

June 3, 2010

Mr. Neil Wilmshurst, Vice President
Nuclear Power Sector and Chief Nuclear Officer
Electric Power Research Institute
1300 W.T. Harris Boulevard
Charlotte, NC 28262

SUBJECT: IMPLEMENTATION OF A REVISED REVIEW PROCESS FOR TOPICAL
REPORTS

Dear Mr. Wilmshurst:

This letter is to inform you that effective December 21, 2009, as part of our ongoing efforts to improve the effectiveness and efficiency of the topical report (TR) program, we have implemented revisions to our TR review process within the Office of Nuclear Reactor Regulation (NRR).

From April 2008 until October 2009, the NRR staff and industry representatives identified numerous areas for improvement within the TR review process during a series of monthly public meetings. Over a period of one year, the NRR staff and industry representatives exchanged perspectives and new ideas, and discussed potential improvements to the TR review process.

The revisions to the TR review process were incorporated into NRR's Office Instruction LIC-500, Revision 4, "Topical Report Process," dated December 21, 2009. LIC-500, Revision 4, provides internal guidance to the NRR staff to support its ability to process TR requests. At the request of the industry representatives, LIC-500, Revision 4, is currently available to the public in the Agencywide Documents and Access Management System (ADAMS) Accession No. ML091520370.

Prior to the issuance of LIC-500, Revision 4, the U.S. Nuclear Regulatory Commission (NRC) staff discussed the key changes to the TR review process with industry representatives during the Nuclear Energy Institute Licensing Forum, held on October 6, 2009. The NRC, through its website, <http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html>, provides guidance to vendors and owners' groups on NRR's TR program. A summary of the key changes of the revised process, are provided below. The NRC public website will be updated to reflect the changes in LIC-500, Revision 4.

1. Issue: During the TR public meetings, the industry representatives requested that NRR provide clarification regarding whether technical reports submitted to the NRC by industry (typically vendors) fall under the scope of a TR review.

Resolution: The revised process describes the difference between a TR and a technical report. Technical reports submitted to support an application for design certification or plant-specific licensing actions are not defined as TR under this program. In addition, LIC-500, Revision 4, incorporates guidance consistent with LIC-109,

“Acceptance Review Procedures,” to ensure that the TR contains complete and detailed information. Refer to LIC-500, Revision 4, Section 4.1.1, “TR Criteria,” for additional detail.

2. Issue: During a series of internal NRR discussions pertaining to the TR process, several NRR staff members identified that there were some details of the fee waiver process that may not be clear to a new project manager. Therefore, the following additional clarifications were recommended by NRR staff members and discussed with industry representatives during the monthly TR public meetings.

Resolution: The revised process incorporates the following additional guidance for NRR staff pertaining to TR review fees. Refer to LIC-500, Revision 4, Section 4.1.2, “TR Review Fees,” for additional detail.

- The NRR staff does not begin its review (or open a Technical Assignment Control (TAC) number) until the Office of Chief Financial Officer (OCFO) decides in writing whether to grant the fee exemption, unless the submitting organization has agreed to pay the fee in case the fee exemption request is denied.
 - Step-by-step guidance is provided to the NRR TR project manager regarding the internal process to open a fee-billable or non-fee billable TAC. Please note that LIC-500, Revision 4, currently refers to the TR project manager as the Special Projects Branch (PSPB) project manager (PM). Since LIC-500, Revision 4, was issued, the PSPB name was changed to the Licensing Processes Branch (PLPB). In the next update to LIC-500, the NRC staff plans to remove all of the references to the PSPB PM, and replace it with a generic title such as, “TR project manager.”
 - If a fee waiver exemption for a TR was approved by the OCFO, and the TR is later withdrawn by the applicant, the applicant may decide to resubmit the TR at a later date. In these cases, the applicant is required to request another fee waiver from the OCFO.
3. Issue: Industry representatives recommended that the use of a pilot plant license amendment application, submitted in parallel with an incoming TR would be useful and beneficial to support the NRC’s review of the TR. The industry representatives proposed an approach for the NRC staff to consider during several TR public meetings. Since the approach recommended by industry representatives would involve significant changes to the process to review a license amendment request, the NRR staff determined that it was not prepared at that time to proceed with implementing the recommendation to incorporate guidance into LIC-500, Revision 4, to support pilot-plant applications.

