



# U.S. Nuclear Regulatory Commission Office of Nuclear Reactor Regulation

## NRR OFFICE INSTRUCTION

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### Change Notice

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Office Instruction No.: **LIC-500, Revision 4**

Office Instruction Title: **Topical Report Process**

Effective Date: **December 21, 2009**

Approved By: **Ben Ficks**

Date Approved: **December 14, 2009**

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Responsible Organization: **NRR/DPR/PSPB**

**Summary of Changes:** This change reflects recent significant revisions to the topical report review process.

Training:

- (1) Self-study by Vendor/Owners group project managers and Technical Branch staff and branch chiefs. Training Session for Vendor/Owners group project managers
- (2) E-mail to all staff

ADAMS Accession No.: **ML091520370**



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**NRR OFFICE INSTRUCTION  
LIC-500, Revision 4**

**Processing Requests for Reviews of Topical Reports**

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**1. POLICY**

It is the policy of the Office of Nuclear Reactor Regulation (NRR) to establish procedures and guidance for its staff to meet the requirements and performance goals established in legislation, regulations, the Agency's strategic plan, and office-level operating plans. Therefore, Topical Reports (TRs) should be reviewed by the Nuclear Regulatory Commission (NRC) staff with the intent of maximizing their scope of applicability consistent with current standards for licensing actions, compliance with the applicable regulations, and reasonable assurance that the health and safety of the public will not be adversely affected. The NRC, through its website <http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html> (Reference 1), provides guidance to applicants on the NRC's TR program.

**2. OBJECTIVE**

The objective of the TR process is, in part, to add value by improving the efficiency of other licensing processes, for example, the process for reviewing license amendment requests (LARs) from commercial operating reactor licensees. The objective of this office instruction is to define the process by which NRR staff and managers process TRs and, thereby, improve NRR's efficiency and consistency in the review of TRs.

A TR is a stand-alone report containing technical information about a nuclear power plant safety topic, which meets the criteria contained in Section 4.1.1, that can be submitted to the NRC for its review and approval. A TR improves the efficiency of the licensing process by allowing the staff to review a proposed methodology, design, operational requirements, or other safety-related subjects that will be used by multiple licensees following approval by referencing the approved TR. The TR provides the technical basis for a licensing action.

**3. PURPOSE**

The purpose of the NRC TR program is to minimize industry and NRC time and effort by providing for a streamlined review and approval of a safety-related subject with subsequent referencing in licensing actions, rather than repeated reviews of the same subject. Under the NRC TR program, industry organizations, such as a vendor or an owners' group (OG), also referred to as an "applicant" throughout this Office Instruction (OI), may on its own choice or at the request of the NRC staff, submit reports to the NRC on specific safety-related subjects and have them reviewed independently of any operating license review.

## **4. BASIC REQUIREMENTS**

### **4.1 Overview of the TR Process**

TRs are typically submitted by an applicant in accordance with the guidance provided on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html>.

NRR's Special Projects Branch (PSPB), within the Division of Policy and Rulemaking (DPR), has the responsibility for managing the TR program. A lead project manager (PM) within PSPB is assigned to manage the overall TR program. The PSPB licensing assistant is responsible for updating the TR website quarterly. Additionally, PSPB PMs are assigned to each of the major TR applicants. A list of the assigned PSPB PMs and the status of the TRs under review are available on the NRC's website.

The review of TRs, for the most part, follows the guidance for reviewing license amendments in Office Instruction LIC-101, "License Amendment Review Procedures" (Reference 2). To the extent possible, this OI will reference existing guidance documents rather than paraphrasing them. Also, the PSPB PM should be familiar with the guidance provided in Office Instruction COM-204, "Interfacing With Owners Groups, Vendors, and NEI" (Reference 3).

This guidance describes a procedure for processing a TR. The process includes the following subprocesses, which are described in Section 4.2 in more detail:

- Pre-submittal meetings
- Submitting the TR
- Work plan preparation, which in conjunction with the Center for Planning an Analysis (CPA) and appropriate technical review branches, the PSPB PM is expected to coordinate.
- Acceptance reviews (includes prioritization of incoming TR's when appropriate)
- Proprietary determinations
- Requests for Additional Information (RAI)
- Preparation and issuance of the draft and final Safety Evaluation (SE)
- Approved version of the TR
- Revisions or supplements to the approved version of the TR

#### **4.1.1 TR Criteria**

To be accepted for review the TR should meet all four of the following criteria:

- A. The report deals with a specific safety-related subject regarding a nuclear power plant that requires a safety evaluation by the NRC staff; for example, component design, analytical models or techniques, or performance testing of components and/or systems that can be evaluated independently of a specific license application.

NOTE: Technical reports submitted to support an application for design certification or plant-specific licensing actions are not defined as TRs under this program. A technical report is typically submitted

by a vendor. The information in the technical report is subsequently captured in an application (perhaps by reference); however, the NRC's evaluation of that technical report is included in the SE for the design certification or plant-specific licensing application (a separate SE is not provided for each technical report).

- B. The TR is expected to be used by multiple licensees in a number of requests for licensing actions. Examples of licensing actions include license amendment requests (LARs), relief requests, and other types of TR-based submittals that are not submitted pursuant to Title 10 of the *Code of Federal Regulation* (10 CFR) Section 50.90 or Section 50.55a. The term LAR is referenced throughout this TR; however, it is not intended to exclude other requests for licensing action that also reference an approved TR.

NOTE: Generally, a report intended for use by multiple sites, from one licensee, is not considered a TR.

- C. Consistent with the criteria in LIC-109, "Acceptance Review Procedures," the TR contains complete and detailed information on the specific subject presented. Conceptual or incomplete preliminary information will not be reviewed.
- D. NRC approval of the report will increase the efficiency of the review process for applications that reference the report.

Exceptions to these criteria, especially criterion B, may be allowed on a case-by-case basis if the NRC staff determines that an exception is in the public interest. The applicant must provide such written justification to the NRC staff prior to submitting the TR for review, preferably at the pre-submittal meeting stage. Justification for an exception could be based on the report's contribution to resolving a safety-related issue, an advancement in technology that would benefit safety or reduce an operational burden, or significant cost savings to the industry. Any NRC staff decision to accept a TR for review that does not meet the four criteria above must also find that the projected NRC staff resources for review of the TR are justified.

#### **4.1.2 TR Review Fees**

Applications for TR reviews are normally subject to fees based on the full cost of the review (see 10 CFR Part 170.21). Exemptions to the fee recovery requirements may be made in conjunction with the Office of Chief Financial Officer (OCFO) on a case-by-case basis (see 10 CFR 170.11).

Guidance for these exemptions include the following:

- A. Any fee exemption must be requested and approved by the OCFO prior to the start of the TR review. The applicant requesting the fee waiver should submit the fee exemption request in writing to the OCFO. (Refer to 10 CFR 170.11.)

A TR may qualify for a fee waiver if the TR is submitted as a means of exchanging information between the industry and the NRC for the purpose of supporting the NRC's generic regulatory improvement program. Occasionally, the NRC staff may determine on its own that addressing a safety-related matter in a TR is desirable. In that case, NRC management (at the Associate Director level or above) will contact the cognizant organization(s) to request a TR and the resulting TR may be reviewed on a fee-exempt basis. The final determination of a fee exemption rests with the OCFO.

- B. The NRC does not begin its review (or open a Technical Assignment Control (TAC) number) until the 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. If the exemption is denied and the applicant still wants the TR reviewed, the applicant must submit a letter requesting a fee-billable review.

A TAC requested by the PSPB PM to support a TR review should be requested in TRIM under Planned Activity (PA) 111-113A. The Activity Code is "RT-Topical Reports." The Template Title is "Rx Lic-vendor/owners groups activities – Topical Report Reviews." This template title contains "fee-billable" and "non-fee billable" options. The PSPB PM should only select the "non-fee billable" option if the OCFO has granted the fee waiver exemption in writing.

If a fee waiver exemption was approved by the OCFO, and the TR is later withdrawn by the applicant, the applicant may decide to re-submit the TR at a later date. In these cases, the applicant is still required to request another fee waiver from the OCFO. Section 4.2.6 provides additional NRC staff guidance on the process to withdraw or close a TR accepted for NRC review.

#### **4.1.3 TRs and Related Plant-Specific Licensing Actions**

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 LIC-109, and are not acceptable. Licensees should wait until the NRC staff publishes the draft 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 an LAR.

