



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

NRR OFFICE INSTRUCTION

Office Instruction No.: **LIC-500, Revision 5**
Office Instruction Title: **Topical Report Process**
Effective Date: **October 7, 2013**
Approved By: **Susan Abraham**
Date Approved: **October 4, 2013**
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Responsible Organization: **NRR/DPR/PLPB**

Summary of Changes: This change reflects: (1) modification of the Topical Report (TR) prioritization scheme, (2) improved process to interface with the Office of New Reactors, (3) added review of Congressional Review Act applicability, (4) added staff verification of "-A" version of TRs, and (5) various editorial updates and changes.

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.: **ML13158A296**



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NRR OFFICE INSTRUCTION
LIC-500, Revision 5

Topical Report Process

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 U.S. commercial operating reactor licensees. The objective of this office instruction (OI) 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 below, that can be submitted to the NRC for its review and approval. TRs improve the efficiency of the licensing process by allowing the staff to review proposed methodologies, designs, operational requirements, or other safety-related subjects on a generic basis so that they may be implemented by reference by multiple U.S. licensees, once approved by the NRC staff. A 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 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> (Reference 1).

NRR's Licensing Processes Branch (PLPB), within the Division of Policy and Rulemaking (DPR), has the responsibility for managing the TR program. A lead program manager within PLPB is assigned to manage the overall TR program. The TR Program Manager is responsible for updating the TR web pages within the NRC public website quarterly. Additionally, PLPB project managers (PMs) are assigned to each of the major TR applicants. A list of PLPB PM assignments and the "NRR Topical Report Project Status" link are available at the PLPB internal Sharepoint site (<http://portal.nrc.gov/edo/nrr/dpr/plpb/default.aspx>).

The review of TRs generally 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, PLPB PMs should be familiar with the guidance provided in OI COM-204, "Interfacing With Owners Groups, Vendors, and NEI" (Reference 3).

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

- Pre-submittal meetings
- Submitting the TR
- Interfacing with the Office of New Reactors (NRO) for dual applicability TRs
- Work plan preparation, which in conjunction with the Center for Planning and Analysis (CPA) and appropriate technical review branches, the PLPB PM is expected to coordinate
- Acceptance reviews (includes prioritization of all TRs)
- Proprietary determinations
- Requests for additional information (RAIs)
- Preparation and issuance of the draft and final safety evaluations (SEs)
- Congressional Review Act clearance
- Submittal and review of the approved ("-A") 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 U.S. 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: 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 multiple requests for licensing actions. Examples of licensing actions include 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 OI; however, it is not intended to exclude other requests for licensing action that also reference an approved TR.
- C. Consistent with the criteria in LIC-109, "Acceptance Review Procedures" (Reference 4), 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 TR will increase the efficiency of the review process for applications that reference the TR.

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 the Chief Financial Officer (OCFO) on a case-by-case basis (see 10 CFR 170.11).

Guidance for fee exemptions includes the following:

- A. Any fee exemption must be requested by an applicant 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).

An applicant 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. However, the NRC must be the primary beneficiary of the NRC's review and approval of these documents. 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 Office Deputy 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. However, 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 number requested by the PLPB PM to support a TR review should be requested in TRIM under Planned Activity (PA) 114-151CA. 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 PLPB 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

Licensees should wait until the applicant receives a final letter from the PLPB PM confirming the outcome of the “-A” (approval version of the TR, Section 4.2.12) verification, following the applicant’s submission of the approved “-A” version with the staff’s final SE, before referencing the TR in an LAR. Unless specifically agreed upon by the NRC staff, separate, concurrent “pilot plant” applications are inconsistent with the guidance in LIC-109, and are generally not acceptable. 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.

