OFFICE OF NUCLEAR REACTOR REGULATION

LIC-115, Revision 1	Processing Requests for Additional Information
Volume 100	Licensing Processes
Approved By:	Michael I. Dudek
Date Approved:	August 5, 2021
Effective Date:	August 9, 2021
Certification Date:	August 9, 2026
Responsible Organization:	DORL

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Summary: This issuance includes changes to add the Request for Confirmation of Information (RCI) process, discussion and examples to Section 4.9, revised Section 4.15, deleted Appendix C and eRAI User Manual and Quick Reference Card as well as editorial and administrative changes.

Training:

RAI: Completed mandatory RAI refresher training in April 2018 for NRR staff and applicable staff in other offices who support NRR licensing reviews.

Licensing: Fundamentals of Reactor Licensing for Technical Reviewers or Fundamentals of Reactor Licensing for Project Managers.

eRAI: Completed initial rollout training in October 2020 for NRR staff and applicable staff in other offices who support NRR licensing reviews. Training aids are available on the eRAI resource page.

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1. POLICY

Staff from the Office of Nuclear Reactor Regulation (NRR) issues a request for additional information (RAI), 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, even when there is no missing information, the staff may still issue an RAI for supporting or confirmatory materials as part of its review. An example would be inputs to an applicant's calculations so the NRC staff can perform independent calculations necessary to support the staff's reasonable assurance findings.[1]

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. RAIs should also not be issued for general knowledge information (i.e., generally known and verifiable by the technical community and available to the public) that 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. RAIs should be as direct as possible and avoid being open-ended.

A specific type of RAIs may be called requests for confirmation of information (RCI). RCIs may be used in cases where the staff has identified specific non-docketed information that is necessary to support a regulatory finding during the review (e.g., during a regulatory audit). The additional information being requested is expected to be limited to providing confirmation, on the docket, of the staff-identified information. RCIs are applicable to low complexity, high confidence, and factual information; and should typically result in a short yes-or-no response from the applicant.

2. OBJECTIVES

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

- regulatory authority that supports request for supplemental information;
- characteristics of a quality request;
- proper construction, review, and transmittal of request;
- role of public meetings and audits in developing questions or requests; and
- required documentation.

The guidance for an RAI applies to an RCI, unless otherwise clarified.[2]

[1] This office instruction uses the term "applicant" to represent licensee, applicant, or vendor, as appropriate.

[2] An RCI is a type of RAI and the distinction between RAI and RCI is somewhat artificial. It is not necessary to specifically refer to an information request as an RCI.

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 enable the staff to obtain information needed to make a regulatory decision on an application so that it is fully informed, technically correct, and legally defensible. The RAI development, submittal, and response process represents an important element in the review of a licensing action. It is important that the RAI process is clearly defined, consistently implemented, repeatable, efficient, and effective to ensure high quality processing of licensing action reviews that is 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 contacts listed for this office instruction. One such improvement that was implemented in this way was the treatment of RCIs.

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 Sections 50.4, 52.3, and 54.7 of 10 CFR, 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

RAI

RAIs enable the staff to obtain information needed to make a regulatory decision on a licensing action so that it is fully informed, technically correct, and legally defensible. RAIs are necessary when the information is not included in the initial submittal, is not contained in any other docketed correspondence, or cannot reasonably be inferred from the information available to the NRC staff. RAIs should be directly related to the applicable regulatory requirements associated with a licensing submittal. 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)), except in cases where deviations are warranted. NRR staff should ensure the policy and guidance in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting,

Issue Finality, and Information Requests," are followed throughout the RAI process.

RAIs should have a clear connection 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 applicant addresses plant-specific aspects for application of the generic approval (e.g., any limitations and conditions approved in the topical report or applicability of the approved traveler to the particular plant design).