**4.2 TR Review Process Steps**

<b>No.</b>	<b>Task</b>	<b>Time Period</b>	<b>Responsibility</b>
1	Pre-submittal meeting	1 to 6 months prior to submittal	Applicant/PM/ Technical Branch(s) (TB)
2	Applicant submits TR to the NRC Document Control Desk (DCD). The DCD assigns an ADAMS accession number to the TR.		Applicant
3	Complete the fee exemption review (if applicable)	Within 60 days of receipt of the TR.	PM/TB/OCFO
4	PM opens a TAC. Process TR through the Center for Planning and Analysis (CPA).	Within 5 working days of receipt of TR or within 5 working days of issuance of the OCFO letter.	PM
5	TBs complete and return the Green sheet to CPA.	Within 14 working days of receipt from the CPA	TBs
6	Hold telephone conference to establish agreed-upon review schedule milestones and estimated costs	During acceptance review period	Applicant/PM/TB
7	Complete acceptance review. PM issues acceptance letter	Within 60 days of receipt of TR or issuance of the OCFO letter.	PM/TB/OCFO
8	Complete proprietary determination (if needed). PM issues proprietary letter	Within 60 days of receipt of TR or issuance of the OCFO letter.	PM/TB
9	Provide Requests for Additional Information (RAIs) to PM (if needed).	10 working days prior to agreed-upon milestone schedule for RAIs	TB
10	Provide RAIs to applicant in accordance with LIC-101, Section 4.3. The RAI cover memo should identify and discuss any anticipated limitations and conditions, if practicable.	Within the agreed-upon milestone schedule	PM
11	Applicant provides RAI response to PM	Within the agreed-upon schedule	Applicant
12	Provide SE to PM.	20 working days prior to agreed-upon milestone schedule for Draft SE	TB
13	Issue Draft SE to applicant.	Within the agreed-upon milestone schedule	PM
14	Applicant provides comments on Draft SE	Within 10 working days for proprietary information, and within additional 10 working days for factual errors or clarity issues	Applicant
15	Provide resolution to applicant's comments to PM	Within 10 working days after receipt of comments	TB

No.	Task	Time Period	Responsibility
16	Issue final SE to applicant	Within 20 working days after receipt of applicant's comments on the Draft SE. The final SE should be issued within 2 years of TAC opening. Note: If the TR is being discussed at an Advisory Committee on Reactor Safety (ACRS) meeting, this may result in a delay in issuing the final SE to applicant due to scheduling conflicts.	PM
17	Applicant submits approved version of TR	Within three months of final SE	Applicant
18	If necessary, verify that changes to the approved version of the TR are made in accordance with the final SE.	Within three months of receipt of the approved version of TR.	PM/TB

#### 4.2.1 Pre-submittal Meetings

##### A. Purpose

The purpose of a pre-submittal meeting is for the applicant to meet with the NRC staff to discuss the TR before it is submitted formally for review. A pre-submittal meeting is required to begin the TR review process, unless the NRC staff and the applicant agree that such a meeting is not necessary. The applicant should contact the designated PSPB PM well in advance of the submittal and request a pre-submittal meeting to discuss the proposed TR with the NRC staff. In accordance with Office Instruction COM-202, "Meetings With Applicants, Licensees, Interveners, Vendors, or Other Members of the Public" (Reference 4), public meetings normally require a 10-day notice period prior to the meeting.

##### B. Preparation

To prepare for the pre-submittal meeting, the PSPB PM notifies the appropriate management and selected NRC staff from the appropriate TB(s) to participate in the meeting. Prior to the pre-submittal meeting, the PSPB PM will discuss with the applicant any future known licensing action requests that plan to reference the approved TR. The PSPB PM will ask the TR applicant if the TR requires a change to the standard technical specifications (STS).

If approval of the TR requires a change to the STS, then the Technical Specifications Branch (ITSB) is the point of contact for determining the acceptability of the proposed TS changes, and any future interaction with the Technical Specifications Task Force about proposed changes to STS.

If the applicant is considering requesting a fee exemption, the PSPB PM should ensure that a representative from the OCFO attends the pre-submittal meeting.

Since the TR has not been formally submitted to the NRC at this point, the PSPB PM may open a pre-submittal TAC for NRC staff supporting this meeting using the Time, Resource and Inventory Management (TRIM) software. This software provides a means of billing the applicant and tracking the work. The TAC should be opened under PA 111-113A.

Select “Activity Code – RM Other Licensing Activities – Pre-Application Reviews.” Appearing at the bottom page of the screen, will be “Template Title – RX-Lic-vendor/owners group activities – pre-application reviews.” Select the fee-billable option.

The PSPB PM should encourage the applicant to provide a draft version of the TR to improve the efficiency, effectiveness, and the productivity of the pre-submittal meeting.

#### C. During the Pre-submittal Meeting

During the pre-submittal meeting, the applicant will brief the NRC staff on the need, purpose, scope, and methodology for the TR and whether it plans to ask for a fee exemption.

The NRC staff should provide feedback to the applicant on the proposed TR. The NRC staff should use its knowledge and experience to inform the applicant of the level of detail expected in the TR. The feedback can include an estimate of the number of review hours and the review schedule the NRC staff can support based on the limited information the NRC staff has received in the meeting. Since the NRC staff has not received the TR submittal from the applicant, the NRC staff will stress to the applicant that these are preliminary estimates only and more realistic estimates will be made when the TR is submitted.

The NRC staff should also inform the applicant if the TR does not meet the criteria for acceptance. Since this meeting is a briefing on the proposed TR, the NRC staff cannot provide a formal determination whether the proposed TR will be acceptable or not. However, the NRC staff should provide their best and candid insights on the merits of the TR and clearly communicate the problem areas they see in the proposed TR.

If approval of a TR requires a change to the STS, the NRC staff should clearly communicate that the STS revision will be issued with the approved TR.

The NRC staff should ask appropriate questions to elicit information on the relationship of the proposed TR to any other ongoing or proposed NRC staff industry efforts and any other information that could affect a subsequent NRC staff decision on acceptability of the proposed TR.

To support TR prioritization, the NRC staff will also provide feedback if they are limited by resources and are, therefore, not capable of reviewing the TR at the time that the TR will be submitted. Additional details on TR prioritization are provided in Appendix B.

#### D. After the Pre-submittal Meeting

After the pre-submittal meeting, and in accordance with Office Instruction COM-202, "Meetings With Applicants, Licensees, Interveners, Vendors, or Other Members of the Public" (Reference 4), the PSPB PM should issue a detailed meeting summary, including any action items or NRC staff requests, within 30 working days. Capturing detailed information in the meeting summary does not preclude the NRC staff from considering or pursuing alternative/different actions or additional requests in the future.

#### E. Post-submittal Meetings

The purpose of holding an initial (early) post-submittal meeting is to provide the applicant with the opportunity to discuss the TR with the assigned technical reviewers after the TR and any supporting documents have been provided to the NRC for review. Post-submittal meetings are encouraged during the acceptance review process, particularly for TRs that involve multiple branches/divisions/offices within the NRC.

Meetings (public meetings or teleconferences) with the applicant are encouraged throughout the TR review, where appropriate, to keep expectations aligned, to discuss progress, and to provide advance notification of pending RAIs, limitations or conditions, or denial letters.

In addition, depending upon the complexity of the TR and the number of TBs involved in the review, the PSPB PM may establish a review team and will coordinate periodic internal meetings to ensure that significant safety issues identified throughout the review are openly discussed and resolved early in the review.

### 4.2.2 Applicant Submits TR

After the pre-submittal meeting, the PSPB PM will ensure that the applicant submits the following documents, where applicable, to the NRC. The PSPB PM will refer the TR applicant to the NRC public website for the following details: <http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html> (Reference 1).

#### A. Fee Waiver Request To the OCFO

Any request for a fee waiver to the OCFO, should be submitted by the applicant in writing directly to the OCFO, as described in 10 CFR 170.11. Requests for a fee waiver exemption should not be addressed to the NRC DCD. Per 10 CFR 170.11, the TR applicant will identify the basis for a fee waiver exemption request. Section 4.1.2 provides additional detail.

A copy of the fee waiver exemption request should also be included in the TR submittal (as discussed below) as a reference for the PSPB PM.