4.2 TR Review Process Steps

No.	Task	Time Period	Responsibility
1	(Optional) Applicant submits fee waiver request to OCFO and receives determination.	Prior to commencing any other TR step (exception: see 4.1.2 B).	Applicant/OCFO
2	Applicant informally notifies PM of intent to submit the TR.	1 to 6 months prior to submittal.	Applicant
3	PM opens a pre-submittal TAC in TRIM and coordinates one or more pre-submittal meetings with applicant and technical branch(es) (TB).	1 to 6 months prior to submittal.	PM/TB
4	Applicant submits TR to the NRC Document Control Desk (DCD). The DCD assigns an ADAMS accession number to the TR.	[Official submission]	Applicant
5	PM closes pre-submittal TAC, opens a new review TAC, and completes the Blue Sheet in Firefly.	Within 5 working days of receipt of TR or within 5 working days of issuance of the OCFO letter.	PM

6	NRC staff determines the dual applicability nature of the submitted TR and coordinates with the applicable TB(s).	Within 30 calendar days of receipt of the TR.	Applicant/PM/TB
7	TB completes the Green sheet in Firefly.	Within 14 working days of receipt in Firefly.	TB
8	If appropriate, applicant submits a proprietary withholding request for the TR. NRC staff issues a proprietary determination letter.	Within 60 days from receipt of withholding request and material.	Applicant/PM/TB
9	Review the TR for technical completeness.	During acceptance review period.	PM/TB
10	PM issues an acceptance letter with milestones dates.	Within 60 days of receipt of TR or issuance of the OCFO letter.	PM/TB
11	TB provides Request for Additional Information (RAI) questions to PM (if needed).	10 working days prior to agreed-upon milestone schedule for RAIs.	TB
12	PM provides RAI questions to applicant in accordance with LIC-101, Section 4.3. The RAI transmittal letter should identify and discuss any anticipated limitations and conditions, if practicable.	Within the agreed-upon milestone schedule.	PM
13	Applicant reviews RAI questions and provides response to PM.	Within the agreed-upon schedule.	Applicant
14	TB provides Draft SE to PM.	20 working days prior to agreed-upon milestone schedule for Draft SE.	TB
15	PM issues Draft SE to applicant.	Within the agreed-upon milestone schedule.	PM
16	Congressional Review Act (CRA) Clearance by OGC or Office of Management and Budget (OMB).	30 to 90 days from date provided to OGC.	PM
17	Applicant provides comments on Draft SE. If appropriate, applicant submits proprietary withholding request for SE.	Within 10 working days for proprietary information, and within additional 10 working days for factual errors or clarity issues.	Applicant

18	NRC staff issues a proprietary determination letter.	During safety review period.	Applicant/PM/TB
19	TB provides resolution of applicant's comments to PM.	Within 10 working days after receipt of comments.	TB
20	Issue Final SE with proprietary and nonproprietary versions as appropriate to applicant.	Within 20 working days after receipt of applicant's comments on the Draft SE.	PM
21	Submit three copies of form GAO-001 and three copies of the SE to OCA for distribution to the House, Congress, and GAO.		
22	PM closes the TAC.	Within the month of the final SE	PM
23	Applicant submits approval version of the TR to DCD.	Within three months of final SE.	Applicant
24	PM opens a new TAC in TRIM.	Within three months of receipt of the approved version of TR.	PM
25	PM and TB 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
26	PM issues a verification letter to applicant and closes the TAC.	Within three months of receipt of the approved version of TR.	PM

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 PLPB 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 OI COM-202, "Meetings With Applicants, Licensees, Vendors or Other Members of the Public" (Reference 5), public meetings normally require a 10-day public notice period prior to the meeting.

B. Preparation

To prepare for the pre-submittal meeting, the PLPB PM notifies the appropriate management and selected NRC staff from the appropriate TB to participate in the meeting. Prior to the pre-submittal meeting, the PLPB PM will discuss with the applicant any future known licensing action requests that plan to reference the approved TR. The PLPB 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 (STSB) is the point of contact for determining the acceptability of the proposed STS changes, and any future interaction with the Technical Specifications Task Force (TSTF) about proposed changes to STS.

If the applicant is considering requesting a fee exemption, the PLPB 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 PLPB PM should open a pre-submittal TAC number 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 number should be opened under PA 114151CA.

The PLPB 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 or 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 Enclosure 2.

