

OFFICE OF NUCLEAR REACTOR REGULATION

LIC-500, Revision 9		Topical Report Process	
Volume 500		Regulatory Improvements	
Approved By:	Bo M. Pham		
Date Approved:	January 27, 2022		
Effective Date:	January 27, 2022		
Certification Date:	January 27, 2027		
Responsible Organization:	DORL		
Primary Contact:	Ngola Otto 301-415-6695 Ngola.Otto@nrc.gov		
Summary of Changes: This issuance of LIC-500, Revision 9, “Topical Report Process,” reflects: (1) incorporation of different review timelines depending on complexity of the topical report and (2) appropriate references to other NRR Office Instructions such as those on acceptance reviews, requests for additional information, and regulatory audits.			
Training: (1) Self-study by vendor/owners group project managers and technical branch staff and branch chiefs; (2) Training Session for NRC project managers.			
ADAMS Accession Number:	ML20247G279		

TABLE OF CONTENTS

1.	POLICY	2
2.	OBJECTIVE	2
3.	BACKGROUND	2
4.	BASIC REQUIREMENTS	2
5.	RESPONSIBILITIES AND AUTHORITIES	3
6.	PERFORMANCE MEASURES	4
7.	PRIMARY CONTACT	4
8.	RESPONSIBLE ORGANIZATION	4
9.	EFFECTIVE DATE	4
10.	CERTIFICATION DATE	4
11.	REFERENCES	4

Office Instruction: LIC-500, Revision 9, "Topical Report Process" Dated: January 27, 2022

ADAMS Accession No.: ML20247G279

OFFICE	NRR/DORL/LLPB/PM	NRR/DORL/LLPB/LA	NRR/DORL/LLPB/BC	NRR/DORL/D
NAME	NOtto	DHarrison	DMorey	BPham
DATE	11/09/21	1/25/22	11/13/21	01/26/22
OFFICE	NRR/DSS/D	NRR/DEX/D	NRR/DRA/D	NRR/DNRL/D
NAME	JDonoghue	EBenner	MFranovich	BSmith
DATE	1/5/22	11/16/21	11/16/21	12/1/2021
OFFICE	NRO/DANU/D	NRR/DRO/D	OGC	NRR/DRMA/DD
NAME	MShams	PMcKenna for CMiller	JEzell NLO	TGorham
DATE	12/16/21	11/22/21	01/26/22	1/26/22
OFFICE	NRR/DORL/D			
NAME	BPham			
DATE	01/27/22			

OFFICIAL RECORD COPY

1. **POLICY**

Topical reports (TRs) are reviewed by the United States Nuclear Regulatory Commission (NRC) staff with the goal of avoiding unnecessary restrictions on the 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.

2. **OBJECTIVE**

A TR is a report containing generic technical or regulatory information on a topic relevant to nuclear power plant safety or licensing. The TR process adds value by improving the efficiency of other licensing processes by allowing the staff to review proposed methodologies, designs, operational requirements, or other safety 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 the Office of Nuclear Reactor Regulation (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 for stakeholders what to expect during the review process.

3. **BACKGROUND**

The NRC TR process is utilized to increase efficiency by providing for a streamlined review of a subject with generic applicability and the potential for subsequent referencing in multiple licensing actions. The TR process may also reduce the burden on industry by minimizing the time and resources that both industry and the NRC staff expend on multiple reviews of the same topic. Industry organizations, such as a vendor or an owners' group, also referred to as a "TR sponsor" 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 Projects Branch (LLPB), within the Division of Operating Reactor Licensing (DORL), 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: Draft Safety Evaluation with "Holes" and Requests for Additional Information;
- Phase 5: Draft Safety Evaluation;

- Phase 6: Final Safety Evaluation; and
- Phase 7: “-A” Version.

4.2 Topical Report 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) 50.90 or 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 TR sponsor's justification to determine if the exception is appropriate.

4.3 Topical Report Review Fees

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

- The LLPB in DORL, NRR, is responsible for managing the TR program;
- The DORL Deputy Division Director has overall responsibility for the TR process;
- Assigned PMs have the responsibility for managing the individual TR reviews;

- Technical staff conduct the TR reviews and determine if the TR is acceptable for use; and
- Licensing Assistants in DORL will ensure that staff documents are consistent with the NRC writing and style guidance in the “NRC Editorial Style Guide.”

6. PERFORMANCE MEASURES

The performance measures are contained in the Performance Goals. Timeliness and completion are also tracked in the quarterly performance report.

