



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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June 27, 2017

MEMORANDUM TO: William M. Dean, Director
Office of Nuclear Reactor Regulation

FROM: Mary Jane Boss-Lee, Acting Director
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

SUBJECT: INTERNAL AUDIT OF THE REQUEST FOR ADDITIONAL
INFORMATION PROCESS

There is significant internal and external stakeholders' interest in ensuring that the U.S. Nuclear Regulatory Commission (NRC) staff's request for additional information (RAI) process to support its licensing review is effective and efficient. In response to stakeholders' interest and as part of continuous improvement, the Office of Nuclear Reactor Regulation (NRR) performed an internal audit of a sample of RAIs that were issued between April and December 2016. The audit team consisted of NRR staff from the Division of Engineering, Division of License Renewal, Division of Operating Reactor Licensing, Division of Policy and Rulemaking, Division of Risk Assessment, and Division of Safety Systems.

The objective of the audit was to assess adherence to the RAI guidance provided in NRR Office Instruction LIC-101, Revision 4, "License Amendment Review Procedures," dated May 22, 2012, and the "Expectations Memorandum," dated April 18, 2016, which was subsequently incorporated into LIC-101, Revision 5, dated January 9, 2017. The audit team reviewed a sample of RAIs from each of the technical branches in NRR and found that the overall adherence to quality, timeliness, and process expectations was satisfactory. The need for second-round RAIs was low. In general, final RAIs were issued to the licensees consistent with a schedule model used by the project managers for work planning. The majority of licensees responded to RAIs either within 30 days or a mutually agreeable response date.

The audit team also identified areas for continued improvement. The NRC staff should ensure appropriate regulatory and technical bases are included in RAIs. The staff should improve on the consistency of transmitting and retaining records for RAIs, including documentation in the Agencywide Documents Access and Management System. The team recommends providing additional training for the staff on adherence to the latest revision of LIC-101 and developing

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associated staff implementation job aids. The team also recommends continuing periodic RAI internal audits at the division level with a smaller team and scope to monitor the effectiveness of staff training.

The internal audit summary and audit report are provided in Enclosures 1 and 2, respectively.

Enclosures:

1. RAI Audit Summary
2. RAI Audit Report

SUBJECT: INTERNAL AUDIT OF REQUEST FOR ADDITIONAL INFORMATION
PROCESS DATED JUNE 27, 2017

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AUDIT SUMMARY

INTERNAL AUDIT OF REQUEST FOR ADDITIONAL INFORMATION PROCESS

BACKGROUND

There is significant internal and external stakeholders' interest in ensuring that the U.S. Nuclear Regulatory Commission (NRC) staff's request for additional information (RAI) process to support its licensing review is effective and efficient. In response to stakeholders' interest and as part of continuous improvement, the Office of Nuclear Reactor Regulation (NRR) performed an internal audit of a sample of RAIs that were issued between April and December 2016. The objective of the audit was to assess adherence to the RAI guidance provided in NRR Office Instruction LIC-101, Revision 4, "License Amendment Review Procedures," dated May 22, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML113200053), and the "Expectations Memorandum," dated April 18, 2016 (ADAMS Accession No. ML16202A029), which was subsequently incorporated into LIC-101, Revision 5, dated January 9, 2017 (ADAMS Accession No. ML16061A451).

KEY MESSAGES

- After review of a sample of licensing RAIs from each NRR technical branch, overall staff adherence to the quality, timeliness, and process expectations in LIC-101 and the April 18, 2016, "Expectations Memorandum," is satisfactory.
 - Overall adherence to the expectation for creating a draft safety evaluation with holes was good for routine licensing actions.
 - The need for second-round RAIs is low, suggesting that the review is generally complete prior to issuing the first-round RAIs. Most second-round RAIs were needed when a licensee's first-round RAI responses were insufficient for the NRC staff to finalize a regulatory decision.
 - In general, final RAIs were issued to the licensees slightly later than assumed in a schedule model used by the project managers for internal work planning.
- The majority of licensees responded to RAIs within 30 days. Those that exceeded had mutually agreeable response dates greater than 30 days.

AREAS NEEDING CONTINUED IMPROVEMENT

- When preparing RAIs, both the technical and regulatory bases should be explicitly identified, except in limited circumstances.
- Continue adherence to drafting a safety evaluation with holes when writing RAIs:
 - Some staff question the requirement for a draft safety evaluation and believe this should be optional.
 - Need to ensure RAIs are relevant to the specific requested licensing action.