## B. TR to the NRC DCD

### Cover Letter

The cover letter transmitting the TR should include the following information:

- Name of the NRC PSPB PM. The NRC PSPB PM will ensure that the NRC technical leads are provided with a copy of the TR.
- Project Number for the applicant.
- A statement indicating whether approval of the TR requires a change to the STS. For TRs that involve TS changes, the applicant must attach to the TR markups of the appropriate vendor STS and Bases TS pages showing proposed changes .
- A proprietary determination for the TR, if applicable. (Refer to Section 4.2.5 for additional information).
- A statement that the TR was requested by NRC senior management at the Associate Director level, if applicable.
- Information to support the NRC's ability to prioritize the incoming TR. The TR applicant should follow the format of the draft prioritization scheme matrix, as shown in Appendix B.
- A copy of the fee waiver exemption request that was submitted directly by mail to the OCFO. (Refer to 4.2.2.A.)

### Method of TR Submission

Documents can be submitted to the DCD by mail (hard copy) or by using electronic submission to the NRC. The guidelines regarding the process to submit documents to the DCD electronically are provided at: <http://www.nrc.gov/site-help/e-submittals/guid-elec-submission.pdf>. The guidelines must be followed to ensure that the document is accepted and processed by the DCD.

This guidance document governs the electronic submission of documents to the NRC. It includes the required procedures for corresponding electronically with the NRC via the Internet using Electronic Information Exchange, by CD-ROM, or by e-mail. It also includes procedures for corresponding by facsimile (fax).

If a document submitted via electronic submission is not accepted by the DCD, the PSPB PM and the applicant will receive an email from the DCD. The email from the DCD will identify the error(s) and reason for rejection. It will also request that the applicant resubmit the document.

### ADAMS Profile For The TR

Once the document is processed by the DCD, the PSPB PM will receive electronic notification via ERIDS that the TR is in the Agencywide Documents Access and Management System (ADAMS).

The TR and cover letter should be profiled in ADAMS as public, unless the applicant meets the requirements for withholding information pursuant

to 10 CFR 2.390. Additional information on proprietary determinations is provided in Section 4.2.5.

#### Opening A TAC To Begin The TR Review

If the review is fee-billable, the PSPB PM can open a fee-billable TAC number to begin the review. If a fee waiver exemption has been requested, the PSPB PM should refer to Section 4.1.2 before requesting a TAC.

Once the TAC has been requested, it is processed through the CPA for review. The TB will provide the CPA with the completed Work Planning and Characterization Form (Green Form) within 14 working days of receipt. The purpose of the Green Form (i.e., typically referred to as the Green Sheet) is to identify the TB(s) involved in the review and to obtain internal management agreement on the review schedule.

#### C. Submitting a Revised TR After it Has Been Closed or Withdrawn

The PSPB PM should coordinate a pre-submittal meeting before any applicant formally re-submits a TR for NRC review to ensure that the necessary information is contained within the revised TR. In general, if a TR review was closed or withdrawn, the revised TR submission should address all of the issues raised previously by the staff, including those identified by the NRC staff in its RAIs.. In cases where the TR was withdrawn or closed before the applicant provided RAI responses, the revised TR should include the applicant's RAI response, and a change summary to describe where changes have been made in the revised TR to incorporate RAI responses. If the PSPB PM and applicant agree that a TR does not need to be revised before it is re-submitted, the applicant should reference the date and ADAMS Accession number of the original TR in the transmittal letter requesting NRC staff review.

#### **4.2.3 Work Plan** (within 60-day acceptance review period)

TRs are generally large, complex reports that may require the involvement of more than one TB. The PSPB PM should develop a work plan. This work plan may be informal (e.g., an e-mail sent to the reviewers involved). Office Instruction LIC-101 provides guidance on developing a work plan when coordinating the review of licensing actions, which is also applicable to TR reviews.

The work plan should:

- set priorities (if applicable, the first priority is to resolve the fee exemption request),
- identify if a proprietary determination is needed,
- identify the NRR lead branch and the supporting branches. A lead technical branch is typically determined by identifying the branch that will be reviewing the majority of the TR and is usually based upon the scope of the technical issue(s) discussed in the TR. The lead technical branch may identify to the PSPB PM that there are

other technical branches that they need to coordinate with (i.e., supporting branches).

- Include ITSB on any TR that involves STS changes, including risk-informed TS initiatives,
- identify if other NRC program offices need to review the TR if its applicability goes beyond the scope of current operating reactors,
- determine the areas to be reviewed by each TB,
- establish completion dates for the supporting branches and for the complete SE from the lead branch,
- If possible, identify the need for a technical champion (refer to Enclosure 6). The need for a technical champion may not be obvious at this phase of the review. Therefore, the PSPB PM should become familiar with the guidance so that he or she can refer to it later in the TR review process, if needed,
- schedule date for RAI,
- estimate review hours for each TB, and
- establish date for DPR to issue Draft SE to the applicant.

This work plan is developed in cooperation with the TBs involved in the review. A meeting is helpful to determine each reviewer's area and to identify any other branches that should be involved in the review. The information in the work plan should be captured in the Work Planning and Characterization Form (Blue Form) sent to CPA. As summarized in Section 4.2.2.2, the TB(s) will provide the PSPB PM (via the CPA) with the completed Work Planning and Characterization Form (Green Form) within 10 working days of receipt. If Green Sheets have not been provided to the PSPB PM after 10 working days, the PSPB PM should notify the appropriate TB Division Planning Representative(s) to ensure that Green Sheets are completed. If a Green Sheet is not provided to the PSPB PM after 15 working days, the PSPB PM should elevate the issue to the PSPB Branch Chief (BC).

The ACRS may wish to review the TR and the associated SE prepared by the staff. The TB involved in the review should notify the designated NRR office coordinator for ACRS activities of TRs that have recently been submitted for NRC staff review (i.e., TR TAC age is less than 3 months). The NRR office coordinator should then provide this information to the Office of Executive Director for Operations and ACRS staff during monthly coordination meetings regarding the scheduling of upcoming ACRS meetings. If the ACRS wishes to be briefed on the TR and SER, the cognizant ACRS staff member should contact the TB to schedule the appropriate briefings. The briefings should be performed by both the TB and the applicant. Additional details on NRR interfaces with the ACRS are discussed in COM-103, "NRR Interfaces with the Advisory Committee on Reactor Safeguards (ACRS)."

The Committee to Review Generic Requirements only reviews TR SEs at the program office director's request.

As described in Section 4.2.1.B, if approval of the TR requires a change to the STS then ITSB should be contacted to determine if the change is significant enough to warrant a TSTF submittal.

#### **4.2.4 Acceptance Review**

As described in Section 4.1.2, if a fee exemption has been requested, then the OCFO must issue a letter approving the exemption before the NRC staff's review can commence. If the exemption is denied and the applicant still wants the TR reviewed, the applicant must submit a letter requesting a fee-billable review. The 60-day acceptance review period would not commence until the fee exemption request has been approved, or if denied, the applicant has submitted the letter requesting a fee-billable review.

The purpose of the acceptance review is to determine if the information provided in the TR meets the administrative and technical sufficiency requirements for the NRC staff to complete its review. The acceptance review is performed by both the PSPB PM and the TB(s). The PSPB PM's responsibility is to ensure that the TR meets the criteria for acceptance in the TR program provided in Section 4.1.1, which includes a review consistent with LIC-109.

The TB's responsibility is to ensure the TR meets the criteria, as described in Section 4.1.1. The TB determination to accept or non-accept a TR for review is due by the agreed upon date listed on the Green Sheet.

If the PSPB PM identifies upon reviewing the Green Sheet, that a technical reviewer can not complete the acceptance review in 60 days, then the TR needs to be prioritized in accordance with the draft prioritization scheme (Appendix B).

- A TR is subjected to the prioritization scheme only when the responsible technical branch(es) can not begin its acceptance review within 60 days of receipt of the TR. The PSPB PM shall follow up immediately with the technical reviewer(s) to discuss the TR prioritization process and inform the PSPB BC.
- The PSPB BC, with the support of the technical branch management, will use the input provided on the cover memo (refer to Section 4.2.2.B) of the TR to prioritize the TR.
- Once the priority of the TR is determined, the technical branch will inform their Deputy Division Director of the TR priority via a formal memo (include DPR/PSPB on distribution).
- The PSPB PM will inform the TR applicant of the incoming TR status during routine weekly/biweekly calls. If no routine status calls are maintained between the vendor/OG and the PSPB PM, calls should be established on a mutually- agreeable frequency, so that the PSPB PM can provide the vendor/OG of a current status on the priority of the incoming TR.

The TB BC should document its acceptance for review (via email or formal memorandum) to the PSPB BC. Any non-acceptances should be documented via a formal memorandum from the TB BC to the PSPB BC.