7. PRIMARY CONTACT

Ngola Otto
301-415-6695
Ngola.Otto@nrc.gov

8. RESPONSIBLE ORGANIZATION

DORL

9. EFFECTIVE DATE

January 27, 2022

10. CERTIFICATION DATE

January 27, 2027

11. REFERENCE

<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
3. Appendix C – Flow charts for the Topical Report Pathways

Appendix A
LIC-500 Change History - Page 1 of 3

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

Enclosure 1

LIC-500 Change History - Page 2 of 3

Date	Description of Changes	Method Used to Announce & Distribute	Training
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
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
03/09/2018	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

LIC-500 Change History - Page 3 of 3

Date	Description of Changes	Method Used to Announce & Distribute	Training
10/18/2018	This change reflects a minor revision that will help ensure the proper process for transmitting documents is followed.	E-mail to all staff	Self-study by vendor/owners group PMs and TB section chiefs. Training session for vendor/owners group PMs
02/06/2020	This change reflects: (1) revisions to integrate the guidance and work processes of both NRR and NRO and (2) changes to the secure electronic file-sharing method.	E-mail to all staff	Self-study by vendor/owners group PMs and TB section chiefs. Training session for vendor/owners group PMs
01/27/2022	This change reflects: (1) incorporation of different review timelines depending on complexity of the topical report and (2) appropriate references to other NRR Office Instructions such as those on acceptance reviews, requests for additional information, and regulatory audits.	E-mail to all staff	Self-study by vendor/owners group PMs and Technical Branch Chief. Training session for vendor/owners group PMs.

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

Appendix B

Guide for Processing Topical Reports LIC-500, Revision 9

Table of Contents

1.0	Introduction	3
1.1	Objective	3
1.2	Process Overview	4
2.0	Topical Report Review Process.....	4
2.1	Phase 1: Submission.....	4
2.1.1	Pre-submittal Meeting (OPTIONAL).....	4
2.1.2	Topical Report Submitted to Document Control Desk.....	6
2.2	Phase 2: Work Plan Development	6
2.2.1	Resource Planning	6
2.2.2	Work Tracking Software Update	8
2.3	Phase 3: Completeness Review and Decision Letter	8
2.3.1	Completeness Review.....	8
2.3.2	Proprietary Review	8
2.3.3	Decision Notification.....	9
2.4	Phase 4: Draft Safety Evaluation with “Holes” and Requests for Additional Information .	9
2.4.1	Initial Review	9
2.4.2	Requests for Additional Information	10
2.4.3	Response to Requests for Additional Information	11
2.4.4	Review of Requests for Additional Information Responses	11
2.5	Phase 5: Draft Safety Evaluation	12
2.5.1	Develop Draft Safety Evaluation	12
2.5.2	Technical Staff Concurrence on Draft Safety Evaluation	12
2.5.3	Legal Review	13
2.5.4	Advisory Committee on Reactor Safeguards	14
2.5.5	Document Check on Draft Safety Evaluation	14
2.5.6	Issue Draft Safety Evaluation	14
2.6	Phase 6: Final Safety Evaluation	15
2.6.1	Develop Final Safety Evaluation	15
2.6.2	Issue Final Safety Evaluation	15
2.7	Phase 7: “-A” Version.....	15
2.7.1	Congressional Review Act Rule Evaluation	15

2.7.2	“-A” Version of Topical Report is Submitted	16
2.7.3	Verify Changes to the Accepted Topical Report	16
2.7.4	Verification Letter	16
2.7.5	Closure of the Project.....	17

1.0 Introduction

The topical report (TR) review process should adhere to the guidelines established within this appendix.

There are four review pathways with varying timelines that can be used to evaluate a TR depending on the complexity of the review (e.g., whether the TR is a completely new report or a revision plus other factors including technical complexity of the subject and level of staff effort needed). The flowcharts in Appendix C show the four different review pathways and summary attributes of each.

A sponsor may propose the use of a particular review process prior to submittal, for the U.S. Nuclear Regulatory Commission (NRC) staff's consideration depending on (1) the information provided and available during the pre-submittal meeting and (2) justification provided by the sponsor as part of the submission. The decision on which timeline and review process is used for a given TR is ultimately made by the NRC when the schedule is developed and documented by the NRC staff as part of the work planning described in Section 2.2, "Work Plan Development," and communicated to the TR sponsor in Phase 3. The NRC review schedule is also reflected in the Reactor Program System (RPS)-Licensing module.

The four review pathways are:

- **Standard Review:** This is for a highly complex new or revised TR. It involves all the steps in conducting an evaluation including an acceptance review, Request for Additional Information (RAI) questions, a Draft Safety Evaluation (SE), Final SE, and -A TR with staff verification. A typical schedule for this review type could be up to two years, but it may be shorter or longer depending on circumstances;
- **Compressed Review:** Use of this review is appropriate for TRs that are less complicated and for which a detailed set of RAI questions is not expected to be necessary (e.g., due to simplicity of topic area, similarity to previous reviews, etc.). Simple or minor RAI questions may nonetheless be necessary to place information on the TR docket. The Compressed Review is intended to be completed within one year;
- **Uncomplicated TR Review:** This review process is used when there are minor revisions to an existing TR and the staff has determined based on information at the pre-submittal meeting that no RAI questions or open items are anticipated. A 6-month review schedule is the nominal planning time, but it may take up to 12 months to complete; and
- **SE Confirmation Review:** The SE Confirmation Review is intended for minimal revisions of TRs where the existing SE does not need to be revised (e.g., administrative transfer of a TR to new vendor).

