# OFFICE OF THE INSPECTOR GENERAL

# U.S. NUCLEAR REGULATORY COMMISSION

Review of NRR's
License Amendment/Safety Evaluation
Process

OIG-01-A-05 September 18, 2001

# AUDIT REPORT

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September 18, 2001

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Stephen D. Dingbaum/**RA**/
Assistant Inspector General for Audits

SUBJECT: REVIEW OF NRR'S LICENSE AMENDMENT/SAFETY EVALUATION PROCESS (OIG-01-A-05)

Attached is the Office of the Inspector General's audit report titled, *Review of NRR's License Amendment/Safety Evaluation Process.*

In June 1999, the U.S. Nuclear Regulatory Commission approved an Indian Point 2 nuclear power plant license amendment request to extend a previously established steam generator inspection interval. In February 2000, a steam generator tube failed, generating considerable public interest. Congressional interest in this event caused the Office of the Inspector General (OIG) to initiate a review of the Office of Nuclear Reactor Regulation's (NRR) license amendment process.

The review determined that NRR has developed a detailed process for responding to license amendment requests that includes the development of safety evaluations. However, the process does not provide adequate controls to demonstrate that all process steps are completed and supported by adequate documentation. OIG is making three recommendations that should enhance the process.

At an exit conference on August 30, 2001, agency staff agreed with our recommendations, and provided editorial suggestions that have been incorporated into the report where appropriate.

If you have any questions, please contact Bill McDowell at 415-5974 or me at 415-5915.

Attachment: As stated

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# EXECUTIVE SUMMARY

## PURPOSE

In June 1999, the U.S. Nuclear Regulatory Commission (NRC) approved an Indian Point 2 nuclear power plant license amendment request to extend a previously established steam generator inspection interval. In February 2000, a steam generator tube failed, generating considerable public interest. Congressional interest in this event caused the Office of the Inspector General (OIG) to initiate a review of the Office of Nuclear Reactor Regulation's (NRR) safety evaluation process to (1) evaluate its efficiency and effectiveness and (2) determine whether refinements are needed.

## BACKGROUND

Commercial nuclear power plant licensees submit approximately 1,500 applications per year to amend their operating licenses. NRR is responsible for processing and responding to these license amendment requests. Safety evaluations are an essential part of NRR's response. Safety evaluations provide the regulatory bases for the staff's decisions on licensing actions and the technical, safety, and legal basis for NRR's disposition of a license amendment request.

NRR's review of license amendment applications is the primary mechanism for regulating changes in licensees' operations at commercial nuclear power facilities. License amendment applications may include: (1) changes to position titles and simple changes to set points or other technical specification details; (2) extensions of allowed outage times or surveillance test intervals, or other changes that do not involve major changes or review of established NRC policies; and (3) significant restructuring of technical specifications, changes that introduce significantly different analytical methodologies, and changes that are related to revising established NRC policies. Additionally, the agency is facing additional challenges in several areas such as license amendment requests for significant power uprates, license renewals, longer operating cycles, and use of higher burn-up fuels. These requests are placing increased demands on NRR's technical review capabilities. Therefore, it is important that NRR have a reliable and predictable license amendment review process that accurately documents agency decisions.

## RESULTS IN BRIEF

NRR has developed a detailed process for responding to license amendment requests which includes the development of safety evaluations. The process is well thought out, thorough, and provides all necessary steps for ensuring that staff perform the required technical reviews to approve or disapprove license amendment requests. During the audit, OIG discussions with NRC officials and stakeholders did not reveal any concerns regarding the technical quality of safety evaluations.

However, the process does not provide adequate controls to demonstrate that all process steps are completed and supported by adequate documentation. In addition, not all process steps could be verified by official or other documentation readily available in NRR. This is because NRR has not met agency record management requirements in documenting the license amendment process. Failure to perform these important administrative steps may lead to weak management practices. NRR's safety evaluation review process needs to be modified to provide a clear documented decision-making path. These improvements will strengthen NRR's regulatory process and also help enhance stakeholder confidence in the license amendment process. Without the improvements, stakeholder confidence could be compromised.

## RECOMMENDATIONS

OIG is making three recommendations to the Executive Director for Operations that NRR should: (1) revise its procedural guidance and related flow charts applicable to license amendment processing to appropriately reflect the work flow and records management steps needed to meet agency records management requirements; (2) implement a process that ensures NRR staff completes all steps necessary to process a license amendment and any resultant safety evaluations; and, (3) implement a process for NRR staff to maintain and appropriately retrieve documents necessary to support the license amendment process and any resultant safety evaluations.

## AGENCY COMMENTS

At an exit conference held on August 30, 2001, agency managers generally agreed with the facts and recommendations contained in the discussion draft audit report. Agency management chose not to provide a formal written response for inclusion in the final report. Editorial suggestions provided by agency management were incorporated where appropriate.

## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **ADAMS** | Agencywide Documents Access and Management System |
| **CFR** | Code of Federal Regulations |
| **FRN** | *Federal Register* notice |
| **IP2-1** | Indian Point Unit 2 license amendment request of April 13, 1994 |
| **IP2-2** | Indian Point Unit 2 license amendment request of December 7, 1998 |
| **Letter No. 803** | *NRR Office Letter No. 803, Revision 3, License Amendment Review Procedures* and the *Guide for Processing License Amendments* |
| **NRC** | U.S. Nuclear Regulatory Commission |
| **NRR** | Office of Nuclear Reactor Regulation |
| **NARA** | National Archives and Records Administration |
| **OAR** | Official Agency Records |
| **OGC** | Office of the General Counsel |
| **OIG** | Office of the Inspector General |
| **PERRY** | Perry Unit 1 license amendment request of September 9, 1998 |
| **PSAB** | Probabilistic Safety Assessment Branch |
| **RAI** | request for additional information |
| **SE** | safety evaluation |
| **SRP** | *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants* |
| **STP2** | South Texas Project Unit 2 license amendment request of February 21, 2000 |
| **TAC** | Technical Assignment Control |
| **U.S.C.** | United States Code |
| **WISP** | Workload Information and Scheduling Program |

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# I. PURPOSE

In June 1999, the U.S. Nuclear Regulatory Commission (NRC) approved an Indian Point 2 nuclear power plant license amendment request to extend the previously established steam generator inspection interval. In February 2000, a steam generator tube failed, generating considerable public interest. Subsequently, Congresswoman Sue W. Kelley of New York questioned the adequacy of NRC's review leading to the approval of the extension. At her request, the Office of the Inspector General (OIG) initiated a review of the Office of Nuclear Reactor Regulation's (NRR) safety evaluation process to (1) evaluate its efficiency and effectiveness and (2) determine whether refinements are needed. Appendix A contains details regarding the scope and methodology of this review.

# II. BACKGROUND

To provide assurance that nuclear power plants operate safely, NRR requires licensees to adhere to specific licensing requirements. Nuclear power plant licensees submit approximately 1,500 requests per year to amend their operating licenses. These applications may include: (1) changes to position titles and simple changes to set points or other technical specification details; (2) extensions of allowed outage times or surveillance test intervals, or other changes that do not involve major changes or review of established NRC policies; and (3) significant restructuring of technical specifications, changes that introduce significantly different analytical methodologies, and changes that are related to revising established NRC policies. In fiscal year 2001, NRR budgeted for 88 staff and almost $870,000 to support the review of licensing actions related to nuclear power plants.

Safety evaluations are an essential part of NRR's response to license amendment requests. Safety evaluations provide the regulatory bases for the staff's decisions on licensing actions and the technical, safety, and legal basis for NRR's disposition of a license amendment request. The safety evaluation should provide sufficient information to explain the staff's rationale in approving or denying the license amendment to someone unfamiliar with the licensee's request. It should also include 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 regulatory requirements. The review of these applications is one of the primary mechanisms for regulating changes in the licensees' operations at commercial nuclear power facilities.

*NRR Office Letter No. 803, Revision 3, License Amendment Review Procedures* and the *Guide for Processing License Amendments* (Letter No. 803) is the guidance NRR staff must follow to complete the license amendment review process. This guidance states that project managers are responsible for the general oversight and coordination of processing license amendment requests. NRR Project Directorate section chiefs assign safety evaluation responsibilities to project managers. Project managers may either perform the license amendment review personally or coordinate a review performed by NRR technical branch staff and/or contractor personnel. Project managers are to ensure that staff assigned adhere to agency guidelines and principles of good regulation throughout the process. For those safety evaluations not prepared

by project managers, section chiefs in NRR's technical branches use their knowledge of the skills and abilities of their staff to assign the technical reviewers. Project managers may also request that a particular technical reviewer perform an evaluation. The Office of the General Counsel (OGC) reviews all amendment packages for legal adequacy and defensibility, unless a memorandum of agreement is developed stating that specific amendments do not require OGC concurrence.