For a TR involving TS changes, the PSPB PM will verify that the applicant attached to the TR the proposed TS pages containing a markup of changes to the appropriate applicant's STS and Bases. If the applicant does not include this information as an enclosure to the TR, the staff could consider it as sufficient grounds to non-accept the TR for review in accordance with Section 4.1.1 (C).

Additional information on acceptance reviews is provided in LIC-109. Refer to Enclosures 1, 2, and 3 for sample acceptance and non-acceptance letters.

During the acceptance review of the TR, a telephone conference will be held among the PSPB PM, TB supervision, and the TR applicant to discuss and obtain a mutual agreement on the review schedule milestones and estimated review costs.

Once agreed upon, the TR-specific review schedule will be documented by the PSPB PM in an acceptance-for-review letter to the applicant (Refer to Enclosure 1). Typically, the TB BC will document its acceptance-for-review within 60 days of receipt of the TR and provide it to the TR PM in PSPB. The PSPB PM will typically issue the acceptance-for-review letter to the applicant within 14 days after receipt of the TB BC input (see Enclosure 1 for a sample acceptance letter). The TB BCs and the PSPB BC concur on the letter.

The established schedules must be adhered to by both the applicant and the NRC staff. If it becomes necessary to update the schedule milestones due to greater-than-anticipated scope of work, or due to significant delays in issuing RAIs or receiving RAI responses, or higher priority work, the NRC staff can extend the review schedule. Additional guidance regarding the impact of greater-than-anticipated scope of work, and incomplete or significantly late RAI responses is provided in Section 4.2.6.

Guidance is provided in LIC-500, to support the NRC staff's ability to document its acceptance review results, including if the NRC staff decides to non-accept the TR due to insufficient technical information. If the NRC staff decides to non-accept the TR because it does not meet the TR program guidance, the letter will be concurred on by the TB BC (see Enclosure 2 for a sample non-acceptance letter). The PSPB PM will notify the applicant in advance of issuing the non-acceptance letter to provide advance notification that that TR will not be accepted for NRC review.

#### **4.2.5 Proprietary Determination**

If the TR is submitted as proprietary, the PSPB PM or licensing assistant will prepare a proprietary determination letter in accordance with 10 CFR 2.390 and Office Instruction LIC-204, "Handling Requests to Withhold

Proprietary Information from Public Disclosure" (Reference 5). In accordance with Section 4.2 of LIC-204, a non-proprietary version of the report or document should be submitted. In instances where a non-proprietary version would be of no value to the public due to the extent of the proprietary information, a non-proprietary version is not required to be submitted to the NRC. Absent such a finding, the submitter should provide a version that could be made available to the public. The task of providing a public version rests on the submitter, not on the NRC staff.

PSPB will issue the proprietary determination letter within 60 days of the incoming TR or issuance of the OCFO letter. For efficiency, the proprietary review should be performed at the same time as the acceptance review. Both the PSPB PM and the TB reviewers are responsible for reviewing the information to determine if it is proprietary. If the NRC staff determines that some or all the information designated by the applicant as proprietary is not proprietary, the PSPB PM should contact the applicant to try to resolve the issue. The NRC staff should not continue with the review if there is a disagreement about the information designated as proprietary. The minimum possible amount of information should be designated as proprietary.

For proprietary TRs, a proprietary and a non-proprietary version of the final SE must be issued, if the final SE contains proprietary information.

#### **4.2.6 RAIs**

##### **A. RAI Issuance**

The RAIs will be prepared and provided to the applicant in accordance with the guidance in LIC-101. The TB reviewer will provide the PSPB PM with RAIs 10 working days prior to the agreed-upon milestone schedule date for RAIs. The PSPB PM will issue the RAIs to the applicant within the agreed-upon milestone schedule date for RAIs. A telephone call to discuss the proposed RAIs with the NRC staff is required, unless the NRC staff and the applicant agree that such a telephone call is not necessary. In the telephone call, if the TR is proprietary, the PSPB PM should ask the applicant if the questions reveal any proprietary information. If the questions do reveal proprietary information, the PSPB PM should either reword the question or issue a proprietary and a non-proprietary version of the RAIs. The applicant will propose a schedule for the RAI response. The applicant's RAI response will be submitted on the agreed-upon schedule.

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 SE, 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 additional limitations and conditions to be identified once the review has been completed and the staff prepares the draft SE (as described in Section 4.2.7). The transmittal letter will also state that if the RAIs are not provided by the agreed-upon date, the NRC staff can close out its review of the TR. The applicant should discuss any request for an extension with the PSPB PM and submit the request in writing (memo or email) to the PSPB BC. If

requested, a grace period of 30 days may be considered reasonable by the NRC staff.

#### B. Review of RAI Responses

The technical leads will review the RAI responses and communicate to the PSPB PM if any of the RAIs remain open and could result in a limitation or condition in the TR SE.

If the TR applicant proposes to make changes to the TR, as a result of the RAIs, the PSPB PM should request that the TR applicant include in its RAI response a mark up of the TR pages that it plans to change. This will support the staff's ability to review the specific words that will appear in the approved version of the TR.

The PSPB PM will facilitate the discussion/resolution between the technical leads and the applicant. Any issues that can not be readily resolved should be handled in accordance with Section 4.2.6.D.

The staff has several options to pursue in the event that RAI responses are late or incomplete (i.e., an apparent omission of a response):

- Extend the review schedule until the complete RAI response is submitted. In such situations, upon receipt of the RAI response, the NRC staff would establish a revised review schedule, which would be documented in a letter to the applicant of the TR. The PSPB PM should also coordinate with the CPA Division Representative to ensure that the revised schedule is captured in the CPA database.
- Close the review. If the applicant can not provide complete RAI responses by the agreed-upon milestone, the PSPB BC, with the agreement of the appropriate TB BCs, can close out its review of the TR via a formal letter from the PSPB BC. Although the basis for closing out the TR review should be communicated ahead of time by telephone to the applicant, the letter will re-iterate the basis for closing the NRC staff's review of the TR.
- After discussing with the associated NRC division and industry management, the staff can request that the applicant withdraw its request for NRC review and approval. The withdrawal letter should be submitted in writing to the PSPB BC and contain the basis for withdrawal of the TR. The PSPB BC will issue a letter to acknowledge receipt of the withdrawal letter and to verify that the NRC's review has been closed.

#### C. Greater-Than-Anticipated Level of Effort

If it is determined during the RAI process that a TR will require a greater than anticipated level of effort by the applicant to be responsive to the RAIs (i.e., substantial revisions/rewrites to the TR which could result in significant changes in the scope of the NRC's review), the applicant can withdraw the TR from NRC staff review, as stated in Section 4.2.6.B. The applicant's letter should provide a basis for withdrawing the TR. This

does not preclude the applicant from addressing the issues and resubmitting a revised version of the TR at a future date, as discussed in Section 4.2.6.E.

#### D. Resolution of Issues

After reviewing the RAI responses, if there is a technical disagreement between the NRC technical staff and the TR applicant about the adequacy of the proposal, or portions of the proposal such that it would be unacceptable or involve imposing limitations and conditions (not identified by the applicant or subsequently agreed to by the applicant), the issue should be elevated to management as soon as practical, but no later than one week after identification.

The TR applicant should be notified by the PSPB PM that the NRC staff does not agree about the adequacy of the proposal (as described in the TR) and that the issue is being elevated to NRR management.

NRC staff shall brief management on the issue, provide possible success paths for resolving the issue including identifying alternative approaches that may be acceptable, and recommend a path forward (e.g., management meeting with the applicant).

Management shall review this information and inform the staff of the results of their review. Consideration should be given to the nature of the issue (e.g., safety significance), past interactions on the issue, and the age of the issue. If the issue can not be resolved within the agreed-upon milestones to issue the SE or if a success path is not clearly identified, the TR review shall be terminated.

The ultimate resolution of the issue should be discussed with the TR applicant.

#### E. Request For A Revised TR

Following resolution of the issues, the staff may determine that, due to the complexity of the RAI responses, a revision to the TR is necessary to capture the changes. In these cases, the PSPB PM would request that the TR applicant provide a revised TR to the NRC DCD (refer to Section 4.2.2.B) to support the staff's development of the draft SE. The technical staff involved in the review should communicate the need for a revised TR to the PSPB PM as part of the recommended path forward (as described in Section 4.2.6.D).

