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

NRR OFFICE INSTRUCTION

Change Notice

Office Instruction No.:	**LIC-500, Revision ~~3~~ 4**
Office Instruction Title:	**Processing Requests for Reviews of Topical Reports**
Effective Date:	**~~June 24, 2005~~ December , 2008**
Primary Contacts:	**~~Girija Shukla~~ ~~Robert Gramm~~** **~~301-415-8439~~ ~~301-415-1010~~** **~~GSS@nrc.gov~~ ~~RAG@nrc.gov~~**
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Responsible Organization:	**~~NRR/DLPM/LPD4~~ NRR/DPR/PSPB**

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

Training:	(1) Self-study by Vendor/Owners group project managers (PMs) and Technical Branch (TB) ~~section~~ branch chiefs (BCs). Training Session for Vendor/Owners group PMs (2) E-mail to all staff
ADAMS Accession No.:	**~~ML051800651~~**

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Position	Primary Contact DPR/PSPB /PM	DPR/PSP B/LA	DPR/ PSPB/BC	DPR/D	PMDA/D
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NRR OFFICE INSTRUCTION
LIC-500, Revision ~~3~~ 4

Processing Requests for Reviews of Topical Reports

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. The NRC, through its website ~~http://www.nrc.gov/what-we-do/regulatory/licensing/topical-reports.html~~ http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html (Reference 1), provides guidance to applicants on the NRC's topical report (TR) program.

2. OBJECTIVE

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.

3. BACKGROUND

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. TRs ~~Topical reports~~ improve the efficiency of the licensing process by allowing the staff to review a proposed methodology, design, operational mode, 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.

Under the NRC TR program, industry organizations, such as a vendor or an owners' group (OG) – also referred to as an applicant throughout this OI - may on ~~their~~ 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. The purpose of the program is to minimize industry and NRC time and effort by providing for a streamlined review and approval of the safety-related subject with subsequent referencing in licensing actions, rather than repeated reviews of the same subject.

4. BASIC REQUIREMENTS

4.1 Overview of the TR Process

TRs are typically submitted by a vendor or an ~~owners group~~ OG in accordance with the guidance provided on the NRC's website at ~~http://www.nrc.gov/what-we-do/regulatory/licensing/topical-reports.html~~ http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html.

NRR's Special Projects Branch (PSPB), within the Division of ~~Licensing Project Management (DLPM)~~ Policy and Rulemaking (DPR) has the responsibility for managing the TR program. A lead ~~program~~ project manager (PM) within PSPB is assigned to manage the overall TR program. ~~The lead PM is responsible for updating the topical report website quarterly.~~ Additionally, ~~project managers~~ PMs are assigned to each of the major ~~owners groups~~ OGs and vendors. A list of the assigned 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 office instruction will reference existing guidance documents rather than paraphrasing them. Also, the PM should be familiar with the guidance provided in Office Instruction COM-204, "Interfacing With Owners Groups, Vendors, and NEI" (Reference 3).

4.1.1 Accepting a TR for Review

To be accepted for the TR program the report should meet all four of the following criteria, in addition to the criteria in LIC-109, "Acceptance Review Procedures:"

(1) The report deals with a specific safety-related subject regarding a nuclear power plant that requires a safety assessment 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 for resolution of industry issues or in support of plant-specific license amendment applications are not defined as TRs under this program.

(2) The report is expected to be referenced by multiple licensees in a number of license amendment requests following NRC staff approval.

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

(3) The report contains complete and detailed information on the specific subject presented. Conceptual or incomplete preliminary information will not be reviewed.

(4) NRC approval of the report will increase the efficiency of the review process for applications that reference the report.

~~Exceptions to these criteria may be allowed on a case-by-case basis. These exceptions must be based on an NRC decision that it is in the public interest to evaluate the proposed report. The justification for the exception may consider savings to the industry, or if the report would contribute in resolving a safety-related subject, or if the report presents advanced technologies that would maintain safety or reduce an unnecessary burden. The applicant should provide the NRC with justification for such exceptions. A decision to accept a report that does not meet the four criteria must find that the resources expended in the review of the TR are worth the reduction of resources committed to other activities, such as licensing actions.~~

Exceptions to these criteria, especially criterion (2), 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 contribution to resolving a safety-related issue, an advancement in technology that would benefit safety or reduce an operational burden, or result in significant cost savings to the industry. Any NRC staff decision to accept for review a TR 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 ~~topical report~~ 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 review. The vendor or OG requesting the fee waiver should submit the fee exemption request ~~should be separately addressed~~ to the ~~Chief Financial Officer~~ OCFO.
(Refer to 10CFR 170.11).