RCI

A specific type of RAIs may be called RCIs, which are primarily suitable for applicant non-docketed information that the NRC staff had access to during a regulatory audit, presentation, or public/closed meeting. This type of information may be contained in procedures, reports, analyses, test results, and additional types of information used by the applicant. RCIs can also be used to document statements made by the applicant during audits, teleconferences, and meetings. An RCI is intended to be an efficient process for docketing information that is of low complexity, high confidence, and factual. RCIs are considered RAIs in the electronic RAI (eRAI) system or the Reactor Program System (RPS).

If used appropriately, an RCI can be more effective and efficient than an RAI to support the staff's regulatory finding. While RAIs often make broad requests for information, such as, "provide analysis or justification," RCIs ask yes or no question on specific information for which the staff has already identified a need, such as, "confirm that the maximum system operating temperature is X as shown in onsite records observed by the staff at an audit." Open-ended requests are more challenging to create and respond to completely and could result in follow-up questions. Well defined questions of low complexity that request information that the staff has identified as needed on the docket should be straight-forward to create and respond to completely.

If an applicant decides a simple yes or no response to an RCI is not appropriate, the applicant has the option to submit a detailed response. For example, if the staff's RCI asks the applicant to confirm that the edition of the Code of Record is "X" based on information observed at an audit, the applicant may choose to respond that it is "X," except that the service water system has been upgraded to "Y" during a recent refurbishment. The RCI, in effect, has become a standard RAI because it is not a simple yes or no answer and now the staff has additional information to review.

4.3 Construction

An RAI should consist of three parts in its construction:

1. Clear and concise regulatory basis
   - refer to applicable regulatory standards or acceptance criteria; and
   - refer to relevant guidance documents.

2. Clear and concise technical or regulatory issue
   - describe the issue;
   - refer to applicable part of submittal; and
   - describe security-related issues at a high level, to avoid making the document Sensitive Unclassified Non-Safeguards Information (SUNSI), but detailed enough to be understood, if appropriate. Otherwise, follow the NRC SUNSI guidance and procedures.

3. Clear, concise statement or question identifying the information needed
   - request information to fully resolve the issue; and
   - multiple questions can be grouped in Part 3 if the discussion in Parts 1 and 2 applies to all of the questions.

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   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 Web page. When appropriate, the staff should issue a redacted version of the RAI and make it available to the public (see Section 4.10).

An RCI should consist of the same Parts 1 and 2 as in an RAI. Parts 1 and 2 describe the regulatory basis and the staff’s issue. For an RCI, the request in Part 3 is, however, worded differently than an RAI. It states the specific information that the staff has identified and requests confirmation of its accuracy.

4.4 Quality

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

- regulatory basis;
- technical complexity;
- safety or risk significance;
- similar previous licensing actions;
- appropriate scope and depth;
- information already on the docket; and

- 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.[3]

While RAIs are a means of communicating staff inquiries to the applicant, it should be noted that it is also another means of informing the public regarding identified issues. As such, the staff's request should be sufficiently clear for a member of the public to understand where information is missing in the application and to understand why the information is needed for the staff to make a regulatory finding.

The following table describes the characteristics of a quality RAI:

Necessity	RAIs should have a clear connection to information necessary to make a determination regarding the licensing action. RAIs should request relevant information from the reports, procedures, or calculations instead of submittal of full reports, plant procedures, or calculations. Similarly, RCIs should only request docketed confirmation of information necessary to support the staff's safety finding.
Regulatory Basis	The regulatory basis and underlying 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 without agreement from NRR management and the Office of the General Counsel (OGC). An RAI should be consistent with the plant's licensing basis and applicable codes, standards, and guidance (e.g., Final Safety Analysis Report (FSAR), as updated, RGs, SRPs), unless a deviation is warranted. 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.)

[3] If the information is already in an application, it may be unnecessary to issue an RAI for the sole purpose of adding generally known and publicly available supporting information on the docket.

