

# OFFICE OF NUCLEAR REACTOR REGULATION

LIC-115	Processing Requests for Additional Information	
Volume 100	Licensing Processes	
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<p>Summary: This is the initial issuance of LIC-115, which consolidates guidance from NRO Office Instruction NRO-REG-101, "Development, Review and Approval Process for Requests for Additional Information," and NRR Office Instruction LIC-101, "License Amendment Review Procedures," regarding requests for additional information (RAIs). This consolidation is due to the NRR/NRO reunification. The staff will update this office instruction after implementation of the electronic RAI (eRAI) system across the reunified office in October 2020. This issuance incorporates and rescinds the related NRO instruction NRO-REG-101.</p>		
Training:	<p>RAI: Completed mandatory RAI refresher training in April 2018 for NRR staff and applicable staff in other offices who support NRR licensing reviews. Future training to be determined.</p> <p style="text-align: center;">Licensing: Fundamentals of Reactor Licensing for Technical Reviewers or Fundamentals of Reactor Licensing for Project Managers.</p>	
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## 1. **POLICY**

It is the policy of the Office of Nuclear Reactor Regulation (NRR) to implement an effective and efficient request for additional information (RAI) process as a modern risk-informed regulator. NRR staff is expected to issue RAIs when necessary to support reasonable assurance findings on the safety of a design, operation, or siting, as well as environmental issues, in accordance with the Nuclear Regulatory Commission (NRC) rules and regulations. The information requested typically addresses missing, incomplete, inconsistent, or unclear information within the application or other docketed correspondence. However, when there is no missing information, the staff may still issue an RAI for supporting materials as part of its review. An example might be inputs to the applicant's calculations so the staff can perform confirmatory calculations necessary to support the staff's reasonable assurance findings.

The staff issues RAIs to obtain the information needed, which may include a set of questions. RAIs should not be issued for information that could be obtained from information already available to the staff on the docket or is generally known and verifiable by the technical community and available to the public and is needed only to support information already on the docket. RAIs should include concise statements of information needed to complete the technical review, indicate the significance of the issue, and possess a clear and understandable regulatory basis.

## 2. **OBJECTIVES**

This office instruction provides guidance in developing and processing RAIs. It discusses:

- regulatory authority supporting gathering supplemental information
- characteristics of a quality RAI
- proper construction, review, and transmittal of RAIs
- role of public meetings and audits in developing an RAI
- RAI documentation

## 3. **BACKGROUND**

There is significant internal and external stakeholder interest in ensuring that the NRC's RAI process to support its licensing review is effective and efficient. Title 10 of the *Code of Federal Regulations* (CFR) Section 2.102(a) states that during review of an application by the NRC staff, an applicant may be required to supply additional information. RAIs serve the purpose of enabling the staff to obtain all relevant information needed to make a regulatory decision on a licensee, applicant, or vendor's licensing request that is fully informed, technically correct, and legally defensible. The process for the development, submittal, and processing responses from RAIs represents an important element in the review of a licensing action. It is important that the RAI process is clearly defined, consistently implemented, and repeatable in an efficient and effective manner to ensure high quality processing of licensing action reviews, consistent with NRC's Principles of Good Regulation.

The staff involved with RAIs should identify potential improvements to this guidance and submit suggestions to their management or to the contact(s) listed for this office instruction.

#### **4. BASIC REQUIREMENTS**

##### **4.1 Regulatory Authority**

Section 182 of the Atomic Energy Act of 1954, as amended, gives the NRC authority to require further written statements to be made under oath or affirmation. Section 2.102(a) of 10 CFR states that during review of an application by the NRC staff, an applicant may be required to supply additional information. Section 2.108(a) of 10 CFR states that the NRC may deny an application if the applicant fails to respond to an RAI within 30 days of the date of the request, or within such other time as may be specified. Additionally, under 10 CFR 50.4, 52.3, and 54.7, all written correspondence must be sent to the NRC through the Document Control Desk. Correspondence related to amendments must be submitted under oath or affirmation as required under 10 CFR 50.30(b).

##### **4.2 Purpose and Scope of RAIs**

RAIs serve the purpose of enabling the staff to obtain all relevant information needed to make a regulatory decision on a licensee, applicant, or vendor's licensing request that is fully informed, technically correct, and legally defensible. RAIs should be directly related to the applicable regulatory requirements associated with a licensee, applicant, or vendor request. RAIs should also be consistent with the plant's licensing basis and applicable codes, standards, and guidance (e.g., Regulatory Guides (RGs), Standard Review Plans (SRPs)). NRR staff is expected to ensure that the information needs addressed through RAIs are made in accordance with policy and guidance in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests."

RAIs should have a clear nexus to information necessary to make a determination regarding the licensing action. Material previously reviewed and approved generically by the NRC (e.g., topical reports, Technical Specifications Task Force (TSTF) Travelers, generic environmental impact statements, etc.) should not be reviewed again for a plant-specific application. Staff concerns with a prior generic approval should be promptly raised to respective branch chiefs (BCs) and division management for consideration of applicable backfitting and forward fitting guidance. However, for individual licensing actions, the staff should evaluate how the licensee, applicant, or vendor satisfied any plant-specific aspects of implementation of the generic approval (e.g., any limitations and conditions approved in the topical report or applicability of the approved TSTF to the particular plant design).

#### 4.3 RAI Construction

An RAI should consist of three parts in its construction:

1. Clear and concise regulatory basis
  - refer to applicable regulatory standard or acceptance criteria
  - refer to relevant guidance documents
2. Clear and concise technical or regulatory issue
  - describe the identified issue
  - refer to applicable part of submittal
  - describe security-related issues to a high level as to not make the document Sensitive Unclassified Non-Safeguards Information (SUNSI), but detailed enough to be understood, if appropriate, otherwise follow SUNSI procedures.
3. Clear, concise, and specific statement or question of the information needed
  - request information to fully resolve the issue

NOTE: If applicable, SUNSI (e.g., proprietary or security-related information) must be clearly marked in the RAI and handled accordingly. If there is SUNSI information in the document, the entire document must be marked and handled in accordance with MD 12.5, "NRC Cybersecurity Program," and internal procedures described in the SUNSI webpage. When appropriate, the staff should issue a redacted version of the RAI and make it available to the public (see Section 4.10).

#### 4.4 RAI Quality

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

- regulatory basis for the question
- technical complexity of the proposed licensing action
- safety or risk significance of the issue in question
- existence of similar previous licensing actions
- appropriate scope and depth of the review
- information already on the docket
- information that is generally known and verifiable by the technical community and available to the public and is needed only to support information already on the docket

While RAIs are a means of communicating staff questions to the licensee, applicant, or vendor, it should be noted that an RAI is also another means of updating the public regarding identified issues. As such, the format of an RAI should be sufficient for a member of the public to understand where the information insufficiency is located in the submittal or supplement and understand why the information is needed to come to a regulatory finding.

The following table describes the characteristics of a high-quality RAI:

Necessity	RAIs should have a clear nexus to information necessary to make a determination regarding the licensing action. RAIs should request relevant information from the reports, procedures, or calculations instead of submitting full reports, plant procedures, or calculations.
Regulatory Basis	The regulatory basis and underlying relevant guidance should be clearly stated in the body of the RAI. Often, the applicable regulatory basis is provided at the beginning of the applicable section of the SRP. The RAI should cite the regulation that includes the requirement the staff is requesting the applicant to address. However, the staff should not cite 10 CFR 50.9 or 52.6 in the regulatory basis. An RAI should be consistent with the plant's licensing basis and applicable codes, standards, and guidance (e.g., Final Safety Analyses Report (FSAR), as updated, RGs, SRPs). Any RAI that relates to a change in staff position or licensing basis is subject to the appropriate backfit or forward fit process in accordance with MD 8.4. (Note that the backfit rule does not apply to non-power production and utilization facilities (NPUFs). However, the Atomic Energy Act of 1954, as amended (AEA), limits the amount of regulation that the NRC can impose on AEA section 104 NPUFs to the minimum that permits the agency to fulfill its obligations under the AEA.)
Clarity	Ensure the RAI states what information is required or needs to be clarified. It may be helpful to refer to the specific section under scrutiny (e.g., subsection of an FSAR or an application) to aid the licensee, applicant, or vendor in determining the specific issue of concern. Additionally, offering a contrarian statement to clearly point out what information is missing may assist both the reviewers and the licensee, applicant, or vendor in determining what specific information is being requested. For example, "The staff is unable to determine X without Y." or "Without Z data, the staff will be unable to make a finding as to X."
Conciseness	Ensure the RAI is succinct. While this attribute may appear to conflict with "clarity," the differentiation between the two becomes clearer when it is determined what details within the RAI are necessary and which are superfluous.
Comprehensiveness	Ensure the RAI asks the entire question. Consider if other relevant subject matter or topical material related to the RAI must also be considered, formulated, and discussed potentially as another question within the RAI

