

December 22, 2004

MEMORANDUM TO: Brian W. Sheron, Associate Director for Project Licensing
and Technical Analysis
Office of Nuclear Reactor Regulation

FROM: Ledyard B. Marsh, Director /RA/
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SUBJECT: EVALUATION OF TRENDS IN REQUESTS FOR ADDITIONAL
INFORMATION - INTERIM ACTIONS

In response to recent industry feedback including discussions held at the Nuclear Energy Institute (NEI) Licensing Forum in October 2004, the Office of Nuclear Reactor Regulation (NRR) will initiate an evaluation of recent trends in requests for additional information (RAIs) related to 10 CFR Part 50 licensing actions. This effort will be performed in parallel with industry activities to evaluate the RAI process with respect to licensee internal processes and licensee interactions with the staff. The Division of Licensing Project Management (DLPM) has solicited an industry commitment of staffing and resources to ensure significant progress is achieved in this evaluation effort. To date, seven representatives of the Licensing Action Task Force (LATF), coordinated by NEI, have agreed to participate in their evaluation activities. A draft outline of proposed actions, including evaluation scope and sampling approaches, is targeted for completion coincident with a scheduled January 27, 2005, LATF meeting with the Nuclear Regulatory Commission (NRC).

In advance of evaluation efforts on RAI trends, DLPM, Division of Engineering (DE), and Division of Systems Safety and Analysis (DSSA) will reinforce current expectations for development and supervisory oversight of draft and final RAIs with the staff. DLPM has requested that the assigned LATF members develop interim actions that licensee representatives can implement to support effective and efficient processing of RAI responses. Industry actions, when received, will be integrated with the interim actions outlined below. The following expectations for draft and final RAIs will be reinforced with the staff. The portion of the first item related to licensee responses to RAIs will be reinforced with licensee representatives during meetings or conference calls that are scheduled to discuss specific RAIs.

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1. The licensee is expected to identify those questions that they feel do not appear needed in making the regulatory finding or refer to information that is already available to the staff. During meetings or conference calls to discuss RAIs, the Project Manager will reinforce the expectations for the meeting or call as supporting the effective and efficient review of the licensing action. The purpose of the call is to discuss the RAIs and ensure that the NRC staff will receive the necessary information in order to complete the review and make the associated regulatory finding and to ensure that necessary information will be placed on the docket. Licensee representatives should identify problematic questions during the meeting or conference call, and in any case, should notify the Project Manager if they feel the questions are not needed.
2. The transmittal of draft or final RAIs from technical branches to DLPM must follow ADM-200, "Delegation of Signature Authority," which requires that the RAIs are signed by the appropriate section chief or team leader. The signature authority can also be re-delegated to a senior staff member. Thus, the questions should receive either supervisory review or an independent review from a senior staff member, particularly for complex issues. It is noted that this supervisory and independent review is similar to ongoing related activities in NRR's Quality Initiative. In addition, technical reviewers should identify to their supervisors licensee requests that will likely require significant RAIs due to incomplete or poor quality submittals. These requests should be discussed with DLPM staff for potential denial or licensee withdrawal of the request.
3. Prior to transmittal of the RAIs to the licensee, including draft RAIs in advance of a meeting or conference call, the cognizant DLPM section chief will perform a review to verify the questions are needed to support the applicable regulatory findings. The section chief is not expected to perform a review of the technical issues in all cases; instead, the review should at a minimum verify that the technical branch provided supervisory or independent review as needed and that the Project Manager has reviewed the questions to ensure that they are needed.
4. NRR staff are encouraged to review the overall guidance for the development, review, and processing of RAIs provided in Section 4.3, "Requests for Additional Information," of Appendix B to LIC-101, "License Amendment Review Procedures." This section is reproduced in the attachment.

DLPM, DSSA, and DE management will discuss these expectations with divisional staff in periodic section meetings and at the next scheduled division meeting. In addition, DLPM will prepare an NRR "Have I Got News for You" article for distribution to all NRR staff.

Attachment: As stated

cc: J. E. Dyer
R. William Borchardt
B. Boger
D. Matthews

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RE: EVALUATION OF TRENDS IN REQUESTS FOR ADDITIONAL INFORMATION -
INTERIM ACTIONS

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4.3 Requests for Additional Information (from NRR Office Instruction LIC-101, Revision 3, Appendix B)

Requests for additional information (RAIs) serve the purpose of enabling the staff to obtain all relevant information needed to make a decision on a licensing action request that is fully informed, technically correct, and legally defensible. RAIs are necessary when the information was 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 amendment application, and consistent with the applicable codes, standards, regulatory guides, and/or the applicable Standard Review Plan sections. RAIs should not be used as general information requests or as a means to encourage commitments from licensees. This guidance can be utilized for other licensing actions such as exemption and relief requests.