Clarity	Ensure that an RAI states what information is requested 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 applicant in determining the specific issue of concern. Additionally, offering a contrarian statement to clearly point out the missing information may assist both the reviewers and the applicant 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." Similarly, ensure that an RCI clearly states factual information for straightforward confirmation and describes how the staff became aware of the information.
Conciseness	Ensure the RAI is succinct. It should not contain superfluous information that distracts from the focus of the RAI. It should convey all pertinent information, but unnecessary details may confuse the applicant of the staff's information need.
Comprehensiveness	Ensure the RAI asks the entire question, or that the RCI confirms all needed information. Consider whether other relevant subject matter or topical material related to the RAI must also be considered, formulated, and discussed as another question within the RAI or as a separate RAI. 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 or a broader question would facilitate receiving all of the necessary information. Similarly, an RCI alone is not suitable if all of the needed information to make the necessary finding will not be provided in the applicant's response.
Significance	Ensure the information or confirmation 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 practical, the RAI 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 the 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." A process such as developed by the Division of Safety Systems (DSS) could be considered in communicating the significance of the issue (ADAMS Accession No. ML18017A064).

To ensure high quality of RAIs, it may be helpful to consider the following questions:

- Is the regulatory basis clear, including the specific safety, security, or environmental significance finding that the staff must make and why the information or confirmation being requested is necessary for the staff to reach its finding?
- Is sufficient context provided to understand the significance of the information with respect to whether the licensing acceptance criteria is met? For example, "The application states that there is a 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 request clear regarding what the staff is seeking in the response, such that the applicant's response can fully resolve the issue? In what ways could an RAI, as worded, be misinterpreted to result in an unintended response?
- 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. Appendix B is a Request for Additional Information Quality Control Checklist, which provides an additional aid to technical reviewers and their BCs.

Example RAI Segments	**Comments**
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. 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). 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.	Clear and concise statement of which regulatory requirement(s) constitute the basis.
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.	Summary of relevant guidance document(s), if applicable.

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, are not contributors 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 Updated FSAR. 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.	Description of how the application may not meet the regulatory requirements and how it may be deficient.
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.	Identification of the significance of the question.
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.	Description of information the staff is requesting the applicant to submit to support the reasonable assurance determination.

The following table shows a deconstruction of an example of a quality RCI. This example relates to aging management for license renewal. The left column shows the deconstruction of the example RCI into segments, and the right column shows associated comments addressing quality.

Example RCI Segments	**Comments**
10 CFR 54.21(a)(3) requires demonstration that the effects of aging will be adequately managed for structures and components within the scope of license renewal.	Clear and concise statement of which regulatory requirement(s) constitute the basis.
Section 3.5 of the license renewal application discusses the aging management program for the containment and recirculation spray piping. However, the information is not sufficiently detailed regarding the inspection coverage for the staff to complete its review following the guidance in NUREG-1800, Revision 2, “Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants.” The NRC staff conducted an audit of the applicant’s onsite records to gain understanding and verify	Background on how the information is deficient, and how the staff identified the information to be confirmed.

information submitted in the license renewal application.	
During the audit, the staff examined Table 6.1-1, "Augmented Inspections," Item 2.2.1, "Containment and Recirculation Spray Piping," from the applicant's Technical Requirements Manual and noted that: (a) six 9-inch square patches will be examined by visual (VT-1) and surface examination; and (b) at least 25 percent of the inspection locations are inspected in each one-third portion of each inservice inspection 10-year interval. Please confirm the accuracy of the information of inspection coverage.	Description of the information the staff is requesting to support the reasonable assurance finding. For RCIs, this is a confirmation of low complexity, high confidence, and factual information identified by the staff.

Another application of an RCI is to address document discrepancies. This example relates to a potential administrative issue in a license renewal application identified by the staff.

Example RCI Segments	**Comments**
10 CFR 54.21(c) requires a time-limited aging analysis for license renewal.	Clear and concise statement of which regulatory requirement(s) constitute the basis.
Section 4 of the license renewal application indicates that metal fatigue is a time-limited aging analysis for the plant. The applicant states it has performed a metal fatigue analysis for "X" cycles to bound 80 years of plant operation. However, Reference 4.1 of the license renewal application contains a metal fatigue calculation that shows the analysis was performed for "Y" cycles.	Background on how the information is deficient, and how the staff identified the information to be confirmed.
Please confirm that the analysis was performed for "Y" cycles, not "X" cycles as stated in Section 4 of the application.	Description of the information the staff is requesting. This would correct a potential discrepancy in the application on the docket, so the staff can rely on "Y" cycles in making its regulatory finding.

