



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

## ***NRR OFFICE INSTRUCTION***

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### Change Notice

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Office Instruction No.: **LIC-500, Revision 7**  
Office Instruction Title: **Topical Report Process**  
Effective Date: **October 22, 2018**  
Approved By: **Michele G. Evans**  
Date Approved: **October 18, 2018**  
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Responsible Organization: **NRR/DLP**

**Summary of Changes:** This change reflects a minor revision that will help ensure the proper process for transmitting documents is followed.

Training: (1) Self-study by Vendor/Owners group project managers and Technical Branch staff and branch chiefs; (2) Training Session for Vendor/Owners group project managers and (3) Email to all staff.

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\*Indicates concurrence via e-mail.

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**NRR OFFICE INSTRUCTION**  
**LIC-500, Revision 7**  
**Topical Report Process**

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**1. POLICY**

It is the policy of the Office of Nuclear Reactor Regulation (NRR) to establish procedures and guidance for its staff to meet the requirements and performance goals established in legislation, regulations, the Agency's strategic plan, and office-level operating plans. Therefore, TRs are 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>, provides submittal guidance on the NRC's TR program, and transparency of NRC processes to public stakeholders.

**2. OBJECTIVE**

The TR process adds value by improving the efficiency of other licensing processes. 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 acceptable for use and verified by the NRC staff. The objective of this office instruction (OI) is to define the process by which NRR project managers (PMs), technical staff, and managers process TRs and, thereby, improve NRR's efficiency and consistency in the review of TRs. Since this OI is made public, it also describes what to expect during the review process.

A TR is a stand-alone report containing technical information about a nuclear power plant safety topic. 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 of a subject with generic applicability and the potential for subsequent referencing in multiple licensing actions. Industry organizations, such as a vendor or an owners' group (OG), also referred to as an "applicant" throughout this OI, may choose or be requested by the NRC staff to submit TRs to address specific subjects.

## 4. **BASIC REQUIREMENTS**

### 4.1 **Overview of the Topical Report Process**

NRR's Licensing Processes Branch (PLPB), within the Division of Licensing Projects (DLP), has the responsibility for managing the TR program.

The major activities covered in this procedure are given below and are separated into the following seven phases:

- Phase 1: Submission
- Phase 2: Work Plan Development
- Phase 3: Completeness Review and Decision Letter
- Phase 4: Preliminary Safety Evaluation and Requests for Additional Information
- Phase 5: Draft Safety Evaluation
- Phase 6: Final Safety Evaluation
- Phase 7: "-A" Verification

Appendix A describes the change history.

Appendix B describes a procedure for processing submitted TRs.

### 4.2 **TR Criteria**

A TR should:

- A. Deal with a specific safety-related or other generic subject regarding a U.S. nuclear power plant that requires a safety evaluation (SE) 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.
- B. Be applicable to multiple licensees, for multiple requests for licensing actions, or both. Examples of requested licensing actions include license amendment requests (LARs), relief requests, and other types of TR-based submittals that are not submitted pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.90 or Section 50.55a.
- C. 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 NRC staff reviews the applicant's justification to determine if the exception is appropriate.

**4.3 TR Review Fees**

TR reviews are subject to fees based on the full cost of the review (see 10 CFR Part 170.21). Exemption requests to the fee recovery requirements may be made concurrently to the Office of the Chief Financial Officer (OCFO) (refer to 10 CFR 170.11).

**4.4 Topical Report Approval Status**

In order to be referenced in a plant-specific requested licensing action, a TR should be approved for use by the NRC. When approved for use, a “-A” is added to the TR title to indicate the TR is approved for use by the NRC staff. The NRC staff then performs a verification review, and following the NRC staff verification review, licensees may then reference the approved TR in plant-specific requests for licensing action.

**5.0 RESPONSIBILITIES AND AUTHORITIES**

The Division of Licensing Projects, (DLP) Deputy Division Director has overall responsibility for the TR process.

**6. PERFORMANCE MEASURES**

The performance measures are contained in the Operating Reactor Business Line Performance Plan. Timeliness and completion are also tracked in the quarterly performance report.