Goals for timely performance on licensee amendment requests are based on the NRR Operating Plan, budget assumptions, and other agency goals. The quality of safety evaluations is based on the professional abilities of the preparers and is assured through a review and concurrence process which verifies the quality and consistency of license amendment packages. A number of administrative documents guide the review process in addition to Letter No. 803. The *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants* (SRP) provides technical guidance for many safety evaluations. *NRR Office Letter No. 101, Revision 13, Delegation of Signature Authority* provides guidance on the authorities required in the review and approval (or concurrence) process.

Safety evaluations receive several levels of review before approval by NRR management. Additionally, license amendment requests identified as needing additional risk assessment insights are referred to NRR's Probabilistic Safety Assessment Branch (PSAB) for an additional level of review of their significance. According to an NRR senior official, about 5 percent of the approximately 1500 incoming licensing actions each year are risk-informed.

However, the agency is facing additional challenges in several areas. Notably, NRR is expecting license amendment requests for significant power uprates, license renewals, longer operating cycles, and use of higher burn-up fuels. As a result, NRR's processing of license amendment requests, and any resultant safety evaluations, needs to be as efficient and effective as possible. Any needed refinements to enhance the process should be implemented in a timely manner.

## III. FINDINGS

Over the past few years, NRR has successfully reduced the age of its backlog of requests. For example, in fiscal year 1998, about 66 percent of licensing actions were less than one year old. By fiscal year 2000, NRR had improved significantly on this performance measure and 98 percent were less than one year old. NRR has developed a detailed process for responding to license amendment requests and conducting independent safety evaluations. The process is well thought out, thorough, and provides all necessary steps for ensuring that required technical reviews to approve or disapprove a license amendment request are performed. In addition, discussions during the audit with NRC officials and stakeholders did not reveal any concerns regarding the technical quality of safety evaluations.

However, the process does not provide adequate controls to demonstrate that the staff completes all steps and can support the internal decision-making process with adequate documentation. In addition, not all NRR process steps could be verified by official or other documentation readily available in NRR. This is because NRR has not met agency records management requirements in documenting certain steps in the license amendment process. As a result, stakeholder confidence in NRR's approval of license amendments and supporting safety evaluations could be compromised.

## A. The NRR Process For Responding To License Amendment Requests And Conducting Safety Evaluations Is Detailed And Well Thought Out

NRR has generally followed the same process for performing license reviews since 1975. As the agency grew in experience, a former NRR Director determined the need to establish guidelines for these review activities and developed the SRP. Subsequently, NRR developed Letter No. 803 to provide license amendment review procedures.

Letter No. 803, with reference to other supporting documents, provides a description of the license amendment review process, including the development of supporting safety evaluations. It outlines procedures for ensuring a detailed technical review of requested license amendments and subsequent NRR generated documents, with qualified staff, in a scheduled manner, and in a priority order.

In fiscal year 2000, NRR further defined the procedures in Letter No. 803 by creating two draft flow charts to depict the procedures outlined in the letter.[1] The flow charts are basically the same. The exception is that one depicts amendment processing by a project manager, without the assistance of technical reviewers, while the other adds the steps required when technical assistance is required. Early steps in each chart identify administrative processing responsibilities for licensees, NRC's document control desk, and NRR's Work Planning Center.[2]

Subsequent steps provide project manager, licensing assistant, and project section chief responsibilities related to further license amendment processing, work planning, safety evaluation development, and final amendment package requirements. In cases when technical branch reviewers are needed to determine the appropriateness of a license amendment request, the applicable flow chart provides detailed steps for the technical branches in generating safety evaluations. Both charts also show the need for OGC to review and concur on the final license amendment package.

To assess the perceived quality of safety evaluations, OIG interviewed NRC officials and stakeholder representatives. These discussions did not reveal any concerns regarding the technical quality of safety evaluations. For example, none of those interviewed could identify any plant where a problem was identified due to a license amendment based on a flawed safety evaluation. Furthermore, a review of allegations received by

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1 *License Amendment with Project Manager Review Process - Composite* and *License Amendment Request with Technical Branch Review Process - Composite* (see Appendix B)

2 NRR's Work Planning Center is currently under development and has not yet been formally implemented.

NRC identified that none were related to safety evaluations. Finally, OGC officials noted that NRC has never lost a legal challenge to an issued license amendment.

## B. All NRR Process Steps Could Not Be Verified By Documents Available In NRR And Retention/Retrievability Of Supporting Documents Does Not Meet Agency Requirements

While Letter No. 803 and the flow charts indicate the steps to be taken in processing license amendments and their supporting safety evaluations, they do not identify the need to document certain steps in the review process. Although there are requirements for documenting some of the steps, other important steps do not require documented evidence of completion. Additionally, the office letter and flow charts do not contain guidance directing which documents should be maintained as official agency records. Consequently, the lack of documentation makes it difficult for NRR to completely support certain aspects of its internal decision-making process.

OIG wanted to assess whether NRR staff processed license amendments, and their related safety evaluations, in accordance with office guidance and maintained adequate documentation to demonstrate that NRR staff met the guidance. To that end, OIG reviewed four license amendment requests, steps to respond to them, and documentation to support the subsequent decisions to allow the requested actions. OIG negotiated with NRR management about providing the supporting documents. OIG indicated the desire to see all documents that would prove each step in the amendment process, but not to the extent that a large amount of agency resources would be expended. Documents not readily available or easily retrievable would indicate a document management or retrievability issue related to the overall process. In this report, OIG will indicate if the unavailability of documents to support the license amendment process steps was important or not. It should be noted that unavailability of documents during this review does not mean they do not exist within the agency. Rather, it means they were not readily available for this review.

The four amendment requests reviewed were for:

- Indian Point Unit 2 (April 13, 1994) - An amendment request to permit steam generator tube sleeving as an alternative to removing defective tubes from service through the use of tube plugs and a proposal for a new tube acceptance criteria that would allow tubes that are degraded in a location not affecting structural integrity of the tube to remain in service (IP2-1);[3]

- Indian Point Unit 2 (December 7, 1998) - An amendment request to permit a one-time only extension of the steam generator tube in service inspection interval (IP2-2);

[3] Subsequent to this amendment being submitted, IP2 asked that the portion of the original amendment request pertaining to steam generator tube sleeving be separated from the original request in order to allow additional review of current sleeving technical issues.

- South Texas Project Unit 2 (February 21, 2000) - An amendment request to implement an alternate-repair-criteria methodology for Unit 2 Model E steam generators (STP2); and

- Perry Unit 1 (September 9, 1998) - An amendment request related to hydrostatic (water) testing of containment isolation valves in the Feedwater System lines (PERRY)[4]

Overall, NRR staff implemented most of the required license amendment and safety evaluation process steps. However, based on the official and other documentation readily available in NRR and supplied to the auditors, OIG could not verify that NRR staff took actions for certain process steps. As such, the process does not provide adequate controls to demonstrate that all process steps are completed and supported by adequate documentation. Chart 1 provides summary results of the OIG analysis for the four license amendment packages reviewed. Appendix C provides a detailed discussion of significant criteria related to NRR's license amendment review process and OIG's analysis of the documents that NRR provided to demonstrate compliance with that criteria. It should be noted that all license amendment requests OIG reviewed involved technical branch reviews. Therefore, OIG's evaluation and subsequent conclusions relate only to the license amendment process when technical staff support is required. However, these types of amendment requests represent the more significant, complex, and technical types of review performed by NRR.

As shown in the "Administrative" portion of Chart 1, NRR staff generally follow the administrative steps for receiving, and initial processing of, license amendment requests and has the documents to prove this. The unavailable documentation associated with STP2 did not affect the technical considerations associated with the amendment requested or its resultant safety evaluations.

However, remaining portions of Chart 1 indicate that documents directly associated with project manager and technical branch staff processing of license amendments are not readily available to prove that all steps have been completed. NRR provided timely and adequate documents for seven of 38 steps (the green indicators), timely but incomplete documentation for 16 steps (the yellow indicators), and no documentation for 15 steps (the red indicators). NRR managers indicated that staff are not required to document several of the steps. However, by not documenting the completion of steps, NRR cannot demonstrate the total process has occurred or that the review was as thorough as it should have been.

[4] After submitting the initial license amendment application, PERRY submitted a "Supplement to a License Amendment Request: Improved Licensing Design" on January 6, 1999. The first line of that supplement states, "This letter supercedes the Feedwater Penetration Improvement license amendment request dated September 9, 1998." The issue of whether this was a "supplement" or "supercedes" the original license amendment application will be discussed in context during various portions of Appendix C.