	<p>or as another RAI entirely. Evaluate whether the wording of the RAI could lead to a response that would necessitate a follow-up (second-round) RAI. If so, consider whether different wording would allow the staff to ask for all the information it needs in one round.</p>
<p>Significance</p>	<p>Ensure the information requested in the RAI clearly documents the significance of the issue with respect to the licensing acceptance criteria related to making a reasonable assurance determination. Whenever possible, the RAI question should include an assessment of the significance and clearly communicate how the staff's concern, if not properly addressed, could pose undue challenge to safety, security, or environment, and result in NRC regulations not being met. RAIs should request information necessary to support a finding of reasonable assurance of adequate protection of public health and safety, and not to achieve "zero risk."</p>

NRR continues to have high expectations for the quality of RAIs. Another way to check RAI quality is to consider the following questions:

- Is the regulatory basis of the RAI clear, including the specific safety, security, or environmental significance finding that the staff must make and why the information requested by the RAI is necessary for the staff to reach its finding?
- Does the RAI provide sufficient context to understand the significance of the information with respect to whether the licensing acceptance criteria is met (using a quantitative example, "The application states that there is 5 percent margin to the applicable regulatory limit, and staff's assessment is that the issue addressed by this RAI could eliminate a substantial amount of that margin")?
- Is the RAI clear regarding what the staff is seeking in response such that the applicant's response can fully resolve the issue? In what ways could the RAI, as worded, be misinterpreted to result in unintended response – and if the chance is not insignificant, rephrase/reword the RAI to improve clarity.
- Does the absence of the information requested prevent the staff from reaching a reasonable assurance determination?

The following table shows a deconstruction of an example of a quality RAI. This example relates to radiation sources. The left column shows the deconstruction of the example RAI into segments, and the right column shows associated comments addressing quality.

Example RAI Segments	Comments
<p>10 CFR 52.79(a)(3) requires that the FSAR describe the kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR Part 20.</p> <p>10 CFR 20.1101(b) requires that the licensee use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).</p> <p>10 CFR 20.1701 requires that licensees use, to the extent practical, process or other engineering controls to control the concentration of radioactive material in air.</p>	<p>Clear and concise statement of which regulatory requirement(s) constitute the basis for the RAI.</p>
<p>SRP Section 12.2 indicates that the description of airborne sources should include a tabulation of the calculated concentrations of radioactive material, by nuclide, for areas normally occupied by operating personnel and that the FSAR should provide the models and parameters used for the calculations.</p>	<p>Summary of relevant guidance document(s), if applicable.</p>
<p>In Section 1.6 of the license amendment request (LAR), the licensee specifies that the radionuclides Mn-56, Br-84, Br-85, Kr-89, Rb-88, Te-131, Xe-135m, Xe-137, Xe-138, Ba-137m, and Pr-144 are not expected to exist and, hence, not a contributor to the Auxiliary Building Fuel Handling Area airborne activity source term. These radionuclides are considered to be present in very low quantities in the current UFSAR. It is unclear why some of these radionuclides would not be contributors to the airborne activity source term based on expected spent fuel pool (SFP) inventories and related radionuclides included in the source term.</p>	<p>Where the application may not meet the regulatory requirements and how it may be deficient.</p>
<p>High airborne activity concentrations in the fuel handling area could significantly increase occupational radiation exposure and/or result in the need to take protective actions that could complicate the refueling process.</p>	<p>Identify the significance of the question.</p>
<p>Provide clarification or additional details, as appropriate, for the assumptions made in determining the Auxiliary Building Fuel Handling Area airborne activity source term and how it was determined that the above radionuclides are not expected to exist.</p>	<p>What information is the staff requesting the applicant provide to support the reasonable assurance determination?</p>

Appendix B is a Request for Additional Information Quality Control Checklist as an additional aid to technical reviewers and their BCs.

#### 4.5 Developing a Draft SE with “Holes” for RAI Response to Close

The staff is expected to develop a draft SE before preparing RAIs such that any “holes” in the SE would inform the staff’s determination of the additional information that is necessary. Developing draft SEs at the RAI stage enhances the staff’s safety focus by ensuring the staff obtains the necessary information to complete the review, while providing greater clarity and discipline in the RAI process. The technical BC should review the draft SE when approving RAIs. The project manager (PM) may request to review the draft SE to better understand the basis and need for the RAI, which would help in any future communication with the licensee, applicant, or vendor regarding the RAI. The expectation that a draft SE be prepared may be waived with agreement between the technical and licensing BCs. Applying this waiver should be the exception and not the rule, and it is anticipated to be used primarily in cases where expediency is necessary (e.g., exigent and emergency amendments) or where development of the draft SE would have an overwhelmingly negative impact on the schedule not commensurate with the benefit. After the RAIs based on the holes are issued, any new RAIs are considered as second-round or subsequent-round RAIs and should be agreed to by division management as discussed in Section 4.12. (Note: Although “holes” in a draft SE inform the need for any RAIs, the final SE need not explicitly cite RAIs and RAI responses. The SE need only address the technical areas under review.)

#### 4.6 Second and Subsequent Round RAI

When a PM sends a technical branch’s initial RAI to the licensee, applicant, or vendor, it is considered a “first-round” RAI. If the same technical branch requests to send an additional RAI to the licensee, applicant, or vendor in the same technical area, it is considered a “second-round” or “subsequent-round” RAI. The staff should make every effort to limit itself to one round of RAIs per technical branch for an application. Multiple rounds of RAIs needed to complete the staff’s review of an application are inefficient and may cause the established timeliness goals to be exceeded. Drafting the SE and then developing RAIs to fill “holes” in the draft SE help reduce the need for second-round RAIs.

The desire for a one-round limit of RAIs for the purpose of efficiency should not interfere with the staff’s primary mission of ensuring that public health and safety are adequately maintained. If necessary to ensure adequate protection of public health and safety, multiple rounds of RAIs are appropriate. However, the staff proposal of additional round of RAI warrants further assessment. The additional round of RAI may be necessary if the licensee, applicant, or vendor was not responsive to the first round RAI and management should be informed. If the first round RAI was not sufficiently clear and led to an incomplete response from the licensee, applicant, or vendor, the staff should reflect this lesson learned in developing future RAIs. RAIs should request information necessary to support a finding of reasonable assurance of adequate protection of public health and safety, and additional round RAIs should not be used to achieve “zero risk.” Any RAI that relates to a change in staff position or licensing basis is subject to the appropriate backfit or forward fit process in accordance with MD 8.4. (Note that the backfit rule does not apply to non-power production and utilization facilities

(NPUFs). However, the AEA limits the amount of regulation that the NRC can impose on AEA section 104 NPUFs to the minimum that permits the agency to fulfill its obligations under the AEA.)

Prior to sending a second (and any subsequent) round of RAIs in a specific technical area, the PM, technical reviewer, and the respective technical and licensing BCs should review the draft SE with “holes” and discuss the need for a second or subsequent round of RAIs and whether alternative approaches, such as a public meeting, conference call, or audit, may be more effective and efficient in determining the necessary information that the licensee, applicant, or vendor should submit formally. Then, the technical and licensing BCs should discuss the proposed path forward with their deputy division directors to obtain division management agreement of the approach. The PM should only send out a second or subsequent-round RAI with agreement from technical and licensing deputy division directors.

#### 4.7 Communications with Licensees, Applicants, or Vendors

The staff should leverage appropriate communication means, such as public meetings and teleconferences, to the maximum extent possible to enhance clarity and understanding both during the development of draft RAIs and after sending RAIs to licensees, applicants, or vendors. Enhanced engagement with licensees, applicants, or vendors should facilitate staff understanding of licensee, applicant, or vendor submittals, reduce the number of RAIs needed, and enhance licensee, applicant, or vendor understanding of RAIs and their ability to respond effectively. These interactions are to be conducted in accordance with NRC requirements and guidance regarding communications with external stakeholders, consistent with the NRC’s policy regarding openness and documented, as appropriate, in ADAMS.