- Improve consistency in transmitting RAIs and retaining RAI records (ADAMS profiles, naming convention):
 - Project managers' process for e-mailing draft and/or final RAIs to licensees.
 - Technical staff's process for capturing RAI input to Division of Operating Reactor Licensing (DORL) as an official agency record in ADAMS.
- Continue to shorten the time to process RAIs from clarification call to issuance ("Expectations Memorandum" target is 5 days and the average is down from 20 to 9 days).
- Stabilize the RAI process by reducing the frequency of issuing interim staff guidance.

RECOMMENDATIONS

1. Increase training for NRC staff and branch chiefs to adhere to RAI guidance in LIC-101, Revision 5, and provide specific examples that illustrate proper adherence to LIC-101 for writing high-quality RAIs.
2. Encourage divisions to develop lower level guidance, as appropriate, to facilitate adherence to the guidance in LIC-101:
 - a. The Division of Safety Systems has already created job aids to improve consistency in transmitting and retaining RAI records (ADAMS profiles, naming convention, RAI input to DORL).
 - b. Create lower level guidance to assist project managers in processing RAIs and draft RAIs using e-mail.
3. Consider revisions to LIC-101 for the Division of License Renewal and Division of Policy and Rulemaking, as appropriate:
 - a. The Research and Test Reactors Licensing Branch of the Division of Policy and Rulemaking has started implementing applicable expectations from LIC-101 and is identifying sections in LIC-101 where additional guidance is needed for non-power utilization facilities. The additional guidance may be captured in a revision to LIC-101 or as a standalone addendum, as appropriate.
 - b. The Division of License Renewal has started implementing LIC-101 expectations.
4. Conduct periodic, more focused, RAI internal audits at a division level, to reinforce RAI expectations and process adherence:
 - a. Focus on routine and complex licensing actions.
 - b. Exclude short turnaround, emergency, or exigent actions.

AUDIT REPORT

INTERNAL AUDIT OF REQUEST FOR ADDITIONAL INFORMATION PROCESS

INTRODUCTION

In response to stakeholders' interest in the request for additional information (RAIs) process and as part of continuous improvement, NRR performed an internal audit of a sample of RAI that were issued between April and December 2016. This audit is intended to assess adherence to the RAI guidance provided in Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-101, Revision 4, "License Amendment Review Procedures," dated May 22, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML113200053), and the "Expectations Memorandum," dated April 18, 2016 (ADAMS Accession No. ML16202A029), which was subsequently incorporated into LIC-101, Revision 5, dated January 9, 2017 (ADAMS Accession No. ML16061A451).

RAI INTERNAL AUDIT TEAM

The audit team consisted of NRR staff from the Division of Engineering (DE), Division of License Renewal (DLR), Division of Operating Reactor Licensing (DORL), Division of Policy and Rulemaking (DPR), Division of Risk Assessment (DRA), and Division of Safety Systems (DSS).

The following are members of the team:

George Wilson, Division Director, DLR (Senior Executive Service Co-Lead)
Mary Jane Ross-Lee, Acting Division Director, DORL (Senior Executive Service Co-Lead)
Undine Shoop, Branch Chief, DRA
John Adams, Senior Technical Advisor for Non-Power Reactors, DPR
Lois James, Senior Project Manager, DLR
Benjamin Parks, Senior Reactor Engineer, DSS
Joel Jenkins, Materials Engineer, DE
Austin Young, Materials Engineer, DE
Roger Pedersen, Senior Health Physicist, DRA
Raymond Gallucci, Senior Reliability and Risk Analyst, DRA
Jerry Dozier, Senior Reliability and Risk Analyst, DRA
Jeanne Johnston, Project Manager, DORL
Doug Broaddus, Branch Chief, DORL (as needed)
Samson Lee, Senior Project Manager, DORL

RAI INTERNAL AUDIT PROCESS

The scope of the internal audit was to assess the overall adherence of licensing RAIs to quality, timeliness, and process expectations in RAI guidance. The scope also included assessing a proposed "Trending Metric" for the timeliness of the licensees in responding to RAIs because the data would be available as part of the audit. In addition, the team was provided out-of-scope comments or observations that the team addressed during the audit. These out-of-scope issues are documented in this audit report for knowledge management purposes.