## Chart 1: OIG Summary Analysis of Documents Supporting NRR's License Amendment/Safety Evaluation Process

| **Flow Steps** | IP2 - 1 | IP2 - 2 | STP2 | PERRY |
|---|---|---|---|---|
| ***Administrative*** | | | | |
| (Licensee) Submit license amendment request | Green | Green | Green | Green |
| (NRC Document Control Desk) Receive/process/distribute | Green | Green | Red | Green |
| (NRR) Assign technical assignment control number | Green | Green | Green | Yellow |
| ***Project Manager/Technical Branch Reviewers*** | | | | |
| Perform acceptance review | Yellow | Yellow | Yellow | Yellow |
| Perform characterization of review | Yellow | Yellow | Yellow | Red |
| Provide guidance on policies and applicable precedents | Red | Red | Red | Red |
| ***Technical Branch Reviewers*** | | | | |
| Define regulatory requirements, policies, applicable precedents | Red | Red | Red | Red |
| Prepare initial questions for use in RAI | Yellow | Green | Green | Red |
| Prepare formal RAI | Yellow | Green | Yellow | Red |
| Prepare safety evaluation | Green | Green | Yellow | Yellow |
| ***Project Managers*** | | | | |
| Notify public and complete no significant hazards consideration | Red | Red | Green | Red |
| Prepare environmental assessment (if necessary) | na | na | na | na |
| Evaluate request for withholding information / prepare response | Red | na | Green | na |
| Review, concur, and prepare final amendment package | Yellow | Yellow | Yellow | Yellow |

Green — Adequate documentation

Yellow — Incomplete documentation

Red — No documentation

na — Not applicable

In addition, NRR is not complying with the agency's own document retention standards in some cases.[5] (See Appendix E for details regarding NRC's record retention requirements.) Working files (e.g., preliminary drafts, rough notes, other similar materials) are to be retained if they contain unique information, such as substantive annotations or comments, that adds to a proper understanding of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities. Letter No. 803 does not contain the same requirements contained in the agency's records management guidance. The documents NRR could not provide in a timely manner to OIG in support of the license amendment process (either those missing or incomplete) constitute official agency records and should be available for review and readily retrievable. Without such documents, NRR cannot provide stakeholders the relative confidence that staff implement the thorough, well planned license amendment process as described.

## IV. SUMMARY

The NRR process for handling license amendment requests and providing for resultant safety evaluations is detailed, well thought out, thorough, and provides all necessary steps for ensuring that required technical reviews to approve or disapprove a license amendment request are performed. However, the process lacks adequate documentation controls to ensure that NRR staff have completed all process steps and can provide adequate documentation to demonstrate this. In addition, NRR has not met agency records management requirements in documenting certain steps in the license amendment process. As a result, NRR does not retain and/or cannot easily retrieve many of the documents that demonstrate certain aspects of NRR's decision making process. Failure to perform these important administrative steps can lead to weak management practices which can result in the improper processing of license amendment requests. NRR's license amendment review process needs to be modified to provide a clear decision-making path. These improvements will strengthen NRR's regulatory process and help to enhance stakeholder confidence in that process. Without the improvements, stakeholder confidence could be compromised.

## V. RECOMMENDATIONS

OIG recommends that the Executive Director for Operations:

1. Revise Letter No. 803[6] and related flow charts applicable to license amendment processing to appropriately document the work flow and records management steps needed to meet agency records management requirements.

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5 Management Directive Handbook 3.53, Part 1, Volume 3, Part 2 - *Records Management, NRC Records Management Program* (MD 3.53) and the ADAMS 3.3 *Desk Reference Guide* (ADAMS Guide).

6 On August 20, 2001, NRR replaced Letter No. 803 with Office Instruction LIC-101, *License Amendment Review Procedures.* The new instruction contained some guidance changes, but nothing that would negate the results of the OIG review. For purposes of this report, to prevent confusion and provide for continuity, OIG's recommendation addresses Letter No. 803. NRR will need to revise LIC-101 to satisfy the OIG recommendations.

2. Implement a process that ensures that NRR staff completes all steps necessary to process a license amendment and any resultant safety evaluations.

3. Implement a process for NRR staff to maintain and appropriately retrieve documents necessary to support the decision-making path of the license amendment process and any resultant safety evaluations.

## VI. AGENCY COMMENTS

At an exit conference held on August 30, 2001, agency managers generally agreed with the facts and recommendations contained in the discussion draft audit report. Agency management chose not to provide a formal written response for inclusion in the final report. Editorial suggestions provided by agency management were incorporated where appropriate.

## SCOPE AND METHODOLOGY

The scope of this Office of the Inspector General (OIG) review was limited to those areas of U.S. Nuclear Regulatory Commission (NRC) operations related to the preparation and processing of safety evaluations for license amendments submitted by nuclear power plant licensees. To complete the audit objectives, OIG (1) reviewed regulatory and NRR program criteria governing the processing of safety evaluations; (2) held discussions with senior NRC officials in the Offices of Nuclear Reactor Regulation (NRR), the General Counsel, and Nuclear Regulatory Research; (3) attended related NRC meetings; (4) conducted interviews with industry and stakeholder representatives; and (5) analyzed a limited sample of license amendment requests and resultant safety evaluations. OIG evaluated the management controls related to NRR's safety evaluation process with the involvement of technical branch review and conducted our work from September 2000 through July 2001 in accordance with generally accepted Government auditing standards. This review was conducted by: Bill McDowell, Team Leader; Bob Moody, Audit Manager; Cathy Colleli, Senior Management Analyst; and, Russell Irish, Staff Assistant for Planning and Reporting.

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# LICENSE AMENDMENT WITH TECHNICAL BRANCH REVIEW PROCESS

**Chart to large to scan into electronic document**

**The following composite flow chart was developed by the Office of Nuclear Reactor Regulation NRR to depict the normal flow process for reviewing license amendment requests and developing resultant safety evaluations. It is provided to help the reader in understanding the process NRR uses, the reported OIG findings, and the OIG's detailed findings analyses contained in Appendix C.**

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# RESULTS OF OIG ANALYSIS OF SELECTED LICENSE AMENDMENT APPLICATIONS

The Office of the Inspector General (OIG) reviewed four license amendment requests, the Office of Nuclear Reactor Regulation's (NRR) steps to resolve them, and NRR generated documents to support the subsequent NRR decisions to allow the requested actions. The four amendment requests reviewed were:

- Indian Point Unit 2 (April 13, 1994) - An amendment request to permit steam generator tube sleeving as an alternative to removing defective tubes from service through the use of tube plugs and a proposal for a new tube acceptance criteria that would allow tubes that are degraded in a location not affecting structural integrity of the tube to remain in service (IP2-1);[7]

- Indian Point Unit 2 (December 7, 1998) - An amendment request to permit a one-time only extension of the steam generator tube in service inspection interval (IP2-2);

- South Texas Project Unit 2 (February 21, 2000) - An amendment request to implement an alternate-repair-criteria methodology for Unit 2 Model E steam generators (STP2), and

- Perry Unit 1 (September 9, 1998) - An amendment request related to hydrostatic (water) testing of containment isolation valves in the Feedwater System lines (PERRY)[8]

Overall, OIG determined that NRR implemented most of the license amendment and safety evaluation process steps required. However, NRR officials could not provide sufficient documented evidence to prove that NRR staff took actions for many of the staff determinations required by agency guidance.[9]

## ADMINISTRATIVE PROCESSING

Licensees are responsible for initiating the actions that precipitate the need for a safety evaluation. The bases for all safety evaluations must be rooted in either a technical, legal, or safety issue. In almost all cases, the document submitted by the licensee to bring about resolution of the issue is a proposed license amendment.

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7 Subsequent to this amendment being submitted, IP2 asked that the portion of the original amendment request pertaining to steam generator tube sleeving be separated from the original request in order to allow additional review of current sleeving technical issues.

8 After submitting the initial license amendment application, Perry submitted a "Supplement to a License Amendment Request: Improved Licensing Design" on January 6, 1999. The first line of that supplement states, "This letter supercedes the Feedwater Penetration Improvement license amendment request dated September 9, 1998." The issue of whether this was a "supplement" or "supercedes" the original license amendment application will be discussed in context during various portions of this appendix.

9 It should be noted that all license amendment requests OIG reviewed involved technical branch reviews and preparation of safety evaluations. Therefore, OIG's evaluation and subsequent conclusions relate only to the license amendment process when technical staff support is required.