~~B.~~ To qualify for a fee wavier, ~~If a fee exemption is requested, NRC does not begin its review until it decides 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 TR ~~is~~ should be submitted as a means of exchanging information between the industry and the NRC for the purpose of supporting NRC's generic regulatory improvement program. ~~the report may qualify for a review fee exemption~~. 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) ~~and discuss preparation of the report~~ to request a TR and the resulting TR may be reviewed on a fee exempt basis. The final determination ~~discussion~~ ~~should include the appropriateness~~ of a fee exemption rests with the ~~and~~ OCFO ~~should be involved~~.

C. The ~~If a fee exemption is requested,~~ NRC does not begin its review (or open a Technical Assignment Control (TAC) number) until ~~it~~ the OCFO decides 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 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 PM should only select the "non-fee billable" option if the OCFO has granted the fee waiver exemption in writing.

D. If a vendor or OG decides to re-submit a TR that they had previously withdrawn, or which was closed by the NRC staff, the applicant should contact the TR PM to discuss if the approved fee exemption request is still applicable. If the original fee waiver still applies, the cover memorandum transmitting the revised TR to the NRC should reference the original fee waiver approval letter from the OCFO. The applicant does not need to request another fee waiver from the OCFO, unless the scope or use of the TR has changed significantly. If there are significant changes in the scope or use of the TR, the lead TR PM will discuss with the OCFO, if the fee waiver previously granted, remains applicable. 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, it should generally be submitted as part of the TR, either in the body of the TR or as appendices to the TR, as opposed to a separate concurrent "pilot plant" application. In general, reviews of plant-specific licensing actions, that reference a TR under review, are not accepted for review in parallel with the referenced TR review until the NRC staff publishes the draft safety evaluation (SE) for the TR following resolution of technical issues and identification of any limitations/conditions to use of the TR. If the vendor/ OG has prior knowledge that a licensee plans to submit a license amendment application referencing a TR, which is either proposed or currently under NRC staff review, the vendor/OG should contact the cognizant NRC TR PM to discuss the merits and potential problems with such a submittal.

The need for a separate concurrent demonstration or pilot license amendment request will be discussed and agreed upon at the pre-submittal meeting. If the cognizant NRC management (up to the Division Director level) and NRC staff supporting the TR review agree that such a pilot amendment will facilitate the TR review, it will normally be submitted as a supplement to the TR and will be reviewed, and either approved or denied, as part of the TR review. Upon NRC staff issuance of the TR final SE, the pilot application licensee must then submit a license amendment request referencing the approved TR. If the amendment request complies fully with the TR, the NRC staff should be able to issue the amendment upon expiration of the *Federal Register* notice.

4.2 TR Review Process Steps

No.	Task	Time Period	Responsibility
1	Pre-submittal meeting	1 to 6 months prior to submittal	Applicant/PM/ Technical Branch (TB)
2	Applicant submits TR to the NRC Document Control Desk (DCD). The PM should determine if the applicant requests a fee waiver before proceeding to Step 3.		Applicant
3	Process TR through Work Planning Center (WPC)	Within 5 working days of receipt of TR	PM
4	TBs complete and return the Green sheet to ~~PM~~ WPC	Within 10 working days of receipt from the WPC.	TBs
5	Hold telephone conference to establish agreed-upon review schedule milestones and estimated costs	During acceptance review period	Applicant/PM/TB
6	Complete acceptance/fee exemption review. PM issues acceptance letter	Within 45 working days of receipt of TR	PM/TB/OCFO
7	Complete proprietary determination (if needed). PM issues proprietary letter	Within 45 working days of receipt of TR.	PM/TB
8	Provide Requests for Additional Information (RAIs) to PM (if needed)	10 working days prior to agreed-upon milestone schedule for Request for Additional Information (RAI)	TB
9	Provide RAIs to applicant and discuss proposed RAIs with the applicant	Within the agreed-upon milestone schedule	PM
10	Applicant provides RAI response to PM	Within the agreed-upon schedule	Applicant
11	Provide SE to PM	20 working days prior to agreed-upon milestone schedule for draft SE	TB
12	Issue draft SE to applicant	Within the agreed-upon milestone schedule	PM
13	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
14	Provide resolution to applicant's comments to PM	Within 10 working days after receipt of comments	TB

15	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 ACRS meeting, this may result in a delay in issuing the final SE to applicant due to scheduling conflicts.	PM
16	Applicant submits approved version of TR	Within three months of final SE	Applicant
17	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 Meeting

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 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.