Resolution: The revised process clarifies that if plant-specific information is needed in support of a TR review, it should be submitted as part of the TR, either in the body of the TR or as an appendix to the TR. Separate, concurrent "pilot plant" applications are inconsistent with the guidance in NRR Office Instruction LIC-109, and are not acceptable. Licensees should wait until the NRC staff publishes the draft safety evaluation (SE) for the referenced TR following resolution of technical issues and identification of any limitations and conditions for using the TR, before referencing the TR

in a license amendment request. Refer to LIC-500, Revision 4, Section 4.1.3, "TRs and Related Plant-Specific Licensing Actions," for additional detail.

4. Issue: For consistency, NRR staff and industry representatives recommended updating the table in Section 4.2 of LIC-500, Revision 4. This table outlines the milestones associated with each phase of the TR review process.

Resolution: The revised process updates the milestones associated with the TR Review Process. Refer to LIC-500, Revision 4, Section 4.2, "TR Review Process Steps," for additional detail.

5. Issue: NRR staff and industry representatives provided numerous recommendations to improve the quality and effectiveness of pre-submittal meetings. The NRR staff considered and discussed these recommendations during the monthly TR public meetings.

Resolution: For pre-submittal meetings, LIC-500, Revision 4, incorporates guidance for the NRR TR project manager regarding the following items. Refer to LIC-500, Revision 4, Section 4.2.1 "Pre-submittal Meetings," for additional detail.

- Including a representative from the Technical Specifications Branch in the pre-submittal meeting, if the approval of the TR will require a change to the standard technical specifications.
- Ensuring that a representative from OCFO attends the pre-submittal meeting, if the TR applicant plans to request a fee waiver.
- Opening a pre-submittal TAC. All TR pre-submittal meetings are fee-billable.
- Obtaining a draft version of the TR, when feasible, to facilitate the discussion during the pre-submittal meeting.
- Providing feedback on prioritization during the pre-submittal meetings, if the technical branches involved in the review are limited by resources, and therefore, not capable of reviewing the TR at the time that the report will be submitted.
- Issuing detailed meeting summaries, to include any action items discussed during the pre-submittal meeting.
- Holding a post-submittal meeting with the applicant to discuss the TR with the assigned reviewers, after the TR is submitted for NRC review.

6. Issue: NRR TR project managers often receive questions from vendors and owners' groups regarding the process to submit a TR for review. To ensure that all NRR project managers are providing this information in a consistent manner to industry representatives, additional detail has been incorporated into LIC-500, Revision 4.

Resolution: The revised process captures updated information regarding the process to submit a TR, including a revised TR, to the NRC for review. Refer to LIC-500, Revision 4, Section 4.2.2 "Applicant Submits TR," for additional detail.

7. Issue: During the TR public meetings, industry representatives had questions about the process that the Advisory Committee on Reactor Safeguards (ACRS) currently uses to request TR briefings.

Resolution: LIC-500, Revision 4, incorporates additional guidance for the NRC staff to facilitate early identification of incoming TRs that are of interest to the ACRS. Refer to LIC-500, Revision 4, Section 4.2.3 "Work Plan," for additional detail.

8. Issue: For TRs that are complex and involve multiple review branches, differing views may arise regarding the acceptability of the TR or regarding the adequacy of the responses to the requests for additional information (RAI). The NRR senior management recommended that the staff develop a technical champion role to facilitate the review of these complex TRs, for incorporation into LIC-500, Revision 4.

Resolution: For a complex TR that involves multiple review branches, LIC-500, Revision 4, provides guidance for the TR project manager to identify a technical champion. The purpose of the technical champion is to facilitate the NRC staff's TR review process and to ensure effective communication between the NRC review branches and management to support timely resolution of issues. Refer to LIC-500, Revision 4, Section 4.2.3 "Work Plan," for additional detail.

