

# Nuclear Regulatory Commission

## Office of New Reactors

### NRO Office Instruction

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**Office Instruction:** NRO-REG-101

**Office Instruction Title:** Development, Review and Approval Process for Requests for Additional Information

**Revision Number:** 2

**Effective Date:** August 15, 2018

**Primary Contact:** Technical Assistant, NRO/DLSE

**Responsible Organization:** NRO/DLSE

**Summary of Changes:** Updated to enhance the description of the RAI development, review, and approval process based upon conclusions drawn by the NRO Audit Team.

**Training:** Training will be provided upon request.

**ADAMS Accession No.:** ML18199A238

Concurrences			
Primary Office Owner	DLSE Front Office		Date
Responsible Manager	Anna Bradford, Deputy Director, DLSE		7/25/18
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DEI	Director (acting)	Shana Helton	7/24/18
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OFFICIAL RECORD

# NRO Office Instruction

## NRO-REG-101

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### Development, Review and Approval Process for Requests for Additional Information

#### 1. **PURPOSE**

The purpose of NRO-REG-101, “Development, Review and Approval Process for Requests for Additional Information,” is to provide procedural guidance to the Office of New Reactors (NRO) staff and managers in the development, review, and approval of requests for additional information (RAIs). This instruction defines the human and electronic workflow processes associated with the handling and management of RAIs.

#### 2. **GENERAL REQUIREMENTS**

RAIs are necessary when the staff identify the need for additional information to support findings on the safety of a design, operation, and siting, as well as environmental issues in accordance with the U.S. Nuclear Regulatory Commission (NRC) rules and regulations. The information needed addresses missing, incomplete, inconsistent, or unclear information within the application or other docketed correspondence. The staff issues RAIs to obtain the information needed, which may include a set of questions. RAIs should not be issued for information that otherwise could be obtained from the information already available to the staff. RAIs must include concise statements of information needed to complete the technical review, indicate the safety, risk, and/or environmental significance of the issue, and possess a clear and understandable regulatory basis.

RAIs in NRO are processed and tracked using the electronic RAI (eRAI) system, a computer-based control and workflow component of Enterprise Project Management (EPM). This office instructions should be used in conjunction with the [eRAI User Manual](#) located within the eRAI SharePoint page under the Project Documents library. The eRAI User Manual contains a more detailed discussion of the tool’s capabilities and operation. RAIs issued to the applicant, licensee, or vendor, hereafter referred to as “the entity,” are sent in the form of e-mails and are official records in the NRC’s official recordkeeping system, the Agencywide Documents Access and Management System (ADAMS).

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. See Section 3.5 for more information.

Additional background and guidance is available in the pamphlet titled “Request for Additional Information Job-Aid,” (ADAMS Accession No. [ML18199A235](#)).

## 2.1 Reason for Revision

On October 7, 2016, the NRO Director issued a memorandum, “Effective Use of Request for Additional Information, Audit, and Confirmatory Analysis in New Reactor Reviews,” (ADAMS Accession No. [ML16278A574](#)) to all NRO staff which included a revised process for preparing, reviewing, approving and issuing RAIs as part of a broader effort to enhance the efficiency of the new reactor licensing process. A cornerstone of the revised process dealt with technical and licensing division-level review and approval of all RAIs before issuance.

In 2018, NRO formed the RAI Audit Team to assess the quality of issued RAIs and the effectiveness of the current RAI review process, and to recommend improvements for developing, reviewing, and processing future RAIs. The audit team documented its results in an April 6, 2018, report (ADAMS Accession No. [ML18096B421](#)). Subsequently, on May 9, 2018, the NRO Director issued a memorandum, “Effective Use of Requests for Additional Information in New Reactor Licensing Reviews,” (ADAMS Accession No. [ML18110A398](#)) which acknowledged the audit team’s assessment and removed the requirement for division-level-licensing management review and approval prior to issuing RAIs. Revision 2 of this office instruction incorporates guidance from the October 7, 2016, and May 9, 2018, memoranda, and integrates the enhancements identified in the April 6, 2018, audit team report.

## 2.2 Audits

Periodically, NRO management may instruct the staff to conduct an audit of RAI quality and the efficiency and effectiveness of the RAI routing and workflow processes. An example of the RAI evaluation form is attached as Attachment 3 and an example RAI Audit Report is located at (ADAMS Accession No. [ML18096B421](#)).

## 3. SPECIFIC REQUIREMENTS

### 3.1 Background

Title 10 of the *Code of Federal Regulations* (10 CFR) 2.102, “Administrative review of application,” states that during the review of an application by the NRC staff, an entity may be required to supply additional information. Section 2.108, “Denial of application for failure to supply information,” 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 by the NRC staff. RAIs enable the staff to obtain all relevant information needed to make a regulatory decision on a license application or amendment request resulting in an agency document that is fully informed, technically correct, and legally defensible.