To prepare for the pre-submittal meeting, the PM notifies the appropriate ~~section chiefs and arranges the meeting. The TB section chiefs and~~ management and selected ~~technical~~ NRC staff from the appropriate TB(s) to participate in the meeting. The applicant will advise the PM, prior to the pre-submittal meeting, of any future plant-specific license amendment requests that plan to reference the approved TR. The applicant will also advise the PM if approval of the TR requires a change to the TS. If approval of the TR requires a change to the standard TSs, then the Technical Specifications Branch (ITSB) should be contacted to determine if the change is significant enough to warrant a Technical Specification Task Force (TSTF) submittal. The TSTF is a joint OG activity of the Boiling Water Reactors Owners Group and the Pressurized Water Reactors Owners Group. The TSTF and the NRC staff maintain standard TSs using the TSTF Traveler process. For an OG to change its standard TSs, the OG submits a proposed TSTF Traveler to the TSTF, which then finalizes and submits the Traveler to the NRC for review and approval. Section 4.2.6 provides additional guidance reqarding when the TSTF should be submitted to the NRC, if it will reference an approved TR.

Since the TR has not been formally submitted to the NRC at this point, the PM may open a pre-submittal TAC for NRC staff supporting this meeting. The NRC provides one non-fee billable pre-submittal meeting for each TR review. The PM should open the pre-submittal meeting TAC in TRIM under PA 111-113A. Select "Activity Code – RM Other Licensing Activities – Pre-Application Reviews" and "Template Title – RX-Lic-vendor/owners group activities – pre-application reviews."

To improve the effectiveness and efficiency of the pre-submittal meeting, an advance draft submittal of the TR, from the vendor or OG, is helpful to make the pre-submittal meeting more productive.

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 ~~they~~ plans to ask for a fee exemption. If the applicant is considering requesting a fee exemption, a representative from the OCFO should attend the meeting.

The NRC staff should provide feedback to the applicant on the proposed TR. The NRC staff should use their knowledge and experience to inform the applicant of the level of detail they expect 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 typically have ~~has~~ not seen the TR, 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.

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.

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 PM should issue a meeting summary within 30 working days.

Post-submittal 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 or denial letters.

In addition, depending up on the complexity of the TR, and the number of TBs involved in the review, the PM will establish a review tea with the technical reviewers and will coordinate periodic internal meetings with them 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 applicant should submit the TR to the NRC Document Control Desk (DCD).

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

- Name of the NRC TR PM. The NRC TR PM will ensure that the NRC technical leads are provided with a copy of the TR.
- Project Number for the vendor or OG.
- Priority of the TR (i.e., when does it need to be approved to support industry efforts and why?).
- Identify if approval of the TR requires a change to the TS.
- Basis for a fee waiver exemption request (or reference the prior approval of a fee exemption request, if applicable). Section 4.1.2 provides additional detail.
- If the contents of the enclosed TR are considered proprietary or non-proprietary. (Refer to Section 4.2.5 for additional information).

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

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 (EIE), 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 PM and the applicant will receive and 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.

Once the document is processed by the DCD, the PM will receive electronic notification via ERIDS that the TR is in the Agencywide Documents Access and Management System (ADAMS). TRs are typically profiled in ADAMS as non-public by the DCD. As a result, the DCD may also profile the cover letter transmitting the TR, as non-public. The PM will verify that the profile of the TR is correct. For example, the TR cover letter should be publicly available, and the TR may be profiled as non-public, if it is considered a proprietary TR. The PM should contact ADAMS IM by email to change the profile, if necessary. Additional information on proprietary determinations is provided in Section 4.2.5.

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

Once the TAC has been requested, it is ~~and~~ processed~~s the TR~~ through WPC for review. The TB will provide the ~~PM~~ WPC with the completed Work Planning and Characterization Form (Green Form) within 10 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.