**7. PRIMARY CONTACT**

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**8. RESPONSIBLE ORGANIZATION**

NRR/DLP

**9. EFFECTIVE DATE**

October 22, 2018

**10. REFERENCE**

1. <http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html>

Enclosures:

1. Appendix A – Change History
2. Appendix B – Guide for Processing Topical Reports

## Appendix A - Change History

### Office Instruction LIC-500

#### Topical Report Process

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

**LIC-500 Change History - Page 2 of 2**

<b>Date</b>	<b>Description of Changes</b>	<b>Method Used to Announce &amp; Distribute</b>	<b>Training</b>
10/04/2013	This change reflects: (1) modification of the TR prioritization strategy, (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 section chiefs. Training session for vendor/owners group PMs
03/09/18	This change reflects a comprehensive update of LIC-500 including: (1) various editorial updates and changes, (2) work planning development, (3) removal of the TR prioritization scheme, and (4) inclusion of a TR process roadmap.	E-mail to all staff	Self-study by vendor/owners group PMs and TB section chiefs. Training session for vendor/owners group PMs
10/18/18	This change reflects a minor revision that will help ensure the proper process for transmitting documents is followed.	Email to all staff	Self-study by vendor/owners group PMs and TB section chiefs. Training session for vendor/owners group PMs

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

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## **Appendix B**

# **Guide for Processing Topical Reports LIC-500, Revision 7**



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## 1.0 Introduction

The Topical Report (TR) review process should adhere to the guidelines established within this section. Variances in durations should be evaluated and managed by the Project Manager (PM) with input from the technical staff.

**\*Note:** The Topical Report Process Roadmap is included with this document as Attachment 1.

### 1.1 Objective

The objective of this guide is to provide the Office of Nuclear Reactor Regulation (NRR) staff a basic framework to process TRs.

### 1.2 Process Overview

This guide provides a procedure for processing TRs. The U.S. Nuclear Regulatory Commission (NRC) staff effort is comprised of:

- discussions prior to submittal, including meetings to solicit staff feedback;
- a submittal that the NRC staff will review;
- work planning, to achieve agency goals;
- an evaluation of the submitted materials for completeness and proprietary protection;
- specific work planning within the reviewing branches;
- a technical evaluation, including but not limited to, confirmatory calculations, audits, or meetings;
- writing a preliminary safety evaluation (SE) with allowances for portions that require resolution of staff concerns (open items);
- requesting information that is essential to complete the drafting of an SE, including discussions to ensure the staffs concerns are understood;
- review of additional materials;
- potentially requesting more information;
- drafting of the SE, including limitations and conditions;
- a comment period for the applicant to indicate proprietary information, factual errors, or interpretation challenges;
- NRC staff resolution of comments received and finalizing the SE;
- submittal of a clean version of the TR, designated as “-A” version that includes all of the materials relied upon by the staff to reach its regulatory decision(s);
- NRC staff verification of the “-A” submittal, including a closeout letter designating the TR as approved-for-use.

The major activities covered in this procedure are given below and are separated into the following seven phases:

- Phase 1: Submission
- Phase 2: Work Plan Development

- Phase 3: Completeness Review and Decision Letter
- Phase 4: Preliminary Safety Evaluation and Requests for Additional Information
- Phase 5: Draft Safety Evaluation
- Phase 6: Final Safety Evaluation
- Phase 7: “-A” Verification

## **2.0 Topical Report Review Process**

The TR review process is organized into seven phases, with each phase separated into a number of tasks. Refer to Attachment 1, *Topical Report Process Roadmap*, for an outline overview of the TR review process.

### **2.1 Phase 1: Submittal**

Much of this phase is focused on those activities which occur before the submittal process, namely the pre-submittal meetings. While these meetings are optional, most applicants choose to use pre-submittal meetings for the efficiencies that they add to the process. As described below, these meetings can be a valuable tool in obtaining NRC staff feedback, if used correctly. This phase ends when the TR has been submitted to the NRC and is placed on the docket.

#### **2.1.1 Notification of Intent to Submit**

The applicant notifies the PM of the intent to submit a TR. This notification can be as simple as an email or as formal as a letter to the NRC. From the notification, the PM should communicate basic details about the TR to the appropriate technical organizations, including the subject area (e.g., fuels related, component inspection, accident analysis), number of licensees likely to utilize the TR, and intended date of submittal. If the organization has not submitted a TR before and does not have a docket number, the PM will obtain one.

#### **2.1.2 Requesting a Fee Exemption (if applicable)**

TR reviews are subject to fees based on the full cost of the review. Title 10 of the *Code of Federal Regulations* (10 CFR) Part 170 sets the basic requirements for collection of fees for services rendered. NRC Management Directive 4.6, "License Fee Management Program," promulgates the broad policy and guidance to NRC offices for fee collection. Requests for exemptions to the fee recovery requirements may be made concurrently with the technical review.

#### **2.1.3 Work Tracking Software**

The PM will generate a new project by providing input to the work tracking software and ensures that the technical staff has the appropriate information to charge their time.

## 2.1.4 Pre-submittal Meeting (OPTIONAL)

### A. Purpose

There are generally two different purposes of a pre-submittal meeting. The first is to obtain NRC technical staff feedback on certain aspects of the planned TR. Such pre-submittal meetings should occur well in advance of the TR submittal (e.g., several months or more), such that any issues identified by the NRC staff could be incorporated into the TR. The second is to inform the NRC staff that a TR will be coming in soon, introduce or remind them of the material, aid in work planning, and should occur as close to the submittal of the TR as reasonably possible. Depending on the novelty and complexity of the TR, multiple pre-submittal meetings may be scheduled.