The RAI review process ensures that high-quality RAIs are issued. The process involves several levels of review in the technical, environmental and/or security branches and divisions, as well as examination and evaluation by personnel in both the licensing (i.e., projects) and legal (i.e., Office of General Counsel (OGC)) organizations – when warranted. To assist staff and management in this review process, the eRAI system is utilized. The eRAI system is an electronic workflow process tool utilized by staff members across the organizations listed above. The term “workflowing” 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 eRAI system models RAIs as a package of required information (in the form of questions). An RAI may contain one question or multiple questions. Additional guidance related to the use of multiple question RAIs is found in Section 3.3.5. 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.

While RAI processing has defined participation by distinct individuals (e.g., reviewer, lead project manager (PM<sup>1</sup>), branch chief (BC), etc.) the eRAI process is accessible to all NRC staff who are interested in monitoring or viewing the RAI status of a particular application.

### 3.2 Roles and Responsibilities

#### RAI Author (Technical Branch Reviewer (TBR) per eRAI):

The RAI author typically serves as a safety or environmental reviewer and is responsible for:

##### Initial RAI Creation through Evaluation

- Creating high-quality RAIs as defined in Section 3.3.3  
Examples of RAIs can be found in the “Quality RAI Examples,” (ADAMS Accession No. [ML18199A234](#)).
- Creating a preliminary safety evaluation report (PSER) to identify the informational “holes” that the responses to the RAIs are expected to close. Refer to Section 3.4.1 for further guidance. Any deviations from this process should be agreed upon by both the RAI Author’s (technical) and licensing (projects) BCs.
- Entering RAI questions into eRAI in accordance with the review schedule.
- Workflowing the RAI to the RAI Author’s BC (typically a technical BC (TBC)).
- Coordinating with the PM to update the “Notes” and the “Related Question” fields.
- Evaluating RAI responses and updating status within 30 calendar days of the response being entered into eRAI. Any deviations from this process should be agreed upon by both the RAI Author’s (technical) and licensing (projects) BCs.

##### Prior to providing a Safety Evaluation Report (SER)<sup>2</sup>:

- All RAI questions have a status of “Resolved - Closed,” “Confirmatory Action,” or “Unresolved – Closed.”
- A follow-up RAI has been issued for all questions with a status of “Unresolved - Closed” and the follow-up RAI has been added to the “Related Question” field.

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<sup>1</sup> PM may refer to the Lead PM or used as a generic term referring to either the Chapter PM or Lead PM, dependent upon the context in which the term is used.

<sup>2</sup> SER in this context refers only to final SERs, Advance SERs or SERs with or without open items.

Alternatively, for SERs with open items only, the “Notes” field contains an alternate path forward, as coordinated with the PM (e.g., awaiting a public meeting, forthcoming audit, etc.).

RAI Author’s BC (TBC per eRAI) is responsible for:

- Ensuring RAI questions are consistent with Section 3.3.3 and either workflowing the RAI to the Technical Division Management (TDM) for review or providing feedback to author within 3 work days.

RAI Author’s Technical Division Management is responsible for:

- Ensuring RAI questions are consistent with Section 3.3.3 and either workflowing the RAI to the Chapter PM (CH PM) for review or providing feedback to the TBC within 3 work days.

Chapter Project Manager (CH PM) is responsible for:

- Ensuring RAI questions are consistent with Section 3.3.3 and either workflowing the RAI to OGC (depending on review type e.g., non-DCA) or to the Lead PM or providing feedback as discussed below within 3 work days.
  1. In the case of editorial changes to the RAI, coordinate/negotiate with the RAI Author to adjust content of the RAI.
  2. If an unresolved issue exists between the RAI Author and the CH PM, before the CH PM workflows the RAI to his or her Licensing BC (LBC), the CH PM must discuss the issue with the LBC to resolve the issue with the RAI Author’s BC.
- Coordinating with the RAI author to update the “Notes” and the “Related Question” fields.
- Coordinating RAI clarification calls between the entity and the staff, if requested by the entity or the staff.
- When a response is received, entering the RAI response date and response accession number in the eRAI system and forwarding to the RAI Author using the eRAI workflow within 3 working days.
- Ensuring the status in eRAI is consistent with the current phase of the project.

Lead PM is responsible for:

- Ensuring RAI questions are consistent with Section 3.3.3 and either issuing the forward and final RAI to the entity or providing feedback to the CH PM within 3 work days.
- Keeping the entity informed of the RAI status.

- Implementing External Communications by:
  1. Periodically running the [0100 eRAI Public Report for Web site](#) report.
  2. Checking the report for accuracy and making changes or updates to the eRAI data when needed.
  3. Downloading the report to a PDF and sending to [NROWebServices.Resource@NRC.gov](mailto:NROWebServices.Resource@NRC.gov) for uploading on the NRC public Web site.

Licensing (Projects/Division of Licensing, Siting and Environmental Analysis (DLSE)) BC (LBC) is responsible for:

- Reviewing PM feedback related to substandard RAI quality and contacting the RAI Author's BC (TBC per eRAI) or resolve with the PM within 3 work days
- Supporting PMs in communicating schedules for issuing and responding to entities regarding the timeliness of RAI and/or open item responses when needed.

Office of the General Counsel (OGC) is responsible for:

- Reviewing and approving questions promptly, typically  $\leq 4$  business days, as noted in Section 3.4.6.
- Returning substandard RAIs to CH PM, with comments, in cases of legal objection or other concerns.