Once a licensee has submitted a proposed license amendment, with a safety analysis of the proposed change, it is received by the NRC Document Control Desk. The Document Control Desk enters the proposed amendment and accompanying documents into the Agencywide Documents Access and Management System (ADAMS) and sees that they are distributed to the appropriate organizations. When proposed license amendments pertain to licensed nuclear reactors, they are sent to NRR. Once received in NRR, a Technical Assignment Control (TAC) number is provided for tracking and fee recovery purposes. Then, the proposed license amendment package is assigned to the appropriate Project Section Chief in the Division of Licensing and Project Management, NRR, who next assigns the package to the appropriate project manager.

## OIG ANALYSIS

For the four license amendment packages OIG reviewed, except for a few insignificant lapses in documentation, the initial administrative processing followed agency guidance and was supported by documented evidence.

- For STP2, the copy of the proposed license amendment request provided to OIG did not contain the ADAMS identifier.

- For PERRY, NRR did not provide the initial document on which the TAC number was assigned; however, subsequent documents NRR provided showed a TAC number was assigned.

## ACCEPTANCE REVIEW

Once the proposed license amendment has been assigned to the appropriate project manager, that individual (assisted by a licensing assistant) is required to perform an acceptance review. In particular, the project manager is responsible for reviewing the license amendment application for completeness and acceptability. Letter No. 803 states:

> The minimal requirements for amendment applications are described in 10 CFR [Title 10, Code of Federal Regulations, Parts] 50.4, 50.90, 50.91, and 50.92.[[10]] The following guidance highlights important key elements that should normally be contained in a license amendment application. It is provided to assist PMs [project managers] in their initial screening process. The guidance is not an interpretation or a substitute for conforming with the legal requirements of the regulations, nor does the guidance itself constitute an absolute requirement.

Letter No. 803 then indicates the key elements in an amendment application, as listed below:

1. oath and affirmation;
2. description of the amendment;
3. licensee's safety analysis/justification for the proposed changes;
4. no significant hazards consideration determination;

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[10] Title 10 Code of Federal Regulations, Part 50, *Domestic Licensing of Production and Utilization Facilities;* Par 50.4, *Written communications.;* Part 50.90, *Application for amendment of license or construction permit.;* Part 50.91, *Notice for public comment; State consultation.;* Part 50.92, *Issuance of amendment.*

5. requested review schedule and/or implementation period;
6. appropriate technical specification pages;
7. environmental assessment; and,
8. copy to appropriate State.

If a licensee's amendment application does not include one or more of the preceding items, NRR Letter No. 803 states that:

> the project manager should contact the licensee and arrange for the information to be submitted. Under these circumstances, the licensee may withdraw the request or may correct the deficiencies within a mutually agreed upon time. If the licensee does not correct the deficiencies within the specified time, the amendment may be denied. If an application is withdrawn or denied due to a deficiency in the submittal (as opposed to a definitive, negative finding by the staff based on the technical merits of the proposed changes), then a licensee may submit a new application (with the identified discrepancies corrected) at any time in the future.

**OIG ANALYSIS**

For the amendment packages reviewed, various key elements were missing in the copy of the licensee's submitted amendment applications provided by NRR.

- For IP2-1, items 5 and 7 were not evident. The NRR Work Request for this amendment says the basis for the priority assigned is "Required for Feb. 95 refueling outage." However, NRR provided no documented support for this date. Additionally, there was no consideration of environmental issues evident in the documents reviewed.

- For IP2-2, items 5, 6, and 7 were not addressed in the NRR supplied documents to support the amendment package. For item 6, there was a document cover sheet which is titled as an attachment to the amendment application, but the contents of the document were not provided to OIG. Again, there was no consideration of environmental issues evident in the documents reviewed.

- For STP2, items 6 and 7 were not addressed in the documents provided for review. For item 6, there were three attachments cited in the amendment application package, but NRR did not provide the attachments.

- For PERRY, items 1 and 5 are not addressed in the amendment application which was submitted as a supplement to the original request. Because the supplemental document indicated that it superceded the original license amendment requested, all information should have been considered new. Therefore, the licensee should have provided a new oath and affirmation. Additionally, although the original license amendment package had a review schedule requested, the supplemental package did not. If the original date requested remained the same (September 29, 1998), when the superceding supplement was submitted (January 6, 1999), this constituted a new amendment request and should have had an exigent public notification (see the section titled Public Notification later in this report).

NRR managers said this acceptance review is not documented. According to them, if the amendment request package is inadequate, no work begins until the matter is resolved or the project manager denies the request due to inadequacy. However, based on the deficiencies cited above, this is not the case. Additionally, if project managers took actions to resolve the omissions, documented evidence was not provided to OIG. Without some format on which to document this acceptance review, missing elements of the license amendment application packages may go undetected. Additionally, the efficiency of the license amendment review process can be impaired if required information is missing and must be resolved later in the process.

## CHARACTERIZATION OF REVIEW

Once administrative processing of the license amendment request is completed, the project manager (with assistance from technical branch staff, as needed) must perform a characterization review of the request. This review consists of searching for precedent licensing actions and developing a work plan for evaluating the license amendment request and processing the subsequent safety evaluation. If it is determined that technical branch personnel will evaluate the amendment request, an NRR Work Request Form must be completed to ensure coordination in the planning effort (See Appendix D).

### Search for Precedent Licensing Actions

The project manager (with assistance from technical branch staff, as needed) has the primary responsibility for conducting a search for precedent licensing actions taken by the agency. Searching for, identifying, and using precedents in the review process maximizes staff efficiency, minimizes the need to issue requests for additional information, and ensures consistency of licensing actions.

According to Letter No. 803, "Precedent licensing actions are those with a similar proposed change and regulatory basis for the SE [safety evaluation]. The search for a precedent should continue until NRR staff are satisfied that either 1) they have identified one or more appropriate precedents, or 2) that no appropriate precedents exist." The letter also provides project managers with available resources to use in their precedent searches:

- **Licensees** - and their contractors who have developed systems to identify precedent amendments and often share information related to requests and the staff's evaluation

- **Staff Input** - from discussion with other project managers and technical branch staff and consultation with staff in the Generic Issues, Environmental, Financial and Rulemaking Branch

- **Staff Guidance** - issued by lead project managers and technical branch staff may include model safety evaluations for some classes of amendments

- **Internal NRC Home Page** - whose software application can be used to search for safety evaluations related to the subject(s) of the amendment request dating from 1990 to the present

- **ADAMS** - whose software application can be used to search for amendments as well as other official agency records

- **WISP (Workload Information and Scheduling Program)** - whose software application can be used to identify precedent licensing actions with comparable titles

- **Standard Technical Specifications (STSs)** - where a comparison of the amendment request with appropriate sections of the corresponding improved STS may result in the identification of current policy pertinent to the amendment request being processes

- **Federal Register Notices** - where the biweekly collection of proposed and issued amendment notices in the *Federal Register* can be scanned to search for similar amendment requests

Letter No. 803 points out that, "Staff should consult with their colleagues or managers to obtain the training or guidance if they are unfamiliar with the use of any of these documents."

**Develop a Work Plan**

Following the preliminary assessment and search for precedent actions, information necessary to develop a detailed plan for processing the amendment application should be available. The plan is to define the scope and depth of the review, resources needed, and the schedule for completion. If the project manager is to complete the safety evaluation, technical branch staff will be consulted regarding the plan. If technical branch staff are to prepare the safety evaluation, they should be involved in the preparation of the work plan. Interaction between the project manager and technical branch staff is dependent on the similarity between the license amendment requested and precedent licensing actions, the risk significance of the amendment request, and the technical complexity of the required review.

**Levels of similarity**

According to Letter No. 803, there are three levels of similarity between an amendment application and any related precedent:

- No or Low Similarity - There is either no precedent to apply, or major modification to the precedent license amendment would be required for use for the application under consideration.

- Medium Similarity - The review of the application could apply a precedent with limited technical modifications.

- High Similarity - The review of the application could directly apply a precedent without technical modifications.

**Levels of complexity**

Additionally, there are three levels of technical complexity into which a required review may be categorized:

- Low Complexity - Includes changes to position titles in the technical specification administrative controls section and simple changes to set points or other technical specification details.

- Medium Complexity - Includes extensions of allowed outage times or surveillance test intervals, or other changes that do not involve major changes or review of established NRC policies.

- High Complexity - Includes significant restructuring of technical specifications, changes that introduce significantly different analytical methodologies, and changes that are related to revising established NRC policies.