When sending the draft RAIs to the licensee, applicant, or vendor, the PM offers an opportunity for a conference call to clarify the questions. Clarification calls are held after the PM has provided the draft RAIs, normally electronically, to the licensee, applicant, or vendor for its review. The intent is to allow the licensee, applicant, or vendor to determine if the request is understood. At the discretion of the PM, and in consultation with the licensee, applicant, or vendor, a call will be held with the licensee, applicant, or vendor to discuss the draft RAI to minimize potential misinterpretation of the RAI wording. The staff can discuss the intent of the RAI and may suggest rewording the question to clarify. This clarification call is not an opportunity for the licensee, applicant, or vendor to provide preliminary answers to the questions and solicit feedback from the staff on the acceptability of the responses. However, if the licensee, applicant, or vendor seeks to discuss the technical substance of the RAI or its proposed response, that should be conducted in a public meeting or public conference call, consistent with Management Directive (MD) 3.5, “Attendance at NRC Staff-Sponsored Meetings.” A public call or meeting ensures that all discussions on the technical substance of a proposed licensing action occur in a public forum, as discussed in Commission Policy Statement on Enhancing Public Participation in NRC Meetings (67 FR 36920; May 28, 2002), and that the NRC’s decision-making process is conducted in accordance with its openness and transparency goals.

#### 4.8 Regulatory Audits

In some cases, it may be warranted to perform a regulatory audit in order to identify additional information that a licensee, applicant, or vendor should formally submit for the staff to rely on in its determination. Following the audit, the information needed to be put on the docket should be requested through the RAI process. For example, the staff reviewed a licensee, applicant, or vendor calculation at a site audit and determined the information is necessary for the staff to make its finding. The staff should ask an RAI for a summary of the calculation or other relevant information to be submitted on the docket. Further information on the audit process is contained in NRR Office Instruction LIC-111, "Regulatory Audits."

An RAI should not reference or question material that has not been submitted on the docket, such as documents posted to a web portal controlled by the licensee, applicant, or vendor and made available to the staff to read in a virtual audit, or documents reviewed during an audit. The staff should not retain any licensee, applicant, or vendor documents. The staff's audit is documented in an audit summary. As stated in LIC-111, the audit summary should include a list of documents that were audited, a description of the audit activities, and identification of potential RAIs that will be issued based on the audit. An RAI should stand alone in explaining the staff's basis for the request and not rely on non-docketed information. A regulatory audit allows the staff to gain a better understanding of the application and to issue high quality RAIs. It also allows the licensee, applicant, or vendor to provide quality and timely RAI response.

#### 4.9 Consideration of Risk-Informed Decision-Making in Licensing

Implementation of an effective and efficient RAI process is an important part of a modern risk-informed regulator. The staff follows the Commission policy on the Safety Goals for the Operation of Nuclear Power Plants (51 FR 30028; August 21, 1986) and the Commission direction in SRM-SECY-19-0036 (ADAMS Accession No. ML19183A408), which states, "In any licensing review or other regulatory decision, the staff should apply risk-informed principles when strict, prescriptive application of deterministic criteria...is unnecessary to provide for reasonable assurance of adequate protection of public health and safety." The staff targets decision-making that is risk-informed and performance-based not to achieve zero risk, but to arrive at a reasonable assurance of adequate protection finding, and this should be considered in the development of RAIs.

Because the SRP, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," is written to apply to a broad array of license amendment requests for operating reactors and applications for new reactors, the staff needs to be judicious in determining the particular aspects of the SRP to utilize for a particular review. The SRP states: "Because the staff's review constitutes an independent audit of the applicant's analysis, the staff may emphasize or de-emphasize particular aspects of an SRP section, as appropriate, for the application being reviewed." The SRP also states, "Risk insights can also be used in determining the depth of review." As each amendment or application presents new and unique issues, the scope and depth of the NRC staff's review should also be customized to reflect the specifics, as

appropriate. This should be reflected in the RAIs the staff determines are necessary to send to licensees, applicants, or vendors.

NRR Office Instruction LIC-206, “Integrated Risk-Informed Decision-Making for Licensing Reviews” (ADAMS Accession No. ML19031C861), documents the guidance resulting from the Risk-Informed Decision-Making Action Plan. LIC-206 provides guidance on a graded approach for expanding the use of risk insights in licensing and other regulatory activities and to better integrate complementary insights from traditional engineering and risk assessment approaches to foster a broadened understanding of the benefits that risk-informed decision-making can bring to the overall regulatory approach. The staff should look for opportunities to enhance the integration of risk information into the organization’s decision-making practices and processes to improve the technical basis for regulatory activities (including RAIs), increase efficiency, and improve effectiveness.

#### 4.10 Sensitive Unclassified Non-Safeguards Information (SUNSI)

If the application and any supplements contain SUNSI (e.g., proprietary or security-related information), the RAIs need to be handled in accordance with MD 12.5 and internal procedures found at the NRC’s SUNSI webpage. The PM may send draft RAIs to the licensee, applicant, or vendor to confirm whether the draft RAIs contain SUNSI (if not so marked) or (if the draft RAI includes SUNSI markings) if the SUNSI markings in the draft RAI are correct. This communication with the licensee, applicant, or vendor is not an official agency record, and additional comments outside the accuracy of the markings should not be accepted or considered. The PM should work with the technical staff to ensure that final RAIs that contain SUNSI are redacted as appropriate and documented in ADAMS.

#### 4.11 OGC Review

The PM should submit RAIs related to combined license applications or early site permits to the Office of the General Counsel (OGC) for legal review. OGC typically does not review RAIs related to license amendments, exemptions, relief requests, or design certification applications. However, RAIs related to subjects that are in litigation, subjects that have attracted substantial interest from members of the public or the Commission, or licensing actions that are the first of their kind may benefit from OGC review. Further guidance on this topic can be found in COM-109, “NRR Interfaces with the Office of General Counsel.”

#### 4.12 RAI and RAI Response Timeliness

The PM should issue final RAIs to licensees, applicants, or vendors within 5 business days after the clarification call of the draft RAIs with the licensee, applicant, or vendor (or the licensee, applicant, or vendor’s notification that a clarification call is not needed), except that the final RAIs should be issued within 3 business days for design certification applicants. During the clarification call, the PM should confirm the RAI response time with the licensee, applicant, or vendor. PMs should notify the technical BCs and staff of the date that RAI responses are due to facilitate effective workload planning.

When issuing RAIs, PMs should default to affording a licensee, applicant, or vendor, 30 days (60 days for NPUFs) to respond to RAIs, and the PM should document this information in the transmittal of the RAIs to the licensee, applicant, or vendor. If the licensee, applicant, or vendor requests a greater than 30-day response time (60 days for NPUFs), the PM should evaluate the impact of the extended response time on the overall project schedule and discuss the licensee, applicant, or vendor's request for a later response date with both the licensing and technical BCs. With agreement from the licensing and technical BCs, up to 60 days (120 days for NPUFs) may be granted to licensees, applicants, or vendors for providing an RAI response. Licensee, applicant, or vendor requests greater than 60 days (120 days for NPUFs) should be elevated, with the technical and licensing BCs' recommendation, to the technical and licensing division management for approval. This approval will focus on whether a licensee, applicant, or vendor's extension request would challenge the review timeliness metrics.

Section 2.108 of 10 CFR states that the NRC may deny an application if the applicant fails to respond to an RAI within 30 days of the date of the request, or within such other time as may be specified. If the staff foresees the possibility of invoking the provisions of 10 CFR 2.108, it is important that the RAI response date agreed to by the licensee, applicant, or vendor be documented as an official agency record (OAR). This documentation can be included in the formal RAI to the licensee, applicant, or vendor using words such as the following:

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

PMs should track licensee, applicant, or vendor timeliness and adherence to RAI response schedules. Any significant delays in licensee, applicant, or vendor responses should be raised to the BCs and deputy division directors for consideration of whether denial in accordance with 10 CFR 2.108 is appropriate. However, this should be an action of last resort for NPUFs because of its resource limitations and minimum regulation requirements that apply. The PM should work with the licensee to develop an acceptable schedule.

For NPUFs, an RAI transmittal letter will accompany RAIs to a licensee to address the following for consistency with the Nuclear Energy Innovation and Modernization Act (NEIMA):

- Historical dates for NPUF amendment submittal and acceptance by the staff
- Date the NPUF licensee, applicant, or vendor is expected to respond to RAIs
- Date the staff is expected to complete the NPUF amendment review
- Explanation of staff actions for late response and late completion of NPUF amendments

For NPUFs licensee, applicant, or vendor RAI response delays of greater than 120 days, or agreed upon date, the PM will issue a letter to the licensee, applicant, or vendor to document the delays and revised response date.

#### 4.13 Maintaining Official Records

Final RAIs issued to licensees, applicants, or vendors are publicly available OARs and are maintained in ADAMS. The preferred approach is for the PM to e-mail the RAIs to the licensee, applicant, or vendor and add the e-mail to ADAMS as a publicly available OAR. The PM will ensure that the appropriate redactions are made to prevent release of SUNSI information (see Section 4.10).