9. Issue: The NRR staff identified that additional guidance should be incorporated into LIC-500, Revision 4, to support the staff's ability to conduct acceptance reviews.

Resolution: The revised process provides guidance to the NRC TR project manager and technical leads on performing acceptance reviews, consistent with the NRC staff's guidance in LIC-109. Refer to LIC-500, Revision 4, Section 4.2.4 "Acceptance Reviews," for additional detail.

10. Issue: Industry representatives have previously expressed concerns to NRR senior management regarding industry's perception that TRs are treated by NRC staff as low priority. To address this concern, the NRR senior management recommended that the staff develop a process to prioritize incoming TRs.

Resolution: Section 4.2.4 of LIC-500, Revision 4, discusses the most significant change to the revised TR review process, which is the prioritization of incoming TRs. Enclosure 7 of LIC-500, Revision 4, refers to this process as a "draft prioritization scheme" and it contains guidance for NRR TR project managers to convey prioritization information for incoming TRs to vendors and owners' groups. If the TR project manager identifies that a technical reviewer cannot complete the acceptance review for an incoming TR in 60 days, then the TR will be prioritized in accordance with the draft prioritization scheme.

Although the prioritization scheme was incorporated into LIC-500, Revision 4, as a draft, the intent of the NRR staff is to utilize the prioritization scheme when needed, collect and analyze the data regarding the incoming TRs that are being prioritized, and consider improvements for the next revision of LIC-500 to further enhance the process of prioritizing incoming TRs.

The guidance in Enclosure 7 to LIC-500, Revision 4, was developed by the NRR staff and industry representatives provided feedback on the draft prioritization scheme during the monthly TR public meetings. In addition, the NRR staff conducted a small pilot of the draft prioritization scheme, with the support of industry representatives.

To support implementation of this draft prioritization scheme by all vendors and owners' groups, the TR project manager will verify that all future incoming TRs submitted for NRR review address the prioritization factors contained in Enclosure 7 of LIC-500. Please note that Section 4.2.2 of LIC-500, incorrectly refers to the draft prioritization scheme as "Appendix B in LIC-500." This is an error which will be corrected in the next revision to LIC-500. Also, as described in Enclosure 7, in addition to the information requested in Section 4.2.2.B of LIC-500, the cover letter transmitting any incoming TRs to the NRC should address the following factors to support TR prioritization:

- Topical Report Classification: Explain if the TR is being submitted to support resolution of a generic safety issue or emergent technical issue. If the TR proposes an alternative approach to meet the NRC regulations, that information should also be stated in the cover memo transmitting the TR.
- Applicability: Assuming adoption or use, provide an estimate of the potential number of licensees that could reference the approved TR. Specifically, identify if all of industry could reference the approved TR, if it's only applicable to entire groups of licensees (BWROG, PWROG, etc.), or if it's applicable only to partial groups of licensees.
- Specialized Resource Availability. The NRC staff's goal is to complete a TR review in two years. If a safety evaluation is needed prior to two years, the TR applicant can request, with justification, that an SE be provided by a certain date to support a licensing activity.

11. Issue: Industry representatives expressed concerns during the TR public meetings regarding the incorporation of limitations and conditions in the draft or final SE by NRR staff, without first being provided with an opportunity to resolve them through the RAI process. Industry representatives recommended that LIC-500, Revision 4, incorporate guidance for the staff to ensure that all vendors and owners' groups are notified as early as practical of issues, which if not addressed appropriately within the RAI response, could result in limitations and conditions. In addition, there were a number of other issues identified by the NRR staff regarding the processes for an applicant to request an extension to an RAI response due date, requesting a mark up of the TR from an applicant, withdrawing a TR, or handling late or incomplete RAI responses.

Resolution: LIC-500, Revision 4, incorporates additional guidance on the following items. Refer to LIC-500, Revision 4, Section 4.2.6 "RAIs," for additional detail.