D. After the Pre-submittal Meeting

The PLPB PM should issue a detailed meeting summary, including any action items or NRC staff requests, within 30 working days in accordance with OI COM-202, "Meetings With Applicants, Licensees, Vendors, or Other Members of the Public" (Reference 4). 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 RAI questions, limitations or conditions, or denial letters.

In addition, depending upon the complexity of the TR and the number of TB involved in the review, the PLPB 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 PLPB PM will ensure that the applicant submits the following documents, where applicable, to the NRC. The PLPB 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>.

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 PLPB PM.

B. TR to the NRC DCD

Transmittal Letter

The letter transmitting the TR should include the following information:

- Name of the NRC PLPB PM. The NRC PLPB 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 Deputy Director level, if applicable.
- Information to support the NRC's effort to prioritize the incoming TR. The TR applicant should follow the format of the draft prioritization scheme matrix, as shown in Enclosure 2.
- A copy of the fee waiver or exemption request that was submitted directly by mail to the OCFO. (Refer to Section 4.2.2.A.)

Method of TR Submission

Hard copy or CD ROM documents can be submitted to the DCD by mail. 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>. These 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 PLPB 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 re-submit the document.

ADAMS Profile for the TR

Once the document is processed by the DCD, the PLPB PM will receive electronic notification via the Electronic Regulatory Information Distribution System (eRIDS) that the TR is in the Agencywide Documents Access and Management System (ADAMS).

The TR and transmittal 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 Number to Begin the TR Review

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

Once the TAC number has been requested, it is processed through the CPA via Firefly 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 PLPB 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 RAI questions. 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 PLPB 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 Interface with the Office of New Reactors for Dual Applicability TR

Occasionally, a submitted TR is applicable to both operating reactors and new reactors, and must also be reviewed under the Part 52 licensing process. TB Branch Chiefs (BCs) and reviewers shall follow OI COM-114 (NRR)/COM-105 (NRO), Revision 2 (Reference 6) to ensure technical consistency in the combined review. The PLPB PM will ensure that proper coordination between the offices takes place in an effort to maintain technical consistency (as defined in COM-114 (NRR)/COM-105 (NRO), Revision 2). The PLPB PM shall also maintain coordination with appropriate NRO PMs. In general, the office that needs the approved TR soonest should take the lead responsibility in the project management, unless otherwise agreed by both offices.

The PMs from both offices should keep their counterparts informed of the process and emergent issues through the periodic interface meetings, shared schedule, copy of related correspondences, RIDS distribution lists, future submittal plans, concurrence, resources, etc. When possible, counterparts should be engaged early in the process beginning with pre-submittal meetings.

4.2.4 **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 PLPB PM should develop a work plan. This work plan may be informal (e.g., an e-mail sent to the reviewers involved). OI 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 TB 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 TB may identify to the PLPB PM that they need to coordinate with other TB (i.e., supporting branches),
- Include STSB 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 TB,

- if possible, identify the need for a technical champion (refer to Enclosure 1). The need for a technical champion may not be obvious at this phase of the review. Therefore, the PLPB 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 TB 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 via Firefly. As summarized in Section 4.2.2.2, the TB will provide the PLPB 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 PLPB PM after 10 working days, the PLPB 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 PLPB PM after 15 working days, the PLPB PM should elevate the issue to the PLPB 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 number 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 SE, 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)" (Reference 7).

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 STSB should be contacted to determine if the change is significant enough to warrant a TSTF submittal.

4.2.5 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, regulatory and technical sufficiency requirements for the NRC staff to complete its review. The acceptance review is performed by both the PLPB PM and the TB. The PLPB 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 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 in Firefly.

The TR shall then be prioritized in accordance with the prioritization scheme (Enclosure 2).

- The PLPB PM, with the support of the technical branch management, will use the input provided on the transmittal letter (refer to Section 4.2.2.B) of the TR to prioritize the TR.
- Once the priority of the TR is determined, the PLPB PM will inform the PLPB BC and the TR Program Manager of the prioritization determination. The TR Program Manager maintains a list of all TR prioritization scores and will add the incoming TR to this list.
- The PLPB 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 PLPB PM, calls should

be established on a mutually- agreeable frequency, so that the PLPB 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 PLPB BC. Any non-acceptances should be documented via a formal memorandum from the TB BC to the PLPB BC.

