Nuclear Regulatory Commission
Office of New Reactors
NRO Office Instruction

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Office Instruction Title:	Processing Requests for Additional Information
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Responsible Organization:	NRO/DNRL/NOEP

Summary of Changes: This issuance of NRO-REG-101, "Processing Requests for Additional Information (RAIs)," provides the guidance on the procedure to be used for use of the RAI process in the Office of New Reactors (NRO).

Training: Group training

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Concurrences			
Primary Office Owner	Organizational Effectiveness and Productivity Branch		
Responsible Manager	Stephen S. Koenick, Acting		03/05/2008
DDNRL	Deputy Director	Patrick Madden	03/06/2008
OGC			02/11/2008
DDNRL	Director	David Matthews	03/06/2008
DSER	Director	James Lyons	03/27/2008
DCIP	Director	Glenn Tracy	03/11/2008
DSRA	Director	Charles Ader	04/14/2008
DE	Director	Michael Mayfield	04/16/2008
ODNRO	Deputy Director	Gary Holahan	05/14/2008

OFFICIAL RECORD

NRO Office Instruction
NRO-REG-101, Rev. 0

"Processing Requests for Additional Information"

1.   PURPOSE

The purpose of NRO-REG-101, "Processing Requests for Additional Information (RAIs)," is to provide procedural guidance to the Office of New Reactors (NRO) staff and managers regarding the basis for developing RAIs (containing non-proprietary information) and their processing through the use of the computer-based control and workflow component, electronic RAIs (eRAIs). The guidance is to be used in conjunction with the user's guide,[1] which contains a more detailed discussion of the tool's capabilities and how to operate them. This office instruction (OI) and the user's guide are based on an initial version of the computer-based tool. Use of the final software package will be addressed in subsequent OI revisions. Although the workflow process has general applicability to the processing of RAIs for most situations, as discussed in this OI, the eRAI is directed toward review of combined license (COL) applications (COLAs) and, with only minor changes, to review of design certifications (DCs).

During the review of applications for new reactors (*e.g.*, COLAs or DCs), typically there is information not included in the application yet determined to be necessary in order for the staff to reach a conclusion that the application conforms to the U.S. Nuclear Regulatory Commission (NRC) rules and regulations and that there is "reasonable assurance" that operation of the power plant or application of the technology will protect people and the environment. The information received as a result of a staff RAI frequently becomes part of the basis for staff acceptance of the application and is referenced in the safety evaluation report (SER). Consequently, it is imperative that the RAIs are correctly developed, reviewed, and issued to the applicants. Applicant's RAI responses are supplements to the application and must be submitted under oath or affirmation. While DC applicant's RAI responses do not have to be submitted under oath or affirmation, it is still important that the processing of RAIs is thorough and controlled.

Background information on the policy basis governing the applicability of RAIs in the licensing process is found in Section 4.3 of Office of Nuclear Reactor Regulation (NRR) OI LIC-101, Revision 3, "License Amendment Review Procedures."

While the particular process described in this OI is directed toward the processing of applications for COLs and DCs, guidance is focused on the process rather than the step-by-step procedures. More detailed information is available in the RAI Tracking Tool Release 1 User's Reference Guide.

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[1]   The reviewer accesses the User Guide from Enterprise Project Management (EPM) as follows: from EPM click on the TECHSUPPORT tab; on the upper center of screen under EPM Staff Guidance, select the Procedures Folder; select the document titled, "RAI Tracking Tool User Guide v 1.0."

As mentioned earlier, this OI is based on an initial version of the software. Subsequent revisions will permit the staff to generate RAIs, obtain internal concurrence, and issue them to the applicants electronically. Responses to RAIs may also be received electronically, in advance of oath or affirmation. This electronic processing will minimize delays in availability of technical information resulting from administrative processing.

2.   <u>GENERAL REQUIREMENTS</u>

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 staff. RAIs should be directly related to the applicable requirements related to the submittal, and consistent with the applicable codes, standards, regulatory guides, and/or the applicable standard review plan (SRP) sections.

It is expected that before the staff determines that an RAI is needed, the submittal has been reviewed for accuracy and completeness, and the need for additional information in order to reach a regulatory determination is clear and unambiguous.