#### 4.14 RAI Workflow and Approval Process

The following is the typical workflow and approval process for an RAI:

1. A technical reviewer should prepare a draft SE and identifies information gaps within the SE (i.e., "holes").
2. A technical reviewer prepares a draft RAI to address the need for additional information to complete the SE.
3. The technical reviewer forwards the draft RAI by e-mail or eRAI (see Section 4.15) to the technical BC for review and approval. Note that documents containing SUNSI may not be processed in eRAI.
4. The technical BC either sends the draft RAI back to the technical reviewer with comments or approves it and forwards the draft RAI to the PM by e-mail or eRAI.
5. The PM reformats and revises the RAI as necessary. The PM either sends the draft RAI back to the technical reviewer with comments or forwards the draft RAI to the licensing BC for review and approval.
6. The PM forwards the draft RAI to OGC for review, as necessary.
7. The PM sends the draft RAI by e-mail to the licensee, applicant, or vendor.
8. The PM holds a conference call with the licensee, applicant, or vendor, and the technical reviewer to clarify the RAI if requested by the licensee, applicant, or vendor, and to establish a response date.
9. Should the draft RAI be revised significantly before final issuance, the changes and reason for the change should be documented and placed in ADAMS.
10. Within 5 business days, the PM sends the final RAI to the licensee, applicant, or vendor after clarifying the draft RAI, as applicable, reflecting the final RAI and agreed upon response date. If there is no change to the draft RAI, the draft RAI e-mail will be added to ADAMS as the final RAI.

#### 4.15 Application of eRAI System

The New Reactors Business Line projects typically use the electronic RAI (eRAI) system for processing and managing RAI workflow as described in Appendix C. The eRAI system was developed and customized for new reactor reviews. NRR conducted a pilot using eRAI for processing an operating reactor LAR and found that modifications to eRAI were needed. The staff plans to work with the Office of the Chief Information Officer to modify eRAI so it can be used to support licensing activities across the reunified office.

NRR management has decided on a phased approach to transition the Operating Reactor Business Line (operating reactor licensing, license renewal, and research and test reactors) to eRAI, with full implementation by October 2020. The PM and technical reviewer should discuss with their BCs on a case-by-case application of eRAI to new projects in accordance with the transition to eRAI. The staff plans to update this office instruction after eRAI implementation across NRR.

## **5. RESPONSIBILITIES AND AUTHORITIES**

### **A. Division Management**

Technical and licensing division management is responsible for:

- providing overall management and oversight of RAI development and processing
- resolving quality issues with RAIs
- evaluating and providing agreement on issuing subsequent rounds of RAIs, if appropriate
- evaluating options, such as audits or public meetings, to facilitate information gathering in lieu of subsequent rounds of RAI as applicable
- evaluating and approving licensee, applicant, or vendor requests to respond to RAIs greater than 60 days
- promoting consideration and application of risk insights in developing RAIs, per LIC-206
- ensuring that written and verbal communications are consistent with MD 8.4. If the staff determines that a forward-fit is necessary to approve a LAR, it will follow MD 8.4. If in reviewing a LAR, the staff identifies an issue where a backfit should be considered, the staff will follow MD 8.4.
- ensuring RAI requests information necessary to support a finding of reasonable assurance of adequate protection of public health and safety
- presiding over denial decisions in accordance with LIC-101 if the licensee, applicant, or vendor is not timely in responding to RAIs or the licensing request may not satisfy safety regulations.

### **B. Branch Chiefs**

Technical and licensing BCs are responsible for:

- reviewing and approving RAIs
- evaluating options, such as audits or public meetings, to facilitate information gathering in lieu of second or subsequent rounds of RAI, as applicable
- ensuring staff is maintaining work scheduling tools (that is, Revised Reactor Program System (RRPS)) up to date
- e-mailing RAIs to the PM, if eRAI is not used
- resolving quality and administrative issues with RAIs
- presenting draft second or subsequent rounds of RAIs to technical and licensing deputy division directors for their agreement
- ensuring that written and verbal communications are consistent with MD 8.4. If the staff determines that a forward-fit is necessary to approve a LAR, it will follow MD 8.4. If in reviewing a LAR, the staff identifies an issue where a backfit should be considered, the staff will follow MD 8.4.

- communicating with the licensee, applicant, or vendor counterparts on their responses to RAIs and any effect on the staff review and schedule
- providing feedback to staff on quality and administrative issues with RAIs
- ensuring appropriate consideration and application of risk insights in developing RAIs, per LIC-206
- ensuring RAI requests information necessary to support a finding of reasonable assurance of adequate protection of public health and safety

### C. Technical Reviewers

Technical reviewers are responsible for:

- adhering to on-time completion of milestones per agreed schedules
- preparing the draft SE with “holes” for RAIs, per LIC-101 and LIC-206
- developing quality RAIs
- maintaining work scheduling tools (that is, RRPS) up to date
- supporting conference calls with the licensee, applicant, or vendor to clarify draft RAIs
- supporting pre-submittal meetings, audits, and public meetings to facilitate review
- entering RAI questions into eRAI in accordance with the review schedule if eRAI is used for the project
- workflowing the RAI to the technical BC using eRAI if eRAI is used for the project
- coordinating with the PM to update the “Notes” and the “Related Question” fields if eRAI is used for the project
- ensuring that written and verbal communications are consistent with MD 8.4. If the staff determines that a forward-fit is necessary to approve a LAR, it will follow MD 8.4. If in reviewing a LAR, the staff identifies an issue where a backfit should be considered, the staff will follow MD 8.4.
- evaluating RAI responses and updating eRAI appropriately if eRAI is used for the project
- presenting draft second or subsequent rounds of RAIs to technical and licensing deputy division directors for their agreement
- incorporating RAI responses into the draft SE
- elevating potential technical and schedule issues promptly with the PM and technical BC
- resolving OGC comments on RAIs, if applicable
- considering and applying appropriate risk insights to focus reviews, in accordance with LIC-206
- ensuring RAI requests information necessary to support a finding of reasonable assurance of adequate protection of public health and safety
- appropriately marking and handling documents that contain SUNSI

### D. Project Managers

Project PMs are responsible for:

- managing project milestones and schedule
- coordinating integrated review teams and technical reviewer consideration for risk insights, in accordance with LIC-206
- communicating with the licensee, applicant, or vendor on project status

- coordinating pre-submittal meetings, clarification calls, audits, and public meetings, as necessary, to facilitate review
- assessing the quality of RAIs provided by the technical staff and providing feedback, including coordinating revisions of RAIs to ensure consistency and quality across various review groups
- establishing RAI response time with the licensee, applicant, or vendor
- evaluating the impact of RAI response time on project schedule and timeliness metrics
- ensuring that written and verbal communications are consistent with MD 8.4. If the staff determines that a forward-fit is necessary to approve a LAR, it will follow MD 8.4. If in reviewing a LAR, the staff identifies an issue where a backfit should be considered, the staff will follow MD 8.4. In addition, it will coordinate as necessary with the appropriate backfitting and forward fitting community of practice members.
- elevating potential technical and schedule issues promptly with management
- coordinating with the technical reviewer to update the “Notes” and the “Related Question” fields if eRAI is used for the project
- ensuring RAI responses are received in a timely manner, updating eRAI and RRPS when received, and notifying the technical reviewer of the response using eRAI if eRAI is used for the project
- coordinating agreement with technical and licensing deputy division directors of draft second or subsequent rounds of RAIs
- issuing draft and final RAIs to the licensee, applicant, or vendor
- entering the RAI response date and response ADAMS accession number in the eRAI system when a response is received and forwarding it to the technical reviewer using the eRAI workflow if eRAI is used for the project
- resolving OGC comments on the RAIs, if applicable
- documenting RAIs in ADAMS in accordance with MD 3.53, “NRC Records and Document Management Program”
- ensuring RAI requests information necessary to support a finding of reasonable assurance of adequate protection of public health and safety

## **6. PERFORMANCE MEASURES**

The percentage of second (or subsequent) round RAIs is a performance measure of the quality of the RAIs. The performance goal is less than 5 percent of RAIs are second (or subsequent) round RAIs.