### B. Preparation

The PM should schedule a pre-submittal meeting (preferably face-to-face) with the applicant and the anticipated NRC technical review staff. In advance of the meeting, applicants are encouraged to provide an executive summary, any supporting documentation, and any presentation materials at least 15 working days in advance of the scheduled meeting. Information provided to the NRC should clearly indicate the intended application and implementation expectations for the TR. The following examples are provided to assist the PM in providing guidance to the applicant:

- Resolves generic safety issue (GSI) or emergent NRC technical issue
- Tied to a lead plant license amendment request (LAR)
- Introduces a new technology with applicant identified safety improvement with expected implementation industry wide
- Current requirements or analytical methods intended only for partial groups of licensees with limited implementation
- Potentially applicable to licensee groups (BWROG, PWROG, BWRVIP, etc.) with expected implementation
- Implementation in the U.S. **is or is not** expected

If this meeting, or any meeting during the TR review, is requested to be closed because the materials are considered proprietary, all materials should be submitted at least 30 days in advance. The 30-day period is needed to allow the NRC staff to review the information and make a determination of whether the NRC staff agrees it is proprietary.

Applicants should also work with the PM to develop a meeting agenda and identify a list of attendees. The PM should identify the appropriate technical branches to participate in the meeting, and work with the respective branch chiefs to identify the correct supporting staff. The PM

should also coordinate OCFO participation in pre-submittal meetings for TRs, for which a fee waiver has been or is likely to be requested.

Occasionally, a submitted TR has dual applicability to both operating and new reactors and must also be reviewed under the Part 52 licensing process. The PM will ensure that proper coordination takes place in an effort to maintain technical consistency.

### C. During the Pre-submittal Meeting

In order to achieve a more constructive pre-submittal meeting, the following list of suggested guidelines is provided:

Applicants:

- Present the subject areas and the intended application of the TR (e.g., how many licensees may utilize the report, proposed applicability limits, the requested review schedule, etc.)
- Provide technical detail on the approach, methods, and key assumptions
- Identify any anticipated “hard spots” or changes from an existing methodology that may require additional attention or review

NRC staff:

- Ask appropriate questions to elicit information on the relationship of the proposed TR to any other ongoing or proposed NRC staff or industry efforts
- Use knowledge and experience to provide feedback on the level of detail expected in the TR to conduct a detailed technical evaluation
- Provide feedback on the merits of the TR and clearly communicate any areas for improvement
- Make no decisions regarding TR acceptability

#### **2.1.5 TR Submitted to Document Control Desk**

The guidelines regarding the process to submit documents to the document control desk (DCD) electronically are provided at:

<https://www.nrc.gov/site-help/e-submittals.html>

## **2.2 Phase 2: Resource Plan Development**

This phase begins once the TR has been submitted on the docket and ends when the work begins. Most of the steps in this phase are focused on determining the level of effort required to complete the work, and the availability of the reviewers to schedule the work.

### **2.2.1 Resource Planning**

The PM will coordinate with the technical BCs to initiate resource planning. Planning considerations include:

- Identification of lead and supporting technical branches
- Estimation of review hours for each technical branch against available full time equivalent (FTE)
- Identification of whether contract support is required
- Identification if a proprietary determination is needed
- Determination of whether the TR requires Technical Specifications (TS) branch review or concurrence. Examples include TRs that would involve Standard TS changes, or plant-specific TS changes upon implementation.
- Identification if the TR has dual applicability with operating and new reactors
- Prioritization of emergent work
- Comparison of emergent work against planned work
- Determination of whether to shed or defer planned work
- Documentation of resource allocation

### **2.2.2 Work Tracking Software Update**

The PM will update the work tracking software to ensure that the technical staff has the appropriate milestones.

## **2.3 Phase 3: Completeness Review and Decision Notification**

This phase will begin when the technical staff assigned to the TR is scheduled to start the technical review. The first step is determining if the document submitted to the NRC is sufficiently complete to allow for an effective and efficient review. In this instance, acceptable for review means that the TR is complete and all proprietary and non-proprietary information has been appropriately marked. During this phase, the technical staff will generate a plan which details how the review will proceed. This phase ends with the issuance of the completeness determination.

### **2.3.1 Completeness Review**

The primary purpose of the completeness review is to determine whether the applicant has submitted a sufficiently complete set of information in order to initiate a detailed technical review of the TR. This effort is similar to, but more subjective than, the acceptance review that is performed for requested licensing actions under LIC-109, "Acceptance Review Procedures."