3.   <u>SPECIFIC REQUIREMENTS</u>

RAI as modeled in the eRAI software refers to a package of required information (in the form of questions) that is to be issued to the applicant. A particular RAI may contain one question or multiple questions. Most often, the RAI is based on staff review of a section of the application against a corresponding section of the SRP. For a given SRP section, the number of RAIs and the number of questions within a given RAI depend in large part on the technical reviewer's process and schedule. The reviewer may wish to quickly prepare those questions that can be generated immediately (*e.g.*, missing information) get that RAI into the work flow while the questions requiring more research are being developed. Questions are bundled into RAIs for convenience of review but may be tracked and closed out on a question-by-question basis. As discussed later, applicants will be encouraged to provide responses to the questions as they are developed rather than to RAIs (packages of multiple questions).

While RAI processing has defined participation by distinct individuals (*e.g.*, technical reviewer, project manager (PM), etc.) the process is accessible to all who are interested in monitoring, managing, or viewing the RAI status of a particular application.

Application Service/Mailing List Informed of Use of Electronic RAI Processing

To maximize the benefits of the RAI workflow, e-mail will be the vehicle used to transmit the RAI to the applicant, and be the official agency record (OAR). In addition for the case of COLAs, posting the RAI and responses to the external web will replace distribution to persons on the service/mailing list. To achieve these efficiencies, the projects branch chief (PBC) or Lead PM should:

●   reach agreement with the applicant on points-of-contact, e-mail addresses, and other protocols related to RAIs.

●   document the process in a letter, with copies to the complete service/mailing list. The letter should include information on availability of RAIs via the NRC website and

Agencywide Documents Access and Management System (ADAMS). The letter should also clearly state that it is the intention of the NRC not to send paper copies of RAIs. For those on the mailing list that do not have computers or access to them, issuance of paper copies may be the only option. However, it is anticipated that most of those on the service/mailing list will be able to use electronic access.

Workflow Process

Technical Reviewer Generates an RAI

A detailed review of the application against the acceptance criteria is conducted in order for the technical reviewer to prepare his/her particular portion of the SER. No RAI is needed if the staff is able to complete the SER, including making its reasonable assurance finding, using the information included in the application, other docketed correspondence, or information that can be reasonably inferred. If sufficient information is neither provided nor readily available to permit the reviewer to reach a conclusion of the design adequacy of the application, the reviewer generates questions necessary to obtain needed information. Often, an initial telephone call with applicant to discuss issues with the applicant is beneficial; it can provide the applicant with a general idea of what informational areas the staff considers deficient as well as give the applicant an opportunity to inform the staff where the information of interest may be found. This corresponds to review phase 1 in EPM.

If it is determined that additional information is indeed needed for the review, the reviewer enters the RAI process through the EPM icon on the computer desktop. The RAI icon is located on the EPM entry page. The reviewer may select "All Questions'" on the left side of the screen to view all RAI questions in the system. A word sort may be used to view questions on a particular topic or SRP section.

Following entry into the RAI program:

●	The reviewer selects "Open a New RAI." It is on the left side of the page under "Common Actions."

●	The next screen that appears requests basic information used to identify the RAI. Fields marked with an asterisk have to be completed before proceeding. Key information to be entered is the docket number, SRP section, application section number, technical branch, and the names of the technical branch chief (TBC), the Chapter PM, and Lead PM. Other information is keyed on the docket number and entered automatically. Application section is the number assigned to a particular section of the application. It may or may not be the same as the SRP section. Optional information can be included later, most likely by the Chapter PM. After completing the basic RAI information, the reviewer selects on OK. This puts the user back into the RAI summary screen. Select "All RAIs" and the RAI that was just created will appear at the bottom of the list. Open the RAI and scroll to the bottom to begin adding individual questions.

While RAIs are available for inspection by all, only the individuals identified for the five key positions, technical reviewer, TBC, Chapter PM, Lead PM, and the Office of the General Counsel (OGC) attorney are the only ones permitted to edit or revise an RAI. However, the individuals assigned to the five key positions can add additional staff to an RAI outside

the normal workflow for tasks such as projects branch chief review, backup positions, assignment of peer reviewers, secondary OGC assignment, etc. For DCs, OGC review is not required. The PM's name may be entered to bypass the OGC step or the name of another reviewer may be entered if needed.