#### **4.2.7 TB Transmits SE to PSPB**

The TB(s) will provide the PSPB PM with its SE 20 working days prior to the agreed-upon milestone schedule date for the Draft SE. If more than one TB provides SE input to the PSPB PM, the PSPB PM will work with the TB leads, if needed, to integrate all of the inputs into one SE.

The SE should follow the general guidance in Office Instruction LIC-101, with the exception that the SE should also specify who can reference the TR (e.g., Westinghouse-designed plants), and clearly identify the

limitations and conditions the NRC staff has placed on the use of the TR in the body of the SE, including plant-specific items that a licensee referencing the TR will need to submit.

“Limitations and Conditions” describe any exceptions on a licensee’s use of the TR that the NRC may take to the content provided within the TR. For example, a limitation imposed by the NRC staff in the SE may not approve the maximum level of requested features and scope of application as requested in the TR. Whereas, a condition is typically imposed in the SE when the staff approves the TR, but may need additional information from the licensee, once the licensee references the approved TR in an LAR.

While adding limitations and conditions to the SE may be necessary in some cases, the NRC staff should identify issues early to the TR applicant and challenge the applicant during the RAI process to provide the technical information necessary to avoid these constraints, if possible. Limitations and conditions amplify the effort that is needed by both the NRC and the licensee on subsequent individual plant applications that reference the accepted version of the TR.

If the TB(s) approves of the technical basis or methodology contained within the TR, but with limitations and conditions, these are identified in the SE discussion and also listed in a separate section of the SE as “Limitations and Conditions.” The limitations and conditions should be explicit to help licensees provide the necessary information in requests for licensing actions that reference the approved TR and to help the NRC reviewers who review LARs that reference an approved TR.

Frequent and effective communications throughout the TR review process will facilitate early identification of NRC staff concerns and ensure that the NRC staff’s basis for imposing any limitations and conditions in the SE are clearly understood by the applicant in advance of issuing the draft SE. Any limitations and conditions that were not identified during the RAI phase, as described in Section 4.2.6.A, should be discussed with the applicant, at least two weeks prior to issuing the draft SE. The PSPB PM will facilitate the discussion and resolution between the technical staff and the applicant where appropriate. Any issues that can not be resolved by the PSPB PM should be elevated to management. The TB(s) should strive to facilitate early identification and issue resolution of technical issues before the TB(s) provides its SE input to the PSPB PM.

In some cases, the TB reviewers may need to identify specific followup steps or actions that need to be verified by the TB(s) once a licensee decides to reference the approved TR in an LAR or a STS change. Any followup actions that a TB(s) needs to verify should be listed in a separate section of the SE titled, “Use and Referencing of the TR.” This section is particularly useful to help ensure that TR limitations and conditions are captured when referenced in an LAR or during the transition to a TSTF (Refer to Enclosure 3).

#### **4.2.8 Issue Draft SE to Applicant**

The purpose of the draft SE is to provide the applicant with the opportunity to identify any proprietary information and to clarify any factual inaccuracies. The applicant's review should not be used to debate technical disagreements.

The PSPB PM will issue the draft SE within the agreed-upon milestone schedule date. The PSPB PM should follow the guidance in Enclosure 3 when drafting the transmittal letter. The PSPB PM may email the applicant a copy of the draft SE, once the transmittal letter is signed and concurred upon, to ensure that sufficient time is provided for review.

Once feedback is provided by the applicant on the draft SE, the PSPB PM will work with the TB(s) to resolve any factual inaccuracies or proprietary concerns.

For both proprietary and non-proprietary TRs, PSPB provides 20 working days to the TR applicant to identify any factual inaccuracies in the draft SE.

- If the TR is non-proprietary, the cover memo transmitting the draft SE will state that the applicant has 20 working days from receipt of the draft SE to identify any factual inaccuracies.
- If the TR is proprietary, the cover memo transmitting the draft SE will also include a statement that the applicant has 10 working days from receipt of the draft SE to identify any proprietary concerns. The 10 working days provided for the applicant to identify any proprietary concerns runs parallel with the 20 working days provided for the applicant to identify any factual inaccuracies in the draft SE.

#### **4.2.9 Issue Final SE to Applicant**

The PSPB PM will issue the final SE for the TR within 20 working days after the applicant provides written feedback in the form of a letter on the draft SE. The final SE will be issued after making any necessary changes and will also be made publicly available. The PSPB PM will disposition any factual inaccuracies or clarity concerns provided by the applicant in an enclosure to the final SE. The PSPB PM will prepare a letter approving the TR for referencing in licensing actions for signature of the Deputy Director, DPR. The SE letter should follow the guidance in Enclosure 4.

Once the final SE is issued, the PSPB PM will close the TAC via TRIM. The PSPB PM should use the date of the SE as the "actual completion date" in TRIM. If additional work is done to support a review after the final SE is signed out (i.e., management briefings), the PSPB PM should charge to another TAC such as a generic vendor/OG interaction TAC.

#### **4.2.10 Applicant Submits Approved Version of TR**

The applicant should submit to the NRC an approved version of the TR within three months of receipt of the final SE, or another mutually acceptable submittal date. The approved version of the TR should incorporate the transmittal letter, the final SE, an appendix containing the NRC staff approved TR TS and Bases markup pages of the appropriate vendor STS (if the TR involved TS changes) and all RAIs with responses after the title page of the TR.

As an alternative, if the TR applicant submitted marked up pages of the TR in response to RAIs (as noted in Section 4.2.6.B), RAIs and RAI responses do not need to be included in the approved version of the TR. The following options are also available to the TR applicant whose RAI responses have been accepted by the NRC staff.

- The RAIs can be included as an Appendix to the TR, OR
- A table inserted after the final SE can be used to summarize the changes resulting from the incorporation of RAI responses. The table should reference the specific RAIs and RAI responses that resulted in changes to the TR.

In either case, the approved version should be identified by a "-A" following the TR identification symbol. For a proprietary TR, ensure that both a proprietary and non-proprietary version is published by the applicant and submitted to the NRC.

#### **4.2.11 Applicant Submits Revision(s) or Supplement(s) to the Accepted Version of TR**

In some cases, an applicant will submit a revision or supplement to the NRC approved version of the TR.

##### A revision to a TR:

- May seek to provide additional information in the revised TR for the purpose of changing or removing portions of the limitations or conditions in the NRC staff's SE.
- When a revision to a TR is approved by the NRC staff, the NRC staff's current SE supercedes the original SE.

##### A supplement to a TR:

- May provide current information to update code references or data that was provided in the approved version of the TR.
- When a supplement to a TR is approved by the NRC staff, the NRC staff's SE supplements the original SE.

- A. Regardless of whether the applicant refers to the information as a revision or supplement, once the PSPB PM receives the revision/supplement, the PSPB PM will follow the TR process (as described in this OI) to review the revision or supplement.
- B. After the NRC staff has completed their review and issued a revised final SE, the applicant should issue a revised approved version (-A) of

the TR. The revised –A report should be identified with the appropriate revision number. For example, “TR {identification symbol}, Revision X to –A.”

## **5.0 RESPONSIBILITIES AND AUTHORITIES**

### **5.1 Technical Reviewers**

The technical reviewers are responsible for:

- participating in the pre-submittal meeting (4.2.1)
- providing input into the work plan (4.2.3)
- identifying when an incoming TR needs to be prioritized (4.2.4 and Appendix B)
- performing technical acceptance and proprietary reviews (4.2.4 and 4.2.5)
- working with the PSPB PM when identifying the need for a technical champion (4.2.6.4 and Appendix A)
- developing RAIs (4.2.6)
- writing the SE (4.2.7)
- providing resolution to the applicant's comments on the Draft SE (4.2.8)

### **5.2 PSPB PM**

The PSPB PM is the principal point of contact between the applicant and the TB for assigned TRs. As the point of contact, the PM ensures that there is good communication between the NRC staff and the applicant.