## **7. PRIMARY CONTACTS**

William Ward  
301-415-7038  
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Samson Lee  
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**8. RESPONSIBLE ORGANIZATION**

DORL

**9. EFFECTIVE DATE**

November 6, 2019

**10. CERTIFICATION DATE**

November 6, 2024

**11. REFERENCES**

1. Uhle, Jennifer L., Office of New Reactors, "Effective Use of Request for Additional Information, Audit, and Confirmatory Analysis in New Reactor Licensing Review," dated October 7, 2016 (ADAMS Accession No. ML16278A574)
2. U.S. Government Accountability Office, GAO-17-344, "Efforts Intended to Improve Procedures for Requesting Additional Information for Licensing Actions Are Under Way," dated April 2017
3. Brown, Fredrick D., Office of New Reactors, "Effective Use of Requests for Additional Information in New Reactor Licensing Reviews," dated May 9, 2018 (ADAMS Accession No. ML18110A398)
4. Bradford, Anna H., Office of New Reactors, "Office of New Reactors Phase Discipline Memorandum," dated June 29, 2018 (ADAMS Accession No. ML18178A568)
5. Akstulewicz, Frank M., Office of New Reactors, "Process and Timeline for Closure of Open Items and Confirmatory Items in Safety Evaluation Reports," dated January 8, 2010 (ADAMS Accession No. ML100060495)
6. Office of New Reactors, "eRAI User Manual," Version 3.1, dated September 2018 (ADAMS Accession No. ML19203A301)
7. Office of New Reactors, "eRAI Quick Reference Card," dated September 2019 (ADAMS Accession No. ML19203A291)
8. Office of New Reactors, "Request for Additional Information Job Aid," Revision 2, dated Summer 2018 (ADAMS Accession No. ML18199A235)

**Enclosures:**

1. Appendix A: Change History
2. Appendix B: Request for Additional Information Quality Control Checklist
3. Appendix C: Guide for eRAI Workflow Process for New Reactors Business Line

**Appendix A - Change History**

**Office Instruction LIC-115**

**Processing Requests for Additional Information**

<b>LIC-115 Change History - Page 1 of 1</b>			
<b>Date</b>	<b>Description of Changes</b>	<b>Method Used to Announce &amp; Distribute</b>	<b>Training</b>
11/06/19	This is the initial issuance of LIC-115, which consolidates guidance from NRO Office Instruction NRO-REG-101, "Development, Review and Approval Process for Requests for Additional Information," NRR Office Instruction LIC-101, "License Amendment Review Procedures," regarding requests for additional information (RAI) because of the NRR/NRO reunification.	E-mail to NRR staff	RAI: Completed mandatory RAI refresher training in April 2018 for NRR staff and applicable staff in other offices who support NRR licensing reviews. Future training to be determined. Licensing: Fundamentals of Reactor Licensing for Technical Reviewers or Fundamentals of Reactor Licensing for Project Managers.

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## **Appendix B**

# **Request for Additional Information Quality Control Checklist**

## **REQUEST FOR ADDITIONAL INFORMATION QUALITY CONTROL CHECKLIST**

Once the safety or environmental reviewer, as appropriate, determines that a request for additional information (RAI) is necessary, the following questions, in the order presented, will help the RAI reviewers/approvers determine if the RAI under development/examination meets the minimum guidelines related to a high quality RAI.

To ensure that an RAI is of sufficient quality, confirm that the RAI has the following attributes:

- 1) The regulatory basis is clearly stated at the beginning of the RAI.
- 2) If applicable, relevant guidance document(s) are cited that help clarify the information being requested (e.g., Standard Review Plans, Regulatory Guide, etc.)
- 3) The RAI clearly identifies the location of the issue in the document being reviewed (e.g., Final Safety Analysis Report Section X.Y or license amendment request Section X.Y).
- 4) The RAI clearly explains why the information provided does not meet the requirements cited in the regulatory basis.
- 5) The RAI clearly identifies potential impacts of the missing information (such as the safety, risk, security, financial, or environmental significance of the question).
- 6) The RAI clearly identifies the specific information being requested from the applicant or licensee to support the reasonable assurance determination.

### **Additional Considerations for Branch Chief Review:**

- Ensure that the context of the RAI has a clear logical basis and information sought is provided in plain language.
- Confirm that the RAI is objective, factual, and written for an audience of suitably qualified safety and environmental reviewers.
- Determine that the RAI is written such that second-round RAIs are not likely.
- Verify that the RAI is safety-focused and risk-informed.
- Determine if any questions are duplicative of other questions generated by the branch.
- Confirm that the requested information is not already on the docket, and is not generally known and verifiable by the technical community and available to the public and is needed only to support information already on the docket.
- Verify that the RAI is requesting only relevant information from reports, procedures, or calculations, not the full documents themselves.
- Determine if coordination with other technical branches is needed.
- Ensure the RAI uses the appropriate format for multiple or follow-up questions.
- Determine if the RAI relates to a change in staff position or licensing basis, and consider the backfit or forward fit process in accordance with MD 8.4, as appropriate.
- For second or subsequent-round RAIs, align with technical and licensing division management.
- For significant RAIs, determine if office or other division level alignment is needed prior to issuance (e.g., to ensure adherence with backfitting and forward fitting policy in MD 8.4).

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## **Appendix C**

# **Guide for eRAI Workflow Process for New Reactors Business Line**

## 1.0 RAI Workflow Process

The New Reactors Business Line projects typically use an electronic system for the development, review, and approval of requests for additional information (RAIs). RAIs are processed and tracked using the electronic RAI (eRAI) system, a computer-based control and workflow component of Enterprise Project Management (EPM). The eRAI system was developed and customized for the New Reactors Business Line. RAIs issued to the licensee, applicant, or vendor are sent in the form of e-mails and are Official Agency Records (OARs) in the NRC's official recordkeeping system, the Agencywide Documents Access and Management System (ADAMS). Additional guidance on using the eRAI system is provided in the eRAI User Manual (ADAMS Accession No. ML19203A301) and eRAI Quick Reference Card (ADAMS Accession No. ML19203A291).

The eRAI system is an electronic workflow process tool. The term "workflow" refers to the action of the user sending or forwarding the RAI and the associated question(s) to the next step in the process. The RAI review process is managed by both staff and managerial interactions, as well as by eRAI workflows. The eRAI workflow process provides workflow tracking, project management, and scheduling support for a standard set of activities to occur by those acting in several roles (e.g., technical reviewer (TR), project manager (PM), chapter PM, technical branch chief (BC), licensing BC) within the RAI review and approval process.

The eRAI system models RAIs as a package of requested information (in the form of questions). An RAI may contain one question or multiple questions. Questions may be bundled into an RAI for the convenience of the reviewer but are tracked and closed out on a question-by-question basis.

RAIs that include multiple questions are acceptable, provided they adhere to the following guidelines:

- Each question presents information from the same topical/subject area.
- If the regulatory basis is the same for all questions in the RAI, it is acceptable to state the regulatory basis at the start of the first question and state that it applies to all questions in the RAI. It does not need to be repeated for every question if the same basis applies to all questions. This is acceptable because the regulatory basis is not part of the unique request being made.
- Each question provides enough information that it does not need to refer to another question within the RAI (except for regulatory basis).

Multiple-question RAIs (new related questions with unique question numbers under the same RAI) are preferable to a single RAI question with an itemized list of sub-questions. Should sub-questions be necessary, each sub-question should be directly related to a narrowly defined topical subject area. In general, the use of sub-questions is discouraged due to the difficulty in tracking and closing these questions within eRAI and the staff's safety evaluation (SE). This may be revisited when eRAI is implemented across NRR in 2020 for the purpose of monitoring office metrics.

RAIs entered into the eRAI system will not include safeguards information (SGI), sensitive unclassified non-safeguards information (SUNSI), export control information (ECI), or critical electric infrastructure information (CEII). However, the eRAI system

may be used to track the status and workflow of such RAIs, but only the tracking information, and not the specific safeguards or other similar information, will be available in the eRAI system.

### 1.1 **Technical Reviewer (Denoted as “TBR” in eRAI) Creates an RAI**

The TR is the RAI author who determines that information critical to the SE’s conclusion is missing, unclear, or unsupported based on the information in the submittal and after researching other avenues, the TR has yielded limited or no success such that development of an RAI is necessary. The TR may reference the eRAI User Manual or Quick Reference Card to assist in filling out the eRAI fields.

While drafting an RAI, the TR and his or her review team, as assigned, are expected to develop a preliminary safety evaluation report (PSER) simultaneously to identify the informational “holes” that the responses to the RAI(s) are intended to close. In this manner, the first draft PSER will provide to both readers and reviewers the level and context of information that has been provided by the licensee, applicant, or vendor, and also reveal areas where information necessary to reach a reasonable assurance determination is lacking. The RAI should be of quality, clearly seeking information to fully resolve the issue.

When generating an eRAI, the TR determines whether or not the RAI is for a design certification (DC) review. The eRAI system is designed to automatically include the Office of the General Counsel (OGC) in the workflow for all RAIs except DC reviews. To include OGC in the workflow, the RAI must be “Non-DC RAI.” If the RAI is “DC RAI,” OGC will not be included in the workflow.