● The reviewer selects the RAI just created (the one at the bottom of the RAI summary screen marked as new) which brings him/her back to a screen showing the information previously provided. The reviewer then scrolls to the bottom of the screen to the area identified as "Questions," selects "Create a New Question;" then lists the acceptance criteria, and types in the specific question. If the question is related to one previously asked, the reference to the previous question may be provided. The reviewer then selects "OK," which brings the reviewer back to the RAI summary screen. Additional questions may be added from that screen.

● When the technical reviewer is satisfied with the number and content of the questions, he/she scrolls back to the top of the RAI summary screen and selects "Workflows." Above the summary screen, a total of six steps are shown. The reviewer selects Step 1, "Send to TBC for Review," which forwards the RAI to the TBC for review and concurrence.

Technical Branch Chief Reviews the RAI

When the technical reviewer completes the initial RAI and sends it forward for concurrence to the TBC, an e-mail notification will appear in the TBC's in-box. The TBC can then click on the RAI link and go directly to the RAI.

● Each question listed at the bottom of the RAI is to be opened and reviewed. Changes to the question (including removal from further consideration, if warranted) may be made by selecting the "Edit Item" button.

● If minor changes are necessary, the TBC makes them. If significant changes are needed (including removal from the RAI) or the question is not clear, the TBC discusses them with the reviewer before editing. It is expected that there will be a discussion(s) between the TBC and the reviewer regarding the reasonableness of the request, bases (regulatory and technical) for requesting the information, and completeness of the information supplied by the applicant. Agreed upon changes may, at this point be made either by the TBC or the reviewer.

● When the TBC determines that a question is acceptable and while still in the "Edit Item" mode, the TBC selects the "Status" button and changes the status to "Reviewed by TBC." Not all questions have to be acted upon at one time. When all questions within the RAI are dispositioned by the TBC, using the electronic workflow, the RAI is forwarded to the next person (*e.g.*, Chapter PM) for review and concurrence.

● As each question has been acted upon, the TBC selects the "OK" button which takes the TBC back to the RAI. Each question is reviewed and the status changed. After the "Status" of the last question in the RAI shows that it has been reviewed and approved by the TBC, the TBC can forward the RAI to the Chapter PM. <u>One should note that RAIs cannot be forwarded within the "workflow" process until the status of each question shows that it has been reviewed and the status changed.</u>

Chapter PM Reviews the RAI

When notified via e-mail that an RAI has been sent for review, the Chapter PM performs a review using the same process described for the TBC review. The Chapter PM review focuses on the clarity of the questions, the regulatory basis, and the need for the information. Although the Chapter PM can modify the RAI, changes that affect content or intent of a question must be discussed with the technical reviewer or TBC first. Editorial or minor changes may be made by the PM without technical consultation. The Chapter PM also enters the remainder of applicant information in the "non-asterisk" fields as well as the name of the OGC attorney assigned to the application if it has not been entered previously. Following review and concurrence, the Chapter PM forwards the RAI to the OGC attorney for concurrence.

Office of General Counsel Reviews the RAIs for COLs

A hearing is required for COL applications. OGC reviews RAIs to confirm that there is a regulatory basis for issuing the RAIs. Moreover, the development of a hearing file is necessary so that the Agency may disclose all relevant documents supporting the staff's review of the application. Therefore, OGC must concur on all RAIs related to COL applications.

For DCs and those other review processes that do not require a hearing, OGC concurrence is not required and this step is not used. To bypass the OGC review step, the PM may enter his/her name in that slot.