The PSPB PM is responsible for:

- arranging and conducting the pre-submittal meeting and including the OCFO in any discussion of fee exemptions (4.2.1),
- developing the work plan (4.2.3),
- identifying when an incoming TR needs to be prioritized (4.2.4 and Appendix B)
- writing the acceptance review letter (4.2.4),
- making a proprietary determination (4.2.5),
- identifying the need for a technical champion (4.2.6.4)
- facilitating open communication between the NRC staff and the vendor or OG,

- issuing RAIs to applicant (4.2.6),
- issuing Draft SE to applicant (4.2.8), and
- issuing final SE to applicant (4.2.9)

### **5.3 Technical Branch Branch Chiefs**

The BCs ensure that the NRC staff follows office instructions. The BCs are responsible for:

- participating and designating NRC staff persons who participated in the pre-submittal meeting (4.2.1),
- working with the PSPB PM to develop a work plan (4.2.3),
- working with the PSPB PM support the OCFO representative during the fee-exemption reviews,
- working with the PSPB PM when an incoming TR needs to be prioritized (4.2.4 and Appendix B),
- concurring in the proprietary determination, acceptance and non-acceptance letters, and SE prepared by the PSPB PM (4.2.5),
- concurring on RAIs and ensuring RAIs are issued on schedule and per LIC-101 (4.2.6),
- transmitting SE to the PSPB BC, DPR, responsible for TRs (4.2.7), and
- transmitting the resolution to the applicant's comments on the SE to the PSPB BC, DPR, responsible for TRs (4.2.8).
- ensuring that working files, background information and other pertinent information to continue the review is transferred when new reviewers are assigned to support ongoing TR reviews.

### **5.4 PSPB BC**

The PSPB BC is responsible for overseeing the daily operation of the TR program. In addition, the PSPB BC is responsible for:

- concurring in the proprietary determination, request for additional information, and the final SE.
- signing acceptance and non-acceptance letters, and the draft SE.

### **5.5 DPR Deputy Division Director**

The DPR Deputy Division Director has overall responsibility for the TR process. The DPR Deputy Division Director ensures the TR process meets the performance measures defined in the NRR Operating Plan. In addition, the DPR Deputy Division Director has signature authority on the final SE.

### **6. PERFORMANCE MEASURES**

The following performance measures for the TR program are contained in the NRR Performance Monitoring Report (Reference 6).

- 80% of TR  $\leq$  2 years (age of inventory)
- 100% of TR  $\leq$  3 years (age of inventory)

### **7. PRIMARY CONTACTS**

**Tanya Mensah**

301-415-3610

[Tanya.Mensah@nrc.gov](mailto:Tanya.Mensah@nrc.gov)

**Stacey Rosenberg**

301-415-2357

[Stacey.Rosenberg@nrc.gov](mailto:Stacey.Rosenberg@nrc.gov)

### **8. RESPONSIBLE ORGANIZATION**

NRR/DPR/PSPB

### **9. EFFECTIVE DATE**

December 21, 2009

### **10. REFERENCES**

1. <http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html>
2. Office Instruction LIC-101, "License Amendment Review Procedures"
3. Office Instruction COM-204, "Interfacing With Owners Groups, Vendors, and NEI"
4. Office Instruction COM-202, "Meetings With Applicants, Licensees, Vendors, or Other Members of the Public"
5. Office Instruction LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure"
6. NRR Performance Monitoring Report
7. Office Instruction LIC-109, "Acceptance Review Procedures"

Enclosures:

1. Sample Letter Accepting Report for Review
2. Sample Non-Acceptance Letter With Opportunity To Supplement
3. Sample Non-Acceptance Letter
4. Sample Draft SE Letter
5. Sample Final SE Letter
6. Technical Champion
7. Draft TR Prioritization Scheme
8. Appendix - Change History

## Sample Letter Accepting Report for Review

**[Addressee]**

SUBJECT: ACCEPTANCE FOR REVIEW OF **[VENDOR/OWNERS GROUP]** TOPICAL REPORT **[TOPICAL REPORT NUMBER AND TITLE]** (TAC NO. [        ])

Dear Mr. **[Last Name]**:

By letter dated **[date of incoming letter]**, **[vendor/owners group]** submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Topical Report (TR) **[number and title of topical report]**. The NRC staff has performed an acceptance review of the **[title of topical report]**, and found that the material presented provides the technical information in sufficient detail to enable the staff to complete a detailed technical review. The NRC staff expects to issue its request for additional information by **[date]** and issue its draft safety evaluation by **[date]**. The NRC staff estimates that the review will require approximately **[number of staff hours]** staff hours including project management time **[and the estimated contractor cost [amount in dollars, if applicable and available]]**. The review schedule milestones and estimated review costs were discussed and agreed upon in a telephone conference between **[you or (name of individual, title)]** and the NRC staff on **[date]**.

**[Use this second paragraph if the topical report is fee billable]**. Section 170.21 of Title 10 of the *Code of Federal Regulations* requires that TRs are subject to fees based on the full cost of the review. You did not request a fee waiver; therefore, NRC staff hours will be billed accordingly.

**[Use this second paragraph if the topical report fee is waived]**. In accordance with the letter dated **[date]** (Agencywide Documents Access and Management System Accession No. **[ML]**), the Office of the Chief Financial Officer has waived the Section 170.21 of Title 10 of the *Code of Federal Regulations* fees associated with this TR review.

**[Use this second paragraph if fee waiver was denied and the applicant still wants the TR reviewed]**. In accordance with letter dated **[date]** (Agencywide Documents Access and Management System (ADAMS) Accession No. **[ML]**), the Office of the Chief Financial Officer denied your fee waiver request, but in letter dated **[date]** (ADAMS Accession No. **[ML]**) you requested a fee-billable review. Section 170.21 of Title 10 of the *Code of Federal Regulations* requires that TRs are subject to fees based on the full cost of the review.

If you have questions regarding this matter, please contact **[First Name Middle Initial Last Name]** at (301) 415-**[XXXX]**.

Sincerely,

Stacey L. Rosenberg, Chief  
Special Projects Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

Project No. XXX

cc: See next page

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**[Tech Branch Involved in Review]**

**[Division for Tech Branch involved in Review]**

SRosenberg (Hardcopy)

**ADAMS ACCESSION NO.:**

**NRR-106**

OFFICE	PSPB/PM	PSPB/LA	Tech Branch	PSPB/BC
NAME		DBaxley		SRosenberg
DATE				

OFFICIAL RECORD COPY

**Sample Non-Acceptance Letter With Opportunity To Supplement**

**[Addressee]**

SUBJECT: REQUEST FOR THE REVIEW OF **[NAME OF VENDOR OR OWNERS GROUP]** TOPICAL REPORT **[TOPICAL REPORT NUMBER AND TITLE]** (TAC NO. [ ])

Dear Mr. [ ]:

By letter dated **[date of incoming letter]** (Agencywide Documents Access and Management System Accession No. **[number]**), the **[name of vendor or owners group]** submitted **[number and title of topical report]** to the U.S. Nuclear Regulatory Commission staff for review.

The purpose of this letter is to provide the results of the U.S. Nuclear Regulatory Commission (NRC) staff's acceptance review of **[number and title of topical report]**. The acceptance review was performed to determine if there is sufficient technical information in scope and depth to allow the NRC staff to complete its detailed technical review. The NRC staff has reviewed **[number and title of topical report]** and concluded that it did not provide technical information in sufficient detail to enable the NRC staff to complete its detailed review and make an independent assessment regarding the acceptability of **[number and title of topical report]**.

In order to make the application complete, the NRC staff requests that the **[name of vendor or owners group]** supplement the application to address the information requested in the enclosure by **[date]**. This will enable the NRC staff to complete its detailed technical review. If the information responsive to the NRC staff's request is not received by the above date, the **[number and title of topical report]** will not be accepted for review pursuant to 10 CFR 2.101, and the NRC staff will cease its review activities associated with **[number and title of topical report]**. If the **[number and title of topical report]** is subsequently accepted for review, you will be advised of any further information needed to support the NRC staff's detailed technical review by separate correspondence.

The information requested and associated time frame in this letter were discussed with and agreed upon in a telephone conference between **[(name of individual, title)]** and the NRC staff on **[date]**.

If you have any questions, please contact the **[PSPB]** Project Manager, **[NAME]**, at (301) 415-XXXX.

Sincerely,

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

Project No. **[number]**  
cc: See next page

Enclosure 2

**Sample Non-Acceptance Letter Without Opportunity To Supplement**

**[Addressee]**

SUBJECT: REQUEST FOR THE REVIEW OF **[NAME OF VENDOR OR OWNERS GROUP]** TOPICAL REPORT **[TOPICAL REPORT NUMBER AND TITLE]**  
(TAC NO. [ ])

Dear Mr. [ ]:

By letter dated **[date of incoming letter]** (Agencywide Documents Access and Management System Accession No. **[number]**), the **[name of vendor or owners group]** submitted **[number and title of topical report]** to the U.S. Nuclear Regulatory Commission staff for review.