4.2.3 **Work Plan** (within ~~45~~ 60 working day acceptance review period)

TRs are generally large complex technical reports that may require the involvement of more than one TB. The 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 for license amendments, which is 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. Include ITSB ~~the Technical Specifications Section~~ on any TR that impacts TSs,
- identify the Office of New Reactors on any TR that impacts new reactors (i.e., does the TR identify the scope of the TR is also applicable to new reactors?),
- determine if a change to standard TSs will be required. If the applicant plans to submit a TSTF which references the approved TR, the TSTF should be submitted to the NRC for review as soon as the RAIs for the associated TR have been resolved,
- determine the areas to be reviewed by each TB, ~~branch~~
- establish completion dates for the supporting branches and for the complete SE from the lead branch,
- schedule dates for RAIs,
- estimate review hours for each TB, and ~~branch~~
- establish date for DPR ~~the Division of Licensing Project Management (DLPM)~~ 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 WPC. As summarized in Section 4.2, the TB(s) will provide the PM (via the WPC) 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 PM after 10 working days, the 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 PM after 15 working days, the PM should elevate the issue to the PSPB BC.

Occasionally, if appropriate, a TB involved in the review may inform the Advisory Committee on Reactor Safety (ACRS) of a TR under review. If the ACRS wishes to be briefed on the TR, it may contact the TB and request a briefing. The briefings may be performed either by the TB or the applicant. ~~This is very infrequent.~~

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

~~If approval of the TR requires a change to the standard TSs then the Technical Specifications Section should be contacted to determine if the change is significant enough to warrant a technical specification task force (TSTF) submittal by the Nuclear Energy Institute (NEI). The TSTF process is the method that the staff and industry (through NEI) use to maintain standard TSs. For an owners group to change its standard TSs, the owners group submits a proposed TSTF to NEI which submits the TSTF to the NRC for review and approval.~~

If approval of the TR requires a change to the standard TSs then the Technical Specifications ~~Section~~ Branch should be contacted to determine if the change is significant enough to warrant a Technical Specification Task Force (TSTF) submittal. The TSTF is a joint owners group activity of the BWROG and the PWROG. The TSTF and the staff maintain standard TSs using the TSTF Traveler process. For an owners group to change its standard TSs, the owners group submits a proposed TSTF Traveler to the TSTF, which then finalizes and submits the Traveler to the NRC for review and approval.

4.2.4 <u>Acceptance Review</u>

If a fee exemption has been requested, then OCFO must issue a letter approving the exemption before the 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 ~~45~~ 60 working day acceptance review period would not commence until the fee exemption request has been resolved, or the submitting organization has agreed to pay the fee, in case the fee exemption request is denied.

The propose of the acceptance review is to determine if the TR is acceptable for NRC staff review. The acceptance review is performed by both the PM and the TB(s). The PM's responsibility is to ensure that the TR meets the criteria for acceptance in the TR program provided in Section 4.1.1. The TB's responsibility is to ensure the TR is technically complete enough to start a review. The TB determination to accept or deny a TR for review is due by the agreed upon date listed on the Green Sheet. The TB BC should document its acceptance for review (via email or formal memorandum) to the PSPB BC. Any denials should be documented via a formal memorandum from the TB BC to the PSPB BC. Additional information on acceptance reviews is provided in LIC-109.

During the acceptance review of the TR, a telephone conference will be held among the project manager, 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 ~~considered a "commitment" by the staff and~~ documented by the PM in an acceptance-for-review letter to the applicant, ~~The agreed-upon schedule will be documented in the acceptance-for- review letter for the topical report,~~ along with the estimated review cost, which will include NRC staff review hours, time required to coordinate the review and develop and issue the draft SE (i.e., project management time, and the estimated contractor cost, if applicable and available). Typically, the acceptance-for-review letter will be issued within ~~45~~ 60 working days of receipt of the TR (see Attachment 1 for a sample acceptance letter). The TB BCs ~~Branch Chief(s)~~ and the ~~DLPM Project Director, Project Directorate IV (PDIV)~~ 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, ~~lack of support from the applicant, such as an incomplete or late RAI response~~, 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. ~~In the case of an incomplete RAI response, the staff may suspend its review of the topical report until the complete RAI response is submitted. In such situations, after receiving all requested information, the staff would establish a revised review schedule, based upon available staff resources, and other considerations. The revised review schedule will be documented in a letter with new agreed-upon milestones.~~

If the NRC staff decides to reject the TR for technical reasons, the TB will provide an explanation in the rejection letter. The letter will also state which acceptance criteria were not met. If the NRC staff decides to reject the TR because it does not meet the TR program guidance, the letter will be concurred on by the TB Branch Chief (see Attachment 2 for a sample rejection letter). The PM will notify the vendor or OG in advance of issuing the rejection 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 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). Although the applicant is not required by 10 CFR 2.390 to submit a non-proprietary version of the TR, the PM should request that they submit one to the DCD for the public. PSPB ~~DLPM~~ will issue the proprietary determination letter within 45 working days of the incoming TR. For efficiency, the proprietary review should be performed at the same time as the acceptance review. Both the 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 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 nonproprietary version of the final SE must be issued.