For a TR involving TS changes, the PLPB 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.

During the acceptance review of the TR, a telephone conference will be held among the PLPB 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 PLPB PM in an acceptance-for-review letter to the applicant. Typically, the TB BC will document its acceptance-for-review within 45 days of receipt of the TR (or in sufficient time to allow the PLPB PM to issue the acceptance letter within 60 days of receipt) and provide it to the TR PM in PLPB. The PLPB PM will typically issue the acceptance-for-review letter to the applicant within 14 days after receipt of the TB BC input. The TB BCs and the PLPB BC should 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, significant delays in issuing RAI questions, delays 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 4.2.7.

Guidance is provided in LIC-109 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 criteria, the letter will be concurred on by the TB BC and

signed by the Deputy Director, DPR. The PLPB PM will notify the applicant in advance of issuing the non-acceptance letter to provide advance notification that the TR will not be accepted for NRC review.

4.2.6 Proprietary Determination

If a TR contains proprietary information for which the applicant has requested withholding from public disclosure, the PLPB PM or licensing assistant will prepare a proprietary determination letter in accordance with 10 CFR 2.390 and OI LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure" (Reference 8). In accordance with Section 4.2 of LIC-204, a non-proprietary version of the report or document should be submitted with the proprietary report. 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.

The PLPB PM 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 PLPB PM and the TB reviewers are responsible for reviewing the information to determine if it is proprietary and meets the criteria for withholding per 10 CFR 2.390. If the NRC staff determines that some or all the information designated by the applicant as proprietary is not proprietary, the PLPB 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.

4.2.7 RAIs

A. RAI Issuance

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

The letter transmitting the RAI questions will list the agreed-upon date for the applicant to provide its RAI response, and describe any known RAI questions that could result in limitations and conditions in the TR SE if not resolved by the applicant during the RAI process. Audits and confirmatory calculations will be performed, if necessary. 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 NRC staff prepares the draft SE (as described in Section 4.2.8). The transmittal letter will also state that if the RAI response is 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 and submit the request in writing (memorandum or email) to the PLPB PM to the PLPB BC. If requested, a grace period of 30 days may be considered reasonable by the NRC staff.

B. Review of RAI Response

The technical leads will review the RAI response and communicate to the PLPB PM if any of the RAI questions 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 RAI questions, the PLPB 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 NRC staff's ability to review the specific words that will appear in the approved version of the TR.

The PLPB PM will facilitate the discussion/resolution between the technical leads and the applicant. Any issues that cannot be readily resolved should be handled in accordance with Section 4.2.7.D.

The NRC staff has several options to pursue in the event that RAI response is 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 PLPB PM should also update Firefly to ensure that the revised schedule is captured.
- Close the review. If the applicant cannot provide the complete RAI response by the agreed-upon milestone, the PLPB BC, with the agreement of the appropriate TB BCs, can close out its review of the TR via a formal letter from the PLPB BC to the applicant. 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 NRC staff can request that the applicant withdraw its request for NRC review and approval. The withdrawal letter should be submitted in writing to the PLPB BC and contain the basis for withdrawal of the TR. The PLPB 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 RAI questions (i.e., responses to initial RAI questions necessitate multiple rounds of questions, 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 4.2.7.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 4.2.7.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 PLPB 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.

The 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).

The NRC 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 cannot 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 NRC staff may determine that, due to the complexity of the RAI response, a revision to the TR is necessary to capture the changes. In these cases, the PLPB 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 PLPB PM as part of the recommended path forward (as described in Section 4.2.7.D).