NOTE: A TR may seek OGC review of a particular RAI even for a DC if the staff determines such review is warranted. Furthermore, the workflow for a DC RAI should include OGC upon OGC request (e.g., RAIs may affect litigation related to a design certification).

The Technical Reviewer:

- Fills out all asterisked fields in the input form to enter an RAI in the system. (If the TR does not know the names of all participants other than his or her BC, the chapter PM’s name should be provided in those fields.)
- Enters questions into the eRAI using the question format described earlier in this office instruction.
- If this is a follow-up question, the TR enters all related questions into the “Related Questions” field in eRAI using the button in the menu.

NOTE: For follow-up questions, this is a second or subsequent-round RAI. The TR, PM, technical BC, and licensing BC should discuss with technical and licensing deputy division directors whether there are other options such as public meetings, conference calls, or audits that would improve the efficiency of the process. If there is agreement from the technical and licensing deputy division directors to proceed with issuing that follow-up question, the TR would use the “Notes” field in eRAI to indicate management

agreement. This is a temporary solution until eRAI is modified for use across NRR in 2020.

When the TR is ready to start the review cycle, he or she uses the eRAI workflow to forward the RAI to his or her technical BC for review and approval.

## **1.2 Technical Reviewer's Branch Chief (Denoted as "TBC" in eRAI) Reviews the RAI**

When notified by e-mail that an RAI has been received for review, the technical BC should click the RAI link and go directly to eRAI to conduct his or her review. Each question listed at the bottom of the RAI must be opened and reviewed. Changes to the questions should be discussed with the TR. The technical BC may send the RAI back to the TR via the workflow process to make major changes, or the technical BC may make minor changes for the TR at his or her discretion.

Once any changes to the RAI and its questions have been completed, the technical BC should "Approve" all questions (either all at once or individually, using the blue checkmark buttons on the menu) and submit the approved RAI via the workflow process to the chapter PM for review and approval.

The technical BC should provide feedback to the TR or forward (workflow via the eRAI system) the RAI to the chapter PM within 3 workdays of being assigned in eRAI.

NOTE: The eRAI system is set up for the technical BC to forward the RAI to technical division management (denoted as "TDM" in eRAI) for review and approval. Although management can always use sample RAIs, technical division management review and approval are no longer required. Until modification is made in eRAI to remove this step, the technical BC should select himself or herself as the technical division management and forward the RAI to himself or herself again as a workaround. The RAI will be routed through the technical BC twice. The first time is for the technical BC to review, approval, and to forward the RAI to himself or herself as technical division management. The second time is for the technical BC to forward the RAI to the chapter PM.

## **1.3 Chapter PM Reviews the RAI**

When notified by e-mail that an RAI has been received for review, the chapter PM should click the RAI link and go directly to eRAI to conduct his or her review. Each question listed at the bottom of the RAI must be opened and reviewed.

Editorial or minor changes that have no impact upon the technical, environmental, safety, or security-related information may be made by the chapter PM without technical consultation. However, it is recommended that the chapter PM consult with the TR prior to changing any RAI information as a matter of practice. Changes that affect the technical, environmental, or security content or intent of an RAI or question within it should be discussed with the TR prior to finalizing that change.

If, after consultation with the TR, the chapter PM believes there is an issue of insufficient quality as it relates to one or more questions within an RAI, the chapter PM will not approve the question and may choose to use the "Notes" field to describe the issue(s). The chapter PM should not workflow the RAI to the licensing BC; however, the chapter

PM should contact and discuss the issue with the licensing BC and take the appropriate steps to resolve the situation.

Within the eRAI system, the chapter PM also verifies the asterisk marked fields to ensure the correct contacts are included and enters the remainder of the licensee, applicant, or vendor's information in the "non-asterisk" fields.

Different design centers have the option of allowing the PM, noted as "Project Manager," in the associated eRAI field (and abbreviated as "PM"), or the chapter PM to process RAIs. The PM may also be called the lead PM for the project. Assigning the chapter PM's name as the PM for the particular RAI allows the chapter PM to process RAIs; however, in this case, the electronic field related to the "role" of PM must have the chapter PM's name in it in order for the chapter PM to formally distribute the RAIs to the given licensee, applicant, or vendor. With this approach, the individual would see the RAI twice, first as chapter PM, then as PM. Regardless, prior to the RAI being issued, the PM must approve all questions and must enter the RAI NRC Letter Number.

Once any changes to the RAI and its questions have been completed, the chapter PM should "Approve" all questions (either all at once or individually, using the blue checkmark buttons on the menu) and submit the approved RAI via the workflow process to the Licensing BC for review and approval. Because the signature authority is the PM in accordance with ADM-200, "Delegation of Signature Authority," the chapter PM's "Approval" reflects concurrence on the RAI.

The chapter PM should, within 3 work days of being assigned an RAI to review in eRAI, provide feedback to the TR or his or her technical BC, or forward via the workflow process described above to the licensing BC.

#### **1.4 Licensing Branch Chief (Denoted as "LBC" in eRAI) Reviews the RAI**

When notified by e-mail that an RAI has been received for review, the licensing BC can click the RAI link and go directly to eRAI to conduct his or her review. Each question listed at the bottom of the RAI must be opened and reviewed. (Note that RAIs entered into the eRAI system will not include SGI, SUNSI, ECI, or CEII information.)

Editorial or minor changes that have no impact upon the technical, environmental, safety, or security-related information may be made by the licensing BC without technical consultation. However, it is recommended that the licensing BC consult with the chapter PM prior to changing any RAI information as a matter of practice. Changes that affect the technical, environmental, or security content or intent of an RAI or question within it should be discussed with the chapter PM or TR prior to finalizing that change.

Once any changes to the RAI and its questions have been completed, the licensing BC should "Approve" all questions (either all at once or individually, using the blue checkmark buttons on the menu). If the RAI is a non-DC RAI, the licensing BC should submit the approved RAI via the workflow process to the OGC attorney for review and approval. If the RAI is a DC RAI, the licensing BC should submit the approved RAI via the workflow process to the PM for review, approval, and issuance, unless the staff believes OGC review is warranted or OGC has requested the staff to send RAIs on the subject of the RAI to OGC for review.

The licensing BC should, within 3 work days of being assigned an RAI to review in eRAI, provide feedback to the chapter PM or the technical BC, or forward it to OGC or the PM via the workflow process described above.

#### Resolution of Potential Quality Issues

If, after consultation with the TR or chapter PM, the licensing BC believes there is an issue of insufficient quality as it relates to one or more questions within an RAI, the licensing BC should contact the technical BC to discuss the issue(s) and then take the appropriate steps to resolve the situation. The licensing BC may direct the chapter PM to workflow the RAI back to the technical BC so that he or she can work with the TR to resolve any deficiencies or the chapter PM may make changes and workflow the resolved RAI to the licensing BC. The licensing BC will then review/approve the RAI following the instructions at the start of this section. The process may be revisited when eRAI is implemented across NRR in 2020 to efficiently end the workflow for RAIs that are determined to be outside of scope or not necessary.

### 1.5 **OGC Reviews the RAIs for Combined Licenses (COLs) and Early Site Permits (ESPs)**

A hearing is required for COL and ESP applications. The PM should submit RAIs related to COLs or ESPs to the Office of the General Counsel (OGC) for legal review. OGC typically does not review RAIs related to license amendments, exemptions, relief requests, or design certification applications. However, RAIs related to subjects that are in litigation, subjects that have attracted substantial interest from members of the public or the Commission, or licensing actions that are the first of their kind may benefit from OGC review. Further guidance on this topic can be found in COM-019, "NRR Interfaces with the Office of General Counsel. Moreover, the development of a hearing file is necessary in litigation before the Atomic Safety and Licensing Board Panel so that the agency may disclose all relevant documents supporting the staff's review of the application. Therefore, OGC should review all RAIs related to COL and ESP applications within 4 business days. For all other applications, OGC may be requested to review RAIs the staff identifies or on topics OGC has requested the opportunity for review. OGC reviews RAIs for legal sufficiency and, if it does not identify any legal issue in an RAI, indicates that it has no legal objection (NLO) to the RAI, which the eRAI system labels as "approval."

The staff must initiate all OGC RAI reviews through the OGC mailroom ([RidsOgcMailCenter.Resource@nrc.gov](mailto:RidsOgcMailCenter.Resource@nrc.gov)) separately by e-mail to stay consistent with OGC processes. If an attorney has already been assigned, the PM should send a copy of the draft RAI to the assigned attorney. If the 4-day OGC review time is reached without comment or contact from OGC, the staff may send the draft RAI to the next review and approval step without OGC review, unless OGC has informed the staff that a subject is in litigation or otherwise warrants OGC review and the RAI is related to that subject. An RAI on such a subject (in litigation or otherwise identified by OGC) may not be issued without OGC review. However, when a question of clarity or regulatory applicability for an RAI not reviewed by OGC exists, a best practice is to have the PM contact the assigned OGC attorney or the attorney's supervisor prior to continuing the RAI review process. This provides OGC with awareness of the eRAI workflow steps that will be taken and allows it to respond, should the given OGC representative deem it appropriate.