### **3.3 Development of RAIs**

Prior to composing an RAI, the RAI author should conduct a detailed review of the application against the acceptance criteria in the SRP or DSRS to prepare his/her portion of the SER or the Environmental Impact Statement (EIS). No RAI is needed if the staff is able to complete the SER or EIS, including making its reasonable assurance finding, using the information included in the application, other docketed correspondence, or information otherwise available on the docket.

When insufficient information has been provided to the staff related to a licensing activity such that the staff is unable to provide a reasonable assurance conclusion related to a licensing application or amendment, the staff member may choose to compose an RAI. However, due to the expense, in both cost and schedule, for the creation, review, distribution, and responses related to RAIs, they should only be utilized when other reasonable actions to resolve an issue have not been successful. That is not to say that RAIs should be avoided, rather that before its development, adequate alternative steps to resolve an issue related to insufficient or unclear information should be considered and discussed as appropriate with the RAI author's branch chief.

### 3.3.1 Typical Measures Taken Prior to Development of an RAI

Before composing an RAI, the staff should undertake various actions to resolve the issue(s) in a more timely fashion.

As examples, these other actions may include:

1. Discussions with staff members (in or outside one's branch) and/or one's branch chief.
2. Phone calls with the entity (when properly noticed).
3. E-mail correspondence (non-substantive) from the PM to the entity.
4. Focused audits in accordance with NRO-REG-108, "Regulatory Audits." (Any information from the audit that will be used to form a staff conclusion within the SE will need to be added to the docket.)

If any of those other mechanisms fail to produce the proper information, and an RAI appears to be the next logical step, the individual should begin composing a high-quality RAI.

### 3.3.2 Electronic Resources to Assist Staff in RAI Workflow Process

There are several electronic tools and resources to assist the RAI developer, reviewer, and approver in the RAI workflow process. Examples of these items are listed below:

[eRAI Home Page](#) – Provides the user access to the eRAI Production Website

[eRAI User Manual](#) – Provides users with a reference guide on how to use eRAI

[eRAI Quick Card](#) – Provides a 2-page reference guide for getting started with eRAI and a basic eRAI workflow process

[Request for Additional Information Job-Aid](#) – Assists the RAI Author while creating an RAI

[Quality RAI Examples](#) – Provides examples of high-quality RAIs to users

[RAI Quality Control Checklist](#) – Presents questions to all users that support the creation, review and approval of a quality RAI

[The eRAI 'Project Documents' Page](#) – Lays out many references for eRAI Users

### 3.3.3 Characteristics of a High-Quality RAI

A high-quality RAI typically possesses several critical attributes to ensure that the intended audience understands what information is being requested in the RAI. The RAI Quality Control Checklist (ADAMS Accession No. [ML18199A233](#)) captures the characteristics described below in a series of questions along with additional considerations specific to branch chiefs and division management and should be referenced by authors and reviewers before approving each RAI. Authors should also review the [Quality RAI Examples](#) and [Request for Additional Information Job-Aid](#) for additional information on RAI quality.

Necessity	RAIs are necessary when the information being requested is: (1) not already available through another docketed source (e.g., information contained in another chapter of a final safety analysis report (FSAR) or other docketed material — a technical or topical report); and (2) technically relevant to the discussion and conclusions in the safety evaluation.
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 section of the SRP the author is using. 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(a) or § 52.6 in the regulatory basis <sup>3</sup> .
Clarity	Ensure the RAI states what information is required or has been presented in an unclear fashion. It may be helpful to refer to the specific section under scrutiny (e.g., which subsection of an FSAR) to aid the entity in determining the specific issue of concern. Additionally, offering a converse or contrarian statement to clearly point out what information is missing from the specific portion of the text provided by the entity may assist both the reviewers and the entity in determining what specific information is being requested. Finally spell out any acronyms during their first use within an RAI.
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 <i>entire</i> 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 or as another RAI entirely.
Significance	Ensure the information requested in the RAI clearly documents the safety, risk, security, or environmental significance of the issue with respect to the licensing acceptance criteria that will be met to provide a reasonable assurance determination. Whenever possible, the RAI question should include a quantitative assessment of the safety, risk, security, and/or environmental significance and clearly communicate how the staff’s concern, if not properly addressed, could result in NRC regulations not being met.

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<sup>3</sup> An RAI that cites to § 10 CFR 50.9 or 10 CFR 52.6 is legally objectionable. If a licensee willfully omits information from an application or willfully provides inaccurate information, the staff should initiate enforcement action against the licensee. The omission of information or inclusion of inaccurate information in an application, without indication of a willful action, does not indicate a violation of § 10 CFR 50.9 or 10 CFR 52.6.

### 3.3.4 RAI Structure

To enable a more efficient review, RAIs are structured as discussed below.

The first portion of an RAI begins with stating the regulatory basis behind the information being requested. In addition, any relevant guidance should also be provided to aid in clarifying the exact issue under consideration. Next, the RAI Author should present the issue in a fashion that points the reader to the specific information within the specific document in question, (e.g., “In Section 2 of LAR 18-XXX, the licensee states...”). Then the potential issue with that information should also be provided. Often, a contrarian or converse statement may be utilized to concisely point out why the issue of concern is an issue at all (e.g., failure to meet the guidance without explaining why taking this approach is acceptable).