4.2.8 TB Transmits SE to PLPB

The TB will provide the PLPB 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 PLPB PM, the PLPB 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 OI 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" add clarity to the scope of the NRC's approval of a TR, and identify additional plant-specific items that may be required during the staff review of a licensee request to implement the TR. Limitations further delineate the extent to which the TR may be found acceptable for referencing in licensing applications. Conditions identify additional information needed from a licensee requesting to reference the TR in a plant-specific licensing request. Examples of each follow:

- | | |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Limitation: | This TR did not provide any information to support qualification of the code system to calculate the performance of mixed-oxide fuel. Therefore, the NRC staff approval of this TR is limited to uranium-dioxide fuel. |
| Condition: | Licensees requesting to implement this TR must provide a plant-specific analysis of the limiting anticipated operational occurrence, assuming the requested setpoint tolerance increase, to show that the plant still meets the applicable acceptance criteria. |

NOTE: 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 will reference the approved version of the TR.

If the TB 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 4.2.7.A, should be discussed with the applicant, at least two weeks prior to issuing the draft SE. The PLPB PM will facilitate the discussion and resolution between the technical staff and the applicant where appropriate. Any issues that cannot be resolved by the PLPB PM should be elevated to management. The TB should strive to facilitate early identification and issue resolution of technical issues before the TB provides its SE input to the PLPB PM.

In some cases, the TB reviewers may need to identify specific follow-up steps or actions that need to be verified by the TB once a licensee decides to reference the approved TR in an LAR or a STS change. Any follow-up actions that a TB 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.

4.2.9 Obtain Congressional Review Act clearance from OMB

TRs (or the NRC staff’s SE for TRs) are potentially considered “rules” under the CRA (see OGC memorandum, “Agency Documents Requiring Congressional Review,” dated December 13, 2010 (ADAMS Accession No. ML103470301)). Prior to issuing the final SE, the PLPB PM shall forward a copy of the draft SE to OGC to determine whether the final SE should be considered a rule with respect to the CRA. If OGC determines that the final SE is considered a rule, the PLPB PM should prepare a CRA input summary to be submitted to the Office of Management and Budget (OMB). See NRR OI LIC-300, Rulemaking Procedures,

Revision 4, Appendix R –“Congressional Review Act” (Reference 9) for detailed guidance. If OGC determines that the final SE is NOT a rule under the CRA, then the PLPB PM need not complete any additional CRA steps.

4.2.10 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 PLPB PM will issue the draft SE within the agreed-upon milestone schedule date. The PLPB 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 PLPB PM will work with the TB to resolve any factual inaccuracies or proprietary concerns.

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

- If the TR is non-proprietary, the letter transmitting the draft SE will state that the applicant has 20 working days from receipt of the draft SE to identify any factual inaccuracies or clarity concerns.
- If the TR is proprietary, the letter 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 or clarity concerns in the draft SE.

4.2.11 Issue Final SE to Applicant

The PLPB 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 PLPB PM will disposition any factual inaccuracies or clarity concerns provided by the applicant in an enclosure to the final SE. The PLPB PM will prepare a letter accepting the TR for referencing in licensing actions for signature of the Deputy Director, DPR.

Once the final SE is issued, the PLPB PM will close the TAC via TRIM. The PLPB 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 PLPB PM should charge to another TAC number such as a generic vendor/OG interaction TAC.

4.2.12 Applicant Submits Approval Version of TR

The applicant should submit to the NRC an approval version of the TR within three months of receipt of the final SE, or another mutually acceptable submittal date. The approval 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 RAI questions and 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 RAI questions (as noted in Section 4.2.7.B), RAI questions and 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 response has been accepted by the NRC staff.

- The RAI questions 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 response. The table should reference the specific RAI questions and responses that resulted in changes to the TR.

The approval version should be identified by a "-A" following the TR identification symbol. For a proprietary TR, the PLPB PM should ensure that both proprietary and non-proprietary versions are published by the applicant and submitted to the NRC.

4.2.13 Provide 3 Copies of GAO-001 and 3 Copies of the SE to OCA

If OGC determined that the staff's SE is NOT a rule under the CRA (see section 4.2.9), then the PLPB PM need not complete the steps in this section. Otherwise, upon issuance of the Final SE to the applicant, the PM should concurrently provide 3 copies of form GAO-001 and 3 copies of the final (signed) SE to OCA. This step is imperative because the basis of CRA is that Congress must have the ability to review all final rules upon issuance. The GAO-001 form is available at http://www.gao.gov/decisions/majrule/FED_RULE.PDF, and the NRR CRA contact is able to answer any questions regarding the content of the form.