OGC review will be similar to that of the PM with the primary focus on the regulatory basis for the questions. The step-by-step procedure used by the OGC attorney is the same as that described in the TBC section. Although the level of effort of each OGC review varies depending on such factors as length and complexity of the RAI, competing priorities, etc., initial OGC review may take up to 4 business days. Re-reviews or review of simple RAI questions is expected to be conducted in a shorter time frame. As with the PM review, minor changes are made by the attorney. Significant changes are brought to the attention of the Chapter PM, who is expected to discuss them with the technical reviewer and/or the TBC. Sometimes a discussion between OGC and the staff is needed in order to determine the disposition (*e.g.*, remove from RAI, reword, etc.) of a particular question. Upon completion, "Workflow" is used to inform the Lead PM that OGC review is complete.

Lead PM Reviews the RAI

The procedure as organized and discussed in this OI has the Chapter PM in the primary coordination role. While the Lead PM has the option of monitoring the progress of an RAI at any stage, after OGC has completed its review, the RAI is sent to the Lead PM. The step-by-step review procedure conducted by the Lead PM is the same as that described previously. While the Lead PM may at any time in the process access the RAI, including the Lead PM in the workflow provides continuity and oversight of the status of that portion of the application review.

Projects Branch Chief (PBC) May Review the RAI

RAI review by the PBC is not specifically included in the workflow process. If the PBC elects to concur on the RAI before it is sent to the applicant, the Chapter PM informs the PBC by e-mail

that the RAI is ready for review and concurrence, and adds to the RAI, the PBC's name using the "Manage Permissions," button on the RAI screen. If the PBC opens the RAI questions, the entry is captured in the version history for each question. Once added to the RAI, the PBC can modify the questions or identify comments directly within the RAI workflow. Any changes to the questions have to be made by the Chapter PM or Lead PM. Documentation of the PBC concurrence is done through an e-mail from the PBC to the Chapter PM that the PBC concurs and that the RAI is ready to be sent to the applicant.

<u>Conference Calls with the Applicant</u>

There is some latitude with regard to the points within NRO licensing and design review processes at which conference calls are held with the applicants. Conference calls can occur at any number of points in the process, from conceptual discussions early in the process to telephone calls after the RAIs are issued. Project managers and technical staff should use this flexibility to ensure the most timely and efficient interactions with applicants to support the NRC review process.

COLAs and ESPs (Processes with Hearings)

For COLAs and ESPs, NRC/applicant telephone conference calls can be held at various points in the process. It could be at an early stage where there is a general discussion with the applicant of areas where additional information may be needed or latter stage after the RAI is issued. The electronic RAI work flow is constructed assuming the RAI is developed and goes through concurrence, including OGC, and is transmitted to the applicant. Conference calls during the review, including during development of an RAI, should be documented in accordance with guidance related to the generation of records to support hearing and mandatory disclosure files.

NRC staff documents provided to an applicant outside of the workflow process (*e.g.*, preliminary RAIs) should be concurred in by OGC before being sent (in paper or electronic forms) to the applicant. Such transmittals should also be captured as official agency records to support the hearing and mandatory disclosure files and unless withheld for reasons described in 10 CFR 2.390 would be profiled as public records. In addition, any written response from the applicant (paper or electronic) would likewise be captured as an official agency record. In addition, any changes to NRC records (*e.g.*, an RAI) that are made as a result of communications outside the workflow process should be described in an official agency record. This documentation can be via a stand-alone record or within a related record (*e.g.*, the RAI cover letter or email, specific questions within an RAI). Changes made to RAIs or other documents that have been concurred in by OGC should be discussed with the OGC staff attorney before issuance. The discussions with OGC will determine if the document needs to be returned to OGC for re-review and concurrence.

Regardless of where in the process the conference call is conducted, several topics should be addressed: (1) will the formal RAI involve the transmittal of proprietary information. Presently the eRAI process does not accommodate the transmittal of proprietary information; and (2) does the applicant understand the questions. If the phone call is held late in the process (i.e., the RAI has been issued to the applicant, at least as a preliminary document); there may be a discussion of the amount of time for the applicant's response. Thirty days is the default response time. Applicants frequently request to have the conference call earlier in the process

because they get an understanding of the questions and therefore are able to begin work on the responses before the official RAI is issued, thus starting the 30 day clock. During the call, the Chapter PM should encourage the applicant to respond to individual questions as soon as the answers are developed and approved by appropriate management.