The team typically audited two RAIs from each of the technical branches in DE, DLR, DPR, DRA, and DSS, which are the divisions that typically generate RAIs in their review of requested licensing actions. To avoid conflicts of interest, auditors did not review RAIs that they generated themselves. Only RAIs prepared by the staff after the issuance of the "Expectations Memorandum" were selected. The audit was based on NRR Office Instruction LIC-101, Revision 4, "License Amendment Review Procedures," and the April 18, 2016, "Expectations Memorandum," which was incorporated into Revision 5 of LIC-101, effective on January 16, 2017. As stated, in part, in Section 4.3, "Requests for Additional Information," of Appendix B to LIC-101, "The intent of this guidance is not to limit the staff from getting the information that is needed to perform a technical review. Rather, it is intended to make the RAI process productive and to focus staff and licensee resources on the pertinent issues necessary for the NRC staff to make a regulatory decision." Each team member reviewed RAIs from within his/her division.

The audit assessed quality, process, and timeliness attributes from LIC-101 and the "Expectations Memorandum." It also assessed a proposed "Trending Metric," which is discussed further below. The audit team used the guidance in LIC-101 and the "Expectations Memorandum" to develop survey questions that were appropriate for assessing quality, process, and timeliness of RAIs. The "Trending Metric" survey question was simply a restatement of that metric. The survey questions also asked for auditor comments, which provided additional insights. The survey questions are listed below. The team provided responses to these survey questions based on review of their sample RAIs. The survey questions and responses were entered into an Excel spreadsheet, which also provided data trending. The team held several meetings to discuss results and observations of the audit. The RAI internal audit required approximately 700 hours to complete.

List of RAI Audit Survey Questions

Your name.

Your Division.

Your Branch.

Enter the RAI letter sent to the licensee ADAMS Accession number.

Enter RAI Cost Activity Code (CAC) number.

Quality:

- Based on your review of the RAI information, describe if the RAI appears to have been developed with appropriate consideration of LIC-101 criteria.
- Did the RAI contain the regulatory and technical bases in the question?
- Was the RAI relevant to the license amendment request?
- Was a peer review completed?
- Was the RAI response addressed in the safety evaluation (SE) as part of the decision bases?
- Did the RAI response fill a "hole" in the draft SE as intended?
- Were there additional rounds of RAI?
- Were similar RAI questions necessary for similar license amendment requests, in particular from licensees in the same fleet?
- Did the RAI change significantly from draft input to final issuance? Describe the changes if any.

- Add any comments regarding the effectiveness of the peer review or any other measures taken to ensure quality of the RAI (e.g., detailed branch chief (BC) review/comments).
- Add any comments about the draft SE with “holes.”
- What was the reason for additional RAIs?
- Describe the related RAIs and include ADAMS Accession Numbers.
- Add any comments regarding the regulatory basis of the RAI.
- Add any comments regarding the RAI being within scope for the licensing action.
- Add any comments on the RAI being addressed in SE.
- Answer the survey considering all questions transmitted in one RAI letter/e-mail to the licensee. How many individual questions are listed in this RAI letter?

Process:

- Did the technical division BC approve the RAI sent to DORL?
- Add a comment about the technical division BC approving the RAI to DORL.
- Did the technical division BC review the draft RAIs to confirm they fill the draft SE with holes when the draft RAIs were sent to DORL?
- Add a comment about the technical division BC reviewing the draft RAIs to confirm they fill the draft SE with holes.
- Did the technical division put the RAI that was transmitted to the project manager (PM) into ADAMS?
- If the draft RAI transmitted to the PM is in ADAMS, enter the Accession number. If no draft RAI was found in ADAMS, leave a comment.
- Was a clarification call held?
- Enter any details about the clarification call (i.e., date) or a comment if one was not held.
- Were other methods employed (e.g., audits, public meetings)?
- Add a comment about the other methods used (audit, public meeting, etc.).
- Did final RAI issued to the licensee identify a due date for the licensee response?
- Enter a comment regarding the licensee due date in the RAI transmittal.

Timeliness:

- How many months between licensing action request submittal (application date) and the RAIs from technical staff to DORL?
- Did the RAIs from technical staff to PM meet the original projected schedule?
- Enter a comment about the schedule changing. Include information on the number of times the schedule was changed?
- How many working days between draft RAI to licensee and clarification call?
- How many days between licensee clarification call and final RAIs to licensee?
- Add a comment about the days between licensee call and final RAIs to the licensee.
- How many working days between RAIs from technical staff and final RAIs to licensee?
- Add a comment about the number of days between tech staff input and final issuance of RAIs.

