated June 15, 2015 (ADAMS Accession No. ML15167A090), the NRC staff will apply the SUNSI policy to review, release, and withhold emergency preparedness documents. Prior to this SRM, these documents were initially profiled by the NRC's DCD as non-publicly available and the staff was not requested to perform a SUNSI review. In response to the SRM, the documents will still be initially profiled as non-publicly available; however, the staff will be requested to perform a SUNSI review.

SUNSI reviews of incoming emergency preparedness documents will be performed in accordance with the guidance in NSIR Office Procedure EP-200, "NSIR Process for the Review of Sensitive Unclassified Non-Safeguards Information in Emergency Preparedness Documents" (ADAMS Accession No. ML16029A366). While this guidance has been written for power reactors, it is generally applicable for NPUF documents. To address ADAMS public release timeliness report concerns, the PM will conduct a SUNSI review of the cover letters of incoming emergency preparedness documents that are added to ADAMS as "Non-Public Pending Review" within 5 working days. NSIR staff will be responsible for performing the SUNSI review of the attachments to the cover letter at a later time. If the PM determines that the cover letter does not contain SUNSI, the PM should send an e-mail to ADAMS IM requesting that the cover letter be made publicly available. In general, the easiest way to do this is to forward the ERIDs e-mail for the subject document to ADAMS IM with a message such as the follows:

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ADAMS IM.

I have reviewed the cover letter for the document below and determined that it does not contain SUNSI and can be made publicly available. However, I have not reviewed the rest of the document. The rest of the document will be reviewed later by NSIR.

In accordance with the guidance in Section 5.1 of NSIR Office Procedure EP-200 (ML16029A366), please create a package with the cover letter designated "Publicly Available" and the remainder of the document designated "Non-Public Pending Review."

Thanks,

[Project Manager Name]

Project Manager for [Facility Name]

The PM should copy the NSIRDPR-ORLT Resource mailbox on the e-mail to ADAMS IM. In addition, the PM should forward the response from ADAMS IM to the NSIRDPR-ORLT Resource mailbox so NSIR is aware of the package accession number.

See NSIR Office Procedure EP-200 for further guidance for performance of the SUNSI reviews.

7.2.3 Safety Evaluation

The SE for all emergency plan changes, including EAL changes, should include a conclusion regarding whether the emergency plan as revised by the proposed change: (1) continues to meet the requirements in Appendix E to 10 CFR Part 50; and (2) continues to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

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

7.2.4 Environmental Considerations

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

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7.2.5 Amendment Page Wording

Amendments for changes to emergency plans typically will not involve a change to the technical specifications or to any of the license pages. As such, the amendment page wording should contain words similar to the following:

2. Accordingly, by Amendment No. [give amendment number], [Renewed (use renewed if applicable)] Facility Operating License No. [give license number] is hereby amended to authorize revision to the [give name of emergency plan] as set forth in [give licensee name]'s application dated [enter date], as supplemented by letters dated [enter dates], and evaluated in the NRC staff's safety evaluation dated [enter date of safety evaluation]. The license amendment is effective as of its date of issuance and shall be implemented within [insert requested days per application] days.

7.2.6 Stakeholder Contacts

If the license amendment is for a testing facility or a facility licensed under 10 CFR 50.22, the NPUF PM should follow the normal license amendment process of contacting the State official in accordance with the requirements in 10 CFR 50.91(b). No other stakeholder contacts are required. However, as with any amendment, the potential need for additional stakeholder communication should be assessed based on the nature of the amendment or stakeholder interest.

7.2.7 Signature Authority

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

- 1) Emergency plan and EAL changes submitted for NRC approval in accordance with 10 CFR 50.54(q) or Section IV.B of Appendix E to 10 CFR Part 50 (except for exemptions as noted below) shall be signed by the NRR Office Director or NRR Deputy Office Director (when acting for the Office Director).
- 2) Exemptions from Appendix E to 10 CFR Part 50 that represent a reduction in effectiveness of the licensee's emergency plan require Commission approval. Guidance on processing exemptions is provided in NRR Office Instruction LIC-102, "Exemptions from NRC Regulations."

These items above require review by OGC.

Item 1 above does not require technical editor review. Item 2 will require technical editor review on the SECY paper requesting Commission approval.

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8.0 Official Agency Records

8.1 Introduction

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, facility docket files are retained until 20 years after the termination of the license. The retention requirement is met by adding the OAR to ADAMS. Some OARS cannot be added to ADAMS, such as video or audio tapes, and in these cases the OAR should be retained in the NRC File Center. For more information on ADAMS and OARs, refer to NUREG/BR-0273, "ADAMS Desk Reference Guide."

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

8.2 Identification of OARs

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

- licensee amendment submittals
- NRC letters and e-mails documenting the acceptance review
- requests for additional information from TB or contractor to project organization
- requests for additional information from project organization to licensee
- licensee responses to requests for additional information
- NRC letters and memoranda transmitting notices for publication in the Federal Register

- SEs written by NRC staff

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

The above records shall be entered in ADAMS as OARs.

In some cases, working files may meet criteria to be considered OARs. However, NRR has determined that working files associated with the license amendment process (such as work requests, cover sheets, 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 SE issued with the license amendment.

8.3 Responsibilities

8.3.1 Project Manager

PMs should ensure that the OARs noted in Section 8.2 are retained as OARs, usually by entry into ADAMS.

8.3.2 Technical Branches

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

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