4.5 Developing a Draft Safety Evaluation (SE) with "Holes" for RAI Response to Close

The staff is expected to develop a draft SE before and during their preparation of 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 efficiency and safety focus by ensuring that 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. Although division management is not required to review and approve first-round RAIs, each division can decide when management would or should do so for their projects of high visibility or those of particularly high safety significance.

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 applicant 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 amendment requests), or where development of the draft SE would have an overwhelmingly negative impact on the schedule not commensurate with the benefit. Other factors to consider may be the complexity of the application, the experience of the technical reviewer in the area of review, and history of technical reviewer in maintaining schedule and discipline. The draft SE with "holes" is a working document that is not needed to be formally transmitted to the PM by the technical BC nor placed into ADAMS.[4] When the technical BC provides the approved RAIs to the PM, the technical BC should indicate whether a draft SE with "holes" was reviewed or was not prepared with a rationale.

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 4.6. (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. This rationale aligns with current office-wide efforts to streamline safety evaluation reports.)

Similarly, the draft SE with "holes" should indicate which statements and findings are predicated on unconfirmed information that is awaiting applicant response to an RCI to close.

4.6 Second and Subsequent Round RAI

When a PM issues a technical branch's initial RAI to the applicant, it is considered a "first-round" RAI. If the same technical branch requests to issue an additional RAI to the applicant in the same technical area, it is considered a

[4] For certain licensing processes, such as traveler and topical report reviews, the staff issues draft SEs to the applicants as formal documents.

"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 should 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. Multiple rounds of RAIs may be needed to ensure adequate protection of public health and safety, as appropriate, if the first RAI did not meet its intent, or if the proposed licensing action is long and/or complex. However, any staff proposal for an additional round of RAIs warrants further assessment. As an example, an additional round of RAIs may be necessary if the applicant was not responsive to the first round RAI. Management should be informed of these cases. If the first-round RAI was not sufficiently clear and led to an incomplete response from the applicant, the staff should consider this lesson learned in developing future RAIs. The staff should also provide feedback to the applicant as appropriate.

Prior to issuing second (and any subsequent) round RAIs, the PM, technical reviewer, and the respective technical and licensing BCs should review the draft SE with "holes" and discuss the need for second or subsequent round 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 applicant should submit formally. The technical and licensing BCs should then discuss the proposed path forward with their division management to obtain agreement of the approach. The PM should only issue second or subsequent round RAIs with agreement from technical and licensing division management.

4.7 Communications with Applicants

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 submission to applicants. Enhanced engagement with applicants should facilitate staff understanding of the applications, reduce the number of RAIs needed, and enhance applicant understanding of staff requests 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 issuing the draft RAIs to the applicant, the PM offers an opportunity for a conference call to clarify the questions, and to confirm or identify any Sensitive Unclassified Non-Safeguards Information (SUNSI) (see Section 4.10). Clarification calls are held after the PM has issued the drafts to the applicant for its review. The intent is to allow the applicant to fully understand the request. At the discretion of the PM, and in consultation with the applicant, a call can be held with the applicant to discuss the draft RAIs to minimize potential misinterpretation

of the wording in the request. The staff can discuss the intent of the staff request and may suggest rewording the question to clarify. A non-public clarification call is not an opportunity for the applicant to provide preliminary answers to the questions and solicit feedback from the staff on the acceptability of the responses. Any discussion of the technical substance of the RAI or its proposed response 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 decisionmaking 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 to identify additional information that an applicant should formally submit for the staff to rely on in its determination. Following the audit, the information to be put on the docket should be requested using an RAI. For example, if the staff examined an applicant's calculation during a site audit and determined the information is necessary to make a finding, then the staff should develop an RAI that requests a summary of the calculation or other relevant information to be submitted on the docket. If the staff identifies specific information (e.g., the value of the net positive suction head margin) in an applicant calculation that is needed to support a regulatory finding, the staff may ask an RCI to get the specific information on the docket. Further information on the audit process is contained in NRR Office Instruction LIC-111, Revision 1, "Regulatory Audits" (ADAMS Accession No. ML19226A274).