Proposed "Trending Metric":

- How many calendar days did the licensee take to respond to the staff RAI? (Note the corresponding trending metric is, "Percentage of licensee responses to RAIs within 30 days of communicating to the licensee or the initial date granted.")
- Enter a comment about the number of calendar days for the licensee to respond.

The audit team reviewed a total of 32 RAIs (NRR typically issued 25 RAIs a month during 2016). The team considered one RAI as one RAI letter or e-mail, which may have included multiple questions.

The audit team identified several challenges in analyzing the information, including (1) small sample size; (2) difficulty in obtaining information necessary to consistently answer all of the above questions; (3) presence of atypical license amendments (i.e., emergency and exigent amendments); (4) potential for inconsistencies in auditor interpretation of and response to the survey questions; and (5) limited resources to research a specific license amendment to answer the survey questions. In consideration of these challenges, the team determined that meaningful observations and insights could be obtained. However, the team also determined that a quantitative assessment would be neither practical nor acceptably accurate. The team also provided comments in the survey responses, which aided this auditing strategy.

RESULTS OF RAI INTERNAL AUDIT

Quality

From the audited sample of RAIs, the audit team found that the overall RAI quality was satisfactory, based on criteria in LIC-101 and the "Expectations Memorandum." Overall RAIs were consistent with RAI guidance in obtaining information to make a regulatory decision.

An RAI should result in a licensee response that fills a "hole" in a draft SE to support the staff's regulatory decision. In general, the technical staff prepared a draft SE with "holes" for the RAIs. However, these drafts typically were not retained or readily retrievable. In the case of short turnaround, emergency, or exigent license amendments, draft SEs with "holes" were not always prepared, and LIC-101 and the "Expectations Memorandum" allow for waiving this expectation under appropriate circumstances. Most of the RAI responses were addressed or incorporated in the associated SE. This shows that the NRC staff included information from the RAI response to document its review and decision making process.

There were few second-round RAIs needed in the sample, demonstrating that the NRC staff was able to generally complete their review with one round of RAIs. In the audited sample, most second-round RAIs were needed because the licensees' responses to the first-round RAIs did not provide sufficient information for the staff to make a regulatory decision. This suggests that the technical staff performed a reasonably complete review prior to transmitting first-round RAIs to DORL.

Section 4.3, "Requests for Additional Information," in Appendix B to LIC-101 provides staff guidance relating to RAIs. However, the audit team found that some criteria in LIC-101 for RAIs could be clarified. The team recommends increased staff and supervisor training, using illustrative examples, to reinforce the LIC-101 RAI guidance. Illustrative examples can be used in training to effectively communicate and clarify the guidance.

LIC-101 states that RAIs should be developed with proper consideration of the regulatory basis for the question. LIC-101 also states that questions should not include unnecessary detail and including the regulatory basis in the question is a good practice. This may imply that a brief RAI without an explicit regulatory basis is acceptable. However, the team believes that, in most cases, the NRC staff should explicitly articulate the regulatory and technical bases in the RAIs. It is important to clearly explain the relevancy of the RAI to the specific requested licensing action and describe the regulatory and technical bases. Exceptions to this practice should only be made in a small number of scenarios, for example, when requesting clarifications of information already on the docket. There should be additional staff training to facilitate implementation of the guidance in LIC-101.

A peer review was generally conducted by the technical staff. The DORL PMs worked with the technical staff to further improve the readability and clarity of the draft RAIs. The RAIs mostly did not change between the draft and final versions issued by DORL to the licensees, indicating that the draft RAIs were generally of acceptable quality and were understood by the licensees. However, the RAI sample was too small to ascertain whether similar RAIs were necessary for similar actions. Completing such an assessment would require significantly more research to review additional RAIs associated with similar, precedent licensing actions.