In order to determine if a TR should be considered complete, such that the review may be started, the NRC staff should determine if one of the following criteria are true for that TR:

- For TRs on subjects with which the assigned technical staff has great familiarity, the report should contain sufficient technical information such that the technical staff could be reasonably expected to complete the detailed technical review in an appropriate time frame.
- For TRs on subjects with which the assigned technical staff has little familiarity, the report should not exclude obvious necessary technical information such that the technical staff could not be reasonably expected to complete the detailed technical review in an appropriate time frame.

If the relevant criterion is true, the TR should be accepted for review. If the relevant criterion is not true, the missing information should be summarized and quantified. If only a small amount of information is lacking, such that the TR could be supplemented in a reasonable time frame, the applicant should be informed of the missing information and given a chance to supplement the TR. If a large amount of information is lacking, such that the TR could not be supplemented in a reasonable time frame, the applicant should be informed of the missing information and the TR should be rejected.

### **2.3.2 Proprietary Review**

#### **A. Purpose**

The purpose of the proprietary review is to determine if the material marked as proprietary in the submittal satisfies the requirements of 10 CFR 2.390 for withholding from public disclosure.

#### **B. Proprietary Review**

The proprietary review should be performed at the same time as the completeness review. The NRC staff should follow the guidelines set forth in LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure," to perform this review. The technical staff will support this effort as required.

If the NRC staff determines that some or all of the information designated by the applicant as proprietary is not proprietary, the PM should attempt 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.



### C. Withholding Letter

The PM will issue a letter documenting the results of the proprietary determination review.

#### **2.3.3 Work Planning**

Leveraging, to the extent practical, the information obtained from the completeness and proprietary review, the assigned technical staff should set out a work plan. This plan should focus on estimating the hours to complete the remaining assigned tasks. Additionally, other work which may be required to complete the review should be identified and the time to complete that work estimated. The following are examples of components of the overall review plan:

- Reviewing the TR for understanding
- Performing the Audit for understanding
- Performing confirmatory analysis
- Visiting experimental facilities
- Obtaining contractor support
- Obtaining support from the Office of Nuclear Regulatory Research
- Generating the preliminary SE and requests for additional information (RAIs)
- Holding the preliminary RAI call
- Updating the preliminary SE with RAI responses
- Completing the Draft SE
- Accounting for CRA rule determination (a 90-day period for Office of Management and Budget (OMB) Congressional Review Act (CRA) review between the Draft and Final SE. OMB may complete sooner, but it is allowed up to 90 days.)
- Accounting for Office of the Advisory Committee on Reactor Safeguards (ACRS) review, if necessary

Consider the above review activities when establishing a review plan in the work tracking software. This should include an estimation of review hours for each technical branch against available FTE.

Monthly management meetings are held with applicants who currently have a high quantity of TRs being processed or who have requested a meeting on the basis of one or more high priority TRs. Meetings are held with respective BCs, PM, and Division management. The objective of these meetings is to ensure that status is communicated, challenges and major actions are assigned correctly, and completion dates (e.g., TR submission, acceptance letter issued, RAIs issued, applicant response to RAIs, draft SE issued, applicant comments to draft SE submitted, and final SE issued) are adjusted as needed. Applicant TR priorities are discussed and reevaluated. Reevaluation is based on major delays, new applications received, or critical input from applicants. Additional background information is also provided to applicable management, such as responsible division, technical review staff, and cognizant PM.

### **2.3.4 Decision Notification**

The PM will notify the applicant about the results of the completeness review by telephone, including the anticipated schedule and level of effort. This should be followed by an e-mail to document the decision notification.

If, during the completeness review, the NRC staff determines that the TR will not be reviewed because it is not sufficiently complete, a letter to the applicant documenting this decision will be signed by the Branch Chief of DLP. The PM will notify the applicant in advance of issuing the letter.

## **2.4 Phase 4: Preliminary Safety Evaluation with Open Items**

This phase marks the formal beginning of the detailed technical review. It begins directly after the completeness determination and ends when the RAIs have been sent. The primary goal of this phase is the generation of the preliminary SE (i.e., SE with open items).

It is expected that a preliminary SE with open items will be prepared prior to the issuance of any RAIs. However, in some cases, preparation of a preliminary SE with open items prior to issuance of RAIs may have an overwhelmingly negative impact on the review schedule not commensurate with the benefit. In such cases, the requirement to complete a preliminary SE with open items prior to issuing RAIs may be waived, provided the technical and project management BCs agree. This practice should be a rare exception to the general process.

### **2.4.1 Notify NRR Advisory Committee on Reactor Safeguards Coordinator of Topical Report**

The Advisory Committee on Reactor Safeguards (ACRS) may wish to review the TR and the associated SE. Per the memorandum of understanding between the Office of Executive Director for Operations (OEDO) and the ACRS, and COM-103, the PM and the technical staff should coordinate with the NRR ACRS Coordinator to keep the ACRS informed of active reviews and determine if the ACRS desires to review the TR and associated SE.

