From: Joseph Sebrosky
Sent: Thursday, February 28, 2008 8:48 AM
To: 'pmray@tva.gov'
Cc: Ravindra Joshi
Subject: RAI draft office instruction
Attachments: NRO-REG-101.pdf

Phil,

We have 3 questions that are in process (they need OGC review before we discuss them with you). We intend to follow the attached draft office instruction NRO-REG-101, "Processing Requests for Additional Information," to process the RAIs electronically. The draft office instruction is publicly available in ADAMS under ML080230058.

In response to a question from Andrea, there is a step in the process for the Chapter PMs to discuss the RAIs with the applicant before they are issued (see page 5). In addition, page 2 of the office instruction states that the staff needs to "reach agreement with the applicant on points-of-contact, e-mail addresses, and other protocols related to RAIs."

Ravi Joshi in our organization has been assigned to get the RAI electronic flow process up and running for Bellefonte. I hope to have a phone call with you a Ravi to introduce you to each other and to begin discussions on what needs to be done to get the RAI process moving. The South Texas projects team is also trying to get the system up and running so we intend to coordinate with them on our end to make sure that we are being consistent.

Please let me know if you have any questions.

Joe

Hearing Identifier: Bellefonte_COL_Public_EX
Email Number: 98

Mail Envelope Properties (C4A4C9A16294FB4CBA5A36312D05FFAC034CBD2C4D)

Subject: RAI draft office instruction
Sent Date: 2/28/2008 8:47:37 AM
Received Date: 2/28/2008 8:47:37 AM
From: Joseph Sebrosky

Created By: Joseph.Sebrosky@nrc.gov

Recipients:
"Ravindra Joshi" <Ravindra.Joshi@nrc.gov>
Tracking Status: None
"'pmray@tva.gov'" <pmray@tva.gov>
Tracking Status: None

Post Office: HQCLSTR02.nrc.gov

Files	**Size**	**Date & Time**
MESSAGE	1210	2/28/2008 8:47:37 AM
NRO-REG-101.pdf	144416	

Options
Priority: Standard
Return Notification: No
Reply Requested: No
Sensitivity: Normal
Expiration Date:
Recipients Received:

Nuclear Regulatory Commission
Office of New Reactors
NRO Office Instruction

Office Instruction:	NRO-REG-101
Office Instruction Title:	Processing Requests for Additional Information
Revision Number:	Draft 0, For Use and Comment
Effective Date:	January 25, 2008
Primary Contacts:	George Dick, NRO/DNRL
Responsible Organization:	NRO/DNRL/NOEP

Summary of Changes: This draft 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:

ADAMS Accession No.: ML080230058

Concurrences			
Primary Office Owner	Organizational Effectiveness and Productivity Branch		
Responsible Manager	Stephen S. Koenick, Acting		1/25/08
DDNRL*	Deputy Director	Patrick Madden	1/25/08

*Expanded concurrence with formal issuance

OFFICIAL RECORD

NRO Office Instruction
NRO-REG-101, Draft Rev. 0
For Use and Comment
“Processing Requests for Additional Information”

1. PURPOSE

The purpose of NRO-REG-101, “Processing Requests for Additional Information,” is to provide procedural guidance to the Office of New Reactors (NRO) staff and managers regarding the basis for developing requests for additional information (RAIs) (containing non-proprietary information) and their processing through the use of the computer based control and workflow component. The guidance is to be used in conjunction with the user’s guide 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[1] are based on an initial version of the tool. Use of the completed software package will be addressed in subsequent OI revisions.

During the review of applications for new reactors, 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 technology or the power plant will protect people and the environment. The information received as a result of the 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 to be considered accurate and factual.

Background information on the policy basis governing the place 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 combined licenses (COLs), the supporting software is general enough that the process (with some minor variations) is applicable to acceptance reviews, requests for design certifications, amendments to applications, and license amendments. More detailed information is available in the RAI Tracking Tool Release 1 User’s Reference Guide.

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. Initial responses to RAIs will also be received electronically permitting the technical reviews to run smoother, with fewer breaks in the review resulting in more efficient reviews.

---

[1] The User Guide is accessed from EPM, Click on TECHSUPPORT tab; On upper center of screen under EPM Staff Guidance click on Procedures Folder; Click on document titled, RAI Tracking Tool User Guide v 1.0

2. GENERAL REQUIREMENTS

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 preliminary safety evaluation report (PSER) has been developed. Thus, the need for additional information in order to reach a regulatory determination is clear and unambiguous.

3. SPECIFIC REQUIREMENTS

RAI as used in NRO refers to a package of required information (in the form of questions) 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 an application against a specific section of the SRP.

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 reviewing the RAI status of a particular application.

Application Service List Informed of Use of Electronic RAI Processing

One of the advantages of the RAI Workflow process is that because so much of it can be done electronically (including issuance to the applicant), processing is faster. Consequently, there will be fewer paper copies generated. However, following issuance of an RAI, the questions are available quickly through the NRC website. Early in the review process, the Projects Branch chief 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 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 service list that do not have computers or access to them, issuance of paper copies may be the only option. However, it is anticipated that the most of those on the service list will be able to use electronic access

Technical Reviewer Generates an RAI

Subsequent to performing the acceptance review and docketing of an application, a detailed review of the application against the acceptance criteria is conducted in order for the technical reviewer to prepare the particular portion of the PSER. No RAI is needed if the staff is able to complete the PSER, including making its reasonable assurance finding, using the information included in the application, other docketed correspondence, or that can be reasonably inferred. If sufficient information is neither provided nor readily available to permit the review to reach a conclusion of acceptability of the application, the reviewer generates questions necessary to obtain needed information. The reviewer enters the RAI process through the Enterprise Project Management (EPM) icon on the computer desktop. The RAI icon is located on the EPM entry page.