**Risk insights**

Risk insights, whether provided by the licensee or estimated by NRR staff, should be considered and incorporated into the development of the work plan. These risk insights should be handled in a similar manner to technical complexity. In general, technical complexity categories correlate to risk significance categories as follows:

Figure 1. Technical Complexity and Risk Significance

| Technical Complexity | Risk Significance |
|---|---|
| Low | Very Low Risk Significance |
| Medium | Low to Moderate Risk Significance |
| High | Substantial Risk Significance |

According to Letter No. 803, if precedents can be readily applied and the risk significance and technical complexity are relatively low, the project manager should prepare a plan and proceed with the review. Technical staff should be informed of this intent, with the project manager identifying the precedent being used. In this way, technical staff can understand the approach and acceptance criteria, suggesting alternate precedents or identifying key issues that need to be addressed in the safety evaluation. If a project manager intends to perform the review and has a general understanding of how to proceed, but needs input from a technical branch to develop the plan, an initial plan should be drafted. The technical branch will then perform an informal review. If a technical branch review is being requested, the project manager can prepare and submit a work request to the technical branch without significant prior discussions.

However, when precedents are not readily applied and the risk significance and/or technical complexity are relatively high, the project manager must take more strategic steps. The project manager should prepare an information package regarding the

license amendment requested for technical staff. Next, a meeting should be convened to review issues and draft a review plan before submitting work request forms. Letter No. 803 further cites that, "Involving licensees in meetings or conference calls before or soon after submittals may be useful for amendment applications that involve complex technical issues or policy changes for the NRC."

Figure 2. Project Manager's Guidance for Amendment Package Review and Concurrence

| Technical Complexity or Risk Significance | Similarity between application and precedent | | |
|---|---|---|---|
| | Low | Medium | High |
| Low | | | PM develop work plan and inform tech staff |
| Medium | | PM develop work plan for discussion with tech staff | |
| High | PM and tech staff jointly prepare work plan | | |

Figure 2, taken from Letter No. 803, provides guidance to project managers in determining the level of support needed from technical branch staff in developing a work plan. License amendments with low technical complexity and high precedents require minimal technical staff involvement, while those with high technical complexity and low precedents require direct involvement.

## Scope and Depth of Review

In most cases, the technical review of the amendment application represents the largest amount of technical resources expended in processing an amendment. Careful identification of what will be addressed in the review is essential to effective planning. The following should be identified in either the statement of scope and depth or as part of the review:

- the regulatory basis for the amendment request;
- the plant specific licensing bases including regulatory requirements and commitments upon which the subject technical specifications were originally developed;
- the design, operating, and maintenance related safety concerns that will be addressed by the review;
- any previous licensing amendments that will serve as a model in conducting the review;
- all appropriate technical branch reviews required;
- the data or information required to conduct the evaluation; and,
- the relative risk significance of the amendment request.

In some cases, in lieu of providing a formal safety evaluation, technical staff may provide informal guidance and responses to information needs by the project manager.

## Resources to be Used in the Review

The time of the project manager, technical staff, and contractor staff is the primary resource expended in the review process. Estimates of staff responsibilities and hours to be expended are required to ensure the efficient and timely use of this resource.

A project manager will normally conduct the review and prepare the safety evaluation for amendment requests that are relatively low in technical complexity and risk significance, while having relatively high similarity to precedent licensing actions. Conversely, technical staff will normally involve itself with requests that are relatively high in technical complexity and risk significance, but having relatively low similarity to precedent licensing actions. Discussions between the project manager and technical staff will generally determine the assignment of responsibility for other types of amendment requests that fall between these two extremes. Use of contractors is determined by the technical staff based on (1) technical expertise required to perform the scope of work, (2) availability of NRR technical staff to support the review in a timely manner, and (3) availability of funds to support contractor review efforts.

Figure 3. Complexity/Risk Cross Matrix
to Similarity of License Application and Precedents

| | **Similarity Between Application and Precedent**[11] | | |
|---|---|---|---|
| **Technical Complexity and/or Risk Significance** | **No or Low** | **Medium** | **High** |
| Low | 72 hours | 40 hours | 20 hours |
| Medium | 96 hours | 72 hours | 40 hours |
| High | Case-specific project plan | 96 hours | 72 hours |

While it is often difficult to estimate the staff hours needed to perform a review, developing a reasonable estimate is critical to developing a quality work plan. In considering all elements of the plan, best estimates of the number of hours for each NRR staff are supposed to be developed. Significant increases in these estimates during the course of the review must be brought to the attention of appropriate NRR management. Letter No. 803 provides general guidance for estimating the hours of effort needed to complete a review (see Figure 3), using the same complexity and similarity matrix contained in Figure 2. The hour ranges given are used for general guidance only.

**Schedule of Review**

It is essential for a complete work plan to have a firm date for completion of the amendment request review and preparation of the safety evaluation. Factors to be considered in the schedule determination are:

- safety significance and agency priorities;
- licensing action timeliness goals;
- licensee needs and desires, including implementation date;
- application priority;

[11] Per NRR Letter No. 803, these resource estimates are based on historical data and hours expended to produce the safety evaluation. Administrative effort is not included. Additionally, the hours expended are based on a per review basis (the safety evaluation or branch-specific portion of a safety evaluation) and not on a per TAC basis.

- review resource requirements and availability; and,
- contractor resource requirements and availability.

The priority of an amendment review task is primarily determined on the basis of safety significance, risk considerations, and operational impact. Three levels of priority are defined in Letter No. 803:

Priority 1: High Priority - Immediate action usually is required; the review completion date must be met; and, a firm commitment of resources is required. Priority 1 efforts involve the following:

✓ highly risk-significant safety concerns that require a firm commitment of resources;

✓ actions needed to prevent or require plant shutdown, or allow restart; and

✓ issues for which immediate action is needed for compliance with statutory requirements, or Commission or Executive Director's Office directives.

Priority 2: High Priority Near-Term[12] - Short-term actions and/or minor changes to the review completion date can be negotiated. Priority 2 efforts involve the following:

✓ significant safety issues that do not rise to the level of immediate action but require near-term staff evaluation; and

✓ activities needed to support continued safe plant operation, reload analyses, or evaluation of necessary modifications or enhancements.

Priority 3: Low Priority - Longer-term actions where the review completion date is flexible (but still required to support timeliness goals). Priority 3 efforts involve the following:

✓ cost beneficial licensing actions (CBLAs) are the highest priority for this category;

✓ issues of moderate to low safety significance that do not directly impact plant safety; and

✓ requests for technical specification amendments required for economic advantage (e.g., changes in core and equipment operating limits, limiting

[12] As a minimum, risk-informed licensing actions are required to be assigned as Priority 2 unless Priority 1 is required due to safety significance or the need for immediate action.

conditions for operation and surveillance requirements, deletion of equipment that is no longer used, and administrative technical specification changes).

Once the planning process is complete, the project manager should communicate the results (i.e., the categorization of the application, estimated technical review staff-hours, and completion time) to the licensee. The project manager and technical branch staff should resolve any concerns or issues raised by the licensee with respect to the staff's planning of the license amendment review.

If a review is performed by a technical branch, any changes in the safety evaluation completion date or estimated staff hours must be negotiated between the project manager and technical branch designee.

**Work Request Form**

Project managers use an NRR Work Request Form (See Appendix E to view a copy of the form and related instructions) when coordinating the planning of amendment reviews to be performed by technical branch personnel. This form, with sections completed providing background information and a description of the assistance being requested, is then submitted to the appropriate technical branch(s). The project manager must be as specific as possible with respect to the products requested by the work request. If proposed changes to a previously accepted work request form are agreed to by the project manager and the technical branch(s) involved, the project manager must document those changes in a revised work request.

## OIG ANALYSIS

NRR Work Requests associated with the license amendment packages did not provide sufficient evidence that all procedural and flow steps for the characterization reviews took place.

- For IP2-1, the NRR Work Request is an older version of the one currently in use. Except for the assignment of a "Priority 3" no other information outlined in Letter No. 803 is evident on the form; however, this was a 1994 amendment request.

- For IP2-2, the NRR Work Request shows a priority assigned, a target date provided, staff hours estimated, and the assigned technical reviewer. However, the other information outlined in the procedures is not provided.

- For STP2, multiple technical branches were involved in the safety evaluation review. There are three NRR Work Requests that show a priority assigned, a target date provided, staff hours estimated, possible precedents, and assigned technical reviewers for three branches. Each of the work requests also identifies a fourth technical branch being involved; however, there is no work request for that branch and no safety evaluation was provided by that branch. OIG cannot determine if that branch did or did not perform a review, but there are no records

to support that such a review was done. Almost one month after the project manager completed the work request for one branch, that branch almost doubled the proposed time estimate for its work, without evidence of project manager involvement.

- For PERRY, NRR managers said that work plans were developed, but not maintained. According to these managers, four NRR Work Requests were generated due to the involvement of four different technical branches. However, absent those documents, there is no evidence this planning took place.

Additionally, none of the documents NRR supplied to support the processing of the license amendment requests contained any evidence that NRR had categorized precedents by similarity or characterized the amendment requests by complexity. There also is no indication as to what documents NRR utilized for each amendment request in determining the scope and depth of the necessary review. Finally, there was no documented evidence that technical branch chiefs participated in the characterization review or provided guidance on policies and applicable precedents.

