

C.2.5 Application Review and Requests for Additional Information

OVERVIEW

The NRC staff conducts a detailed technical review of a COL, ESP, or DC application subsequent to completion of the acceptance review process and docketing of the application. The regulations at 10 CFR 2.102, “Administrative review of application,” provide that the staff may require an applicant to supply additional information to support its review. Pursuant to 10 CFR 2.108, “Denial of application for failure to supply information,” the NRC may deny an application if the applicant fails to respond to a request for additional information (RAI) within 30 days of the date of the request, or within such other time as may be specified by the NRC staff.

Consistent with the regulations, the NRC staff issues RAIs to acquire additional information from an applicant to determine the safety of the application design, operation, and siting, and to address environmental issues. RAIs are issued to verify, supplement, or clarify information not available in the initial application submittal, other docketed correspondence, or reasonably inferred from the information available to the staff. RAIs are intended to enable the NRC staff to obtain all relevant information needed to make a regulatory decision on an application. The RAI process allows for safety and environmental evaluations that are fully informed, technically correct, and legally defensible. RAIs may address varied regulatory and technical subject matter; however, RAIs typically exhibit the common characteristics described in Attachment 1, Characteristics of Requests for Additional Information (RAIs).

The NRC staff employs a computer-based system and internal website to prepare, issue, process, and track RAIs. The computer-based system and internal website are not used for RAIs that contain safeguards information. RAIs are issued to applicants electronically in the form of e-mails and are saved as official records, publicly available, in the NRC’s recordkeeping system, Agencywide Documents Access and Management System (ADAMS).

NRO-REG-101¹

The NRC office instruction, NRO-REG-101, provides comprehensive and detailed guidance to the staff for the RAI process to include the preparation and issuance of RAIs, communication and interactions with applicants regarding RAIs, evaluation of applicants’ responses, resolution and closure of RAIs, and issuance and website posting of RAI reports. Although developed for use by the staff, this publicly-available document is a resource that is 1) useful to stakeholders for a general understanding of the RAI process and 2) valuable to applicants for a detailed understanding of the staff’s RAI-related activities and schedule, the staff’s communications with applicants and expectations of applicants, and the process for RAI closure and reporting.

GUIDANCE

The guidance herein correlates to the contents of NRO-REG-101 and is focused on RAI-related information of importance to applicants. The guidance is intended to assist applicants in achieving a more efficient application review by enhancing applicants’ understanding of, and support to, the NRC staff’s review process.

Application Review and RAIs

The applicant should be familiar with the application review and RAI process. Further

¹ NRO-REG-101, “Processing Requests for Additional Information,” Revision 1, July 2014 (Adams ML14091A802)

information about these can be found in NRO-REG-101. The applicant should understand that the review, although encompassing the entire application, is focused on the safety analysis report and the environmental report. The staff conducts a detailed review and evaluation against the acceptance criteria contained in NUREG-0800, design-specific review standards (if applicable), NUREG-1555, and other application-related guidance. The staff generates RAIs to acquire the information necessary to fill data gaps and/or correct misleading, unclear, or erroneous information and to complete the evaluation and determine whether or not there is a reasonable assurance of adequate protection of public health and safety.

The applicant should anticipate communications and interactions with the staff pertaining to RAIs throughout the application review to include both oral and written communications, participation in public meetings, and, potentially, the need for revision of the application and submittal of documentation supplemental to the application. The applicant should be aware that RAIs, as well as the staff and applicant correspondence related to RAIs, unless containing withheld information or safeguards-related information, are made publicly available.

The applicant should understand that the RAI process is a structured, formal and regulation-based process. Each RAI undergoes a multi-level review and approval sequence and the applicant should expect to receive RAIs that are succinct and clearly identify the requested information (e.g., the methodology, equation, assumption, etc.). The RAIs should additionally avoid requests for extraneous information or the inclusion of anticipated or acceptable answers. RAIs vary in scope, content, and level of technical detail depending upon the issue being addressed; however, the applicant should anticipate that all RAIs demonstrate the characteristics discussed in the NRC staff pamphlet titled "Request for Additional Information Best Practices," (ADAMS Accession No. ML12220A577). This document provides useful examples of RAIs under three common scenarios related to clarifications, omissions, and technical acceptability.

Communications

The applicant should understand that proactive communication and interactions with the staff are key to an efficient application review. The applicant should expect the staff, as prescribed in NRO-REG-101, to initiate and maintain communication with the applicant throughout the review. The communications include a combination of teleconferences, e-mails, meetings, and formal correspondence. The applicant should be prepared to respond to staff-initiated communications in a timely manner with substantive and accurate information and, additionally, to proactively initiate communication with the staff when warranted.

Throughout the application review, the applicant should maintain an awareness of the staff's progress and acquire a detailed understanding of any potential issues. When necessary to ensure a mutual understanding of potential issues and the path to resolution, the applicant should initiate appropriate communication with the staff to support a timely and efficient review.

Project Manager

The applicant should understand that project manager with lead responsibility for the review is the applicant's primary interface with the NRC staff. The applicant should expect the project manager (or designated alternate) to initiate and coordinate the review-related communications and interactions, to include issuance and follow-up of RAIs, on behalf of the staff. Accordingly, the applicant should coordinate review-related telephone, electronic, and correspondence communications, meeting arrangements, and other staff interactions with the project manager.