4.2.6 RAIs

4.2.6.1 – 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 PM with RAIs 10 working days prior to the agreed-upon milestone schedule date for RAIs. The 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 the PM should, if the TR is proprietary, ask the applicant if the questions reveal any proprietary information. If the questions do reveal proprietary information, the PM should either reword the question or issue a proprietary and a nonproprietary version of the RAIs. The applicant will provide the PM with 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. The transmittal letter will also state that if the RAIs are not provided by the agreed upon date, the NRC NRC staff can close out its review of the TR. The applicant should discuss any request for an extension with the TR 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, if it does not adversely affect the NRC staff's ability to meet the performance measures shown in Section 6.0.

4.2.6.2 - Incomplete or Late RAI Responses

In the event of an incomplete or late RAI response from the applicant, the staff has several options:

A. ~~can~~ Extend the review schedule until the complete RAI response is submitted, so long as it does not adversely affect the NRC staff's ability to meet the performance measures as shown in Section 6.0. ~~or suspend its review of the topical report.~~ In such situations, upon receipt of the completed 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 PM should also coordinate with the WPC Division Representative to ensure that the revised schedule is captured in the WPC database.

B. 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 ~~or suspend~~ 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.

C. 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 letter and to verify that the NRCs review has been closed.

4.2.6.3 – 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 NRCs review), the applicant can withdraw the TR from NRC staff review, as stated in Section 4.2.6.2.c. Withdrawal of a TR would be recommended by the PSPB BC if the revisions needed to the TR are considered significant and would adversely impact the NRC staff's ability to complete the TR review in 2 years or less. The applicant's letter should provide a basis for withdrawing the TR.

4.2.6.4 - Submitting a Revised TR After it Has Been Closed or Withdrawn

The 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, after the NRC issued its RAIs, the applicant may decide to re-submit the TR to address those RAIs. Typically, 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 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.

4.2.7 TB Transmits SE to ~~DLPM~~ PSPB

The ~~lead~~ TB(s) will provide the PM with the SE 20 working days prior to the current agreed-upon milestone schedule date for the draft SE. If more than one TB provides SE input to the PM, the 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 conditions and limitations 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.

"Conditions and Limitations" describe any exceptions or conditions on a licensee's use of the TR, that the NRC may take to the content provided within the TR. If the TB(s) approves of the technical basis or methodology contained within the TR, but with some exceptions, those exceptions are identified in the SE discussion and listed in a separate section of the SE as "Conditions and Limitations." The conditions and limitations should be explicit to help licensees provide the necessary information in license amendment requests (LARs) 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 conditions or limitations in the SE are clearly understood in advance of issuing the draft SE. The TB(s), PM, and applicant should strive to facilitate early identification and issue resolution of technical issues before the TB provides its SE input to the 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 a LAR or a TSs 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 conditions and limitations are captured when referenced in an LAR or during the transition to a TSTF (Refer to Attachment 3).

~~These conditions and limitations shall also be listed in a separate section titled Conditions and Limitations.~~

4.2.8 Issue Draft SE to Applicant

The purpose of the draft SE is to provide the applicant with the opportunity to identify if the SE contains any proprietary information and to clarify any factual inaccuracies. The draft SE is not provided to the applicant so that the technical merits of the NRC's SE can be debated.

The PM will issue a draft SE within the agreed-upon milestone schedule date for the draft SE. The draft SE letter should follow the guidance in Attachment 3, and will be signed by the ~~DLPM Section~~ PSPB BC ~~Chief~~, ~~PDIV-2, with concurrence from the Project Director, PDIV~~. The PM may email the applicant a copy of the draft SE, once concurred upon, to ensure that sufficient time is provided for comment.

Once feedback is provided by the applicant on the draft SE, the PM will work with the TB(s) to resolve the comments which are identified by the applicant as factual errors or clarity concerns. The PM will inform the applicant if there are comments that will not be accepted.

If the TR is proprietary, the letter transmitting the SE will state that the applicant has 10 working days from receipt of the SE to review it for proprietary information. After 10 working days, the NRC staff will make the SE publicly available unless the applicant has informed the NRC staff that the SE contains proprietary information. An additional 10 working days will be provided to the applicant to comment on any factual errors or clarity concerns contained in the SE. If no feedback is provided from the applicant within 20 working days, the SE will be made final and publicly available. The PM will provide the applicant's comments on the draft SE to the TB, and the TB will provide the PM with resolutions to the applicant's comments within 10 working days after receipt of the draft SE comments.