Significant changes by the attorney are brought to the attention of the chapter PM, who is expected to discuss them with the TR and/or his or her BC. Sometimes a discussion between OGC and the staff is needed in order to determine the disposition (e.g., reword an RAI, etc.) of a particular question. Upon completion, the OGC attorney workflows the questions to the PM in the eRAI system workflow or by e-mail to the designated PM (in accordance with a project-specific agreement), individually or all at once, and changes the status of the questions in the eRAI system to “OGC Reviewed.” The eRAI workflow is then used to forward the RAI to the PM to undertake the appropriate action.

## **1.6 PM Reviews the RAI**

When notified by e-mail that an RAI has been received for review, the PM, denoted as the “Project Manager” in eRAI, should click the RAI link and go directly to eRAI to conduct his or her review. The PM may also be called the lead PM for the project. Each question listed at the bottom of the RAI must be opened and reviewed. If the PM believes there is an issue of insufficient quality as it relates to one or more questions within an RAI, after the PM has conferred with the chapter PM or TR and has been unable to reach resolution, the PM must workflow the RAI to the chapter PM and have the chapter PM take the appropriate steps to resolve the situation. Refer to Section 1.3 for further guidance.

Once any changes to the RAI and its questions have been completed, the PM should “Approve” all questions (either all at once or individually, using the blue checkmark buttons on the menu), and then the RAI is ready to be issued in Advance RAI (ARAI) form to the licensee, applicant, or vendor.

An ARAI is a reviewed and approved RAI that the staff presents to the licensee, applicant, or vendor to identify sensitive information, confirm the response time, and verify the RAI is clear and well understood. When the ARAI is delivered to the licensee, applicant, or vendor, the PM generates the RAI document by clicking on the “Issue RAI,” to start the clock for the 30-day response period (or other predetermined time period negotiated between the licensee, applicant or vendor, and NRC) for which the licensee, applicant, or vendor has to formally respond.

As discussed in Section 1.3, the PM role is assigned as determined by the Design Center – it can be the actual PM for the project or the chapter PM. Whichever is chosen, the actual PM for the project still has the option of monitoring the progress of an RAI at any stage.

The PM should provide feedback to the TR or the licensing BC, or transmit the ARAI to the licensee, applicant, or vendor within 3 workdays of being assigned in eRAI.

The PM sends the ARAI to the licensee, applicant, or vendor with the following questions:

- Does the ARAI state sensitive (CEII, ECI, proprietary, or security-related) information? (If the RAI is known, or reasonably expected to state sensitive information, the ARAI must be encrypted when sent, per NRC policy in accordance with MD 12.5 and internal procedures found on the SUNSI webpage.)

- Can the licensee, applicant, or vendor respond within 30 days or another predetermined time period? If not, how long will it take to respond and what is the reason for the additional response time?
- Does the licensee, applicant, or vendor need a clarification meeting or phone call regarding the request before it begins to answer it?

The licensee, applicant, or vendor is expected to respond to the question(s) listed above within 5 business days. If the licensee, applicant, or vendor requests a clarification call, the staff should strive to set that call up within 5 workdays. If the clarification call results in a substantive revision to the RAI, the revised RAI should be reissued as an ARAI, and the process described above should be repeated, including a reset of the response clock.

Otherwise, once the licensee, applicant, or vendor's concerns (if any) are addressed, the PM makes any necessary non-substantive changes to the ARAI and issues the ARAI as the final RAI to the licensee, applicant, or vendor by e-mail, placing the e-mail and RAIs in ADAMS, and entering the ADAMS accession number for the RAI into the "RAI Accession No." field in eRAI. The issuance of the final RAI does not reset the response clock.

If the licensee, applicant, or vendor requests a greater than 30-day response time, the PM should raise the licensee, applicant, or vendor's request for a later response date with both the licensing and technical BCs. With agreement from the licensing and technical BCs, up to 60 days may be granted to licensees, applicants, or vendors for providing an RAI response. Licensee, applicant, or vendor requests greater than 60 days should be elevated with the technical and licensing BCs' recommendation, to the technical and licensing division management for approval. This approval will focus on whether a licensee, applicant, or vendor's extension request would challenge the review timeliness metrics.

### **1.7 RAIs Containing Safeguards or Sensitive Unclassified Non-Safeguards Information**

Currently, ECI is treated as proprietary, which is Sensitive Unclassified Non-Safeguards information (SUNSI). The staff should handle SUNSI information in accordance with MD 12.5 and internal procedures described on the NRC internal SUNSI webpage.

No Safeguards Information (SGI), SUNSI, or Critical Electric Infrastructure Information (CEII) can be included in the eRAI system. The "Sensitivity" field is used to flag the RAI questions that are SGI, SUNSI, or CEII. For these RAIs, the eRAI system is used for workflow purposes only. RAI questions containing SGI are prepared and processed outside the eRAI system and outside of ADAMS (The Secure Local area network Electronic System may be used for this purpose). RAI questions containing SUNSI or CEII material are prepared outside of the eRAI system, following the appropriate controls for SUNSI material. When the RAI is issued, the PM will produce the RAI (with the non-SUNSI placeholders in the questions for the SUNSI material prepared outside of eRAI) from eRAI. The PM will add the SUNSI material where it belongs in the RAI prior to issuing it to the applicant. As part of this process, the e-mail capture has been set up with a non-public e-mail capture to put the non-public RAI containing SUNSI in ADAMS. The PM then instructs the chapter PM to use the eRAI version to create a redacted,

publicly available version of the RAI to be put in ADAMS. In each of these cases, the “Notes” field should be used to identify where staff can find the non-public versions of the RAI documents.

The “RAI Accession No.” and “Response Accession No.” fields should point to “Publicly Available” versions of SUNSI documents. While the NRC controls the RAI to be issued, the licensee, applicant, or vendor controls the structure of its submittal. The licensee, applicant, or vendor provides separate documents for its response, namely the publicly available submittal letter (with affidavit, if necessary); the public version of the RAI response; and the non-public version of the RAI response (if necessary). The PM should remind the licensee, applicant, or vendor to include any affidavits in the non-sensitive portion of the submittal. These documents will be placed in a single, publicly available package by the Document Processing Center. The document package number can be used as the response accession number. This approach allows the use of a single accession number either inside the NRC network, or for the public, with the actual access to the documents controlled by the user’s access (web-based ADAMS restricting the public to publicly available documents only).

### **1.8 RAI Document Generated and Issued as an Official Agency Record**

Before the RAI is issued final, the PM adds the NRC RAI letter number to the eRAI system. The letter number does not refer to an actual letter but indicates chronological ordering. An e-mail is generated by the system and sent to the PM with the RAI attached as a Microsoft Word document.

After the RAI is generated, it is converted to an Adobe portable document format (PDF) file by the PM and sent to the licensee, applicant or vendor, and the NRC electronic e-mail capture box as an attachment to an e-mail. The e-mail will copy the NRC electronic e-mail capture mailbox, which must be set up with the Office of the Chief Information Officer (OCIO) prior to the RAI issuance. In using this process for creating an official agency record (OAR) from e-mails, the e-mail and attachment are entered into ADAMS to become an OAR via electronic e-mail capture. Both the draft and final RAIs must be entered into the hearing file as instructed by OGC. It is recommended that each project should have an electronic e-mail capture system. When the PM sends the RAIs to the licensee, applicant, or vendor, the e-mail capture address can be included as a “cc.” There are two different e-mail capture boxes, one for public use and one for non-public (proprietary, etc.) RAIs.

In addition, the development of a hearing file is necessary for litigation before the Atomic Safety and Licensing Board Panel so that the agency may disclose all relevant documents supporting the staff’s review of the application.

### **1.9 Formal Documentation and External Distribution of RAIs**

To maximize the benefits of the RAI workflow, e-mail is used as the vehicle to transmit the RAI to the licensee, applicant, or vendor, and it is the OAR. In the case of COL applications, as an option, posting the RAI and responses to the external website replaces distribution to persons on the service/mailling list. However, the staff should take care to ensure that this arrangement is acceptable to members of the public whose names have been added to the service/mailling list. To achieve these efficiencies, the licensing BC or PM should:

- Reach agreement with the licensee, applicant, or vendor on points of contact, e-mail addresses, and other protocols related to RAIs. The use of a single e-mail address controlled by the licensee, applicant, or vendor to place the burden of internal distribution on the licensee, applicant, or vendor is an efficient method.
- Document the process in a letter with copies to the complete service/ mailing list. The letter should include information on the availability of RAIs via the NRC website and ADAMS. The letter should also clearly state that it is the intention of the NRC not to send paper copies of RAIs.