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

In general, the major activities covered in this procedure are given below and are separated into the following seven phases, as appropriate, depending on which review process is chosen by Phase 3:

- Phase 1: Submission;
- Phase 2: Work Plan Development;
- Phase 3: Completeness Review and Decision Letter;
- Phase 4: Draft Safety Evaluation with “Holes” and Requests for Additional Information;
- Phase 5: Draft Safety Evaluation;
- Phase 6: Final Safety Evaluation; and
- Phase 7: “-A” Version.

2.0 Topical Report Review Process

2.1 Phase 1: Submission

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 TR sponsors 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 Pre-submittal Meeting (OPTIONAL)

A. Purpose

A sponsor planning to submit a TR should inform the project manager (PM) well in advance of the submittal. While pre-submittal meetings are not required, the NRC encourages the TR sponsor to have early engagement with the staff prior to submittal of the TR for NRC review. Multiple pre-submittal meetings can be held if needed. Noticing of pre-submittal meetings and opening or closing the meeting should follow Management Directive 3.5, “Attendance at NRC Staff-Sponsored Meetings.”

Pre-submittal meetings should occur with enough time for the sponsor to incorporate any preliminary NRC staff feedback received into the TR. The objectives of a pre-submittal meeting are to: (1) provide the NRC staff with the scope of the proposed TR; (2) discuss which of the four review pathways the sponsor is requesting as well as the justification for that pathway; (3) obtain staff feedback on the proposed scope and schedule for the planned TR; and (4) discuss the expected submittal date and review schedule, which is dependent on the review pathway ultimately used.

Because TRs often involve complex topics, the PM should request that pre-submittal information be provided sufficiently prior to the meeting so the technical staff can identify key questions and provide feedback concerning the proposed review approach. In addition, receiving the information well in advance of the pre-submittal meeting will allow the staff to review any proprietary information and determine if the meeting should be closed.

B. Preparation

The PM should schedule a pre-submittal meeting (face-to-face, videoconference, or teleconference) with the TR sponsor and the anticipated NRC technical review staff. Topical Report sponsors are encouraged to provide to the staff 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. For example, a TR could:

- Resolve generic safety issue or emergent NRC technical issue;
- For example, a TR could be tied to a lead plant LAR;
- Introduce a new technology or TR sponsor identified safety improvement with implementation anticipated industry wide;
- Address analytical methods associated with current requirements intended only for partial groups of licensees with limited implementation; and
- Potentially be applicable to facilities for which the licensees have formed groups (BWROG, PWROG, BWRVIP, etc.) with implementation anticipated by many if not all the group members.

Regardless, TRs must contain complete and detailed information on the specific subject presented. Conceptual or incomplete preliminary information will not be reviewed. If the sponsor requests to close any pre- or post-submission meeting because the materials to be discussed are proprietary, the sponsor should submit all such materials at least 30 days in advance of the meeting. 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.

Topical Report sponsors should also coordinate with the PM to develop a meeting agenda and identify a list of attendees for each meeting. 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 the Office of the Chief Financial Officer 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 to maintain technical consistency.

C. Conduct of Meeting

To support a productive meeting, the TR sponsor should provide adequate technical detail concerning the approach, methods, and key assumptions. The TR sponsor should further identify anticipated review challenges or significant changes from the existing state of practice, which may require additional attention during the review.

Active NRC staff engagement during pre-submittal meetings is critical to the effectiveness of these meetings. The NRC staff should ask questions to clarify or confirm points that are not fully understood and to elicit important information that was not covered in the sponsor's presentation. The NRC staff should further provide preliminary feedback on the scope, level of detail, and key aspects of the proposed TR, noting in particular any areas for improvement and associated technical and regulatory context. The NRC staff will reserve judgment on the acceptability of the TR and the sponsor's proposed TR review pathway until completion of its acceptance review.

2.1.2 Topical Report 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: Work Plan Development

This phase begins once the TR has been submitted on the docket. Most of the steps in this phase are focused on determining the level of effort needed 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 branch chiefs (TBCs) 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 needed;
- Identification if a proprietary determination is needed;
- Determination of whether the TR needs 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; and
- Need for legal review from OGC.

Upon receipt of a submittal, the PM will verify whether the sponsor has an NRC-issued docket number. If no docket number has been assigned, the PM can obtain one by sending an e-mail to MDMS_HELP.Resource@nrc.gov requesting a new docket and providing the following information:

- Name of New Project/Docket No.: This will describe the site or sponsor associated with the billing;
- Name of the Sponsor;
- Docket Type: Vendor, power, fuel facility, etc.;
- Region in Which Project Will Be Located; and
- Legal Address and Point of Contact (only required for a company brand new to NRC): Name, mailing address, e-mail, and phone number.