The audit team attempted to assess the relevancy of the sample RAIs but found it challenging. Requests for additional information should be relevant to the requested licensing action. As stated, in part, in Section 4.3 of Appendix B to LIC-101, "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." The RAIs should not be used to challenge a plant's licensing basis. There is a special case where the licensee has provided information in the application that is unclear or may be incorrect, but is not relevant to the application. In this case, the NRC staff should question the licensee to prevent any tacit acceptance of incorrect information that could be construed as having been approved by the staff. Alternatively for this case, if the staff did not rely on the information and to avoid spending unnecessary staff resources, the staff could clearly state in the SE that the staff did not review or accept the specific licensee-provided information. Although the team reported that most of the RAIs were relevant, there were differing team interpretations on relevancy and limited resources to more thoroughly research the relevancy of a specific RAI to the specific requested licensing action. Additional staff training in addressing relevancy of RAIs, using illustrative examples, should be considered.

There was an NRC staff concern about making draft SE with "holes" mandatory. However, most audit team members believed it was appropriate and provided discipline in the staff review process. An argument against the draft SE with "holes" was for cases where the license amendment request submittals were insufficient. Preparing draft SEs based on insufficient information in the license amendment requests would not be an appropriate use of staff resources. Under this situation, the staff should assess whether the application should be non-accepted or denied. If an application that was accepted will be denied, the draft SE with "holes" will identify any insufficiencies, and support development of the required denial SE, as discussed in Section 6.3 of LIC-101. Additionally, NRR should reinforce the need to perform acceptance reviews in accordance with NRR Office Instruction LIC-109, "Acceptance Review Procedures," dated January 9, 2017 (ADAMS Accession No. ML16144A521), which should preclude acceptance of license amendment requests with significant information insufficiencies.

The guidance in LIC-101 also recognizes there are situations where preparing a draft SE with "holes" may be waived with agreement between the technical and DORL branch chiefs. This waiver is primarily anticipated for short turnaround licensing actions or "where development of

the draft SE would have an overwhelmingly negative impact on the schedule not commensurate with the benefit.” For example, a waiver could be considered for a complex, first-of-a-kind or pilot license amendment request where the licensee is likely to make significant changes to its amendment request based on the NRC staff review. The need for a waiver should be discussed with the technical and DORL branch chiefs during the internal kick-off meeting to plan the review.

Process

From the audited sample of RAIs, the audit team found that the overall adherence to the RAI process is satisfactory, because the staff generally followed the procedures in LIC-101 and the “Expectations Memorandum.”

The technical branch chiefs generally approved the RAIs before they were provided to DORL. However, there was insufficient information to determine the extent that the technical branch chiefs reviewed the draft SE with “holes” at the time of their reviewing the RAIs.

During the audit, a question was raised by the staff on whether DORL should have access to the draft SE with “holes” as part of the RAI process. While the technical staff and branch chiefs need not provide the draft SE with “holes” to the PM on a routine basis, if a PM has a question regarding a particular RAI from the technical staff, the PM could ask the technical staff for a copy of the draft SE with “holes” to better understand the relationship of the RAI to the “hole” that needs to be filled in the SE.

Most of the time, licensees requested a telephone call with the NRC staff to clarify the draft RAIs. On occasion, the NRC staff conducted audits to facilitate gathering of information. The staff did not hold any public meetings to discuss RAIs in the audited sample. Most of the RAIs issued to the licensee identified a due date for the licensee response. The response date was mostly 30 days and there were a few at 60 days in the sampled RAIs. Because the 60-day RAIs had been approved by the branch chiefs, LIC-101 allows this exception to the 30-day response time.

The team found that about half of the RAI transmittals from the technical branches to DORL were documented in ADAMS. For those RAI transmittals that the team found, the method of RAI transmittal and ADAMS profiling varied, making it difficult to search for RAIs in ADAMS. Similarly, the method of RAI transmittal from PMs to licensees and ADAMS profiling varied with DORL PMs. The team recommends that lower level guidance be developed, such as the DSS “job aids,” as appropriate, to facilitate adherence to the NRR and Agency guidance and policies in transmitting RAIs to DORL and from DORL to licensees, and documenting RAIs and profiling them in ADAMS. Such effort should improve consistency and make the staff task more straightforward. This would increase transparency to the public by making RAIs issued to licensees easier to find in ADAMS. This would also ensure documents supporting the staff’s decision-making process in a review are retained. However, the guidance should retain flexibility to allow the staff to complete their work efficiently. The DSS has started this effort and will share their experience with other divisions.