4.2.9 <u>Issue Final SE to Applicant</u>

The PM will issue the final SE for the TR within 20 working days after receipt of the applicant's comments on the draft SE. The final SE will be issued after making any necessary changes, and will also be made publicly available. If the comments go beyond mere editorial corrections (i.e., misspelled words) the PM will ~~The staff's~~ disposition ~~of~~ the applicant's comments ~~will be discussed~~ in ~~the~~ an attachment to the final SE. The PM will prepare a letter approving the TR for referencing in licensing actions for signature of the ~~DLPM Project Director, PDIV~~ Deputy Director, DPR. The ~~final~~ SE letter should follow the guidance in Attachment 4. For a proprietary TR, the transmittal letter will state that both the proprietary and nonproprietary versions must be referenced in future licensing applications.

Once the final SE is issued, the PM will close the TAC via TRIM. The PM should use the date of the SE as the “actual completion date” in TRIM. For example, if the final SE was issued on February 4, but eh PM doesn’t close the TAC until February 7, the PM should enter the TAC completion date as February 4 (the date of the Final SE). The TAC is closed on the completion date (February 4) and not on the date that the PM closes it (February 7). If additional work is done to support a review after the final SE is signed out (i.e. management briefings), the PM should charge to another TAC such as a generic vendor/OG interaction TAC.

4.2.10 <u>Applicant Submits Approved Version of TR</u>

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 to accommodate vendor/OG that rely on a committee review and publication process. The approved version of the TR should incorporate the final SE letter with the final SE and all RAIs and their responses after the title page of the TR. The approved version should be identified by a "-A" following the TR identification symbol. For a proprietary topic TR, both proprietary and nonproprietary versions must be published and submitted to the NRC.

If the SE states that changes need to be made to the TR, the PM should verify that these changes are made once the approved TR is received. Any changes that need to be made to the TR will be captured by the NRC staff in the SE section titled, “Use and Referencing of the SE.” A separate audit TAC (coded as fee-billable) should be requested by the PM to verify that changes to the TR have been made in accordance with the final SE.

4.2.11 <u>Applicant Submits Revision(s) Or Supplement(s) To The Approved Version Of TR</u>

In some cases, an applicant will submit a revision to the NRC approved version of the TR. The revision may seek to provide additional information for the purpose of changing or removing portions of the final NRC SE (i.e., a limitation or condition). Similarly, an applicant may provide “supplemental information” to update code references or data that was provided in the approved version of the TR. Typically, the revision or supplement will only identify the information that has been updated or revised since the approved version of the TR was issued.

A. Regardless of whether the applicant refers to the information as a revision or supplement, once the PM receives the revision/supplement, they will follow the TR process (as described in this OI) to conduct a pre-submittal meeting (if needed), and open a TAC to obtain TB(s) review of the updated information.

B. After the NRC staff has completed its review and issued a final SE, the applicant should issue a revised –A. The revised –A should be identified with the appropriate revision or supplement number. For example, "TR {identification symbol}, Revision X to –A."

5. RESPONSIBILITIES AND AUTHORITIES

5.1 TB Branch ~~and Section~~ Chiefs

The branch chiefs ~~and section chiefs~~ ensure that the NRC staff follows office instructions. The branch ~~and section~~ chiefs are responsible for:

- participating and designating NRC staff persons who participated in the pre-submittal meeting (4.2.1),
- working with the PM to develop a work plan (4.2.3),
- performing fee-exemption reviews,
- concurring in the proprietary determination, acceptance, rejection letters and SE prepared by the PM (4.2.5),
- concurring on RAIs and ensuring RAIs are issued on schedule and per LIC-101 (4.2.6),
- transmitting SE to ~~be issued as a draft for comment, to the DLPM PDIV-2 Section Chief~~ the PSPB BC, DPR, responsible for TRs (4.2.7), and
- transmitting resolution to the applicant's comments on the ~~draft~~ SE to the ~~DLPM PDIV-2 Section~~ PSPB BC, DPR, ~~Chief~~ responsible for TRs (4.2.8).
-

5.2 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)
- performing technical acceptance and proprietary reviews (4.2.4 and 4.2.5)
- 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)

5.3 Responsible Manager

The ~~DLPM Project Director, PDIV~~ DPR Division Director has overall responsibility for the TR process. The ~~Project Director~~ DPR Division Director ensures the TR process meets the performance measures defined in the NRR Operating Plan.