NRR managers said this characterization review is not documented other than the information contained on the NRR Work Request. According to these managers, the steps outlined in Letter No. 803 take place through discussions between the project managers and technical branch reviewers. Furthermore, they said the NRR Work Request, and the information contained therein, represents the results of these discussions.

## TECHNICAL BRANCH INVOLVEMENT

Letter No. 803 and the NRR flow charts depicting the license amendment review process indicate that technical branches are to be involved in the license amendment review process as determined by the assigned project manager. One or more technical branches may be assigned to work on a license amendment request.

### Regulatory Requirements, Policies, and Applicable Precedents

When technical branches are responsible for developing safety evaluations, technical branch chiefs provide guidance on policies and applicable precedents. Additionally, technical branch reviewers are to define the regulatory requirements, policies, and applicable precedents to be used and compare the license amendment proposal to them.

## OIG ANALYSIS

NRR provided no record of this activity for any of the license amendment request packages. NRR managers said these reviews are not documented. Technical branch chief involvement related to providing guidance on policies and applicable precedents is performed during the characterization of review, and the resultant NRR Work Request generated represents (in part) this process. They further said that any precedents will be identified in the safety evaluation if precedents are found and are used in generating the safety evaluation. With regard to the technical branch reviewers, NRR managers said that at the point that regulatory requirements, policies, and applicable precedents are being defined and compared to the submitted license amendment proposal, the review of the particular license amendment request has gotten underway. They said the different documents applicable to the review are utilized and will be

identified in the final safety evaluation generated. Nothing is formally documented at this point. Project managers involved with the license amendment requests OIG reviewed said there is no documentation available that demonstrates these steps take place.

Although technical branch chiefs provide guidance on policies and applicable precedents, nowhere in the process are technical branch chiefs required to sign off on the final safety evaluations or license amendment packages. Additionally, in preparing the initial characterization review at the project manager level, there is no document developed that requires verification by the technical branch reviewers. In order to provide better confidence in the process, NRR could develop an attachment to the NRR Work Request that outlines the available resources used, and the results achieved, in the precedent searches (see the previous Search for Precedent Licensing Applications section). Then, technical branch chiefs and technical branch reviewers could add or delete from the initial list as the in-depth review takes place. In this manner, better assurance would be provided that technical branch chiefs are in agreement with the actions taken by their staff.

**Requests for Additional Information**

According to Letter No. 803,

> Requests for additional information (RAIs) serve the purpose of enabling the staff to obtain all relevant information needed to make a decision on a licensing action request that is fully informed, technically correct, and legally defensible. RAIs are necessary when the information was not included in the initial submittal, is not contained in any other docketed correspondence, or cannot reasonably be inferred from the information available to the staff. RAIs should be directly related to the applicable requirements related to the amendment application, and consistent with the applicable codes, standards, regulatory guides, and/or the applicable Standard Review Plan sections. RAIs should not be used as general information requests or as a means to encourage commitments from licensees.

RAIs should be appropriate and ensure that each question was developed with proper consideration of the: regulatory basis of request; technical complexity of request; risk significance of issues in question; existence of precedent amendments; appropriate scope and depth of review; resource implications for both the staff and the licensee; and, information already on the docket. Letter No. 803 provides guidance for common RAI concerns:

1. Questions included in the formal RAI should ask for information that is required to make the regulatory finding. Each question should have a clear nexus to the staff's regulatory finding. Including the regulatory finding in the question is a good practice.

2. The staff should not issue any RAIs if the staff has (or can infer with a reasonable degree of confidence) the necessary information to make the regulatory finding. When an RAI is necessary, the staff should make every effort to limit itself to one round of RAIs per TB [technical branch] for an amendment application. The established

timeliness of goals are likely to be exceeded if multiple RAIs are needed to complete the staff's review of a license amendment application.[13]

3. Frequent and early communications between the PM [project manager], TB [technical branch] staff, and the licensee can avoid the need for many RAIs. To ensure an effective and efficient review, project managers are required to notify the licensee prior to issuing an RAI and document the conversation in the RAI cover letter. This notification should be a meeting or conference call attended by the PM, TB reviewer, and licensee. The proposed RAI questions should be discussed and a mutually agreed upon due date should be established. This due date should be reflected in the RAI cover letter. In order to facilitate resolution of the issues, questions may be faxed or e-mailed to the licensee prior to the meeting or conference call. Answers that are needed to make a regulatory finding (i.e., that are not merely clarifications of information already on the docket) should be placed on the docket. The staff's questions may be docketed by forwarding an official RAI to the licensee, generating a memo to file and placing it on the docket or by having the licensee refer to the teleconference/e-mail/fax in their docketed response. The specific method used is case-specific and depends on the needs of the licensee, the potential public interest, and the needs of the NRC staff.

4. Before developing an RAI, the staff should ensure that the information is not already available to the staff or that the answer could not reasonably be inferred from general knowledge, existing regulatory requirements, previously docketed correspondence, or generally accepted industry practice.

5. Questions should be specific rather than overly broad, and the response to the RAI should be of value to the staff's safety evaluation basis.

6. If an RAI is issued and the licensee's response does not fully address the RAI, the PM will set up a meeting or conference call attended by the PM, TB reviewer, and licensee management to discuss the discrepancy and what needs to be provided to the staff on a timely basis in order to complete the amendment review. Failure of the licensee to provide timely information may result in a denial or withdrawal of the amendment based on a deficiency in the submittal as opposed to a definitive, negative finding by the staff based on the technical merits of the proposed change. The licensee may submit a new application (with the identified discrepancies corrected) at any time in the future.

7. If a disagreement arises with the licensee regarding the appropriateness of an RAI or whether or not the information was provided, the issues should be raised immediately to management for proper resolution.

8. Consistent with Section 4.2, the staff should make use of previous reviews in order to avoid asking unnecessary questions.

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[13] On November 3, 2000, the Director, NRR, provided a letter to NRR technical employees clarifying RAIs. In his letter, the Director says "...there is a concern that some staff may be taking the OL [Letter No. 803] guidance of 'one round of RAIs' as an absolute limit to be implemented without exception. In addition, the current wording in OL 803, Rev 3, may be contributing to a misinterpretation by stating that 'every effort' should be made to limit the staff to one round of RAIs per TB [technical branch]." In his summary, the Director states, " I would like to reinforce that although it is desirable to obtain the necessary information in 'one round of RAIs,' additional RAIs may be necessary."

9. The timely issuance of an RAI, if necessary, and the licensee's agreed upon time to respond should be factored into the schedule established to complete the review within the licensing action timeliness goals (e.g., FY00 and beyond goals of completing 95% of applications in less than 1 year).

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

**OIG ANALYSIS**

OIG's review of the four license amendment packages revealed mixed results.

- For IP2-1, there was an RAI. However, NRR provided no evidence of concurrence by the technical branch section chief for the initial questions. Additionally, documents related to the staff evaluation of the proposed amendment reference a telephone conversation of January 11, 1995, between NRC and the licensee. However, no documents were provided that indicated what was discussed. NRR met all other requirements for submitting the formal RAI.

- For IP2-2 and STP2, NRR provided evidence to substantiate initial RAI question preparation and concurrence with the technical branch section chief's signed concurrence. Additionally, NRR met all other requirements for submitting the formal RAI. In the case of STP2, after NRR submitted the RAI, the licensee requested a meeting to discuss the questions and possible responses. NRR properly provided public notice for the meeting, as well as a subsequent meeting. When the licensee responded to the original RAI, it referred to an informal submittal of an addendum to NRC and indicated that NRC staff comments on the draft addendum had been incorporated into the attachments to the RAI. NRR did not provide evidence of the licensee's informal submittal or staff comments.

- For PERRY, NRR provided no evidence that RAIs were prepared. Rather, NRR held three separate meetings with the licensee to discuss issues associated with the amendment request. Although documented summaries of the meetings were provided to OIG, they only allude to the questions which NRR might have raised and the responses the licensee gave. However, specific questions were not provided. Subsequently, after these meetings, the licensee submitted a "supplement" to the initial amendment request which superceded the original request. It appears that this occurred due to the exchange of information in the meetings between NRC and the licensee. In this case, there is no evidence that the RAI steps were ever taken.

While NRC must docket responses to RAIs, summaries of meetings with licensees are not addressed in NRR guidance and there was no evidence provided that NRC docketed the PERRY meeting summaries. Additionally, NRR provided no evidence that the information provided by the licensee in the meetings was under oath or affirmation. Therefore, if NRR considered the information received in the three meetings when reviewing the "supplemental" amendment request, that information did not have the same strength of support as responses

to an RAI submitted under oath and affirmation. Letter No. 803 does say that, "Involving licensees in meetings or conference calls before or soon after submittals may be useful for amendment applications that involve complex technical issues or policy changes for the NRC."