Following entry into the RAI program:

- The reviewer clicks on “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. Pull-down menus are provided for applicant name, application title, SRP section, and technical branch fields. Docket number is automatically added. Other asterisked information (application accession number, application section, technical branch chief, chapter PM, and PM) need to be entered before proceeding. 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 clicks on OK. This puts the user back into the RAI summary screen.

- Click on the RAI just created (the one at the bottom of the RAI summary screen marked as new). This will bring the user back to a screen showing the information previously provided. Scroll to the bottom of the screen to the area identified as “Questions.” Click on “Create a new Question.” List the acceptance criteria and type in the specific question. If the question is related to one previously asked, provide the reference to the previous question. Click on “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, scroll back to the top of the RAI summary screen and click on “Workflows.” There are a total of six (6) steps that must be followed sequentially. Click on Step 1, “Send to TBC for Review.”

Technical Branch Chief (TBC) 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 opened and reviewed. Changes to the question (including removal from further consideration, if warranted) may be made by clicking on the “Edit” 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.

- When the TBC determines that a question is acceptable, the TBC clicks on the “Status” button and change the status to "Reviewed by TBC." Not all questions have to be acted upon at one time. However, the RAI cannot be sent to the next person for review and concurrence until all questions within the RAI are reviewed dispositioned by the TBC.

- As each question has been acted upon, the TBC clicks 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. 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.

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. The Chapter PM should use technical discretion regarding any proposed changes to RAI questions. 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 pertinent information in the "non-asterisk" fields, particularly the name of the Office of General Counsel (OGC) attorney assigned to the application if the application is for a COL. Following review and concurrence, the Chapter PM forwards the RAI to the OGC attorney for concurrence.

Office of General Counsel (OGC) Reviews the RAIs for COLs

A hearing is required for COL applications. Therefore, 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. Other review processes (*e.g.*, design certification) do not provide for a hearing so OGC concurrence is not required for those situations and this step is not used[2]. The public has an opportunity to participate in the design certification during the rulemaking process.

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 TBC section. Although the level of effort of each OGC review varies depending on such factors as length and complexity of RAI, competing priorities, etc., initial OGC review may take up to 4 business days. Re-reviews or review of simple RAI questions is expected 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 Chapter PM that OGC review is complete.

[2] In this release of the application, to skip the OGC workflow step, the PM would enter himself/herself as the OGC representative and has to concur on the questions.

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 May Review the RAI

RAI review by the projects branch chief (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 provides the PBC with the information needed to access and review the RAI. 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.

Chapter PM Conducts a Conference Call with the Applicant

Prior to issuing the RAI, the Chapter PM conducts a conference call with the applicant, technical reviewer, and TBC. The purpose of the call is to: (1) determine if there is any proprietary information contained in the RAI; (2) assure that the applicant understands the questions; and (3) agree on a response schedule. Thirty days is the default response time. During the call, the Chapter PM should encourage the applicant to respond to individual questions as soon as the answer is developed and approved by applicant management. Note that if the draft RAI is sent to applicant at this time, the Chapter PM must enter it into ADAMS. It is then an official agency record. The PM must document the conference call via meeting summary. If there were no changes to the document, the meeting summary is very brief.

RAI Document Generated and Issued as an Official Agency Record

After any changes resulting from the conference call are made, the RAI document is generated by clicking on the “Create RAI Document.” An e-mail is generated by the system and sent to the Chapter PM with the RAI attached as a “Microsoft Word,” document. Either the Lead PM or Chapter PM may send the e-mail to the applicant. That person then becomes the recipient of the applicants informal responses (see section on Receipt of RAI Response).

For the initial implementation of the RAI process, after the RAI is generated, it is sent to the applicant as an attachment to an e-mail. The e-mail and the attachment then become an official agency record (OAR) and entered into ADAMS. Further, a PDF file will be created and posted on the web site.

Receipt of RAI Response

Applicants are encouraged to provide preliminary answers to individual RAI questions as soon as the answers are prepared and the applicant is reasonable 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 preliminary 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. Other times a follow-up question is 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 all of the questions in an RAI, they are sent officially 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.

After the RAI response is accepted, if the draft SER input with open items has not been issued by the technical staff to projects, the reviewer includes the date of the applicant’s official response. If the SER input has been issued, the PM includes (with the reviewer’s agreement) the date of the response.

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. However, the efficiencies can only be realized through effective communications between all 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.

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 accessed by other staff member’s, 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 enacted 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.

Reports may be generated based on a combination

Not All Questions are Issued with the Original RAI

As mentioned previously, specific RAI questions may be deleted or modified independent from 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, bring the question up on the screen. Click on “Edit Item,” and then use the drop down menu for “RAI ID” to transfer the question 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 are sequential.

Change History is Captured and Retained for Each RAI and RAI Question

Each RAI and each question has a change history that is generated and maintained, and can easily be accessed for review purposes or retained as part of the hearing file for COL applications. The RAI history can be viewed by clicking on “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 are shown.

4. REFERENCES

1. Office of New Reactors (NRO), Request for Additional Information (RAI) Tracking Tool User’s Reference Guide, Version 1.0, For Use and Comment, January 23, 2008.

2. Office of Nuclear Reactor Regulation (NRR) OI LIC-101, Revision 3, “License Amendment Review Procedures.”

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