The applicant should confirm with the project manager the applicant's primary/alternate points of

contact and contact information and should reach agreement regarding protocols related to RAIs. The applicant should verify the acceptability of its planned method for receipt of issued RAIs and the submittal of RAI responses and other review-related material.

Conference Calls

The applicant should understand that public conference calls are an element of the RAI process that is mutually beneficial and efficient for the staff and the applicant. For example, the staff may initiate public conference calls early in the application review to discuss review issues prior to generating RAIs; and, such public teleconferences provide the applicant with a general idea of what informational areas the staff considers deficient as well as an opportunity for the applicant to address and potentially resolve the staff's issues. The applicant also may initiate public conference calls, via the project manager, to proactively discuss a potential review issue. Public conference calls may include a portion that is closed to the public in order to discuss proprietary material or other sensitive material withheld from disclosure.

During the application review, the staff may initiate non-public conference calls, for example, to clarify impending RAI questions prior to RAI issuance and/or to clarify the intent of issued RAIs. The applicant also may initiate non-public conference calls, for example, to ensure a clear understanding of RAI questions prior to submittal of RAI responses. The technical aspects of the RAI or possible responses to the RAI may not be discussed during a non-public conference call. The NRC staff will document that the non-public conference call only involved clarification of the RAI.

Meetings

The applicant should be prepared to participate in RAI-related public meetings throughout the application review. For example, the staff may request a public meeting if the staff determines that the information provided in a RAI response has not resolved the identified issue. At the public meeting, the staff and applicant would discuss the information in the RAI response and how the applicant would address supplemental response information. The applicant may volunteer to submit a supplement to the RAI response or may request the staff to provide a follow-up RAI that describes the specific information to be submitted by the applicant.

The applicant, for example, may request a public meeting early in the application review to allow an opportunity to develop an understanding of the questions being developed by the staff and to begin work on the responses before the official RAI is issued.

Non-public meetings may be conducted to discuss proprietary material or other sensitive material withheld from disclosure. The staff will prepare a public summary of these meetings.

Draft/preliminary RAIs

The applicant should understand that the staff may, as provided in NRO-REG-101, issue an RAI in draft or preliminary form. In general, a draft RAI is used to support clarification of the staff's issue and the timeliness of the applicant's response. Following receipt of the draft RAI, the applicant should initiate efforts for response to the draft RAI while awaiting the official RAI. If necessary, the applicant should request a public teleconference or public meeting to discuss and further clarify the issue before the official RAI is issued.

RAI issuance

The applicant should understand that the NRC staff uses e-mail as the vehicle to transmit non safeguards information RAIs to applicants. The project manager transmits RAIs in the form of letters or PDF files as attachments to e-mails. Accordingly, the applicant should coordinate with

the project manager to ensure the applicant's capabilities for timely and accurate receipt of e-mailed RAIs.

RAI Responses

The applicant should understand that timeliness of the review is supported by the applicant providing answers to individual RAI questions as soon as the answers are prepared and the applicant is reasonably confident of the accuracy of the answers. The applicant response should be comprehensive and address any other technical aspects relevant to their response to the specific RAI request. The applicant should indicate the resolution of all applicable aspects identified by the specific RAI in its response. In coordination with the project manager, the applicant may transmit initial and partial RAI responses via e-mail.

When preparing a RAI response, the applicant should determine whether a revision to its safety analysis report is necessary as part of the RAI response. If a revision is necessary, the applicant should provide a markup of the applicable pages along with the RAI response. The applicant should note that a revision is not always necessary if the RAI response simply clarifies information currently contained in the document. However, to the extent that the NRC Staff is relying on the information to make its finding, or that clarity is necessary to ensure that the licensing basis documents are clear, the FSAR will need to be modified. Although there is no requirement for the applicant to revise its environmental report, it may decide that such a revision is prudent or practical if RAI responses indicate significant changes in the report are needed to prevent miscommunication.

The applicant should be aware of the availability of RAI-related information on the NRC's public website that may assist the applicant's understanding of received RAIs and the preparation of responses. On the website, the NRC maintains publicly-available information for each 10 CFR Part 52 application to include: 1) safety-related RAIs and the applicant's responses; 2) environmental-related RAIs and the applicant's responses; 3) the final safety evaluation report; and 4) the final environmental impact statement. The applicant may find it useful to review similar RAIs and the accepted responses from previous applications. Also, the applicant may find value in the review of the staff's safety evaluation reports or environmental impact statements prepared for previous applications.

The applicant should understand that formal RAI responses are typically required within 30 days and should coordinate any variations in schedule with the project manager. The applicant should transmit the official RAI responses by mail to the NRC's Document Control Desk. The RAI responses are entered in ADAMS and, unless noted by the applicant as containing proprietary information or safeguards/security information, are made publicly available.

RAI Status and Resolution

The applicant should be familiar with the RAI status and tracking system and the RAI publicly-available reports discussed in NRO-REG-101. Throughout the application review, the applicant should maintain awareness of the status of each RAI and understand that "resolved – closed" is the status requisite for completion of the application review. The applicant should initiate communication with the safety and/or environmental project manager to address questions regarding RAI status or the publicly-available RAI report.