Design Reviews, Topical Reports (Non-hearing Processes)

For DCs, the conference calls are held at the time at which the technical and projects staffs have developed the questions to the point that they believe interaction with the applicant is needed. The capture of informal staff/applicant RAI communications as OARs should be done in conformance with the guidance in NRR OI COM-203, Revision 1 (ML050800544).

RAI Document Generated and Issued as an Official Agency Record

As mentioned in the previous section, the OGC attorney must be informed by the Chapter PM of any changes to the RAI resulting from the conference calls on RAIs that have previously received OGC review. The OGC attorney will determine if a formal review of the revised questions is required. If a re-review is necessary, the Chapter PM will forward the RAI back to OGC. After all internal reviews are completed; the RAI document is generated by clicking on the "Create RAI Document." Note that "Create RAI Document," may be selected at any time. It may be beneficial to view the RAI as it would appear in WORD form. However, question numbers are assigned only after the "Issue RAI," button is selected. An e-mail is generated by the system and sent to the Chapter PM with the RAI attached as a "Microsoft Word" document. The Chapter PM then becomes the recipient of the applicant's informal responses (see section on Receipt of RAI Response).

For the initial implementation of the RAI process, after the RAI is generated, it is converted to a pdf file and sent to the applicant as an attachment to an e-mail. Using the current process for creating OARs from e-mails, the e-mail and attachment are entered into ADAMS to become an OAR. Both the draft and official RAIs must be entered into the hearing file. It is expected that each project will have an electronic e-mail capture system. When the RAIs are sent to the applicants, the e-mail capture address can be included as a "cc." Guidance for setting up e-mail capture may be found in the Project Manager "How To" Guide for Hearing Files (http://nrr10.nrc.gov/NRO/training/docs/email-capture.ppt). The e-mail capture guidance will be included in the next version of NRO-PER-105, "Qualification and Training Program." In addition, a PDF file will be created and posted on the web-site.

After the RAI is issued, the Chapter PM should confirm that there are no ongoing activities that would preclude deletion of the "Version History," for each RAI and RAI question.

Receipt of RAI Response

Applicants are encouraged to provide answers to individual RAI questions as soon as the answers are prepared and the applicant is reasonably confident of the accuracy of the answers. Use of e-mail to the Chapter PM to transmit the answers is acceptable. The Chapter PM then "cuts" the answers from the e-mail and "pastes" the answer section of the question using the "Edit Items" function along with the date of the response.

Upon receipt, the answers are forwarded by the Chapter PM to the technical reviewer to determine adequacy of response. The technical reviewer can then use them in preparation of the SER input. If it is determined that the response is not adequate or clarification is needed, resolution may be as simple as a telephone call. At other times a follow-up question may be needed. Revisions to answers are dated and entered in the response portion of the RAI question. The initial response and any revisions are all retained within the response portion of the RAI question response. If a follow-up question is needed, it is necessary to obtain OGC review and concurrence.

When the applicant provides responses to a number of the questions in an RAI for a COLA, they are sent officially under oath or affirmation. Question responses for COLAs may be submitted under oath or affirmation even if not all question responses in an RAI are complete. That is, the oath or affirmation is on a question basis rather than an RAI basis. As mentioned previously, responses for DC RAIs are not required to be submitted under oath or affirmation. Chapter PMs are expected to compare the official responses with the preliminary ones to assure that they are the same. If there are differences, the Chapter PM and reviewer (as needed) will initiate a telephone call with the applicant to discuss the differences. Unless the applicant submits a revised RAI response under oath or affirmation, the previous one is the official response. The Chapter PM ensures that the official responses and the responses incorporated into the RAI Workflow System are the same. If they are different, the responses in the RAI Workflow System are revised accordingly.

After the RAI response is found to be acceptable, and the draft SER input with open items has been issued, the reviewer or the PM (with the reviewer's agreement) includes the date of the applicant's official response and closes the RAI. Closed RAIs are "locked down," to prevent any further changes to the RAI and its enclosed questions. The closed RAIs remain available for viewing.