The acceptance review was performed to determine if there is sufficient technical information in scope and depth to allow the NRC staff to complete its detailed technical review. The NRC staff has reviewed **[number and title of topical report]** and concluded that it did not provide technical information in sufficient detail to enable the NRC staff to complete its detailed review and make an independent assessment regarding the acceptability of **[number and title of topical report]**.

This informational need was conveyed to you **[cite method (e.g., phone call, e-mail, etc.)]**. The NRC staff identified that the following information was needed to complete its technical review:

**LIST INFORMATION NEEDED**

**[IF THE APPLICANT IS NOT BEING ALLOWED TO SUPPLEMENT THE TOPICAL REPORT, USE THIS PARAGRAPH]**

Because of the extensive nature of the information needed, the NRC staff finds the request for approval of the proposed action unacceptable for NRC review pursuant to 10 CFR 2.101. [Additionally, other aspects of the TR may also be insufficient but were not reviewed or identified due to the significance of the aforementioned information insufficiency.] NRC staff activities on the review have ceased and the associated Technical Assignment Control number has been closed.

**[IF THE APPLICANT WAS REQUESTED TO SUPPLEMENT THE TOPICAL REPORT AND DID NOT PROVIDE A SUPPLEMENT, USE THIS PARAGRAPH]**

As of the date of this letter, the NRC staff has not received any communications from you regarding this information need. Therefore, the NRC staff finds the request for approval of the proposed action unacceptable for NRC review pursuant to 10 CFR 2.101. NRC staff activities on the review have ceased and the associated Technical Assignment Control number has been closed. ]

**IF THE APPLICANT WAS REQUESTED TO SUPPLEMENT THE TOPICAL REPORT AND DID PROVIDE A SUPPLEMENT, USE THIS PARAGRAPH]**

By letter dated **[DATE]**, you provided a supplement to this submittal. The NRC staff has found the supplement unresponsive to the cited information needs. Therefore, the NRC staff finds the request for approval of the proposed action unacceptable for NRC review pursuant to 10 CFR 2.101. NRC staff activities on the review have ceased and the associated Technical Assignment Control number has been closed.

Therefore, your request for the review of **[title of topical report]** is non-accepted. This does not preclude you from addressing the deficiencies discussed above and resubmitting the topical report at a future date.

Sincerely,

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

Project No. **[number]**

cc: See next page

**Sample Letter Transmitting Draft SE**

**[Addressee]**

SUBJECT: DRAFT SAFETY EVALUATION FOR **[NAME OF VENDOR OR OWNERS GROUP]** TOPICAL REPORT (TR) **[TOPICAL REPORT NUMBER AND TITLE]**  
(TAC NO. [        ])

Dear Mr. [        ]:

By letter dated **[date of incoming letter]** (Agencywide Documents Access and Management System (ADAMS) Accession No. **[number]**), **[name of vendor or owners group]** submitted **[number and title of topical report]** to the U.S. Nuclear Regulatory Commission (NRC) staff for review. Enclosed for **[name of vendor or owners group]** review and comment is a copy of the NRC staff's draft safety evaluation (SE) for the TR.

**[Use the following paragraph if proprietary material is involved**

Pursuant to Section 2.390 of Title 10 of the *Code of Federal Regulations* (10 CFR), we have determined that the enclosed draft SE does not contain proprietary information. However, we will delay placing the draft SE in the public document room for a period of 10 working days from the date of this letter to provide you with the opportunity to comment on the proprietary aspects. If you believe that any information in the enclosure is proprietary, please identify such information line-by-line and define the basis pursuant to the criteria of 10 CFR 2.390. After 10 working days, the draft SE will be made publicly available, as appropriate, and an additional 10 working days are provided to you to comment on any factual errors or clarity concerns contained in the draft SE. The final SE will be issued after making any necessary changes and will be made publicly available. The NRC staff's disposition of your comments on the draft SE will be discussed in the final SE.

**[Use this paragraph only if the topical report is non-proprietary]**

Twenty working days are provided for you to comment on any factual errors or clarity concerns contained in the SE. The final SE will be issued after making any necessary changes and will be made publicly available. The NRC staff's disposition of your comments on the draft SE will be discussed in the final SE.

Enclosure 4

To facilitate the NRC staff's review of your comments, please provide a marked-up copy of the draft SE showing proposed changes and provide a summary table of the proposed changes.

If you have any questions, please contact **[name of the pm]** at **[telephone no.]**.

Sincerely,

Stacey L. Rosenberg, Chief  
Special Projects Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

Project No. **[number]**

Enclosure: Draft SE

cc w/encl: See next page

**DISTRIBUTION:**

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**[Tech Branch that had input]**

**ADAMS ACCESSION NO.:**

**\*No major changes to SE input.**

**NRR-043**

OFFICE	PSPB/PM	PSPB/LA	Tech Branch	PSPB/BC
NAME		DBaxley		SRosenberg
DATE				

DOCUMENT NAME: G:\ADRA\DPR\PSPB\Boilerplates\Generic Boilerplates\Topical Report\09  
Topical Report Draft SE Letter.wpd  
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DRAFT SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

TOPICAL REPORT [ NUMBER]

"[TITLE OF TOPICAL REPORT] "

[NAME OF VENDOR OR OWNERS GROUP]

PROJECT NO. [number]

1.0 INTRODUCTION AND BACKGROUND

(Introduction must include purpose, scope, and applicability of the review. In addition, if the report is a supplement or revision, this section should specifically state what the supplement or revision is requesting for NRC approval).

2.0 REGULATORY EVALUATION

3.0 TECHNICAL EVALUATION

4.0 LIMITATIONS AND CONDITIONS (If needed)

5.0 USE AND REFERENCING OF THE TR (Specific instructions for NRC reviewers, if applicable).

6.0 CONCLUSION

Principle Contributor:

Date:

**Sample Letter Transmitting Final SE**

**[Addressee]**

SUBJECT: FINAL SAFETY EVALUATION FOR **[NAME OF VENDOR OR OWNERS GROUP]** TOPICAL REPORT **[TOPICAL REPORT NUMBER AND TITLE]**  
(TAC NO. [ ])

Dear Mr. [ ]:

By letter dated **[date of incoming letter]** (Agencywide Documents and Access Management System Accession No. **[number]**), **[name of vendor or owners group]** submitted Topical Report (TR) **[number and title of topical report]** to the U.S. Nuclear Regulatory Commission (NRC) staff. By letter dated **[date]**, an NRC draft safety evaluation (SE) regarding our approval of **[number of topical report]** was provided for your review and comment. By letter dated **[date]**, **[name of vendor or owners group]** commented on the draft SE. The NRC staff's disposition of **[name of vendor or owners group's]** comments on the draft SE are discussed in the enclosure to the final SE enclosed with this letter.

The NRC staff has found that **[number of topical report]** is acceptable for referencing in licensing applications for **[vendor type]** designed **[pressurized or boiling]** water reactors to the extent specified and under the limitations delineated in the TR and in the enclosed final SE. The final SE defines the basis for our acceptance of the TR.

**[Use this paragraph only if this is a fuels TR]**

The NRC staff has found that **[number of topical report]** is acceptable for referencing in licensing applications for **[vendor type]** designed fuel for **[pressurized or boiling]** water reactors to the extent specified and under the limitations delineated in the TR and in the enclosed final SE. The final SE defines the basis for our acceptance of the TR.

Our acceptance applies only to material provided in the subject TR. We do not intend to repeat our review of the acceptable material described in the TR. When the TR appears as a reference in license applications, our review will ensure that the material presented applies to the specific plant involved. License amendment requests that deviate from this TR will be subject to a plant-specific review in accordance with applicable review standards.

**[Use this paragraph if the TR SE is non-proprietary]**

In accordance with the guidance provided on the NRC website, we request that **[name of vendor or owners group]** publish an accepted version of this TR within three months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed final SE after the title page. Also, the accepted version must contain historical review information, including NRC requests for additional information (RAI) and your responses after the title page. The accepted version shall include an "-A" (designating accepted) following the TR identification symbol.

**[Use this paragraph if the TR SE is proprietary]**

In accordance with the guidance provided on the NRC website, we request that **[name of vendor or owners group]** publish accepted proprietary and non-proprietary versions of this TR within three months of receipt of this letter. The accepted versions shall incorporate this letter and the enclosed final SE after the title page. Also, they must contain historical review information, including NRC requests for additional information and your responses. The accepted versions shall include an "-A" (designating accepted) following the TR identification symbol.