If ACRS requests to review the TR and associated SE, the PM and technical staff should coordinate with the cognizant ACRS staff member for the schedule of the sub-committee and full committee meetings. The PM and technical staff will also be responsible for providing a copy of the SE in advance of any scheduled meetings to ensure the ACRS members have adequate time to review the material. Briefings of the ACRS should be performed by the technical staff who performed the review of the TR.

The PM should add ACRS review to the milestone schedule and make adjustments accordingly (typical ACRS review will add approximately two months to the schedule). Any schedule adjustments and potential delays

as a result of ACRS meetings should be communicated to management by the PM.

## 2.4.2 Review for Understanding

The first step in reviewing the TR is for the technical staff to gain an understanding of the report. In the context of this office instruction, a distinction between “reading through” and “understanding” should be noted. Although subject to the complexity of the TR and differences in individual review practices, obtaining an understanding of a TR usually requires substantially more effort than reading the report through a single time.

At the conclusion of the review for understanding, the technical staff should have a relatively complete understanding of the information in the TR, and be able to begin drafting the preliminary SE with open items.

### **\*Note to Reviewers**

Consider using the following:

**Audit for Understanding** – In accordance with LIC-111, “Regulatory Audits,” the technical staff can perform an audit for understanding. Generally, the purpose of such an audit is to allow the staff to confirm the overall understanding of the submittal and gain a better understanding of the detailed calculations, analyses, bases, or any combination of the three, underlying the TR, which may not have been included in the formal submittal.

**Comprehension Questions** – Comprehension questions are generally simple questions about the meaning of the TR. A reviewer may choose to generate a list of such questions to aid in understanding and obtaining clarification regarding material in the TR. In some instances, comprehension questions may evolve into RAIs.

**Three Way Communication** – In three way communication, the sender gives the message, the receiver states the message in their own terms, and the sender confirms that the message was understood. For these purposes, the TR is the message. In some instances, the NRC staff may wish to re-state certain sections of the TR to confirm understanding.

**Topical Report Comprehension** – There are numerous ways to achieve comprehension of a TR. Common ways include: multiple re-readings of the TR, highlighting and making notes in the margin, summarizing key aspects of each section of a TR, etc. The reviewer should find the style that best suits his or her preferences.

**RAI Categorization** – Technical reviewers may wish to use an RAI Categorization Process to help identify the most significant topics addressed in RAIs, and to help focus NRC staff and TR sponsor resources on those topics of highest significance. One example of an RAI Categorization process is given in “DSS RAI Categorization Process” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18017A064).

### **2.4.3 Generate Preliminary Safety Evaluation**

As soon as possible after completing the review for understanding, the NRC technical staff should create the preliminary SE. While drafting the preliminary SE, it is a good practice to focus solely on the TR review and minimize time spent on other tasks. Time spent working on other tasks tends to distract from the preliminary SE and may result in the reviewer having to relearn information. Maintaining dedication to the TR review effort while drafting brings efficiency to the process.

The preliminary SE should be developed before preparing RAIs, excepting only those rare cases discussed in the introduction to Section 2.4. Developing the preliminary SE prior to drafting RAIs helps to ensure that any areas where information is lacking informs the staff's determination of the additional information that is required. Writing a preliminary SE helps ensure that the staff identifies all areas where RAIs are needed in order to make a safety and regulatory finding on the TR. Additionally, writing the preliminary SE prior to issuing RAIs may help reduce the number of rounds of RAIs required.

### **2.4.4 Requests for Additional Information**

An RAI enables the staff to obtain essential information needed to make a regulatory decision, which may have been omitted from the TR as submitted. Additional guidance for writing RAIs is provided in NRR Office Instruction LIC-101, "License Amendment Review Procedures."

When the technical reviewer has completed the preliminary SE and prepared RAIs, an e-mail is sent to the PM. This electronic transmission, either directly from the Technical BC or the technical staff with their BC on concurrence, acknowledges that a preliminary SE has been prepared, and that each RAI relates to a topic of missing information essential to evolve from the preliminary SE to the Draft SE.

The PM will transmit RAIs using the U.S. Army Aviation and Missile Research Development and Engineering Center (AMRDC) Safe Access File Exchange (SAFE) to share files with external parties (ADAMS Accession No. ML17212B223). Subsequently, the PM will schedule a call to discuss the RAIs to ensure that the RAI questions are understandable and the regulatory basis for the questions is clear. The PM and technical staff should participate in the call. Technical staff should discuss the significance of each RAI (including any RAIs that could result in limitations and conditions if not sufficiently resolved) to communicate the expected level of effort required to complete the response. The PM should discuss the expected response date and ensure technical staff resources support the proposed response date(s). Some questions may require additional time. Responses may be provided on a staggered schedule. Finally, a second e-mail should be sent by the PM, retransmitting the RAIs (including updates or revision) and the expected date(s) to provide response(s).