4.2.14 Staff Verification of the Approval Version of TR

After the applicant submits the "-A" version of the TR, the NRC staff will verify the contents of the "-A" with a final review. The purpose of this final review will be to verify that the "-A" version matches the latest version of the TR that was reviewed by the staff and contains the updated information that was submitted and reviewed (i.e., in RAI responses) or called out in the NRC staff's SE. The TB staff may be needed to assist in this review to verify accuracy and consistency with the final SE, or the PM can perform this review with the TB BC concurrence. The PLPB PM will open a new TAC number for this effort and will prepare a final verification letter to the applicant to confirm the outcome of the "-A" review which specifically states whether the TR is NRC approved for referencing in licensing actions.

If NRC staff determines that the submitted "-A" is not approved for referencing in licensing actions due to a technical discrepancy, the PM shall obtain PLPB or TB BC concurrence and contact ADAMS staff immediately to remove the "-A" from ADAMS. If the "-A" is not approved for referencing in licensing actions due to administrative concerns, such as incompleteness of the "-A" package, then the PLPB PM may take appropriate discretionary actions. In any case, care should be taken to preserve the sanctity of the "-A" designation in ADAMS as a public symbol of NRC approval.

PLPB will maintain an official list of TR verification letters for quick referencing by DORL and other NRC staff.

4.2.15 Applicant Submits Revision(s) or Supplement(s) to the Approved Version of TR

In some cases, an applicant will submit a revision or supplement to the NRC approved version of the TR. In general, it will be treated as a new TR following the process described in this OI, including the fee waiver.

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 final SE supersedes the previous final 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.
1. Regardless of whether the applicant refers to the information as a revision or supplement, once the PLPB PM receives the revision/supplement, the PLPB PM will follow the TR process (as described in this OI) to review the revision or supplement.
 2. After the NRC staff has completed its 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." This "-A" will require a new verification check in accordance with 4.2.14.

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 (4.24),

- identifying when an incoming TR has dual applicability to other offices (4.2.3),
- performing technical acceptance and proprietary reviews (4.2.5 and 4.2.6),
- working with the PLPB PM when identifying the need for a technical champion (4.2.4 and Enclosure 1),
- developing RAI questions (4.2.7),
- writing the SE (4.2.8).
- providing resolution to the applicant's comments on the draft SE (4.2.9)
- reviewing the “-A” version of the TR (or assisting the PLPB PM) to verify accuracy and consistency with the final SE.
- ensuring the approval version submitted by the applicant contains the updated information specified during the review in the SE without adding unreviewed new information.

5.2 PLPB PM

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

The PLPB PM is responsible for:

- Coordinating with the counterpart in the other office on dual applicability TRs (4.2.3),
- arranging and conducting the pre-submittal meeting and including the OCFO in any discussion of fee exemptions (4.2.1),
- developing the work plan (4.2.4),
- identifying the priority of an incoming TR (4.2.4 and Enclosure 2) and working with the TB BC to assign prioritization scores,
- writing the acceptance review letter (4.2.5),

- making a proprietary determination (4.2.6),
- identifying the need for a technical champion (4.2.4)
- facilitating open communication between the NRC staff and the TR applicant,
- issuing RAI questions to the applicant (4.2.7),
- issuing the draft SE to applicant (4.2.9),
- submitting the SE to OGC for CRA review, and, if applicable, ensuring CRA clearance from OMB is received (4.2.10),
- issuing the final SE to the applicant (4.2.11), and
- issuing the final letter accepting the approved version ("-A") to the applicant (4.2.13).