As an alternative to including the RAIs and RAI responses behind the title page, if changes to the TR were provided to the NRC staff to support the resolution of RAI responses, and the NRC staff reviewed and approved those changes as described in the RAI responses, there are two ways that the accepted version can capture the RAIs:

1. The RAIs and RAI responses can be included as an Appendix to the accepted version.
2. The RAIs and RAI responses can be captured in the form of a table (inserted after the final SE) which summarizes the changes as shown in the approved version of the TR. The table should reference the specific RAIs and RAI responses which resulted in any changes, as shown in the accepted version of the TR.

If future changes to the NRC's regulatory requirements affect the acceptability of this TR, [name of vendor or owners group] and/or licensees referencing it will be expected to revise the TR appropriately, or justify its continued applicability for subsequent referencing.

Sincerely,

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

Project No. [number]

Enclosure: Final SE

cc w/encl: See next page

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[Division and Tech Branch for input]

SRosenberg (Hardcopy)

**ADAMS ACCESSION NO.:** \*No major changes to SE input. **NRR-043**

OFFICE	PSPB/PM	PSPB/LA	Tech Branch*	PSPB/BC	DPR/DD
NAME		DBaxley		SRosenberg	TBlount
DATE					

DOCUMENT NAME: G:\ADRA\DPR\PSPB\Boilerplates\Generic Boilerplates\Topical Report\09 Topical Report Final SE Letter.wpd

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## Technical Champion

Topical reports (TR) involving multiple review branches may require additional coordination to ensure their timely review. As a result, it may be appropriate to assign a technical champion to facilitate the review process. The technical champion would be responsible for ensuring effective coordination between the review team and management.

### A. Purpose of the Technical Champion

The technical champion facilitates technical interactions amongst the review branches and between the technical branches and management. The technical champion is not responsible for normal day-to-day interaction between a reviewer and his or her supervisor, rather they are to facilitate discussions between review divisions.

### B. Utilizing the technical champion process

A technical champion would typically be required for a technically challenging, complex TR that involves multiple review organizations. Factors to consider when deciding whether a technical champion should be appointed include the following:

- (a) the review is unique or first-of-a-kind,
- (b) the review is low risk, but involves a compliance issue,
- (c) the review involves significant technical or policy issues, and/or
- (d) the technical experts/branches have differing views on the NRC staff's actions going forward.

A technical champion would normally not be necessary for a review that involves one branch since the branch should be able to coordinate any required internal interactions, including interactions with the project manager. A technical champion can be assigned at any point in the review process.

### C. Assignment of a Technical Champion

If a TR meets one or more of the criteria discussed, the PSPB PM will recommend to the division directors whose branches are involved in the TR review that a technical champion should be considered for this TR. The PSPB PM will provide his/her basis for such a recommendation. Based on this recommendation, the affected division directors will assign a technical champion, if appropriate.

### D. Technical Champion's Role

There are many reasons that a technical champion may be used in the TR process. The main purpose of the technical champion is to facilitate the review. As a result, the technical champion (along with the reviewers) may need to perform the following activities:

- (a) identify the issues that require resolution,
- (b) develop pros and cons of various approaches,
- (c) develop recommendations to management on a path forward, and
- (d) identify areas where close interaction between the review branches is needed (i.e., branch "a" needs the following information for branch "b" to complete its review).

It is not the role of the technical champion to make a final decision on an issue when two organizations disagree. If technical agreement can not be reached through the technical champion process, the issue should be elevated to management.

Section 4.2.6.D of this Office Instruction provides general guidance that can also be used to resolve internal disagreements, including providing the pros and cons of the various sides. Depending on the resolution of the issue, the issue may need to be discussed with the TR applicant. For example, if the resolution of the issue resulted in a limitation or condition being added to the safety evaluation, then that would need to be discussed with the TR applicant to ensure that they understand the NRC staff's basis for adding the limitation and condition.

## Draft Topical Report Prioritization Scheme

A draft prioritization scheme was developed to support the NRC's ability to properly allocate resources for TRs, by ranking and prioritizing incoming TRs. This draft prioritization scheme will only be utilized by NRR when the responsible technical branch(es) assigned to a TR review are not able to complete an acceptance review within 60 days of receipt of the TR. This draft prioritization scheme does not apply to TRs that have already been accepted for review and does not apply to TRs assigned to other NRC program offices.

### A. Pre-submittal or Pre-planning Meetings:

- In accordance with Section 4.2.1 of this OI, the PM will coordinate a pre-submittal meeting with the applicant.
- For the purpose of this prioritization scheme, if there are technical branches already aware that they are not capable of reviewing an additional TR (due to reduced resources (i.e., budget or staff)), they shall communicate with the TR applicant at the pre-submittal meeting, the need to delay submission of the TR. Within one to two weeks after the pre-submittal meeting, the technical branch, after discussing with its Deputy Director or Division Director, should propose a more reasonable timeframe for the TR applicant to submit the TR and provide that feedback to the PSPB PM. The PSPB PM will provide this feedback via email to the TR applicant, after informing the PSPB BC.
- The PSPB PM will inform the technical leads of the incoming TR. If another pre-submittal meeting is needed or requested by the staff, it will be arranged by the PSPB PM, prior to the submission of the TR.

### B. TR Submitted To The NRC:

As described in Section 4.2.2 of this OI:

- The TR is submitted to the NRC for review and the PSPB PM opens a TAC (as soon as fee waiver requests are resolved).

Section 4.2.2.B "Cover Letter" of this OI contains additional details on the transmittal of the TR. In addition to the information requested in Section 4.2.2.B, the cover letter transmitting every TR should contain the following information to support NRR's prioritization.

- TR 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, BWRVIP, 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 an SE 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.

NRR recommends that TR applicants use the following matrix to address these factors and to determine the points for each factor, as it relates to the incoming TR, in the cover memo. Please note that for some of the factors, the points are cumulative because the TR applicant may meet more than one criteria for a particular factor. Once all of the points for each factor have been assigned, a total score will be determined by NRR after evaluating the specialized resource availability factors (as shown below).

<b>Draft TR Prioritization Scheme Matrix*</b>			
* NRR will evaluate the shaded areas. Industry input on these areas is not requested.			
<b>Factors</b>	<b>Select the Criteria That the TR satisfies</b>	<b>Points Assigned For Each Criteria</b>	<b>Total Points (if points are cumulative, total them for each factor in this column)</b>
<b>TR Classification</b> (Points are cumulative)	Generic Safety Issue	6	
	Emergent Technical Issue	3	
	Standard TR	1	
<b>Applicability</b> (Points are not cumulative)	Industry-wide Implementation	3	
	Applicable to entire groups of licensees (BWROG, PWROG, BWRVIP, etc.)	2	
	Applicable only to partial groups of licensees	1	
<b>Specialized Resource Availability</b> (Points are cumulative)	NRC staff expertise is readily available <i>(The NRC staff will evaluate this criteria)</i>	1.5	
	Technical data is available/readily accessible <i>(The NRC staff will evaluate this criteria)</i>	1	
	A SE is requested by a certain date (less than two years) to support a licensing activity. Provide justification.	0.5	
Total Points (Add the total points from each factor and total here): (NRC staff will total the points)			

\* This TR Prioritization Scheme will be used by NRR to support the prioritization of incoming TRs, when necessary. NRR maintains its discretion to prioritize incoming TRs on a case-specific basis, when NRR management deems it necessary to consider other criteria not captured in this prioritization scheme.

## Appendix - Change History

### Office Instruction LIC-500 Revision 3

#### Processing Requests for Reviews of Topical Reports

LIC-500 Change History - Page 1 of 1			
Date	Description of Changes	Method Used to Announce & Distribute	Training
08/08/2002	Initial Issuance	E-mail to all staff	Self-study by owners group PMs and TB section chiefs.
10/18/2002	This change adds: (1) a requirement for the staff to include in the safety evaluation conditions and limitations for the topical report, and (2) a choice of paragraphs that explain the billing policy to the acceptance review letter. There are also editorial changes, including a new web address.	E-mail to all staff	Self-study by owners group PMs and TB section chiefs.
12/25/2003	This change reflects recent revisions to the topical report review process.	E-mail to all staff	Self-study by owners group PMs and TB section chiefs.
06/24/2005	This change reflects recent revisions to the topical report review process.	E-mail to all staff	Self-study by Vendor/Owners group PMs and TB section chiefs. Training Session for Vendor/Owners Group PMs
12/21/2009	This change reflects recent revisions to the topical report review process.	E-mail to all staff	Self-study by Vendor/Owners group PMs and TB section chiefs. Training Session for Vendor/Owners Group PMs