Unless a fee exemption is granted, as discussed in Section 2.2.4, "Fee Exemption," the Enterprise Project Identifier will be opened under the billable Cost Activity Code listed in RPS Licensing for that sponsor.

The PM will input a tentative review plan into the workload management system based on: (1) the staff-selected review process; (2) information provided at the pre-submittal meeting, if conducted; (3) the likelihood of additional interim milestones, such as staff audits, review by the Office of General Counsel or the Advisory Committee for Reactor Safeguards; and (4) the schedule and priority requested by the sponsor.

The TBCs should assess the proposed schedule and office review priorities and assign technical reviewers. In parallel with the acceptance review, if conducted, the technical reviewers should assess the tentative review plan input by the PM to determine its reasonableness. After conferring, as necessary, with the TBC, the technical reviewer will input proposed revisions to the schedule, additional resources such as the use of a contractor, review milestones, or any combination of the above.

The technical reviewers and PM should consider the need for and timing of any regulatory audits. The TBC may also consider whether to assemble a team of technical specialists to complete a high-priority review on an accelerated schedule. The uniqueness of the submittal and complexity should be considered in determining if an audit is necessary. Any significant changes to the work plan, identified any time during the review, should be discussed with the PM.

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 Letter

This phase will begin when the technical staff assigned to the TR is scheduled to start the completeness 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 sufficiently complete for the staff to begin its detailed technical review 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 staff will perform an acceptance review using the criteria, as applicable, in Sections 3.1.1, "PM Criteria," and 3.1.2, "Technical Staff Criteria," of LIC-109, "Acceptance Review Procedures." The acceptance review will determine if there is sufficient information to conduct a detailed review.

The sponsor of the TR may request that a review be done under the Uncomplicated TR or SE Confirmation Reviews. If the NRC staff agrees to conduct the reviews in either of those processes, an acceptance review can be abbreviated, as the staff's agreement to either process represents acceptance for review.

For Standard Review submittals, the technical reviewers should provide acceptance input to the PM within 60 days of the submittal letter date. If the requested review schedule is shortened, the technical reviewers will be requested to provide acceptance review input sooner.

Prior to communicating the acceptance decision to the TR sponsor, the PM and technical reviewer should confirm the feasibility of the review plan or revise it as appropriate.

2.3.2 Proprietary Review

If a TR sponsor designates information in the TR as proprietary and requests the NRC to withhold it from public disclosure, the NRC staff should conduct a proprietary information withholding determination and document it on NRC Form 897, "Topical Report Withholding Determination." Withholding determinations are done for the TR submittal and any subsequently submitted information that is not covered by the original determination. Details for conducting a withholding determination are in LIC-204, "Handling Requests to Withhold Proprietary Information from Public Disclosure."

2.3.3 Decision Notification

The PM will notify the TR sponsor about the results of the completeness review by telephone and, if accepted, which review pathway (i.e., described in Appendix C) the staff has chosen and the anticipated schedule and level of effort. This should be followed by an e-mail to document the decision notification via NRC Form 898, "Topical Report Completeness Determination," which includes the schedule for the review and resource estimate or the reason the staff declined to docket the TR. For any significant (e.g., 25 percent or greater) change in the review schedule or resource estimates, the PM will notify the Division of Operating Reactor Licensing (DORL) management and contact the TR sponsor to communicate the change.

If, during the completeness review, the NRC staff determines that the TR will not be accepted for detailed technical review because it is not sufficiently complete, the decision will be documented and provided to the TR sponsor via NRC Form 898. Generally, and depending on the circumstances, the PM may notify the sponsor before issuing the NRC Form 898.

2.4 Phase 4: Draft Safety Evaluation with "Holes" and Requests for Additional Information

This phase marks the formal beginning of the detailed technical review. It begins immediately upon a staff decision to docket a TR and ends when the RAI questions have been sent. The goal of this phase is the generation of the Draft SE with "holes" to support the development and issuance of the RAI questions, as appropriate, in accordance with LIC-115, "Processing Requests for Additional Information." The staff will maintain the Draft SE with "holes" as an internal pre-decisional document for use in tracking issues and sponsor submissions to close them. When all issues are closed, the staff may convert the Draft SE with "holes" into a complete Draft SE for proprietary review or public disclosure in connection with Advisory Committee on Reactor Safeguards (ACRS) review or other reasons, as discussed below.

2.4.1 Initial Review

The first step in the technical review phase of the TR (Phase 4) is for the technical staff to gain an understanding of the report.

At the conclusion of the initial review, the technical staff should have a relatively complete understanding of the information in the TR and be able to begin drafting the SE with "holes" and developing RAI questions, as appropriate, in accordance with LIC-115.