The transmittal of RAIs from technical branches to DLPM should follow ADM-200, "Delegation of Signature Authority" (i.e., the questions should be approved by the appropriate Section Chief, team leader, or senior staff member, as authorized by the Section Chief). The transmittal of RAIs from technical branches to DLPM may be in the form of e-mails or memoranda (see Section 9.0 for additional guidance for when an internal document may warrant preservation as an Official Agency Record).

The staff is accountable for the appropriateness of RAIs and should ensure that each question in an RAI was developed with proper consideration of the following:

- < regulatory basis of request
- < technical complexity of request
- < risk significance of issue in question
- < existence of precedent amendments
- < appropriate scope and depth of review
- < resource implications for both the staff and the licensee
- < information already on the docket

The following guidance is provided for common RAI concerns:

1. Questions included in the formal RAI should ask for information that is required to make the regulatory finding. Each question should have a clear nexus to the staff's regulatory finding. Including the regulatory basis in the question is a good practice.
2. The staff should not issue any RAIs if the staff has (or can infer with a reasonable degree of confidence) the necessary information to make the regulatory finding. When an RAI is necessary, the staff should make every effort to limit itself to one round of RAIs per TB for an amendment application. The established timeliness goals are likely to be exceeded if multiple RAIs are needed to complete the staff's review of a license amendment application.

Caution - the desire to limit ourselves to one round of RAIs for the purpose of efficiency should not interfere with our primary mission of ensuring that we maintain public health and safety. If necessary to ensure safety, multiple RAIs are appropriate. Reviewers should work with the PM and the licensee to determine the best way to resolve questions (e.g., have a meeting, prepare multiple RAIs, arrange for a site visit, etc).

3. Frequent and early communications between the PM, TB staff, and the licensee can avoid the need for many RAIs. To ensure an effective and efficient review, PMs are required to notify the licensee prior to requesting the licensee to submit additional information to support the staff's review of a licensing action. This notification should be a meeting or conference call attended by the PM, TB reviewer, and licensee. The proposed RAI questions should be discussed and, if the licensee is requested to submit additional information, a mutually agreed upon due date should be established. This due date should be reflected in the RAI on its issuance. To help resolve the issues, preliminary questions may be faxed or e-mailed to the licensee prior to the meeting or conference call. Answers that are needed to make a regulatory finding (i.e., that are not merely clarifications of information already on the docket) need to be placed on the docket. All of the staff's questions shall be docketed using one or a combination of the following methods: (1) forwarding an official RAI to the licensee by letter, (2) generating a memo to file (publicly available), or (3) having the licensee include the questions from the teleconference, e-mail, or fax in their docketed response. The specific method or combination used is case-specific and depends on the needs of the licensee, the potential public interest, and the needs of the NRC staff.
4. Before developing an RAI, the staff should ensure that the information is not already available to the staff or that the answer could not reasonably be inferred from general knowledge, existing regulatory requirements, previously docketed correspondence, or generally accepted industry practice.
5. Questions should be specific rather than overly broad, and the response to the RAI should be of value to the staff's safety evaluation basis.
6. If an RAI is issued and the licensee's response does not fully address the RAI, the PM will set up a meeting or conference call attended by the PM, TB reviewer and licensee management to discuss the discrepancy and what needs to be provided to the staff on a timely basis in order to complete the amendment review. Failure of the licensee to provide timely information may result in a denial or withdrawal of the amendment based on a deficiency in the submittal as opposed to a definitive, negative finding by the staff based on the technical merits of the proposed change. The licensee may submit a new application (with the identified discrepancies corrected) in the future.
7. If a disagreement arises with the licensee regarding the appropriateness of an RAI or whether or not the information was provided, the issues should be raised immediately to the appropriate level of management for proper resolution.

8. Consistent with Section 4.2, the staff should make use of previous reviews in order to avoid asking unnecessary questions.
9. The staff should not use license amendments as an opportunity to force licensees to take actions beyond those that relate directly to the amendment and are needed to provide reasonable assurance of plant safety (see LIC-202 (OL 901), "Plant-Specific Backfits").
10. The timely issuance of an RAI, if necessary, and the licensee's agreed upon time to respond should be factored into the schedule established to complete the review within the licensing action timeliness goals.

The intent of this guidance is not to limit the staff from getting the information that is needed to perform a technical review; rather, this practice is needed to ensure that the information requests will be productive and focus staff and licensee resources on the pertinent issues necessary to make a regulatory decision.