5.4 ~~DLPM Section~~ PSPB BranchChief

The ~~DLPM PDIV-2 Section~~ PSPB Branch Chief is responsible for overseeing the daily operation of the TR program.

5.5 Project Manager

The 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 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),
- writing the acceptance review letter (4.2.4),
- making a proprietary determination (4.2.5),
- issuing RAIs to applicant (4.2.6),
- issuing draft SE to applicant (4.2.8), and
- issuing final SE to applicant (4.2.9)

6. PERFORMANCE MEASURES

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

- 80% of TR ≤ 2 years (age of inventory)
- 100% of TR ≤ 3 years (age of inventory)

7. **PRIMARY CONTACTS**

~~**Girija Shukla Robert Gramm**~~
~~**301-415-8439 301-415-1010**~~
~~**GSS@nrc.gov RAG@nrc.gov**~~

Tanya Mensah	**Stacey Rosenberg**
301-415-3610	301-415-2357
tme@nrc.gov	slr1@nrc.gov

8. **RESPONSIBLE ORGANIZATION**

~~NRR/DLPM/LPD4~~ NRR/DPR/PSPB

9. **EFFECTIVE DATE**

~~June 24, 2005~~

10. **REFERENCES**

1. ~~http://www.nrc.gov/what-we-do/regulatory/licensing/topical-reports.html~~
   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”

Attachments:

1. Sample Letter Accepting Report for Review
2. Sample Rejection Letter
3. Sample Draft SE Letter
4. Sample Final SE Letter
5. Appendix A: LIC-500 Change History

<u>Sample Letter Accepting Report for Review</u>

[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]**. We have found that the material presented is sufficient to begin our comprehensive 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]** 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 fee branch 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 fee branch 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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ADAMS ACCESSION NO.: **NRR-106**

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

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Sample Rejection Letter

[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**.**

As we notified you on **[date]**, we have completed our acceptance review of your application and all of the supporting information in accordance with the topical report program criteria and have concluded that your report is not acceptable for review for the reasons discussed below.

[Describe reasons for rejecting the topical report].

Therefore, your request for the review of **[title of topical report]** is denied.

Sincerely,

Ho K. Nieh, Deputy Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. **[number]**

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ADAMS ACCESSION NO.: **NRR-106**

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NAME		DBaxley		SRosenberg	HNieh
DATE					

DOCUMENT NAME: G:\ADRA\DPR\PSPB\Boilerplates\Generic Boilerplates\Topical Report\Topical Report Rejection Letter.wpd

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Attachment 2

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, 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 to 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.

Attachment 3

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

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

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DATE				

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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 of 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

6.0 CONCLUSION

Principle Contributor:

Date:

<u>Sample Letter Transmitting Final SE</u>

[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 comments. 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 attachment 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.

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.

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.

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,

Ho K. Nieh, 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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SRosenberg (Hardcopy)

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

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DATE					

DOCUMENT NAME: G:\ADRA\DPR\PSPB\Boilerplates\Generic Boilerplates\Topical Report\Topical Report Final SE Letter.wpd
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Attachment 4