#### 2.4.5 Response to Requests for Additional Information

The applicant will review the RAIs and respond to the NRC by the agreed upon date(s). The response will include the question, the answer to the question, and appropriate markings for any information in the RAI or their responses that is considered proprietary. If new proprietary information is included, a new affidavit will need to be submitted along with the RAI responses in accordance with 10 CFR 2.390. PMs will track timeliness and adherence to RAI response schedules. Any delays in responses should be raised to the BCs for schedule consideration as appropriate. Trends will be evaluated on the average timeliness to assess our processes and metrics.

If the applicant proposes changes to the TR as a result of the RAIs, the applicant should include with the RAI responses a mark-up of the TR pages that it plans to change.

#### 2.4.6 Review of Requests for Additional Information Responses

The technical staff will review the RAI responses and then communicate to the PM whether any of the responses are incomplete (i.e., an apparent omission of requested information). If any RAIs are found to be incomplete, the PM will then contact the applicant to identify the responses of concern and present options to the applicant for resolution. Options, under most anticipated circumstances, include public meetings and/or audits to help to clarify information needed by the NRC staff to reach a safety conclusion. The result of these exchanges may or may not facilitate an additional round of RAIs.

Under circumstances where a resolution cannot be reached between the applicant and the NRC staff on any incomplete RAIs, the NRC staff will evaluate how to proceed with the SE. This may be in the form of limitations and conditions applied on the use of the TR within the SE, or may result in the suspension or closure of a TR review. The basis for suspending or closing out a TR review should be communicated ahead of time by telephone to the applicant. Additionally, applicants may request the TR to be withdrawn via letter submission to the DCD.

Any efforts associated with the resolving incomplete RAIs which have been determined to extend the review schedule will be identified to the applicant by the PM and updated in the appropriate tracking software.

#### 2.4.7 Proprietary Determination on Requests for Additional Information Responses

If the RAI responses contain any new proprietary information, a proprietary determination review will be conducted in a manner similar to that described in Section 2.3.2.

## **2.5 Phase 5: Draft Safety Evaluation**

This phase begins after the RAI responses have been received and ends when all of the open items in the preliminary SE are closed and the preliminary SE becomes the Draft SE. This phase may also include any additional rounds of RAIs.

### **2.5.1 Develop Draft Safety Evaluation**

The technical staff will update the preliminary SE as necessary with relevant information from the RAI responses.

### **2.5.2 Technical Staff Concurrence on Draft Safety Evaluation**

The Technical Staff BC will provide the Draft SE (as opposed to the preliminary SE with open items) to the PM via e-mail according to the schedule date. If more than one technical staff branch is responsible for providing SE input, an agreement should be reached ahead of time as to whether the technical lead should coordinate the inputs and provide an integrated SE to the PM or if each technical branch should provide separate inputs that the PM will subsequently combine.

The SE should clearly specify the scope of the TR's applicability. For example, in many cases TRs are only applicable to reactors of a certain type (e.g., BWR or PWR), reactor vendor (e.g., General Electric or Westinghouse), fuel type, etc. The applicability should be defined based upon key distinguishing features, and need not be restricted to the examples above. The TR should also clearly identify any limitations and conditions the NRC staff has placed on the use of the TR, including plant-specific action items that a licensee referencing the TR will need to submit.

"Limitations and Conditions" are additional restrictions imposed by the NRC staff to further frame the scope of applicability of a TR and identify any additional plant-specific action items that will be required to support the staff's review of a licensee's request to implement the TR. Limitations and conditions identify the efforts needed by the licensee on subsequent individual plant applications that will reference the TR. The limitations and conditions should be written with sufficient clarity that licensees will be able to provide the necessary information in requests for licensing actions and NRC reviewers will be able to efficiently process the licensing action.

Limitations describe where the TR is applicable. For example, a submitted TR may have a model valid over all pressures, but the TR may state that the pressure range is limited to specific values.

Conditions identify additional information or actions needed from a licensee in order to reference the TR in a plant-specific licensing request. For example, licensees requesting to implement the TR must provide plant-specific data or analysis to show that the plant still meets the applicable acceptance criteria.

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 in advance of issuing the Draft SE.

### **2.5.3 Congressional Review Act Rule Evaluation**

The NRC staff's SE could be potentially considered a "rule" under the congressional review act (CRA). The PM should forward a copy of the Draft SE to OGC to determine whether the SE should be considered a rule with respect to the CRA.