The staff's audit is documented in an audit summary. As stated in LIC-111, Revision 1, the audit summary should include a list of staff members that participated, a record of the documents that were audited, a description of the audit activities, and identification of potential RAIs that will be issued based on the audit. The staff should not retain any applicant documents and any RAIs developed as a result of the audit should stand alone in explaining the staff's basis for the request. A regulatory audit allows the staff to gain a better understanding of the application and to issue quality RAIs. It also allows the applicant to submit a quality and timely RAI response. The applicant also has the option to supplement its application to address issues raised at the regulatory audit without the staff issuing any RAIs.

Note: An applicant has the responsibility to provide adequate technical justification for its licensing requests. The staff is not responsible for constructing a technical justification for the applicant through RAIs based on the staff's examination of documents at an audit.

4.9 Consideration of Risk-Informed Decisionmaking 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 part, that "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 decisionmaking that is risk-informed and performance-based not to achieve zero risk, but to arrive at a reasonable assurance of adequate protection finding. This aspect should be considered in the development of RAIs.

The Office of Inspector General (OIG) audited the NRC's use of RAIs in the licensing processes for spent nuclear fuel and found, in part (ADAMS Accession No. ML21103A001):

> …opportunities exist for improvement with regard to enhancing understanding of the risk-informed concept as it relates to RAIs…

The OIG found an inconsistent understanding of applying the risk-informed concept to RAIs. The OIG recommended:

1. Update guidance to document strategies or tools to be used for risk-informing requests for additional information, and

2. Conduct training across the division on how to risk-inform relative to the request for additional information process, and conduct refresher training on an as needed, periodic basis.

Because the SRP, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [light-water reactor] Edition," is written to apply to a broad array of LARs for operating reactors and applications for new LWRs, the staff should be judicious in determining the particular aspects of the SRP to utilize for each review (similar consideration should be applied to guidance for non-LWR and NPUF licensing reviews). 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 that the staff determines are necessary to issue to applicants. The current SRP Modernization effort should develop additional guidance for the depth of review considering risk insights.

Risk insights should be considered in the scope and depth of the staff's review to reach a reasonable assurance finding. Following is guidance on the scope and depth of RAIs for a low-risk issue that is a regulatory requirement (e.g., a regulation, rule, or license requirement; not SRP, RG, or other guidance):

Scope

The applicant must address the requirement in the application. If not, it warrants an RAI.

Depth

If the applicant has addressed the requirement in the application but the staff desires to probe deeper, it becomes a depth of review matter. If the issue is low risk, the staff review, and any RAI should be commensurate with the risk insights. The staff is encouraged to consider the information needed to achieve reasonable assurance of public health and safety. An RAI may not be warranted for low risk issues.

NRR Office Instruction LIC-206, Revision 1, "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, Revision 1, provides guidance on a graded approach for expanding the use of risk insights in licensing and other regulatory activities. It also provides guidance on how to better integrate complementary insights from traditional engineering and risk assessment approaches to foster a broadened understanding of the benefits that risk-informed decisionmaking can bring to the overall regulatory approach. LIC-206, Revision 1, also provides technical staff with tools and guidance to adjust the scope and depth of technical reviews and assist in determining whether RAIs are necessary. The staff should look for opportunities to enhance the integration of risk information into its decisionmaking to improve the technical basis for regulatory activities (including staff RAIs), increase efficiency, and improve effectiveness.