As a part of its review, and as allowed by LIC-115, the NRC staff may also opt to perform regulatory audits to help: (1) efficiently gain an understanding of the submittal and a better understanding of detailed calculations, analyses, and Bases; (2) verify information; and (3) identify information that will require docketing to support a staff decision. Regulatory audits are addressed in LIC-111, "Regulatory Audits."

The technical reviewers and PM should consider if a regulatory audit is necessary to support the review and at which point it should be conducted. For example, an audit to gain understanding may be beneficial early in the review. An audit to review details supporting design information in the TR or identify information that may require docketing could be conducted in concert with preparation of RAI questions, or once RAI questions have been transmitted to the TR sponsor.

Consistent with LIC-111, information necessary to support the NRC staff decision should be placed on the docket by the TR sponsor per Title 10 of the *Code of Federal Regulations* (10 CFR) 50.4, "Written communications."

2.4.2 Requests for Additional Information

In accordance with LIC-115, the staff should prepare the Draft SE with "holes" to document the staff review and develop RAI questions by identifying any areas where information is needed to complete the review. LIC-115 also provides for means to communicate/transmit the RAI questions to the TR sponsor, including different options the staff could consider to obtain the desired information more efficiently (e.g., public meeting/conference call, requests for confirmation of information). Nonetheless, any information on which the staff relies to reach conclusions in the SE must be docketed.

As indicated above, the sponsor of the TR may request that a review be done under the Uncomplicated TR or SE Confirmation Reviews. If the NRC staff decides to conduct its review in either the Uncomplicated TR or SE Confirmation Review processes, RAI questions are not expected, though the staff is not precluded from issuing RAI questions in these processes.

When the Standard Review process is chosen, the staff may issue RAI questions using Section 4.14, "RAI Workflow and Approval Process," of NRR Office Instruction LIC-115, "Processing Requests for Additional Information," to obtain any additional information needed.

If RAI questions are prepared that contain controlled unclassified information (e.g., proprietary information), the technical reviewers should apply the appropriate portion markings.

The PM will ensure that the proprietary markings have been appropriately placed in the header and footer of RAI questions. Next, the PM will send the RAI questions to the sponsor, preferably via the secure information sharing application authorized by the Office of the Chief Information Officer or via encrypted e-mail consistent with the guidance in Management Directive 12.5, "NRC Cybersecurity Program." Even if the NRC staff did not identify proprietary information in the RAI questions,

they should still be securely sent in case proprietary information was missed.

An e-mail documenting the transmittal shall be sent to the sponsor. The e-mail will instruct the sponsor that the RAI responses need to include a proprietary and non-proprietary version of the RAI questions and the responses. This ensures the RAI questions are made available to stakeholders, including the public. The e-mail will also include a response date agreed upon by the sponsor and PM and state that the response must be submitted via letter with an authorized signature.

The transmittal e-mail and RAI questions will be placed in ADAMS by the PM so that they can be declared Official Agency Records. The e-mail availability is public while the proprietary RAI questions availability is non-public. An RAI file that is completely non-proprietary should be declared public. The PM should ensure that redacted RAI questions are made publicly available.

2.4.3 Response to Requests for Additional Information

The TR sponsor is responsible for responding to the RAI questions on the docket by the agreed upon date(s). The response should include the NRC's question verbatim, the TR sponsor's answer to the question, and appropriate markings for any information in the RAI or the responses that is considered proprietary. If new proprietary information is included in the response to the question, the TR sponsor needs to include a new affidavit 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 TR sponsor proposes changes to the TR because of the RAI questions, the TR sponsor should include with the RAI responses a mark-up of the TR pages that it plans to change.

2.4.4 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 unsatisfactory (i.e., an apparent omission of requested information or an overall inadequate response). If any RAI responses are found to be unsatisfactory, the PM will then contact the TR sponsor to identify the responses of concern and discuss pathways for resolution. Under most anticipated circumstances, potential resolution pathways, include public meetings and/or audits, as described in LIC-115, to help to clarify information needed by the NRC staff to reach a safety conclusion. The result of these exchanges may or may not warrant an additional round of RAI questions or other actions, including, but not limited to, suspension or termination of the review

and/or rejection of the TR. Information that the staff relies upon to make a regulatory finding must be submitted on the docket.

Under circumstances where the TR sponsor cannot resolve any incomplete RAI responses, 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 discussed with DORL management and communicated by telephone to the TR sponsor. Additionally, at any point during this process, the TR sponsor may also request its TR to be withdrawn via letter submission to the DCD.

Any effort associated with resolving incomplete RAI responses that have been determined to extend the review schedule will be identified to the TR sponsor by the PM and updated in RPS.

2.5 Phase 5: Draft Safety Evaluation

For the Standard Review pathway, this phase begins after the RAI responses have been received and ends when the “holes” in the Draft SE are closed. For the Compressed, Uncomplicated, or SE Confirmation reviews, this phase begins upon receipt of the TR.