- The cover letter transmitting the RAIs will list the agreed-upon date for the applicant to provide its RAI responses, and if known, describe any RAIs that could result in limitations and conditions in the TR safety evaluation, if not resolved by the applicant during the RAI process. Since the NRC staff's review is not complete at this point, it is possible for limitations and conditions to be identified once the review has been completed and the staff prepares the draft SE.
- The revised process also describes the process for:
 - Requesting an extension to the RAI response date,

- Requesting a mark up of the TR pages, if the applicant proposes to make changes to the TR as a result of the RAIs,
- Dealing with late or incomplete RAI responses,
- Withdrawing a TR from NRC staff review,
- Elevating internal technical disagreements between review branches, regarding the adequacy of RAI responses, and
- The basis for requesting a revised TR from the applicant prior to development of the NRC staff's safety evaluation.

12. Issue: The NRR staff identified that additional discussion should be provided to define the differences between a limitation and a condition for a TR. In addition, industry representatives recommended that any additional guidance capture the need to inform vendors and owners' groups of limitations and conditions early in the review process (at the RAI phase preferably) to facilitate early resolution prior to the issuance of the draft SE.

Resolution: The revised process provides additional clarification on including limitations and conditions in the safety evaluation and the steps that the TR project manager can take to ensure that the basis for imposing any limitations and conditions are identified by the NRR staff early in the review process and understood by the applicant. Refer to LIC-500, Revision 4, Section 4.2.7 "TB Transmits SE to PSPB," for additional detail.

13. Issue: The NRR staff identified that the guidance on preparing a draft SE for a proprietary or nonproprietary TR should be described in more detail for clarity.

Resolution: The revised process provides guidance for the NRC TR PM on how to prepare the draft SE whether the TR is considered proprietary or non-proprietary. Refer to LIC-500, Revision 4, Section 4.2.8 "Issue Draft SE to Applicant," for additional detail.

14. Issue: The NRR staff identified that the TR project managers needed guidance to ensure that TACs were consistently closed out once the final SE was issued. This was especially important for fee-billable TACs to ensure that the applicant was not being billed beyond the date of issuance of the final SE.

Resolution: The revised process provides guidance for the NRC TR PM on when to close the TAC. Refer to LIC-500, Revision 4, Section 4.2.8 "Issue Final SE to Applicant," for additional detail.

15. Issue: During the monthly TR public meetings, industry representatives raised concerns about the format of the approved version of the TR. For example, industry representatives stated that additional flexibility is needed to allow for vendors and owners' groups to attach RAI responses as an appendix to the approved TR, instead of placing the RAIs with responses after the title page of the TR.

Resolution: The revised process describes alternatives for the TR project manager to discuss with the TR applicant when they are preparing the approved version of the TR. (LIC-500, Revision 4, Section 4.2.10 "Applicant Submits Approved Version of TR").

16. Issue: The NRC staff discussed during the TR public meetings that some vendors and owners' groups submit revisions or supplements to NRR after a TR has been approved by the staff. Questions have been raised by the TR project managers regarding the review process for a revision to an approved TR, versus the process for a supplement to an approved TR.

Resolution: The revised process explains the difference between a supplement and a revision to an approved TR, the process that the TR PM will follow to review the revision or supplement, and the proper markings for the revised –approved version of the TR. (LIC-500, Revision 4, Section 4.2.11 “Applicant Submits Revision(s) or Supplement(s) to the Accepted Version of TR”).

If you have any questions, or need clarification, please call Tanya Mensah, Senior Project Manager, Topical Report Program, at 301-415-3610, or me at 301-415-5710.

Sincerely,

/RA/

Thomas B. Blount, Deputy Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

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Resolution: The revised process explains the difference between a supplement and a revision to an approved TR, the process that the TR PM will follow to review the revision or supplement, and the proper markings for the revised –approved version of the TR. (LIC-500, Revision 4, Section 4.2.11 “Applicant Submits Revision(s) or Supplement(s) to the Accepted Version of TR”).

If you have any questions, or need clarification, please call Tanya Mensah, Senior Project Manager, Topical Report Program, at 301-415-3610, or me at 301-415-5710.

Sincerely,

/RA/

Thomas B. Blount, Deputy Director
 Division of Policy and Rulemaking
 Office of Nuclear Reactor Regulation

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