Appendix A - LIC-500 Change History

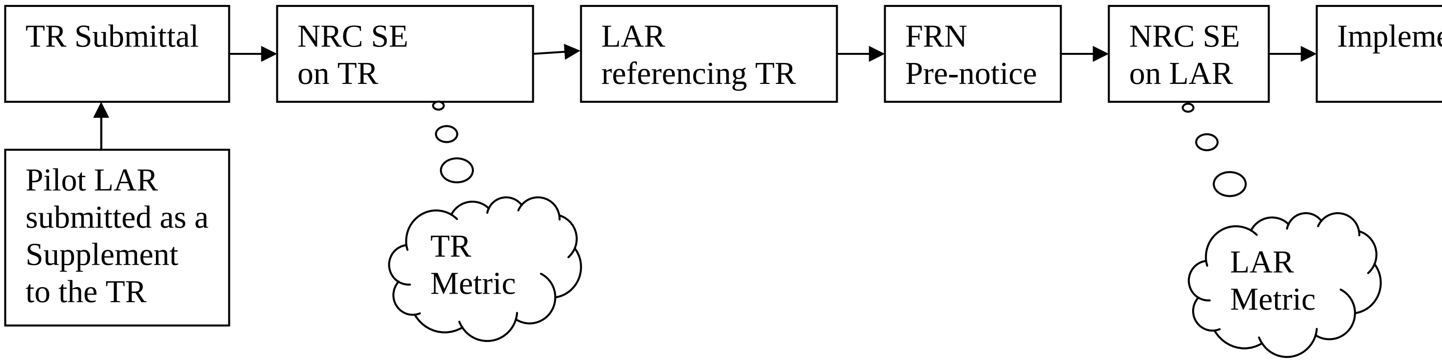
Office Instruction LIC-500, Revision 3

Processing Requests for Reviews of Topical Reports

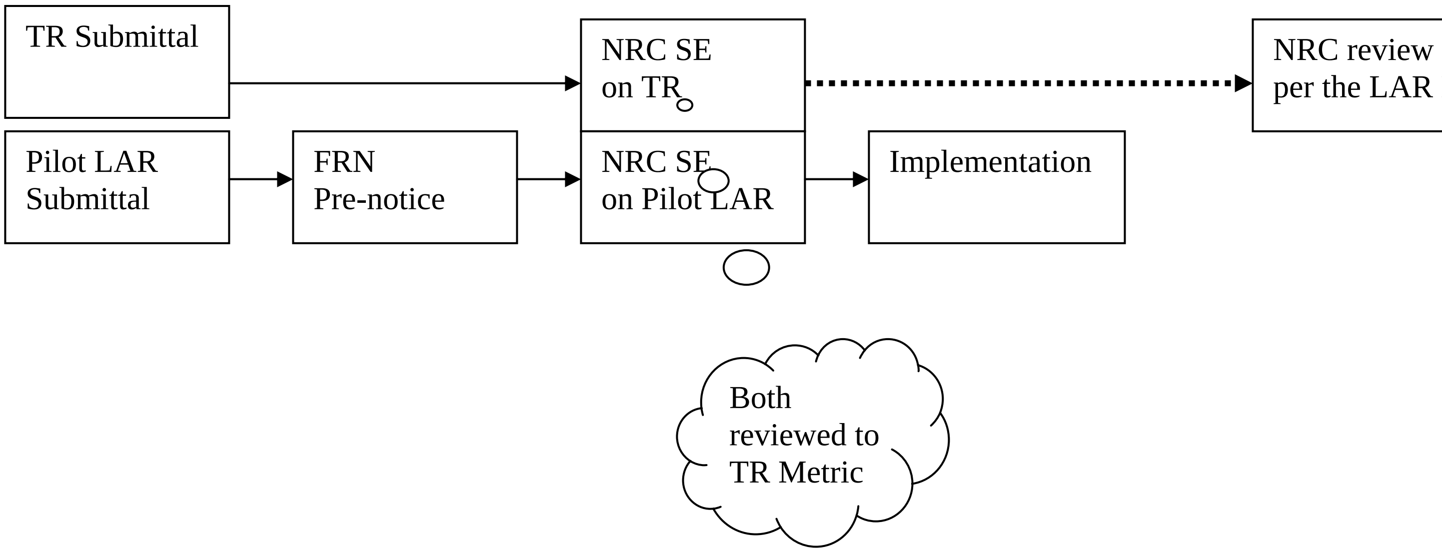
LIC-500, Revision 3 - Change History			
Date	**Description of Changes**	**Method Used to Announce & Distribute**	**Training**
08/08/2002	Initial Issuance	E-mail to all staff	Self-study by owners group PMs and TB section chiefs.
10/18/2002	This change adds: (1) a requirement for the staff to include in 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
(New Date)	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

INSERT A

NEI TR Team flow chart interpreting of 4.1.2.D:



NEI TR Team alternative flow chart:



INSERT B

Alternately, the responses to RAIs and the final SE may be incorporated in the body of the TR for purposes of continuity and clarity of technical information. In such cases, the RAIs, SE, and associated document changes may be incorporated elsewhere in the TR, such as an appendix that documents the “history of changes.”

INSERT C

In the event it becomes necessary to reassign a reviewer after the reviewer’s portion of a TR review is partially complete,

the TB chief will ensure that:

(a) the original reviewer provides a draft Safety Evaluation (SE) that is complete to the extent of the completed review activity,
(b) the original reviewer shall meet with the replacement reviewer to conduct a thorough turnover, including a walk-through of the draft SE,
(c) the replacement reviewer shall resume the review using the original reviewer’s draft SE as the point of departure, such that the completed review effort is not duplicated,

and the Project Manager will ensure that:

(a) the applicant is not invoiced for any replacement reviewer’s on-the-job training or duplication of completed review work, and
(b) efforts are made to achieve a final SE in accordance with the original schedule.