If OGC determines that the SE is NOT a rule under the CRA, then the PM need not complete any additional CRA steps.

### **2.5.4 Document Check on Draft Safety Evaluation**

The licensing assistant will ensure that the document satisfies the NRC requirements according to the NRC Style Guide. Following the document check, the PM will provide the technical staff with an electronically marked-up version of the Draft SE so the technical staff can ensure that no changes impacted the technical information provided in the Draft SE.

### **2.5.5 Draft Safety Evaluation Issued for Review and Comment**

The purpose of the Draft SE is to provide the applicant with the opportunity to identify any proprietary information and to correct any factual inaccuracies, or clarify any potential misunderstandings.

The PM will issue the Draft SE by the scheduled date. Once the transmittal letter is signed and concurred upon by the PLPB BC, the PM may provide a copy of the Draft SE via AMRDC SAFE.

The letter transmitting the Draft SE will typically provide 20 business days to identify any factual inaccuracies or clarity concerns.

- The letter transmitting the Draft SE will also include a statement that there are 10 business days to identify any proprietary concerns. The 10 business days are provided for the applicant to identify any proprietary concerns runs concurrent with the 20 business days provided to identify any factual inaccuracies or clarity concerns in the Draft SE. Other time frames may be agreed to by the NRC staff.
- Draft SEs that are found to contain proprietary information will remain non-public.

### **2.5.6 Comment on Draft Safety Evaluation**

The applicant should read the Draft SE and provide comments to the NRC staff. Comments should generally be limited to topics such as (1) clarifications, (2) correction of inaccuracies, (3) markups of proprietary language, and (4) questions on the conditions and limitations. Depending on the resolution of the RAIs, the applicant may wish to delay the review to provide more information to reduce or remove a condition or limitation. Depending on the magnitude of a supplement, the NRC staff may need to develop a new schedule.

### **2.5.7 Resolve Comments on Draft Safety Evaluation**

The applicant will identify any proprietary information, any factual inaccuracies, or request clarification in the Draft SE within the given time frame. The PM will provide these comments to the technical staff, and the technical staff will assist in the resolution of the comments.

## **2.6 Phase 6: Final Safety Evaluation**

This phase begins after the Draft SE is complete and ends once the Final SE has been issued.

### **2.6.1 Develop Final Safety Evaluation**

The technical staff will update the Draft SE as necessary with relevant information from the Draft SE comments. Some Final SEs will contain a comment resolution table.

### **2.6.2 Issue Final Safety Evaluation**

The PM will issue the Final SE by the scheduled date. Once the transmittal letter is signed and concurred upon by the PLPB BC, the PM should provide the submitter a copy of the Final SE via AMRDC SAFE. The PM issues the cover letter with the non-proprietary SE publicly. Another cover letter with the proprietary SE is issued as non-public.



## **2.7 Phase 7: “-A” Version**

The final phase of the review process begins once the applicant delivers the “-A” version to the NRC. It ends once the verification letter from the PLPB BC is issued, stating that the NRC staff has placed the accepted “-A” version into ADAMS.

### **2.7.1 “-A” Version of Topical Report is Submitted**

The “-A” version of the TR should be submitted within three months of receipt of the final SE.

The “-A” version of the TR should incorporate the transmittal letter, the final SE, an appendix containing the TR, TS, and Bases markup pages of the appropriate vendor STS (if the TR involved TS changes).

- The RAI questions and responses should be included as an appendix to the TR. Alternately, if the TR has been revised to incorporate the RAI responses directly into the report, a table listing each RAI and where the changes were made in the TR can be used.

For a proprietary TR, the PLPB PM should ensure that both proprietary and non-proprietary versions are submitted to the NRC.

### **2.7.2 Verify Changes to the Accepted Topical Report**

The NRC staff will verify the contents of the “-A” version with a final review. The purpose of this review will be to verify that the “-A” TR contains the updated information that was submitted and reviewed (i.e., in RAI responses).

If NRC staff determines that the submitted “-A” version has not technically changed from what formed the basis for the NRC staff SE, the PLPB BC will sign a verification letter stating the TR can be used in future licensing actions.

### **2.7.3 Congressional Review Act Rule Evaluation**

If OGC determines that the SE is NOT a rule under the CRA (Section 2.5.3), then the PM need not complete any additional CRA steps.

If OGC determines that the SE is considered a rule, the PM should prepare a CRA input summary to be submitted to OMB and inform the applicant of additional delays that may occur. Under the CRA, OMB can take up to 90 days to conduct its review.

Once the OMB determination is provided, the PM will prepare and submit to the Office of Congressional Affairs three copies of the final (signed) SE and complete the respective GAO-001 forms for the Senate, the House, and the Government Accountability Office:

[https://www.gao.gov/decisions/majrule/FED\\_RULE.PDF](https://www.gao.gov/decisions/majrule/FED_RULE.PDF). This step is imperative because the basis of CRA is that Congress must have the ability to review all final rules upon issuance.