2.5.1 Develop Draft Safety Evaluation

The technical staff will update the Draft SE as necessary with relevant information from the RAI responses (generally not applicable for Compressed, Uncomplicated, or SE Confirmation reviews).

2.5.2 Technical Staff Concurrence on Draft Safety Evaluation

The TBC will provide the Draft SE 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 SE should also clearly identify any limitations and conditions that 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 needed to support the staff’s review of a request to implement the TR. Limitations and conditions identify the matters that will need to be addressed in subsequent individual plant applications that will reference the TR. The limitations and conditions should be written with sufficient clarity that applicants 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 an applicant in order to reference the TR in a plant-specific licensing request. For example, applicants requesting to implement the TR must provide plant-specific data or analysis to show that the plant 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 Legal Review

The Office of General Counsel (OGC) review of TRs associated with licensing actions should be consistent with the OGC review described in LIC-101 regarding such action. In addition, the no legal objection (NLO) review performed by OGC for the related licensing actions is discussed in COM-109, Section 4.1.2, “No Legal Objection Reviews.”

Topical report SEs that are referenced in and required to establish the safety or regulatory basis for a rulemaking or a licensing action such as a LAR or exemption, design certification, or phased design review, should be submitted to OGC for legal review (NLO). The factors below provide considerations for the timing of the legal review.

- When a prospective applicant or an applicant provides a letter documenting the planned use of a vendor, owners’ group, or industry organization TR in a near-term (within 18 months) licensing action, the PM must submit the TR SE for OGC NLO review. OGC will review the SE for the TR cited by the licensee in its letter;
- Topical report SEs for new, small modular, advanced, or micro reactors should be submitted to OGC for legal review (NLO) before issuance;
- OGC review of other TR SEs will be at the discretion of the PM

with technical staff input and based on COM-109, "NRR Interfaces with the Office of General Counsel." If the TR SE is not submitted for OGC NLO review prior to issuance, then the PM will mark "NOT REVIEWED" in the OGC concurrence block. This will indicate for future users of the TR that NLO review was not conducted and is needed; and

- If a TR SE is not submitted for legal review prior to its issuance, when the NRR staff accepts for review the first LAR or other application referencing an approved TR SE not previously reviewed by OGC, the staff will provide OGC with the TR and the TR SE for review immediately after the acceptance of the LAR or other application referencing the unreviewed TR SE. The staff will also provide the review schedule to OGC when it becomes available. This approach should provide enough time for OGC to complete the legal review of the TR SE before the staff issues any RAI questions on the LAR or other application that references staff's previous approval and SE of the TR. Specific guidance for this process is incorporated in LIC-101.

2.5.4 Advisory Committee on Reactor Safeguards

The ACRS may wish to review the TR and the associated SE. The ACRS interactions are addressed in the Memorandum of Understanding (ADAMS Accession No. ML010790468) between the Office of Executive Director for Operations and the ACRS, and COM-103, "NRR Interfaces with the Advisory Committee on Reactor Safeguards (ACRS)." The PM should add the ACRS review to the milestone schedule and adjust the schedule accordingly.

2.5.5 Document Check on Draft Safety Evaluation

The licensing assistant will ensure that the Draft SE reflects standard NRC usage and format 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 the changes did not impact the technical information provided in the Draft SE.

2.5.6 Issue Draft Safety Evaluation

The purpose of the Draft SE is to provide the applicant with the opportunity to identify any proprietary information. The PM will issue the Draft SE by the scheduled date. Once the transmittal letter (or e-mail) is signed and concurred upon by the LLPB BC, the PM may provide the TR sponsor a copy of the Draft SE via a file-sharing method established by the Office of the Chief Information Officer.

The staff's request should be limited to confirmation that it has appropriately identified and marked the TR sponsor's proprietary information.

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 comments from the sponsor (i.e., identification of proprietary information) from the Draft SE, the staff's concurrence review, and any ACRS comments, as appropriate.

2.6.2 Issue Final Safety Evaluation

The PM will issue the Final SE by the scheduled date via e-mail. Once it is signed and concurred upon by the LLPB BC, the PM should provide the TR sponsor a copy of the Final SE via file-sharing method established by the OCIO. The PM issues the cover letter (or e-mail) with the non-proprietary SE publicly. Another cover letter (or e-mail) with the proprietary SE is issued to the TR sponsor and maintained in ADAMS as non-public.

2.7 Phase 7: "-A" Version

The final phase of the review process begins after the Final SE is sent to the TR sponsor. This phase ends once the verification letter from the LLPB BC is issued, stating that the NRC staff has placed the accepted "-A" version into ADAMS.

2.7.1 Congressional Review Act Rule Evaluation

All SEs must be submitted to OGC for Congressional Review Act (CRA) review. OGC must determine whether the NRC staff's SE qualifies as a "rule" under the CRA.