Below is an example of a situation where the staff should issue an RAI to address a regulatory requirement even though it may be of low safety significance:

Example: Regulatory Requirement Issue

An applicant submitted a LAR to modify a postulated design-basis accident, which could potentially result in a harsh environment in the turbine building. The regulations at 10 CFR 50.49 require the environmental qualification of electrical equipment important to safety for design-basis accidents. However, the applicant did not address how they will meet the requirements of 10 CFR 50.49(b)(2), which requires qualification of non-safety-related electrical equipment whose failure under postulated environmental conditions could prevent satisfactory accomplishment of safety-related equipment functions. The staff should issue an RAI for the applicant to address the requirements of 10 CFR 50.49(b)(2).

Below is an example of a situation where the staff may consider not issuing an RAI because of risk insights:

Example: Potential Low Safety Significant Issue

An applicant submitted a LAR addressing Appendix J to 10 CFR Part 50. The applicant requested to extend the containment integrated leak rate test interval based on a topical report, which the staff has approved as an acceptable method to meet Appendix J. The topical report shows that the safety risk is very low. In addition to addressing the conditions and limitations of the topical report, the applicant also provided a brief discussion of its Diverse and Flexible Coping Strategies (FLEX) implemented after the Fukushima accident. With FLEX, the applicant indicated that the plant risk would be further reduced. The staff is considering whether to issue an RAI to quantify the risk reduction with FLEX.

The Integrated Review Team checklist in Section 4.0 of Appendix C in LIC-206, Revision 1, helps guide the staff to determine an appropriate level of review. In this particular case, the applicant proposed to meet the regulation using an NRC-approved methodology; the change is not risk significant as demonstrated in the approved topical report; the extension of the test interval is a precedent that has been approved for many licensees; and defense-in-depth and safety margins are not challenged. Thus, the staff should consider limiting its scope and depth of review. Because the risk is already very low in the approved topical report, further probing of the risk reduction with FLEX would not significantly impact the safety conclusion. The objective of the staff review is to determine whether the LAR provides reasonable assurance of adequate protection of public health and safety, not zero risk. Thus, issuing an RAI to further quantify the risk with FLEX may not be warranted.

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 Web page. The PM may transmit draft RAIs to the applicant 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 applicant is not an official agency record, and additional comments that are outside the scope of the accuracy of the staff's proposed markings should not be accepted or considered by the staff. 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 Office of the General Counsel Review

The PM should submit RAIs related to combined license applications or early site permits to 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. For example, OGC may perform a review of RAIs for license renewal applications that are in litigation.

4.12 Staff Issuance and Licensee Response Timeliness

The PM should issue final RAIs to applicants within 5 business days after the clarification call with the applicant (or the applicant'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 applicant response time. PMs should notify the technical BCs and staff of the date that applicant responses are due to facilitate effective workload planning.

When issuing RAIs, PMs should default to affording an applicant 30 days (60 days for NPUFs; as agreed upon date for topical reports) to respond, and the PM should document this information in the transmittal of the RAIs to the applicant. If the applicant 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 applicant'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 applicants for providing a response. Any applicant requests that are 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 an applicant's extended response 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 otherwise 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 applicant be documented in ADAMS as an official agency record (OAR). This documentation can be included in the formal RAI to the applicant using words such as the following:

> During a phone call with [applicant contact name] of your staff on [date], it was agreed that a response would be submitted 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 applicant timeliness and adherence to RAI response schedules in eRAI or RPS. Any significant delays in applicant responses should be raised to the BCs and division management 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 applicant to develop an acceptable schedule.

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

For all new reactor reviews, the 30-day response clock will start when the draft RAI is issued. If the draft RAI requires significant changes following the clarification call, the staff will either revise the RAI and issue the final RAI or issue a revised draft RAI. The 30-day clock will be restarted if a revised RAI is issued to the applicant.