Note that SUNSI information is handled in accordance with MD 12.5 and internal procedures on the NRC's SUNSI webpage.

### **1.10 Receipt of RAI Responses**

The licensee, applicant, or vendor should be encouraged by the PMs to provide answers to individual RAI questions as soon as the answers are prepared and the licensee, applicant, or vendor is confident of the accuracy of the answers. However, the official response must be sent through the mail or electronically (e.g., by e-mail) or through the Electronic Information Exchange (EIE) to the Document Control Desk to be placed in ADAMS. After the RAI response is processed, it can be distributed within the NRC via the electronic Regulatory Information Distribution (eRIDS) system. The PM must work with OCIO to establish and maintain the eRIDS distribution list. The PM should work with the licensee, applicant, or vendor to establish how RAI responses are to be submitted.

The chapter PM should inform the licensee, applicant, or vendor that e-mail can be used to initially transmit the responses. The chapter PM may reference the eRAI User Manual or Quick Reference Card for guidance.

Once all responses in a licensee, applicant, or vendor's submittal have been entered, the chapter PM uses the eRAI workflow to forward each question with its response to the appropriate safety or environmental TR responsible for reviewing the RAI response. The eRAI workflow places the question "In Evaluation." The eRAI system will generate an e-mail to the TR, providing a link and informing the TR that a response has been assigned to them. The safety or environmental TR reviews the response and determines whether it is acceptable. If it is acceptable, the TR uses the eRAI workflow to status the response as either "Resolved - Closed" or as a "Confirmatory Action." If the TR determines that the response is not adequate, or clarification is needed, the TR should work with the chapter PM to coordinate a path forward (e.g., arrange for a public conference call to discuss the question). If a public conference call is needed, include this information in the eRAI "Notes" field for the parent RAI.

Note the staff should not review draft RAI response as described in Office Instruction COM-203, "Informal Interfacing and Exchange of Information with Licensees and Applicants."

## 2.0 RAI Tracking and Reporting

RAI status is tracked in the eRAI system. In addition, eRAI can generate reports. This report feature can be accessed in the eRAI SharePoint page and can generate reports based on current RAI data.

### 2.1 RAI Status Tracking

The status of RAIs will be maintained in the eRAI system using the eRAI workflow and the fields set up to enter notes and identify related questions. Whether it is an initial response or a supplemental response, the chapter PM receives the response and uses the applicable section in the eRAI workflow to forward the response to the associated safety or environmental TR. The eRAI workflow will change the status to “In Evaluation.” If the response is later revised, the chapter PM is responsible for reopening the question or RAI and setting the appropriate status. The TR is responsible for using the eRAI workflow to change the status from “In Evaluation” to “Confirmatory Action,” “Unresolved - Closed,” or “Resolved - Closed.” The TR is also responsible for documenting the current status in the “Notes” field when the question is noted as other than “Resolved - Closed,” so that, in the future, the path to closure for the question can be understood. In addition, the TR is responsible for noting any related questions in the “Related Question” field for that question.

The question statuses and definitions that are to be used include:

- **Issued/Waiting for Response:** The question has been issued to the licensee, applicant, or vendor, and the NRC is waiting for a response. [Note: This is the only status for a newly issued question.] Follow-up questions are new questions in new RAIs. So, they will also start with this status.
- **In Evaluation:** The licensee, applicant, or vendor has provided a response to the question and it is being evaluated by the NRC.
- **Waiting for Response/Supplemental:** The evaluation of the question identified errors or missing information in the response. This feedback has been provided to the licensee, applicant, or vendor (see Section 3.9). The licensee, applicant, or vendor has committed to provide a supplemental response to revise or supplement an existing response. This is not the same as creating a new follow-up RAI with an associated question (see Unresolved - Closed for additional information).
- **Confirmatory Action:** The licensee, applicant, or vendor has responded to the question. The NRC has reviewed and agrees with the response and the proposed markups, but some action is still needed as part of the response (e.g., FSAR or Technical Report change has not been formally submitted and the update, as committed by the licensee, applicant, or vendor in its RAI response to the FSAR or Technical Report, will need to be verified in the revised document once formally received).
- **Resolved - Closed:** The NRC has accepted the response and no additional issues or concerns are remaining for that question.

- **Unresolved - Closed:** The licensee, applicant, or vendor has provided a response that did not adequately resolve the issue and the staff has either issued a follow-up RAI with associated question(s) or included an alternate path forward that has been coordinated with the PM (e.g., awaiting a public meeting, forthcoming audit, denial, etc.) in the “Notes” field.

Some examples of how to address questions where the response does not adequately address the question include:

- For a question where the licensee, applicant, or vendor responded with a stated need to change the design/methodology or provided a response without specifically addressing the raised issues or committing to a course of action to address the issues, do the following:
  - Update the “Notes” field with a brief discussion of the issue (or provide an alternate path forward external to eRAI that has been coordinated with the PM). Then, workflow the question to “Unresolved - Closed.”
  - If the issue is to be resolved using RAIs, create a follow-up RAI with a description of the issue to ensure the issue is responded to and closed by the entity. Add the follow-up RAI to the “Related Question” field of the original question.
- For a COL question where the COL applicant provided a response but the staff is aware of changes coming in the DC application review that will impact this COL question, workflow the question to “Waiting for Response/Supplemental” and add the explanation in the “Notes” field stating that the COL applicant will revise this response as a result of changes to the DC application.

For unique situations not addressed by the examples above, consult with the chapter PM or PM on proper status conventions.

## 2.2 **External Communications Public Website**

“0100 eRAI Public Report for Website” is a report designed to be posted on the agency public Web page to allow the public to maintain an understanding of the RAI status. The report can be accessed on the eRAI SharePoint page. The PM is responsible for running the report, checking the report for accuracy, making changes and updates to the eRAI data when needed, downloading the report to a PDF, and sending it to [NRRWebServices.Resource@nrc.gov](mailto:NRRWebServices.Resource@nrc.gov) for uploading onto the public website.

## 2.3 **eRAI Reports**

Several reports are available on the eRAI SharePoint page for the NRC staff and management to track the progress of RAIs. Current information related to these reports can be found at the eRAI Reports Library, which provides a listing of the available reports in categories such as status, distribution, and history. These reports can be used by the staff to track status and maintain an understanding of the RAIs and questions in the eRAI system.

## **2.4 Open Item Timeliness**

The New Reactors Business Line previously implemented a process for resolution of open and confirmatory items that provided timeliness expectations as described in a memorandum titled, "Process and Timeline for Closure of Open Items and Confirmatory Items in Safety Evaluation Reports" (ADAMS Accession No. ML100060495), dated January 8, 2010. In practice, the timeliness expectations in Section III.A of the memorandum call for more effort to track than they provide in efficiency improvements. However, it is anticipated that this memorandum will be revised in the future. As a tracking option, the eRAI system contains fields to track the planned and actual response review and SER completion dates for open items. If utilized, the chapter PM should ensure that accurate dates are entered in these fields in accordance with the expectations and the dates negotiated with the technical BC responsible for the review area. The PM should track these dates and contact the TR or his or her technical BC if the dates are not met. The memorandum allows for negotiation between the PM and the TR's BC for difficult review areas or where the system-assigned date of 30 days after the response is received and it cannot be supported. The eRAI Report No. 108 can be used by the PM to check on the status of open items for his or her review area.

## **2.5 Project Performance Tracking**

The eRAI system provides the ability to report on the status of RAIs and questions at routine managerial meetings related to tracking project status and performance. This could include discussing the total number of RAIs, how many have been resolved, how many RAIs remain open in later phases (after Phase 3), and how many RAIs are being tracked as Open Items or Confirmatory Actions. In addition, the staff in the New Reactors Business Line is reminded to adhere to the phase discipline policy guidance provided in the memorandum, "Office of New Reactors Phase Discipline" (ADAMS Accession No. ML18178A568), dated June 29, 2018.

## **2.6 Safety Evaluation Report Appendix of RAIs**

Once the application review is complete and the final safety evaluation report is ready to be issued, eRAI will be used to print out an appendix listing all the RAIs and responses, including dates and ADAMS accession numbers. This is a corrective action put in place to address issues identified with previous licensing reviews and the staff's ability to show how the RAI questions for the review were dispositioned. eRAI Report No. 102 currently fills this function. It can be accessed from the eRAI SharePoint page.