Because the guidance in LIC-101 may not explicitly apply to license renewal applications in DLR and research and test reactor licensing actions in DPR, the team recommends considering a review to realign these divisions’ guidance and processes relative to the expectations of LIC-101, Revision 5. The Division of License Renewal indicated that they are aligning with LIC-101, but acknowledges that the license renewal application review process requires a

longer acceptance review schedule than is specified in LIC-109. The Division of License Renewal plans to revise Office Instruction RNWL-100, "License Renewal Application Review Process," to be consistent with LIC-101 and the "Expectations Memorandum." The Division of Policy and Rulemaking is reviewing gaps between LIC-101 and the non-power utilization facilities licensing process and plans to develop a revision or addendum to LIC-101 to address any unique attributes of that process, as appropriate.

During the conduct of the audit, the audit team received feedback from the NRC staff that the license review process should be stabilized. Within the last year, NRR issued two "Expectations Memoranda," an update to LIC-101, and interim guidance on RAI transmittal from technical staff to PMs. The staff could benefit from a reduction of the frequency of interim or updated guidance on the license review process.

Timeliness

From the audited sample of RAIs, the audit team found that the overall adherence to RAI timeliness is satisfactory, because RAIs were issued generally within the timeliness goals in LIC-101 and the "Expectations Memorandum."

The Division of Operating Reactor Licensing has developed a generic licensing review milestone schedule model for internal work planning purposes, which includes a standard schedule for issuing RAIs to the licensee 3.5 months after the submittal date. The final RAIs were transmitted to the licensees, on average, 4 months after the licensing action submittal date, slightly later than the assumed generic schedule of 3.5 months. The generic schedule was developed before the issuance of the "Expectation Memorandum" describing the preparation of draft SE with "holes" for the RAIs. It provided 3 months for the technical division to transmit RAIs to DORL and 0.5 month for the DORL PM to transmit final RAIs to licensees. However, with increased emphasis on the LIC-109 acceptance review and the need to prepare a draft SE with "holes" up front with the RAIs, the DORL management has extended this generic time period for technical division transmittal of RAIs to DORL from 3 months to 4.5 months to allow sufficient time for development of a draft SE in conjunction with the RAIs.

In general, the technical staff's RAIs to DORL met the schedule. However, the team was not able to identify the original schedule date for many RAIs because the staff was encouraged to update the schedule in the database and the original data was not readily retrievable.

On average, RAIs were issued 4 months after the licensing action submittal date. The average time between draft RAIs to the licensee and conference call was about 11 days. The average time to process RAIs from clarification call to issuance was 9 days based on the audited sample. The goal in the "Expectations Memorandum" is to issue the RAIs 5 days after the clarification call. However, the NRC staff has improved from 20 days based on the result of a previous timeliness review a year ago.

Proposed "Trending Metric"

Recently, NRR has proposed certain licensing action performance metrics, which consist of "New QPR Metrics" and "Trending Metrics." One of the proposed "Trending Metrics" is:

Percentage of licensee response to RAIs within 30 days of communicating to the licensee or the initial date granted.

Since these data were available from the audited RAI sample, the audit team gathered it to help inform this metric. From the audited sample, the licensees mostly met the RAI response due dates. Thus the team expects the percentage as stated in this "Trending Metric" to be at or close to 100 percent. However, the RAI to the licensee should clearly state the response due date to avoid ambiguity, as observed in two RAIs that did not specify a due date.

RECOMMENDATIONS OF RAI INTERNAL AUDIT

The following are the team's recommendations:

- Increase training for NRC staff and branch chiefs to adhere to RAI guidance in LIC-101, Revision 5, and provide specific examples that illustrate proper adherence to LIC-101 for writing high-quality RAIs:
 - Management should emphasize that the branch chiefs have an important role in ensuring quality of RAIs. This can be accomplished through training developed by DORL that is focused on the branch chief and staff roles in the RAI process. Office and division management should strongly encourage the branch chiefs and staff to attend the training session.
- Encourage divisions to develop lower level guidance, as appropriate, to facilitate adherence to the guidance in LIC-101:
 - The Division of Safety Systems has started an effort to create job aids to improve consistency in transmitting and retaining RAI records (ADAMS profiles, naming convention, RAI input to DORL). Other technical divisions should develop similar guidance.
 - DORL should create lower level guidance to assist project managers in processing RAIs and draft RAIs using e-mail in a consistent manner.
- Consider revisions to LIC-101 for the Division of License Renewal and Division of Policy and Rulemaking, as appropriate:
 - The Research and Test Reactors Licensing Branch of the Division of Policy and Rulemaking has started implementing applicable expectations from LIC-101 and is identifying sections in LIC-101 where additional guidance is needed for non-power utilization facilities. The additional guidance may be captured in a revision to LIC-101 or as a standalone addendum, as appropriate.
 - The Division of License Renewal has started implementing LIC-101 expectations.