If OGC determines that the SE is NOT a rule under CRA, then this process is complete.

If OGC determines that the SE is considered a rule, the PM should prepare a CRA input summary to be submitted to the Office of Management and Budget (OMB) via the Office of Nuclear Material Safety and Safeguards (NMSS) rulemaking staff who are responsible for coordinating with OMB regarding the CRA and inform the TR sponsor of additional delays that may occur. These summaries are generally submitted to the NMSS rulemaking staff once the Final SE has been

issued and the -A version of the TR is being prepared. OMB uses these summaries to help determine whether rules qualify as “major rules” under the CRA. Though it occurs only rarely for NRC rules, if OMB finds a rule to be “major,” the CRA generally would prohibit the rule from taking effect until at least 60 days after completion of the Congressional notification step.

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/legal/other-legal-work/congressional-review-act>.

This step is imperative because the basis of CRA is that Congress must have the ability to review all final rules upon issuance.

2.7.2 “-A” Version of Topical Report is Submitted

The TR sponsor should submit the “-A” version of the TR to the NRC within three to six months of receipt of the Final SE.

The “-A” version of the TR should incorporate the NRC’s Final SE transmittal letter, the Final SE, an appendix containing the TS and Bases mark-up pages of the appropriate vendor Standard TS (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 LLPB PM should ensure that both proprietary and non-proprietary versions are submitted to the NRC.

2.7.3 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 is to verify that the “-A” TR contains the updated information that was submitted and reviewed (i.e., in RAI responses).

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

2.7.4 Verification Letter

The PM will prepare Verification Form 896, “Office of Nuclear Reactor Regulation -A Topical Report Verification Review Determination,” 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 whether the SE is 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 Verification Form 896, all actions toward the TR review are complete. The PM will close the project and notify the technical staff of its closure.

Appendix C: Flow charts for the Topical Report Pathways

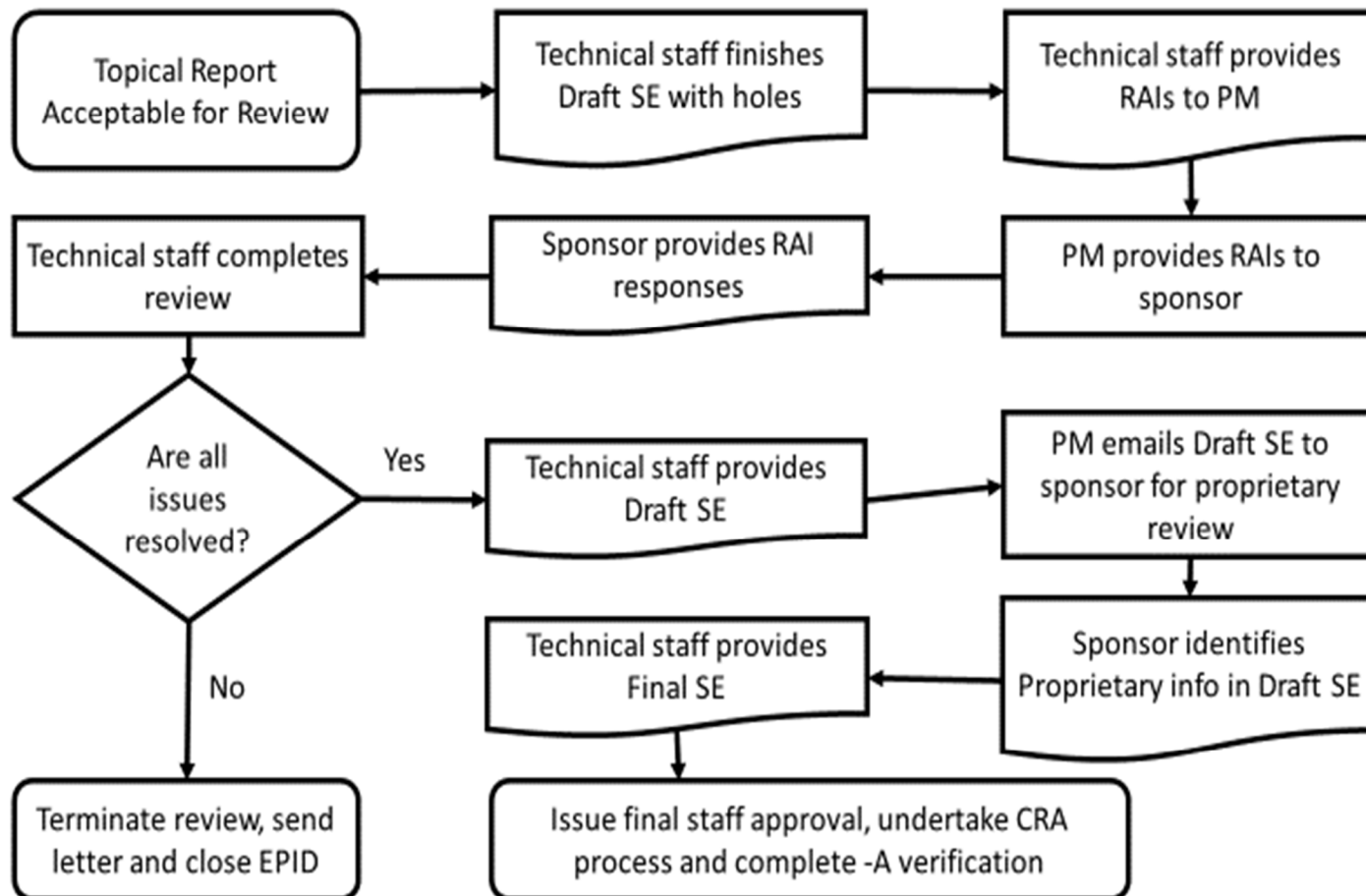
Figure 1: Topical Report Standard Review (Two-year Schedule)