5.3 TB BCs

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

- participating in and designating NRC staff persons to participate in the pre-submittal meeting (4.2.1),
- working with the PLPB PM to develop a work plan (4.2.4),
- working with the PLPB PM to support the OCFO representative during the fee-exemption reviews,
- working with the PLPB PM to prioritize an incoming TR (4.2.5 and Enclosure 2),
- concurring on the proprietary determination, acceptance and non-acceptance letters, and SE prepared by the PLPB PM (4.2.5 and 4.2.6),
- concurring on RAI questions and ensuring RAI questions are issued on schedule and per LIC-101 (4.2.7),
- transmitting the draft SE input to the PLPB BC, DPR, responsible for TRs (4.2.8), and
- transmitting the resolution to the applicant's comments on the draft SE to the PLPB BC, DPR, responsible for TRs (4.2.9).

- 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.
- ensuring the approved version submitted by the applicant contains the updated information specified during the review in the SE without adding unreviewed new information.

5.4 PLPB BC

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

- concurring on the proprietary determination, RAI, and the final SE transmittal letter,
- signing acceptance and non-acceptance letters, and the draft SE transmittal letter,

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

Performance measures for the TR program have been suspended until further notice.

7. PRIMARY CONTACTS

Steve Philpott
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8. RESPONSIBLE ORGANIZATION

NRR/DPR/PLPB

9. EFFECTIVE DATE

October 7, 2013

10. REFERENCES

1. <http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html>
2. OI LIC-101, "License Amendment Review Procedures"
3. OI COM-204, "Interfacing With Owners Groups, Vendors, and NEI"
4. OI LIC-109, "Acceptance Review Procedures"
5. OI COM-202, "Meetings With Applicants, Licensees, Vendors, or Other Members of the Public"
6. OI COM-114, "Protocol to Ensure Appropriate Technical, Regulatory, and Policy Consistency Between the Office of Nuclear Reactor Regulation and the Office of New Reactors"
7. OI COM-103, "NRR Interface with the Advisory Committee on Reactor Safeguards (ACRS)"
8. OI LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure"
9. OI LIC-300, Revision 4, "Rulemaking Procedures, Appendix R – Congressional Review Act"

Enclosures:

1. Technical Champion
2. TR Prioritization Scheme
3. Appendix - Change History

Technical Champion

Topical Reports (TRs) 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 PLPB project manager (PM). 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 above, the PLPB 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 PLPB 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 cannot be reached through the technical champion process, the issue should be elevated to management.

Section 4.2.7.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 the applicant understands the NRC staff's basis for adding the limitation and condition.

Topical Report (TR) Prioritization Scheme

A prioritization scheme was developed to support the NRC's ability to prioritize and properly allocate resources for TR reviews. Priority scores are determined and continuously updated for all TRs that have been accepted for review, new TR submittals, and identified future submittals. The intent is to provide a method to determine a relative ranking for TRs within a particular TB to aid in the allocation of resources and to identify which TRs are able to be reviewed as a priority.

When submitting a new TR, NRR recommends that the TR applicant uses the following matrix to propose scores for each of the factors in the prioritization scheme and include the proposed scores in the submittal letter. The Licensing Processes Branch (PLPB) PM will coordinate with the technical branch (TB) reviewers and branch chief (BC) to assign scores for each factor, with consideration given to the proposed scores provided by the applicant. The PLPB PM should discuss the assigned scores with the applicant and note any resulting impact on the review schedule. In some cases where the score determines that a TR is considered "low" priority (relative to other TRs and considering the resources available for the assigned TB), that TR may be designated as "inactive" until resources become available to begin or continue that TR review. The PLPB PM should continue to monitor the priority and review status of all assigned TRs and discuss those with the applicants on a regular basis.