Within the contrarian statement or directly after it, the RAI Author should explain *why* the issue is a concern of significance from a technical, environmental, safety and/or security standpoint. In this explanation, the author should take care to provide a detailed technical (or environmental or security) explanation that an individual within his/her specific discipline can understand and interpret. However, the issue should also be stated in a manner such that an individual who is performing a review or approval function for the RAI, and who may not be a technical expert in the given topical area, is able to understand the issue. The use of examples as part of the significance reasoning may offer better understanding to all parties.

Finally, the author should specifically request what information he/she is seeking from the entity so all stakeholders understand the context, content, and amount of information being requested. An example of typical RAI structure is included as Attachment 2 and links to specific examples of high-quality RAIs are included in the [“Request for Additional Information Job-Aid.”](#)

### 3.3.5 Multiple-Question RAIs/ Sub-Questions within RAIs

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 meets the attributes of Section 3.3.3.
- 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.

### 3.4 RAI Workflow Process

The RAI development, review, and approval processes have been established to ensure that only high-quality RAIs are distributed outside of the NRC. The RAI review process is managed via 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., TBC, CH PM, PM, etc.) within the RAI review and approval process. A process diagram is depicted as Attachment 1.

An individual's role and responsibilities along with the actions he or she must take to accomplish different stages of the RAI review and approval process are listed below and in Section 3.2.

#### 3.4.1 RAI Author (TBR per eRAI) Creates an RAI

The RAI Author determines that information critical to the safety evaluation's conclusion is missing, unclear, or unsupported based upon the information in the submittal and, after researching other avenues, has yielded limited or no success, such that development of an RAI is necessary. (Refer to Section 3.3.1 for additional information.)

When initially drafting an RAI, the Author should review Section 3.3.3, "Characteristics of a High-Quality RAI" to ensure the RAI reflects these attributes. Additionally, the Author may choose to consider the [Quality RAI Examples](#) to assist in facilitating the development of high-quality RAIs and the [eRAI User Manual](#) to assist the Author when filling out the eRAI fields.

While drafting an RAI, the RAI Author and his or her review team, as assigned, are expected to develop a 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 entity and also reveal areas where information necessary to reach a reasonable assurance determination is lacking.

NOTE: If the RAI contains SGI, SUNSI, ECI, or [CEII](#) information, the sensitive information is NOT to be added to the question content. Refer to Section 3.5 for additional information.

When generating an eRAI, the RAI Author determines whether or not the RAI is for a design certification (DC) review. The eRAI system is designed to automatically include 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. See [eRAI User Manual](#) for specifics.

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

The RAI Author:

1. Fills out all asterisked fields in the input form to enter an RAI in the system. (If the author does not know the names of all participants other than his/her BC, the CH PM's name should be provided in those fields.)
2. Enters questions into the eRAI using the question format described above.
3. If this is a follow up question, the RAI Author would enter all related questions into the "Related Questions" field in eRAI using the button in the menu.

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

### **3.4.2 RAI Author's Branch Chief (TBC per eRAI) Reviews the RAI**

When notified via e-mail that an RAI has been received for review, the TBC 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 for consistency with Section 3.3.3. Changes to the questions should be discussed with the RAI Author. The RAI Author's BC may send the RAI back to the RAI Author via the workflow process to make major changes, or the TBC may make minor changes for the author at his or her discretion. If the Chapter PM field does not include the name of the appropriate CH PM, the Author's BC should complete the field with the name of the appropriate CH PM.

Once any changes to the RAI and its questions have been completed, the RAI Author's 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 TBC's division management for review and approval.

The TBC should provide feedback to the author or forward (workflow via the eRAI system) the RAI to the TDM within 3 work days of being assigned in eRAI.

### **3.4.3 Technical Division Management (TDM) Reviews the RAI**

When notified via e-mail that an RAI has been received for review, the TDM 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 for consistency with Section 3.3.3. Changes to the questions should be discussed with the RAI Author's BC. The TDM may send the RAI back to the RAI Author's BC so that the TBC can work with the RAI Author to resolve any deficiencies or make minor changes for the author.

Once any changes to the RAI and its questions have been completed, the TDM 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 CH PM for review and approval.

The TDM should provide feedback to the TBC or forward (workflow via the eRAI system), the RAI to the CH PM within 3 work days of being assigned in eRAI.

### **3.4.4 Chapter PM (CH PM) Reviews the RAI**

When notified via e-mail that an RAI has been received for review, the CH PM 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 for consistency with Section 3.3.3.

Editorial or minor changes that have no impact upon the technical, environmental, safety, or security related information may be made by the CH PM without technical consultation. However, it is recommended that the CH PM consult with the RAI Author 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 RAI Author prior to finalizing that change.

If, after consultation with the RAI Author, the CH PM believes there is an issue of insufficient quality as it relates to one or more questions within an RAI, the CH PM will not approve the question and may choose to use the “Notes” field to describe the issue(s). The CH PM should not workflow the RAI to the Licensing BC, however the CH PM should contact and discuss the issue with the Licensing BC and take the appropriate steps to resolve the situation. Refer to Section 3.4.5 for further guidance.