4.13 Maintaining Official Records

Final RAIs issued to applicants are publicly available OARs and are maintained in ADAMS. The preferred approach is for the PM to e-mail the RAIs to the applicant 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 prepares a draft SE and identifies information gaps within the SE (i.e., “holes”).
2. A technical reviewer prepares an RAI to address the need for additional information to complete the SE.
3. The technical reviewer forwards the RAI by e-mail or eRAI (see Section 4.15) to the technical BC for review and approval. (Note that the staff may not process documents containing SUNSI in eRAI. This is a precautionary restriction to prevent an inadvertent release of sensitive information, as eRAI information is sometimes extracted and used in public reports.)
4. The technical BC either sends the RAI back to the technical reviewer with comments or approves it and forwards the RAI to the PM by e-mail or eRAI. If division management has decided to review and approve all first-round RAIs for its projects of particular significance that include this project, the technical BC forwards the RAI to division management before

forwarding to PM. After division management approval, the technical BC forwards the RAI to the PM.

5. The PM reformats and revises the RAI as necessary. The PM either sends the RAI back to the technical reviewer with comments or forwards the proposed draft RAI to the licensing BC for review and approval.
6. The PM forwards the draft RAI to OGC for review, as necessary. Refer to Section 4.11.
7. The PM must handle and transmit an RAI that contains or potentially contains SUNSI information in accordance with MD 12.5 and internal guidance located at the NRC's SUNSI Web page (see Section 4.10).
8. The PM issues the draft RAI by appropriate means to the applicant. The PM should ask three questions: (1) Can the applicant respond within 30 days (or whatever the agreed upon time is); (2) Does the applicant need a clarification call; and (3) Does the RAI contain any proprietary/SUNSI information.
9. If requested by the applicant, the PM holds a conference call to clarify the draft RAI and to establish a response date.
10. Within 5 business days, the PM issues the final RAI to the applicant 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 may be added to ADAMS as the final RAI.

4.15 Application of eRAI and RPS Systems

The Operating Reactors Business Line projects typically use the RPS system for processing and managing RAI workflow. The New Reactors Business Line projects uses both the eRAI system (i.e., for large and complex projects) and RPS (i.e., for smaller less complex projects) for processing and managing RAI workflow. The eRAI system was developed and customized for new reactor reviews. NRR planned on fully implementing the eRAI system but had issues with functionality of the platform when it rolled out.

NRR management is aware that using different systems may introduce unnecessary complication to the staff's work. As such, currently, NRR management is undertaking efforts to assess both eRAI and RPS system changes and enhancements with the goal of process alignment and an efficient and effective tool for all staff. The PM and technical reviewer should discuss with their BCs on a case-by-case application of eRAI or RPS for new projects in accordance with the ongoing assessments of these electronic platforms.

5. RESPONSIBILITIES AND AUTHORITIES

A. Division Management

Technical and licensing division management is responsible for:

- providing overall management and oversight of staff information request development and processing;
- resolving quality issues;
- reviewing and approving all first-round RAIs for projects of particular significance as management has decided for the division;

- 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 applicant requests of an RAI response date of 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 that staff requests information necessary to support a finding of reasonable assurance of adequate protection of public health and safety; and
- presiding over denial decisions in accordance with LIC-101 if the applicant 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, including reviewing draft SE with “holes,” as appropriate;
- 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 (i.e., RPS) up to date.
- sending RAIs to the PM;
- resolving quality and administrative issues with staff requests;
- presenting RAIs to technical and licensing division management for their agreement, when needed;
- 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 applicant 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 staff requests, per LIC-206;
- ensuring that the staff requests information necessary to support a finding of reasonable assurance of adequate protection of public health and safety; and
- if eRAI is used for the project:
    - workflowing the RAIs to technical reviewer, PM, and division management, as needed.

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, as agreed with the technical BC;
- considering RCIs, as appropriate;
- developing quality requests;
- maintaining work scheduling tools (i.e., RPS) up to date;
- supporting conference calls with the applicant to clarify draft RAIs;
- supporting pre-submittal meetings, audits, and public meetings to facilitate reviews;
- 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 applicant responses;
- presenting draft RAIs to technical and licensing division management for their agreement, when needed
- incorporating applicant 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 or support regulatory findings, in accordance with LIC-206;
- ensuring requests are necessary to support a finding of reasonable assurance of adequate protection of public health and safety;
- appropriately marking and handling documents that contain SUNSI; and
- if eRAI is used for the project:
    - entering RAI questions into eRAI in accordance with the review schedule
    - workflowing the RAI to the technical BC
    - coordinating with the PM to update the “Notes” and the “Related Question” field
    - updating eRAI appropriately for applicant responses.