#### **2.7.4 Verification Letter**

The PM will prepare a verification letter that specifically states whether the TR can be referenced in licensing actions. If the SE has been provided to OMB for review under the CRA, the verification letter should not be issued until OMB determines the SE is not a major rule. If OMB determines the SE is a major rule, the PM should consult with OGC on the next actions.

#### **2.7.5 Closure of the Project**

Following the issuance of the verification letter, all actions toward the TR review are complete. The PM will close the project and notify the technical staff of its closure.

**Topical Report Process Roadmap**

Phase	Task	Responsibility	Deliverable / Action	Time Period
<b>Phase 1: Submission</b>				
2.1.1	Notification of Intent to Submit	Applicant	Email to PM	1 to 12 months prior to planned submittal date
2.1.2	Requesting a Fee Exemption (if applicable)	Applicant	Letter to the OCFO in accordance with 10 CFR 170.11	Concurrently with TR submittal, or 6 to 12 months prior to submittal
2.1.3	Work Tracking Software	PM	Email containing Project number sent to all staff involved with review	Follows receipt of notification from vendor on planned TR submittal
2.1.4	Pre-submittal Meeting	Applicant, PM, Technical staff	Meeting (face to face)	Several months prior to planned submittal date
2.1.5	TR Submitted to DCD	Applicant	Submission of TR	Applicant identified submittal date
<b>Phase 2: Work Plan Development</b>				
2.2.1	Resource Planning	PM, Technical Staff BC	Meeting	Following TR submission
2.2.2	Work Tracking Software Update	PM	Update in work tracking software	Following TR submission
<b>Phase 3: Completeness Review and Decision Letter</b>				
2.3.1	Completeness Review	Technical Staff	Technical staff assessment to PM on level of completeness	
2.3.2	Proprietary Review	Technical Staff, PM	Letter from PM	
2.3.3	Work Planning	Technical Staff and BC	Review plan is given to PM	
2.3.4	Decision Notification	PM's BC	Decision is issued by the BC	

**Topical Report Process Roadmap**

<b>Phase 4: Preliminary Safety Evaluation with Open Items</b>				
2.4.1	Notify NRR ACRS Coordinator of Topical Report	PM	Email is sent to NRR ACRS Coordinator	Following Decision Notification
2.4.2	Review for Understanding	Technical Staff	Initial set of questions developed by Technical Staff for use in an Audit for Understanding	
2.4.3	Generate Preliminary SE	Technical Staff	Preliminary SE for NRC use; basis for RAI development	Follows Audit for Understanding
2.4.4	Requests for Additional Information	PM, Technical Staff	RAIs issued	
2.4.5	Response to RAIs	Applicant	RAI responses sent to NRC	
2.4.6	Review of RAI Responses	Technical Staff	Inform PM if responses are acceptable	
2.4.6	Proprietary Determination on RAI Responses	Technical Staff	RAI responses are appropriately marked	

<b>Phase 5: Draft Safety Evaluation</b>				
2.5.1	Develop Draft SE	Technical Staff	Draft SE	
2.5.2	Concurrence on Draft Safety Evaluation	Technical Staff and BC	All open items are resolved	
2.5.3	Congressional Review Act (CRA) Rule Evaluation	PM	PM forwards Draft SE to OGC	
2.5.4	Document check on Draft Safety Evaluation	PM, Technical Staff	Technical Staff and Technical BC review	
2.5.5	Draft Safety Evaluation Issued for Review and Comment	PM	Draft SE issued	
2.5.6	Comment on Draft Safety Evaluation	Applicant	Comments provided to NRC	
2.5.7	Resolve Comments on Draft Safety Evaluation	PM, Technical Staff	Technical Staff provide comment dispositions	

**Topical Report Process Roadmap**

<b>Phase 6: Final Safety Evaluation</b>				
2.6.1	Develop Final SE	Technical Staff	Final SE with Comment Resolution Table, if needed	
2.6.2	Issue Final Safety Evaluation	PM	Final SE issued	

<b>Phase 7: “-A” Version</b>				
2.7.1	“-A” Version of TR is submitted	Applicant	“-A” version of the topical report submitted to the NRC	
2.7.2	Verify Changes to the Accepted TR	PM, Technical staff	All changes to the “-A” version of the TR are verified to be consistent with the Technical staff’s expectations	
2.7.3	Congressional Review Act (CRA) Rule Evaluation	PM	CRA input summary to the Office of Management and Budget	
2.7.4	Verification Letter	PM	Verification Letter	
2.7.5	Closure of the Project	PM	PM closes the project	