RECOMMENDATIONS FOR FUTURE PERIODIC INTERNAL AUDITS

The audit team recommends continuing the RAI internal audit, but with a smaller team and a narrower scope. The future audits would be opportunities to reinforce the RAI training to the NRC staff provided by DORL. These audits will serve as a training effectiveness review. A DORL instructor could oversee an NRC staff member assigned from a division to audit a sample of the RAIs from that division and provide refresher training and lessons learned from prior audits to enhance consistency. The audit should review RAIs from each branch within their division. The staff should audit routine and complex licensing actions, excluding short

turnaround, emergency, or exigent actions that would skew the data. The future RAI audits should address adherence to RAI guidance in LIC-101, focusing on these areas:

- Inclusion of appropriate regulatory and technical bases in the written RAI.
- Relevancy of the RAI to the requested licensing action.
- Effectiveness of the lower level guidance, such as job aids, in documenting RAIs.
- For DPR: implementation of new revision or addendum to LIC-101 for research and test reactors.
- For DLR: implementation of LIC-101 expectations.

The NRC staff could consider developing more straightforward and simpler set of criteria, based on LIC-101, to facilitate future audits. A member of the audit team prepared a list of RAI Quality Attributes, which is provided in the Attachment. The staff performing the future audits could consider such information. The staff could also consider re-using some of the survey questions. The auditors should seek to minimize inconsistencies in interpretation and response. Because the future audits will be based on a small sample size, the result would be primarily a qualitative assessment.

After the completion of audit for one division, the audit should move to another division. Based on the findings from the future audits, DORL should adjust the RAI training to capture lessons learned in ongoing and refresher RAI training as appropriate.

Attachment:
RAI Quality Attributes

RAI Quality Attributes
Including Supporting Excerpts from LIC-101, Appendix B, §4.3

- **Technical Relevance** RAIs should not be used “as a means to encourage commitments from licensees.” “The staff’s review of an application will be limited to the scope of the licensing action and RAIs should have a clear nexus to information required to make a safety determination regarding the licensing action.” The staff is accountable for ensuring the RAI is developed with proper consideration of the technical complexity of the request and the risk significance of the issue. “The staff should not use RAIs as an opportunity to force licensees to take actions beyond those that relate directly to the amendment.”
- **Legal/Regulatory Basis** “RAIs should be directly related to the applicable regulatory requirements associated with the amendment request... should also be consistent the plant’s licensing basis and applicable codes, standards, and guidance (e.g., Regulatory Guides, Standard Review Plan)” The staff is accountable for ensuring the RAI is developed with a proper regulatory basis. “Questions included in the RAI should ask for information that is required to make the necessary regulatory finding... Including the regulatory basis in the question is a good practice.”
- **Specificity** “RAIs should not be used as general information requests” “Questions should be specific rather than overly broad.”
- **Clarity and Brevity** “...enhance clarity and understanding both during the development of draft RAIs and after sending RAIs to licensees.” “Questions should not include unnecessary detail and should clearly state the information that is required.”
- **Consistency with NRC Records Management Requirements** “transmittal... should follow ADM-200...” “...signature authority lies with the technical staff BC...” “...RAI transmittals are appropriately preserved as Official Agency Records in ADAMS...” “The preferred method for transmitting RAIs from the technical staff is via e-mail, in accordance with the guidance provided in a memorandum dated June 8, 2016 (ADAMS Package Accession No. ML16144A692).”
- **Comprehensiveness**¹ The staff is accountable for ensuring the RAI is developed with proper consideration of scope and depth of review. A draft SE is expected to be developed before RAIs are prepared to enhance “our safety focus by ensuring we obtain the necessary information to complete the review, while providing greater clarity and discipline in the RAI process.” “...the staff should make every effort to limit itself to one round of RAIs... for an amendment request.”
- **Uniqueness** The staff is accountable for ensuring the RAI is developed with proper consideration of the existence of precedent, and the occurrence of information already on the docket. “Before developing an RAI, the staff should ensure that the information is not already available to the staff or that the answer could not be reasonably inferred...” “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.”

¹ Comprehensiveness is an attribute of the *technical review* that leads to a high-quality set of RAIs.