Internal Communications

The electronic RAI process is intended to improve the efficiency of the process and reduce the processing time through electronic transmission, work flow, and statusing. <u>However it is not intended to replace the normal communication channels that exist between project's staffs, technical staffs, and applicants</u>. The maximum work flow efficiencies can be realized through maintaining effective communications between all those involved in using the 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. Examples are: (1) after the reviewer is satisfied with the initial formulation of the RAI questions, each subsequent step in the review and concurrence process is expected to take 1 to 2 days. Times in excess of that should be known by the Chapter PM and either

accepted or actions taken to bring the times back in line with expectations; (2) arrangement between the Lead PM and Chapter PM regarding the PM responsibility for oversight and management of an RAI; and (3) arranging for PBC review and concurrence on RAIs.

For individuals who desire to maintain cognizance of the progress of an RAI to which he/she is a party, the use of the "Alert Me," button on both the RAI and question screens permits that individual to be informed any time there are changes to that particular screen.

Special Features of the Software

<u>RAI Process Workflow Software Tool Permits Open Monitoring</u>

RAI processing is an open process. Although specific individuals are assigned responsibilities during the processing, an RAI and its associated questions may be viewed by other staff members, thus increasing communications and information sharing for multiple reviews.

<u>Filters and Sorting Capabilities Assist Staff with Monitoring</u>

There are several sorting features and filters that can be used to assist staff, supervisors, and managers to focus on their area of interest. As presently set up, all RAIs for all applications can be displayed on the RAI Home Page (summary page) at the same time. On the far right of the bar immediately above the column headings, next to the word "view," there is a drop down menu with options for displaying various broad RAI categories (*e.g.*, open RAIs, closed RAIs, past due RAIs, etc.). In addition, the title for each column (*e.g.*, application title) has a drop down menu filter associated with it which permits the user to select a specific identifier. The filter for each column can be enabled at the same time as filters for other columns. For example, if the user wants to find all of the RAIs on the William Lee plant that are in OGC review, those two filters can be used together to define the search.

<u>Not All Questions are Issued with the Original RAI</u>

As mentioned previously, specific RAI questions may be deleted or modified independently of the RAI to which they were originally attached. Sometimes, upon other considerations, certain questions require more internal discussion, research, etc. Rather than delay processing the RAI while decisions are made on a specific question, the question of concern can be set aside while the RAI with the remaining questions is processed. The question of concern can be added later, if practical, or issued at a later date as part of another RAI, or deleted altogether. For the initial release of the RAI program, sidelining questions are done by setting up a holding RAI. It has the same attributes as the original RAI, but has a different title and a different RAI number. To remove a question from an RAI in process, it must be brought-up on the screen. The user then selects "Edit Item," and then uses the drop down menu for "RAI ID" to transfer the question from the original RAI to the RAI number of the holding RAI. The transferred question will remain in the holding RAI until a decision is made regarding how to proceed with it. When the RAI is issued to the applicant, the numbering of the remaining questions is sequential.

<u>Change History is Captured and Retained for Each RAI and RAI Question</u>

Each RAI and each question has a change history that is generated and maintained, and can easily be accessed for review purposes. The RAI history can be viewed by selecting the "Version History" button on the RAI summary screen. The summary screen for each question also has a "Version History" button.

The RAI history primarily shows the information entered when the RAI was created and the progression through the workflow. The question history shows, in addition to the initial information entered, workflow history, and any changes made to it as it was undergoing review and concurrence, those fields that were revised, along with who revised them and when they were revised.

The version histories are intended as an aid in following the progress of the RAI and questions during the generation process and are not part of the hearing file. The version histories are deleted after the RAI is initially issued (i.e., sent to the applicant and entered in to ADAMS) unless there are unusual circumstances such as an active FOIA request. The Chapter PM needs to ascertain that there are no outstanding issues that would preclude the version history deletions.

4.   <u>REFERENCES</u>

1. NRO, "RAI Tracking Tool User's Reference Guide," Version 1.0, For Use and Comment, January 23, 2008.

2. NRR OI LIC-101, Revision 3, "License Amendment Review Procedures."

3. NRO, "Project Manager (How To) Guide For Hearing Files."

NRO-REG-XXX - Change History			
Date	**Description of Changes**	**Method Used to Announce & Distribute**	**Training**