Within the eRAI system, the CH PM also verifies the asterisk marked fields to ensure the correct contacts are included and enters the remainder of the entity’s information in the “non-asterisk” fields.

Different design centers have the option of allowing the Lead PM, noted as “Project Manager” in the associated eRAI field (and abbreviated as (PM)) or the CH PM to process RAIs. Assigning the CH PM’s name as the Lead PM for the particular RAI allows the CH PM to process RAIs; however, in this case the electronic field related to the “role” of Lead PM must have the CH PM’s name in it in order for the CH PM to formally distribute the RAIs to the given entity. With this approach, the individual would see the RAI twice, first as CH PM, then as Lead PM. Regardless, prior to the RAI being issued, the Lead 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 CH 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.

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

### **3.4.5 Licensing (Projects/DLSE) (LBC) Reviews the RAI**

When notified via e-mail that an RAI has been received for review, the LBC 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 for consistency with Section 3.3.3.

Editorial or minor changes that have no impact upon the technical, environmental, safety, or security related information may be made by the LBC without technical consultation. However,

it is recommended that the BC consult with the CH 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 CH PM or RAI Author prior to finalizing that change.

Once any changes to the RAI and its questions have been completed, the LBC 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 LBC should submit the approved RAI via the workflow process to the OGC Attorney for review and approval. OGC attorney concurrence is necessary for all RAIs when a hearing is required, such as in the case of Combined Licenses (COLs) or Early Site Permits (ESPs). If the RAI is a DC RAI, the BC should submit the approved RAI via the workflow process to the Lead 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 CH PM or the Technical BC, or forward to OGC or the Lead PM via the workflow process described above.

#### Resolution of Potential Quality Issues

If, after consultation with the RAI Author or CH PM, the LBC believes there is an issue of insufficient quality as it relates to one or more questions within an RAI, the LBC should contact the TBC to discuss the issue(s), then take the appropriate steps to resolve the situation. The Licensing BC may direct the CH PM to workflow to the RAI back to the RAI Author’s BC so that he or she can work with the RAI Author to resolve any deficiencies or the CH PM may make changes and workflow the resolved RAI to the LBC. The LBC will then review/approve the RAI following the instructions at the start of this section.

#### **3.4.6 OGC Reviews the RAIs for COLs and ESPs**

A hearing is required for COL and ESP applications. OGC reviews RAIs to ensure clarity and confirm that there is a regulatory basis for issuing the RAIs. Moreover, the development of a hearing file is necessary in litigation before the Atomic Safety and Licensing Board so that the agency may disclose all relevant documents supporting the staff’s review of the application. Therefore, OGC should review<sup>4</sup> 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. The staff must initiate all OGC RAI reviews through the OGC mailroom ([OGCMailCenter.Resource@nrc.gov](mailto:OGCMailCenter.Resource@nrc.gov)) separately via 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

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<sup>4</sup> 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.”

awareness of the eRAI workflow steps that will be taken and allows it to respond, should the given OGC representative deem it appropriate.

As with the PM review, minor changes that do not affect technical content of the question can be made by the attorney. Significant changes are brought to the attention of the CH PM, who is expected to discuss them with the RAI Author and/or the author's 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 Lead 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 Lead PM to undertake the appropriate action.

### **3.4.7 Lead PM Reviews the RAI**

When notified via e-mail that an RAI has been received for review, the Lead PM (PM), noted as the "Project Manager" in eRAI, 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 for consistency with Section 3.3.3. 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 CH PM or RAI Author and been unable to reach resolution, the PM must workflow the RAI to the CH PM and have the CH PM take the appropriate steps to resolve the situation. Refer to Section 3.4.4 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 entity.

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

As discussed in Section 3.4.4, the PM role is assigned as determined by the Design Center – it can be the actual PM for the project or the CH 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 RAI Author or the LBC, or transmit the ARAI, whose definition appears above, within 3 work days of being assigned in eRAI.

The PM sends the ARAI to the entity with the following questions:

- 1) 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.]
- 2) Can the entity respond within 30 days or other predetermined time period? If not, how long will it take to respond and what is the reason for the additional response time?

- 3) Does the entity need a clarification phone call regarding the request before it begins to answer it?

The entity is expected to respond to the question(s) listed above within 5 work days. If the entity requests a clarification call, the staff should strive to set that call up within five work days. If the clarification call results in a substantive revision<sup>5</sup> 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 entity'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 entity 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.

### **3.5 RAIs Containing ECI, SGI, SUNSI, or CEII**

Currently, ECI is treated as proprietary which is SUNSI. It's NRO's practice that no SGI or SUNSI can be included in the system. The "Sensitivity" field is used to flag the RAI questions that are SUNSI or SGI. 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 (SLES) may be used for this purpose). RAI questions containing SUNSI material are prepared outside of the eRAI system, following the appropriate controls for SUNSI material. When the RAI is issued, the (Lead) 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 CH 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 nonpublic versions of the RAI documents.