However, holding meetings in lieu of sending out RAIs is not recognized in Letter No. 803 or the corresponding flow charts. The need to notice these meetings also is not formally recognized in these agency documents. NRR should develop appropriate guidance if this practice is considered to be acceptable.

**Preparing the Safety Evaluation**

There are several sections to a typical safety evaluation. The introduction section should provide a brief description of the licensee's amendment request, as well as other specific information identified in Letter No. 803. The background section provides the regulatory framework for the licensing action. A description of the system or component, if applicable, may also be needed to better describe the effects of the change. Additionally, the "why" of a licensee's request may be provided -- a summary of the licensee's rationale for the proposed change, including operating problems, changes in technology, or changes in analytical approaches. Any precedent licensing actions utilized in the review should also be mentioned in this section, with any differences in circumstances and/or regulatory finding between the submittal in question and the precedent being noted and addressed. Material related to regulatory acceptance criteria and the licensee's incentive for the proposed change may be included in the introduction and evaluation sections in lieu of having a separate background section. However, the preferred format includes a background section.

The evaluation section documents the staff's evaluation of a proposed change against the relevant regulatory criteria. This should include a description of the proposed changes and an analysis of the proposal in terms of regulatory requirements, established staff positions, industry standards, or other relevant criteria. The evaluation should also contain the staff's specific conclusion that the proposed change is acceptable in terms of public health and safety. Information contained in the safety evaluation should be consistent with the licensee's submittal(s), should not contradict the submittal(s), and should not impose any commitments not agreed upon by the licensee in the submittal(s).

**<u>OIG ANALYSIS</u>**

OIG's review revealed that the safety evaluations prepared for both IP2 amendment requests met procedural guidance. However,

- For STP2 there was no safety evaluation from one branch originally assigned to perform a review as indicated on an NRR Work Request. A different branch, for which no assignment had been made, did complete a safety evaluation. NRR did not supply any evidence that the NRR Work Request had been revised and changes were made in branch assignments. Furthermore, two branches did not follow the safety evaluation format contained in Letter No. 803. Additionally, except for one branch, the safety evaluations NRR provided for review did not contain evidence of the required concurrence signatures.

- For PERRY, safety evaluations were provided by four technical branches, but they also did not conform to the format contained in Letter No. 803. Although the information provided covers the topical areas, the specific areas are not clearly delineated. In addition, except for one safety evaluation, NRR provided no evidence of required concurrence signatures.

## ANCILLARY PROJECT MANAGER RESPONSIBILITIES

After the project manager receives a license amendment request, performs the acceptance review, participates in the characterization of review, completes the NRR Work Request, and provides the amendment documents to the assigned technical branch reviewers, the project manager completes a number of significant ancillary responsibilities. These include preparing a public notification about the amendment request, determining whether an amendment request involves no significant hazards consideration, preparing an environmental assessment (as applicable), and reviewing/evaluating licensee requests for withholding information.

### Public Notification and No Significant Hazards Consideration

Public notification is the primary mechanism for the NRC to meet its goal regarding openness to the public. The staff needs to determine whether an amendment request involves no significant hazards consideration, as well as, seek public comment and provide an opportunity for a hearing regarding the proposed amendment as defined in 10 CFR 50.91. The no significant hazards consideration standard is a procedural criterion that governs whether NRC must provide an opportunity for a prior hearing before NRC takes action and whether prior notice for public comment may be dispensed with in emergency situations or shortened in exigent circumstances.[14] For those amendments that do not satisfy the criteria, an individual notice in the *Federal Register* will announce the opportunity for a hearing prior to the issuance of the amendment.

According to Letter No. 803, the majority of amendment requests are found to satisfy the no significant hazards consideration criteria and, therefore, can be handled in the routine fashion. The regulations specify that the normal course of business is to provide a 30-day comment period following publication of a description of the proposed amendment, along with its associated proposed no significant hazards consideration determination. If the staff determines that the request involves no significant hazards consideration, the regulations allow for issuance of the amendment with less than a 30-day comment period. The letter provides the criteria for normal (30-day), emergency, and exigent (15-day) public notification, as well as exigent local notification. Project managers are responsible for evaluating the significant hazards consideration and preparing the *Federal Register* notice (FRN). Licensing assistants and project section chiefs are to review and concur with the FRN. The project manager is then responsible for signing the FRN.

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

**OIG ANALYSIS**

For the license amendment requests OIG reviewed, the STP amendment was the only one for which NRR provided sufficient evidence that the public notification and significant hazards consideration steps were adequately completed.

- For IP2-1 and IP2-2, NRR did not provide the *Federal Register* notices. This resulted in OIG not being able to evaluate the determination by the project manager regarding the significant hazards consideration. Additionally, OIG could not determine if appropriate concurrences were provided. Although NRR did provide a log maintained by a licensing assistant which revealed the *Federal Register* notice identification numbers and dates of publication, OIG did not seek to verify their veracity as this would not demonstrate that the required actions took place.

- For PERRY, NRR did not provide the draft *Federal Register* notices to provide evidence that proper concurrences were made. Additionally, when NRR received the "supplement" which superceded the original license amendment request, NRR did not provide documentation of the public notification.

**Environmental Assessments**

The *Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions* (10 CFR Part 51) provides, among other things:

> The criteria for and identification of licensing and regulatory actions requiring environmental impact statements [Part 51.20];
>
> The criteria for and identification of licensing and regulatory actions requiring environmental assessments [Part 51.21]; and,
>
> Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review [Part 51.22].

In preparing a response to an amendment request, the project manager must prepare an environmental assessment or list the appropriate categorical exclusion to explain why one was not prepared. The issued amendment must reference the environmental assessment's publication in the *Federal Register*, which must occur prior to issuance of the amendment.

**OIG ANALYSIS**

The four OIG reviewed license amendment requests had categorical exclusions that relieved the project manager from preparing an environmental assessment. All of the NRC license amendment packages approving the requests contained a statement identifying the environmental assessment category exclusion.

### Withholding Information

The project manager is responsible for determining if a licensee's submittal includes any proprietary information. Criteria regarding the withholding of records is contained in 10 CFR 2.790.[15] The project manager is responsible for the review of the material requested to be withheld from the public in order to ensure that the information satisfies that criteria. NRR provides project managers with additional guidance pertaining to proprietary information in NRR Office Letter No. 602, "*Procedures for Handling Requests to Withhold Proprietary Information*." Project managers may also get assistance in making this determination from licensing assistants, technical branch staff, and OGC.

If a licensee submits an amendment request and indicates it contains proprietary information, the project manager must prepare a response to the request. The request is then to be routed for review and concurrence by the licensing assistant, technical branch chiefs involved in the review, OGC, and the cognizant project section chief. Once this is accomplished, the project manager signs the final response.

## OIG ANALYSIS

For two of the amendment requests (IP2-2, PERRY), licensees did not claim proprietary information.

- For IP2-1, the licensee indicated in its response to the RAI that it considered certain items proprietary. However, NRR provided no evidence that a response was prepared to address this issue. NRR staff said they had done so, but could not locate the document. OIG notes that the NRR Work Request and the Amendment Routing Sheet that NRR uses during license amendment reviews do not contain any area to note that proprietary information must be considered.

- For STP2, the licensee claimed proprietary information and the project manager handled the request according to agency guidance.

If proprietary information is to be withheld, the agency must ensure that the basis for such withholding is clearly articulated and available for public review. This is necessary to help ensure stakeholder confidence in the license amendment process.

### Review and Concurrence

According to Letter No. 803, "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." The project manager is responsible for ensuring that appropriate concurrences are received for the amendment package. Once the concurrence chain is determined, the name, title, and organization of each individual is entered on an amendment routing form. When the project manager has prepared the amendment package, the technical branch(s) associated with the technical area(s) of the proposed changes

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[15] Title 10, Code of Federal Regulations, Part 2 [*Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders]*, Subpart G [*Rules of General Applicability]*, Section 2.790 [*Public inspections, exemptions, requests for withholding.*]

must concur on the package. However, the technical branch(s) may agree to let a project manager perform their function (e.g., for certain line item improvements) in some cases.

Before sending the amendment package to other NRR organizations, licensing assistants perform an initial review and concurrence. During this review, they ensure the package is complete, in the correct format for text and graphics, and all required steps have been taken.