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 applicant on project status;
- coordinating pre-submittal meetings, clarification calls, audits, and public meetings, as necessary, to facilitate review;
- assessing the quality of the documents provided by the technical staff and providing feedback, including coordinating revisions to ensure consistency and quality across various review groups;
- establishing the RAI response time with the applicant;

- evaluating the impact of applicant 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;
- ensuring applicant responses are received in a timely manner, updating RPS when received, and notifying the technical reviewer of the response;
- coordinating agreement with technical and licensing division management of RAIs, when needed;
- issuing draft and final RAIs to the applicant;
- resolving OGC comments on RAIs, if applicable;
- documenting RAIs in ADAMS in accordance with MD 3.53, "NRC Records and Document Management Program";
- ensuring RAIs request information necessary to support a finding of reasonable assurance of adequate protection of public health and safety; and
- if eRAI is used for the project:
  - coordinating with the technical reviewer to update the "Notes" and the "Related Question" fields
  - updating eRAI when applicant RAI responses are received
  - entering the applicant's 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

6. PERFORMANCE MEASURES

None

7. PRIMARY CONTACTS

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8. RESPONSIBLE ORGANIZATION

DORL

9. EFFECTIVE DATE

August 9, 2021

10. CERTIFICATION DATE

August 9, 2026

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, Frederick 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,” 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 the Inspector General, OIG-21-A-08, “Audit of the NRC’s Use of Requests for Additional Information in Licensing Processes for Spent Nuclear Fuel,” dated April 9, 2021 (ADAMS Accession No. ML21103A001).

7. Division of Safety Systems, Office of Nuclear Reactor Regulation, “DSS Open Item Categorization Process,” added to ADAMS on February 15, 2018 (ADAMS Accession No. ML18017A064).

Enclosures:
1. Appendix A: Change History
2. Appendix B: Request for Additional Information Quality Control Checklist

Appendix A - Change History

Office Instruction LIC-115

Processing Requests for Additional Information

LIC-115, Revision 1 - Change History – Page 1 of 1			
Date	**Description of Changes**	**Method Used to Announce & Distribute**	**Training**
11/06/2019	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) 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.
08/05/2021	Changes in Revision 1 include: (1) added Request for Confirmation of Information (RCI) process, (2) added discussion and examples to Section 4.9, "Consideration of Risk-Informed Decisionmaking in Licensing," (3) revised Section 4.15, "Application of eRAI System," to update the eRAI effort, (4) deleted Appendix C, "Guide for eRAI Workflow Process for New Reactors Business Line," (5) deleted eRAI User Manual and Quick Reference Card as references, and (6) miscellaneous editorial and administrative changes.	E-mail to NRR staff	RCI: NRR staff Town Hall meeting on June 16, 2020. Public meeting on July 28, 2020 (presentation slides in ADAMS at Accession No. ML20212L770). eRAI: Training aids are available on the eRAI resource page.

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

Appendix B

Request for Additional Information Quality Control Checklist

Enclosure 2

REQUEST FOR ADDITIONAL INFORMATION QUALITY CONTROL CHECKLIST

Once the technical reviewer determines that a request for additional information (RAI) is necessary, the following should help determine if the RAI under development meets the minimum guidelines related to a quality RAI.

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

1) The RAI clearly states the regulatory basis at the beginning;

2) If applicable, the RAI cites the relevant guidance document(s) that help clarify the information being requested (e.g., Standard Review Plans, Regulatory Guides, 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 in the application 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); and

6) The RAI clearly identifies the specific information being requested from the applicant 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 technical 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 the 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 Management Directive (MD) 8.4, as appropriate;
- Align with technical and licensing division management as needed; and
- 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).