The "RAI Accession No." and "Response Accession No." fields should point to 'Publicly Available' versions of SUNSI documents. While NRC controls the RAI to be issued, the entity controls the structure of its submittal. The entity 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). 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 users access (web-based ADAMS restricting the public to publicly available documents only).

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<sup>5</sup> A substantive revision to an RAI includes significant changes to the regulatory basis or scope of an RAI such that the entity would reasonably require recapturing of time elapsed on the response clock to support a timely RAI response.

### **3.6 Conference Calls with the Entity (Applicant/Licensee/Vendor)**

Non-public conference calls may be used to provide clarification and discuss response timing of RAIs that have been issued to the entity. PMs and technical staff should use this flexibility to ensure the most timely and efficient interactions with entities to support the NRC review process. However, RAI discussions involving the entity's response must be public in accordance with guidance provided in [Management Directive \(MD\) 3.5](#), "Attendance at NRC Staff-Sponsored Meetings," to ensure that all discussions on the technical substance of a proposed licensing action occur in a public forum, as required by the Commission, and that NRC's decision making process is conducted in accordance with its openness and transparency goals.

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

Before the RAI is issued final, the Lead PM (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 Lead 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 entity 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 (must be set up with the Office of the Chief Information Officer (OCIO) prior to the RAI issuance). In using this process for creating Official Agency Records (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 official 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 entity, 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.

### **3.8 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 entity, 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/ mailing 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/ mailing list. To achieve these efficiencies, the LBC or PM should:

- Reach agreement with the entity on points-of-contact, e-mail addresses, and other protocols related to RAIs. The use of a single e-mail address controlled by the entity to place the burden of internal distribution on the entity 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.

### 3.9 Receipt of RAI Responses

The entity should be encouraged by the PMs to provide answers to individual RAI questions as soon as the answers are prepared and the entity 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 Lead PM must work with OCIO to establish and maintain the eRIDS distribution list. The Lead PM should work with the entity to establish how RAI responses are to be submitted. (Refer to discussion in the latter portion of Section 3.5).

The CH PM should inform the entity that e-mail can be used to initially transmit the responses. The CH PM is to follow the [eRAI User Manual](#) available on the eRAI SharePoint page. Another useful and quick reference document for the PM is also located within the eRAI SharePoint page is the pamphlet [eRAI Quick Card](#).

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

### 3.10 RAI Status Tracking

The status of RAIs will be maintained in the eRAI system by the licensing branch and cognizant reviewers 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 CH PM receives the response and uses the applicable section in the eRAI workflow to forward the response to the associated safety or environmental reviewer. The eRAI workflow will change the status to "In Evaluation." If the response is later revised, the CH PM is responsible for reopening the question or RAI and setting the appropriate status. The reviewer is responsible for using the eRAI workflow to change the status from "In Evaluation" to "Confirmatory Action," "Unresolved - Closed," or "Resolved - Closed." The reviewer is also responsible for documenting the current status in the "Notes" field when the question is statused as other than "Resolved - Closed" so that in the future the path to closure for the question can be understood. In addition, the reviewer 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 entity 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 entity 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 entity (see Section 3.9). The entity 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 entity 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 is not complete (e.g., FSAR or Technical Report (TR) change has not been formally submitted and the update, as committed by the entity in its RAI response to the FSAR or TR, 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 entity 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, 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 entity 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 examples above, consult with the CH PM or PM on proper statusing conventions.

### 3.11 Internal Communications

The eRAI process is intended to improve the efficiency of processing RAIs for the office and reduce the processing time through electronic transmission and work flow, and providing up to date status. This process is not intended to replace the normal communication channels that exist between the licensing staff, technical staff, management, and entities. Maximum work flow efficiencies can be realized by maintaining effective communications among all those involved in using the eRAI workflow tool. While internal staff discussions are not necessarily expected at each step, it is important for each individual in the process to recognize and initiate communication outside of the process when needed.

The PMs must follow all questions waiting for a response to ensure that the response is submitted by the agreed upon response date. The PMs need to work closely with the technical staff when public meetings are being held with the entity to discuss an RAI response. Close coordination between PMs and technical staff ensure that a unified NRC position is presented and that the response is evaluated in a timely manner. The PM and CH PMs must establish their respective roles and responsibilities regarding the oversight and management of RAIs and keep the technical staff informed if there are changes made to the roles of the PMs (e.g., will the “PM” role in eRAI be filled by the Lead PM or the CH PM for all RAIs – if not following the standard approach, identify which RAIs will have the CH PM fulfilling the Lead PM role).

### 3.12 External Communications

“[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 [NROWebServices.Resource@NRC.Gov](mailto:NROWebServices.Resource@NRC.Gov) for uploading onto the public website.

### 3.13 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.

### 3.14 Open Item Timeliness

NRO 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 called for more effort to track than they provided 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 CH PM should ensure that accurate dates are entered in these fields in accordance with the expectations and the dates negotiated with the TBC responsible for the review area. The PM should track these dates and contact the reviewer or their TBC, if the dates are not met. The memorandum allows

for negotiation between the PM and the reviewer's TBC 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 their review area.