If a technical branch prepares the safety evaluation, the project manager has the responsibility to integrate it into the overall amendment package. If the project manager makes substantial changes to the safety evaluation, the technical branch reviewer who prepared the original safety evaluation should be an early reviewer in the concurrence chain. This is to ensure that there is no change in the technical content of the safety evaluation. If the project manager includes the safety evaluation from a technical branch with only minor editorial changes, that technical branch does not need to provide additional concurrence. However, in these cases, the concurrence document must identify the technical branch in the concurrence block. The technical branch can then be crossed off the concurrence block with a note indicating that safety evaluation input was provided by the technical branch and no major changes were made.

Letter No. 803 indicates that, to assist those requested to concur, amendment packages should include:

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

It is permissible to expedite the review and concurrence process by using parallel concurrences if the amendment requires several concurrences and timing is of concern. Project managers must ensure that comments incorporated during the concurrence process do not affect the bases for concurrences received before the changes were made to the amendment package. Project section chiefs or their designees (possibly the project managers) must provide the final concurrence for all amendments processed. If not, they must confirm and document amendment package correctness by their signature on the amendment cover letter and amended license.

### Amendment Preparation and Issuance

After required concurrence signatures are obtained, the amendment package is issued to the licensee and notice is sent for transmittal to the *Federal Register*. NRR must call the affected State's contact for no significant hazards consideration for comments prior to issuance of an amendment. Additionally, the Offices of Administration and the Secretary are contacted prior to issuance to determine if the agency received comments from the public or petitions to intervene on the proposed amendment. While project managers are responsible for issuing amendments, licensing assistants perform most of the required administrative functions. A final license amendment package should include:

- a letter transmitting the amendment to the licensee for signature by the project manager;
- a standard distribution or "cc:" list;
- the license amendment for final signature by the appropriate level of management;
- the revised technical specification or license pages;
- the safety evaluation, with reference to an environmental assessment, if appropriate (the environmental assessment is issued as a separate document);
- input to the biweekly *Federal Register* notice or a separate *Federal Register* notice of issuance; and,
- a listing for internal distribution to organizations within the agency.

Letter No. 803 also identifies several different areas that should be addressed in the final amendment package. In addition to the technical considerations of the safety evaluation, the issued amendment will include regulatory commitments, emergency/exigent provisions, a final no significant hazards consideration determination (if needed), evidence that NRR has consulted with the appropriate State official and addressed any state comments, environmental considerations, and a conclusion that the amendment will not endanger public health and safety. All documents referenced in the safety evaluation should be readily available for public inspection (if not proprietary) in the NRC Public Document Room or available for purchase from other sources in the public domain.

## OIG ANALYSIS

OIG's review of documents related to the four final amendment packages revealed that NRR staff completed most review, concurrence, and final preparation steps as required. However,

- For IP2-1 and IP2-2, there was no block for technical branch staff to sign or line through (if no significant changes were made to the safety evaluation prepared by the technical branch and contained in the final amendment approval package) to indicate concurrence. Additionally for IP2-1, while all documents referenced in the safety evaluation portion of the amendment approval package should be

readily available for public inspection, a referenced letter of January 12, 1995, from the licensee to NRC, was not provided.

- For STP2, the approved amendment package contains the relevant information required, but the copy provided does not contain evidence of review and concurrence signatures.

- For PERRY, the approved amendment package also contains the relevant information required, but the copy provided did not contain evidence of review and concurrence signatures for two of the technical branches involved.

Additionally, for the different areas beyond the technical considerations of the safety evaluation identified above, all are not required in all cases. For the packages reviewed, there is no indication of when these exceptions exist other than they have not been addressed (i.e., regulatory commitments, emergency/exigent provisions). Therefore, there is no way to determine by review of the documents NRR provided if they should or should not have been addressed. Additionally, NRR did not provide the amendment routing sheet for IP2-1, IP2-2, or PERRY.

Review and concurrence with the final license amendment package is integral to the overall decision making process NRR uses in approving or denying license amendment requests. Inability to demonstrate that all responsible individuals have participated in this part of the process can erode stakeholder confidence in the overall process.

## NRR WORK REQUEST FORM

# NRR WORK REQUEST

| PM REQUEST | AGREED TO* |
|---|---|
| Priority: | Priority: |
| Target Date: | Target Date: |
| Staff-hr Estimate: | Staff-hr Estimate: |

SC Signature/Date:_____ Branch Signature/Date: _____

### BACKGROUND INFORMATION

Plant: _____ Unit(s): _____
Section Chief: _____
Project Manager:_____ Phone: _____ E-mail:_____ M/S: O-_____
TAC No(s): M_____ M_____ M_____
Licensee Proposed Action/Submittal Date: _____

### ASSISTANCE REQUESTED

Technical Branch: _____
Other TBs Providing Input/Concurrence: _____
Scope of Review/Product Requested: _____

Possible Precedents: _____
PM Signature/Date: _____

### TECHNICAL BRANCH RESPONSE

TB Product: _____

Assigned Reviewer: _____ Phone: _____ E-mail: _____
Comments: _____

** Any change in target date, priority or staff-hr estimate should be negotiated with the PM before revising. In addition, please inform the PM of any additional TBs required, that are not identified above, for the review.*

**- Return to PM Within 5 Working Days of Receipt -**

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## RECORD RETENTION REQUIREMENTS

NRC has established requirements for defining, identifying, and retaining official agency records. These requirements are specifically outlined in Management Directive Handbook 3.53, Part 1 (Volume 3, Part 2 - *Records Management, NRC Records Management Program* - MD 3.53) and in the ADAMS 3.3 *Desk Reference Guide* (ADAMS Guide).

Significantly, information regarding official agency records provided in MD 3.53 says:

**Defining Federal Records (1)**

Federal records are statutorily defined in 44 U.S.C. [United States Code] 3301 as follows: (a)

> 'All books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as **evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the government or because of the informational value of the data in them**.' [emphasis added]
>
> Several key terms, phrases, and concepts in the statutory definition of records are defined in 36 CFR 1222.12, as follows: (b) ...
>
> **Made** means the act of creating and recording information by agency personnel in the course of their official duties, regardless of the method(s) or the medium involved. The act of recording is generally identifiable by the circulation of the information to others or by placing it in files accessible to others. (iii) ...
>
> **Appropriate for preservation** means made or received documentary materials that in the judgment of the agency should be filed, stored, or otherwise systematically maintained by an agency because they are evidence of agency activities or contain unique information, even though the materials may not be covered by the agency's current filing or maintenance procedures. (vi) ...

**Identifying Federal Record (2)**

> To ensure that **complete and accurate** [emphasis added] records are made and retained in the NRC, it is essential that NRC employees distinguish between record and non-record materials by the appropriate application of the statutory definition of records to NRC documentary materials. The following guidelines issued by NARA [National Archives and Records Administration] in 36 CFR 1222.34 should be applied to all documentary materials to determine their record or nonrecord status.

**Record status** - Documentary materials are records when they meet both of the following conditions: (a)

> 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. (i)
>
> 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. (ii)

**Working files and similar materials** - Working files, such as preliminary drafts and rough notes and other similar materials, will be maintained for purposes of adequate and proper documentation if - (b)

> They were circulated or made available to employees, other than the creator, for official purposes such as approval, comment, action, recommendation, follow up, or to communicate with agency staff about agency business. (i)
>
> They contain unique information, such as substantive annotations or comments included therein, that adds to a proper understanding of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities. (ii) ...

Additionally, the ADAMS Guide reiterates much of this same information. This document contains either exact or similar definitions for official agency records and addresses the same issues contained in MD 3.53. The ADAMS Guide adds:

In summary, the legal definition has three key points:

1. Records are made or received by a Federal agency either to comply with a law or to conduct public business. As a result, they belong to the Government rather than to individuals, and their legal disposition depends on the prior approval of the Archivist of the United States.

2. Records are, or should be, preserved because they constitute evidence or contain information of value. They document an agency's organization, functions, and activities or the persons, places, things, or matters dealt with by an agency.

3. Records vary widely in their physical form or characteristics. They may be on paper, electronic, audio-visual, microform, or other media.

Examples of Official Agency Records [OAR]. Some examples ...

> Communications related to NRC programs, policies, organizations, **decisions, decision making,** [emphasis added] minutes, or agendas.
>
> Messages that contain unique information that explain why the agency made a decision or took an action.
>
> Messages that direct one to take an action or that one uses to direct another to act.
>
> Draft of records ... circulated for approval, comment, or action that are significantly changed in the final version and for which the written comments on the drafts provide insight into the basis for an agency position or decision and are not documented in the OAR.
>
> Information that the NRC creates or acquires via e-mail, facsimile, telephone record, or meeting notes, about an inspection of a licensee's facility that (1) contains unique information, (2) the rationale for an NRC decision, or (3) guidance that is not documented in the OAR.