Instructions for completing the modified score card:

1. TR Classification – nuclear safety should always be #1 priority
 - a. Generic Safety Issue (GSI) should be taken credit only if this topical report (TR) directly addresses a issue specifically on the GSI list (e.g. GSI-191), (<http://www.nrc.gov/reading-rm/doc-collections/generic-issues/quarterly/index.html>),
 - b. If this TR ties to the resolution of an item on NRR's priority list or supporting NRC safety initiatives, or the ACRS requested resolution, then it should also be credited as Emergent Technical Issue.
 - c. New technology improves safety. This includes technology outside commercial nuclear industry with proven reliability.
 - d. TR revision reflecting current regulatory requirements/guidance or analytical methods.
 - e. Routine vendor initiated TRs.
2. TR Applicability –this measures the potential application scope of this TR
 - a. Industry-wide implementation expected – it is so generic that all reactors can apply it.
 - b. Potentially applicable to entire groups of licensees (e.g. BWR, PWR, etc.)
 - c. Intended for only partial groups of licensees (e.g. a specific type of steam generators, a new fuel-design some reactors, etc.).

3. TR Implementation Certainty – this measures the certainty and quantity of licensing action resources savings in the near term (~2 years)
 - a. U.S. industry-wide implementation expected by sponsoring the TR together with commitment to implement shortly after the approval.
 - b. Expected implementation by an entire group of U.S. licensees (e.g. BWROG, PWROG, BWRVIP, etc.) who sponsored the TR with commitment to implement shortly after the approval.
 - c. A letter of intent has been sent to the DCD by U.S. plant(s) but no formal/firm LAR schedule has been submitted yet.
 - d. No US plants have indicated strong interest to implement yet at this time by letter of intent to the docket. The vendor is seeking the SE in order to better promote its product/methodology for commercial interests. No credit is given to this category.
4. A SE is requested by a certain date (less than two years) to support a licensing activity or renewal date submitted to the docket by a licensee. Provide details in comments.
5. Progress of Review – this measures the value of the efforts already invested. Each of the four key milestones reflects the level of efforts. They must have formal notification from the TB of the technical work completion, in order to be taking credit.
6. NRC management discretion adjustment – occasionally used as a tie breaker or for special situations requiring management decisions. Provide reference in comments.

TR Prioritization Scheme Matrix			
Title:			
Expect submittal in FY	TAC	PM	Today's Date:
Technical Review Division(s)		Technical Review Branch(s)	
Factors	Select the Criteria that the TR Satisfies	Points to be Assigned for Each Criteria	Assigned Points
TR Classification (Select one only)	Resolve Generic Safety Issue (GSI)	6	
	Emergent NRC Technical Issue	3	
	New technology improves safety	2	
	TR revision reflecting current requirements or analytical methods	2	
	Standard TR	1	
TR Applicability (Select one only)	Potential industry-wide applications	3	
	Potentially applicable to entire groups of licensees	2	
	Intended for only partial groups of licensees	1	
TR Implementation Certainty (Select one only)	Industry-wide Implementation expected	3	
	Expected implementation by an entire group of licensees (BWROG, PWROG, BWRVIP, etc.) who sponsored the TR	2	
	Docketed intent by U.S. plant(s) but no formal LAR schedule yet	1	
	No U.S. plants have indicated strong intent on docket to implement yet	0	
Tie to a LAR (Select if applicable)	A SE is requested by a certain date (less than two years) to support a licensing activity or renewal date (note it in comments)	3	
Review Progress (Points are cumulative as applicable)	Accepted for review	0.3	
	RAI issued	0.5	
	RAI responded	1.2	
	SE drafted	2.0	
NRC Management discretion adjustment		-3 to +3	
Total Points (Add the total points from each factor and total here):			
Comments: Provide as much as relevant information as possible, such as: supporting NRC initiatives and pilots; requests from ACRS, Commission, EDO, NRO needs, etc.			

Appendix - Change History

Office Instruction LIC-500 Revision 5

Topical Report Process

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 chiefs. Training Session for Vendor/Owners Group PMs

LIC-500 Change History - Page 1 of 1			
Date	Description of Changes	Method Used	Training
10/04/2013	This change reflects: (1) modification of the TR prioritization scheme, (2) improved process to interface with NRO, (3) added review of Congressional Review Act applicability, (4) added staff verification of “-A” version of TRs, and (5) various editorial updates and changes.	E-mail to all staff	Self-study by Vendor/Owners group PMs and TB chiefs. Training Session for Vendor/Owners Group PMs