### **3.15 Project Performance Tracking**

The eRAI system provides the licensing branch with 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 NRO staff are 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, or its most recent revision.

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

Once the application review is complete, and the final safety evaluation report, (FSER) 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. The [eRAI Report No. 102](#) currently fills this function. It can be accessed from the [eRAI SharePoint](#) page.

## **4.0 REFERENCES**

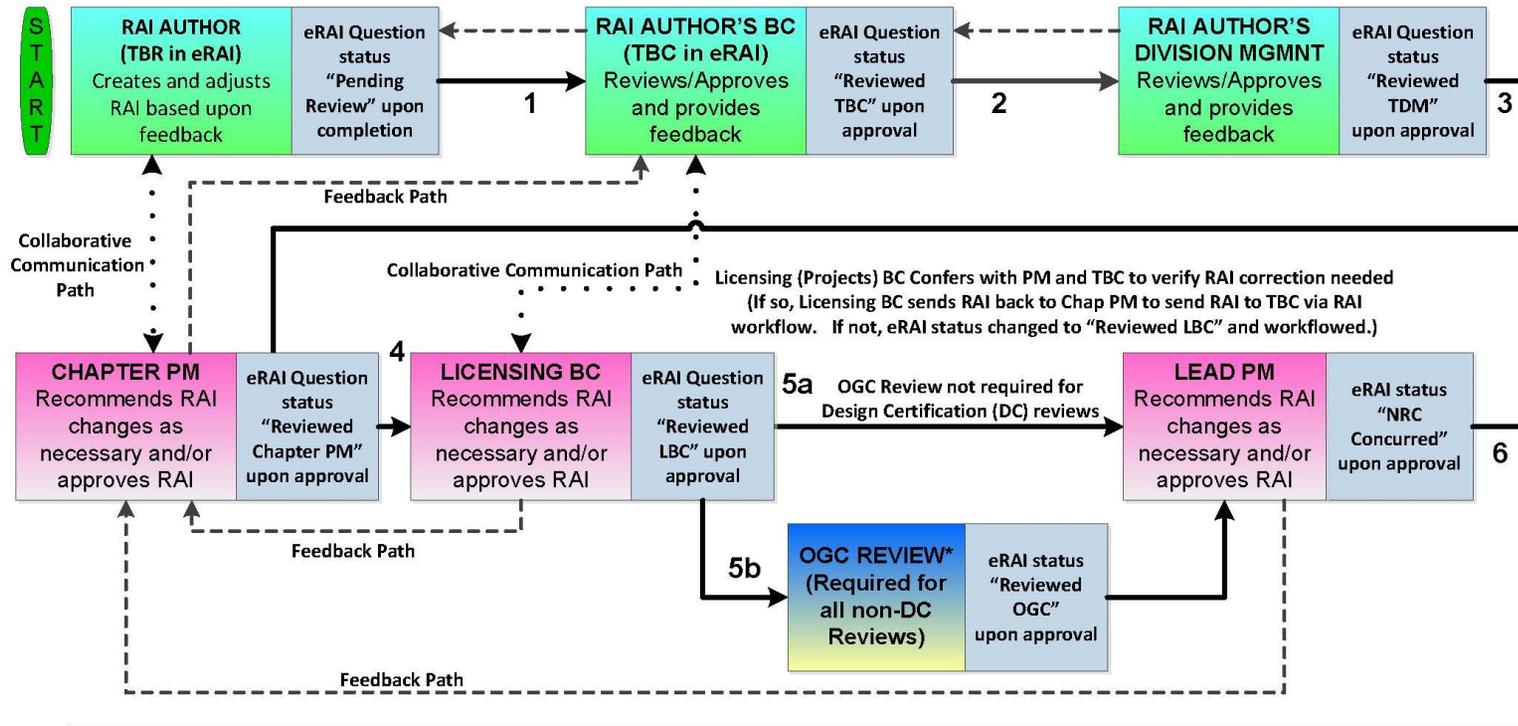
1. "Request for Additional Information Job-Aid" (ADAMS Accession No. [ML18199A235](#)).
2. Office of New Reactors, "Request for Additional Information Audit Team Phase 1 Report," ADAMS Accession No. [ML18096B421](#)
3. Brown, Fredrick D., Office of New Reactors, "Effective Use of Requests for Additional Information in New Reactor Licensing Reviews," issued May 9, 2018, ADAMS Accession No. [ML18110A398](#).
4. Office of New Reactors, "eRAI 3.0 User Manual," issued March 2018 ([eRAI User Manual](#))
5. Bradford, Anna H., Office of New Reactors, "Office of New Reactors Phase Discipline," issued June 29, 2018, ADAMS Accession No. [ML18178A568](#).
6. Akstulewicz, Frank M., Office of New Reactors, "Process and Timeline for Closure of Open Items and Confirmatory Items in Safety Evaluation Reports," issued January 8, 2010, ADAMS Accession No. [ML100060495](#).
7. Uhle, Jennifer L., Office of New Reactors, "Effective Use of Request for Additional Information, Audit, and Confirmatory Analysis in New Reactor Licensing Review," issued October 7, 2016, ADAMS Accession No. [ML16278A574](#).

**5.0 ACRONYMS**

ADAMS	Agencywide Documents Access and Management System
ARAI	Advance RAI
BC	Branch Chief
CEII	Critical Electric Infrastructure Information
CFR	Code of Federal Regulations
CH PM	Chapter PM*
COL	Combined License
DCIP	Division of Construction Inspection and Operational Programs
DEI	Division of Engineering and Infrastructure
DLSE	Division of Licensing, Siting, and Environmental Analysis
DSRA	Division of Safety Systems, Risk Assessment and Advanced Reactors
DSRS	Design Specific Review Standard
eRAI	Electronic RAI
eRIDS	Electronic Regulatory Information Distribution System
ECI	Export Control Information
EIE	Electronic Information Exchange
EIS	Environmental Impact Statement
EPM	Enterprise Project Management
LAR	Licensee Amendment Request
LBC	Licensing Branch Chief (may also be referred to as Projects BC)
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
OAR	Official Agency Record
OD	Office Director
OGC	Office of General Counsel
PM	Lead Project Manager* (may also refer to a Project Manager)
PSER	Preliminary Safety Evaluation Report
RAI	Request for Additional Information
SER	Safety Evaluation Report
SGI	Safeguards Information
SLES	Secure Local area network Electronic System
SRP	Standard Review Plan
SUNSI	Sensitive Unclassified Non-Safeguards information
TBC	Technical Branch Chief
TBR	Technical Branch Reviewer (may also be referred to as RAI Author)
TDM	Technical Division Management

\*Consistent with abbreviations found  
in eRAI

# ATTACHMENT 1 – NRO RAI REVIEW AND APPROVAL PROCESS THROUGH INITIAL RAI ISSUANCE



**NOTES:** 1. Sending Advance RAIs is a standard practice, but it is not accounted for in the eRAI process.  
 2. In eRAI, the individual's role when sending the formal RAIs must be "Lead PM"

\*Refer to the appropriate "RAI Workflow Process" section of this OI (NRO-REG-101).

 TECHNICAL/ENVIRONMENTAL BRANCH/DIVISION (typically, may also be from NSIR)	 LICENSEE/APPLICANT/VENDOR	→ APPROVAL WORKFLOW PROCESS
 DLSE (PROJECTS or LICENSING) BRANCH	 eRAI QUESTION WORKFLOW STATUS	← FEEDBACK PATH (when required)
 OFFICE of GENERAL COUNSEL (OGC) REVIEW	<b>1 - 8</b> WORKFLOW PROCESS STEPS	◀ • • ▶ COLLABORATIVE COMMUNICATION PATH

## ATTACHMENT 2 – RAI STRUCTURE

An RAI should begin with stating the regulatory basis behind the information being requested.

Next, provide a summary of relevant guidance document(s) to aid in clarifying the exact issue under consideration.

Following that, provide a discussion of where the application does not meet the regulatory requirements and how it may be deficient.

Whenever possible, include a specific example of why the application does not meet the regulatory requirements cited above (e.g., failure to meet a regulation).

An example supporting both the deficiency in the application and the associated request can be helpful. This may include an explanation of what the staff expects the applicant to provide.

Clearly identify the safety, risk, or environmental significance of the question in a way that the applicant, staff, and outside interested parties are able to understand.

Specify what specific information the staff is requesting from the applicant to support the reasonable assurance determination. (The “significance” section above should support the “why” the information is necessary)

**ATTACHMENT 3 – RAI QUALITY EVALUATION FORM**

Number	Attribute	Evaluation Question	Evaluation (1, 2, 3)	Comments: (If a 1 or 2, explain why)
1	Necessity	The RAI is necessary when: (1) the requested information is not located in the application, or in other docketed material; and (2) the information is technically relevant to the reasonable assurance determination in the SE; or (3) the information does not meet the requirements of 10 CFR 50.9(a) related to its consistency and/or accuracy.		
2	Regulatory Basis	Is the regulatory basis and underlying guidance clearly stated in the body of the RAI?		
3	Clarity	Does the RAI clearly state what information is required or what information has been omitted or has been presented in an unclear fashion? Is the reasoning clear to those who are involved with the review and approval process?		
4	Conciseness	Is the RAI written in a concise manner (i.e., does not contain unnecessary detail)?		
5	Comprehensiveness	Does the RAI ask the “entire” question or are there other subject matter for the same topic that should be considered, described and asked when formulating the question?		
6	Significance	Does the information requested in the RAI directly apply to the risk, environmental or safety significance of the conclusion drawn in the safety evaluation?		

For each question above, the evaluator should grade each RAI attribute utilizing the following grading criteria:

- 1 = RAI does not meet attribute (i.e., answer to question is “No.” Explain why RAI does not meet attribute)
- 2 = RAI partially meets attribute (Explain why RAI does not fully meet attribute)
- 3 = RAI fully meets attribute (i.e., answer to question is “Yes”)

(If the Evaluation Grade is a “1” or a “2”, the evaluator must comment as to why the question has not earned a value of “3”.)

**In order for RAI to be considered ready for distribution to the applicant/ licensee, the RAI Attributes must each earn a value of “3”.**