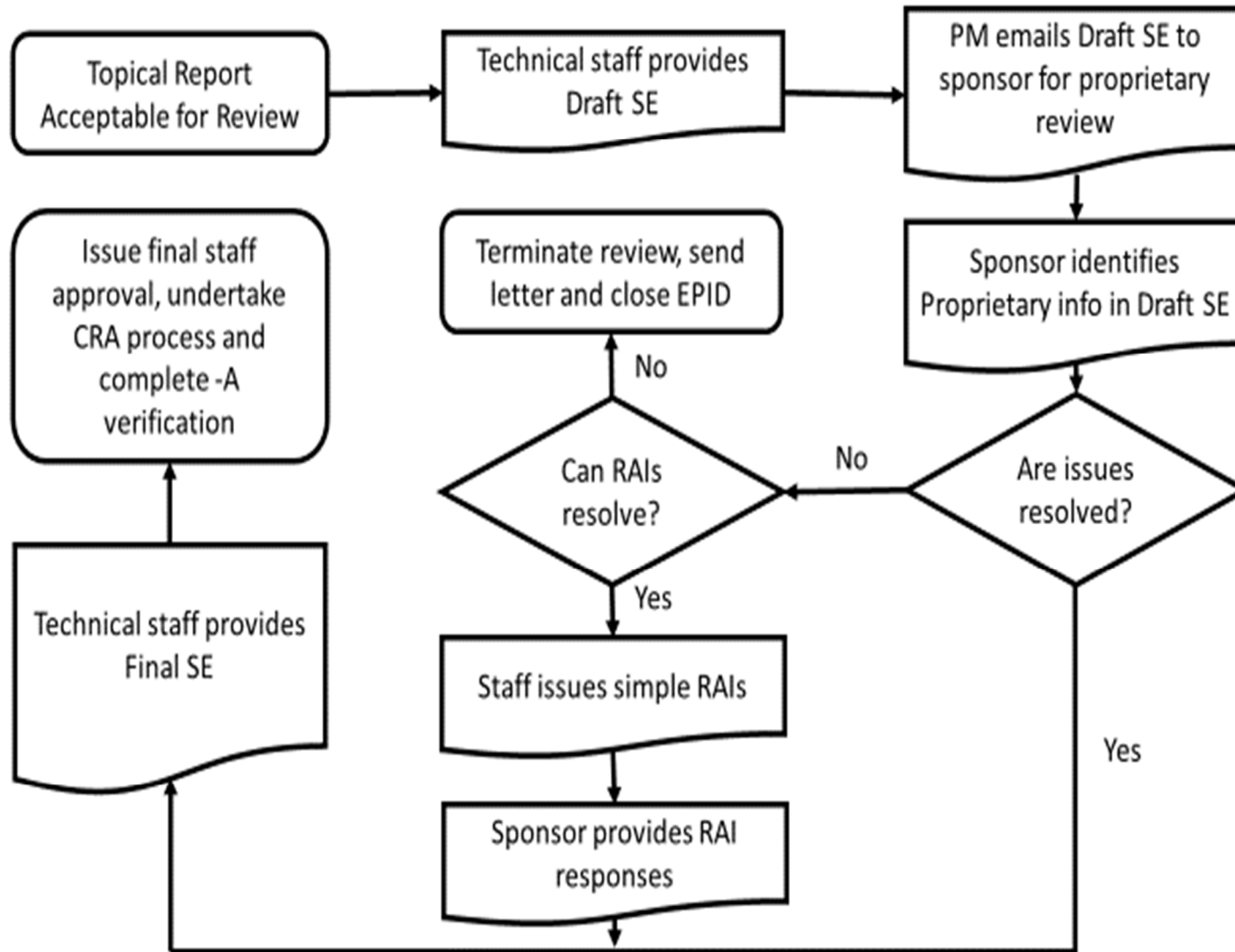
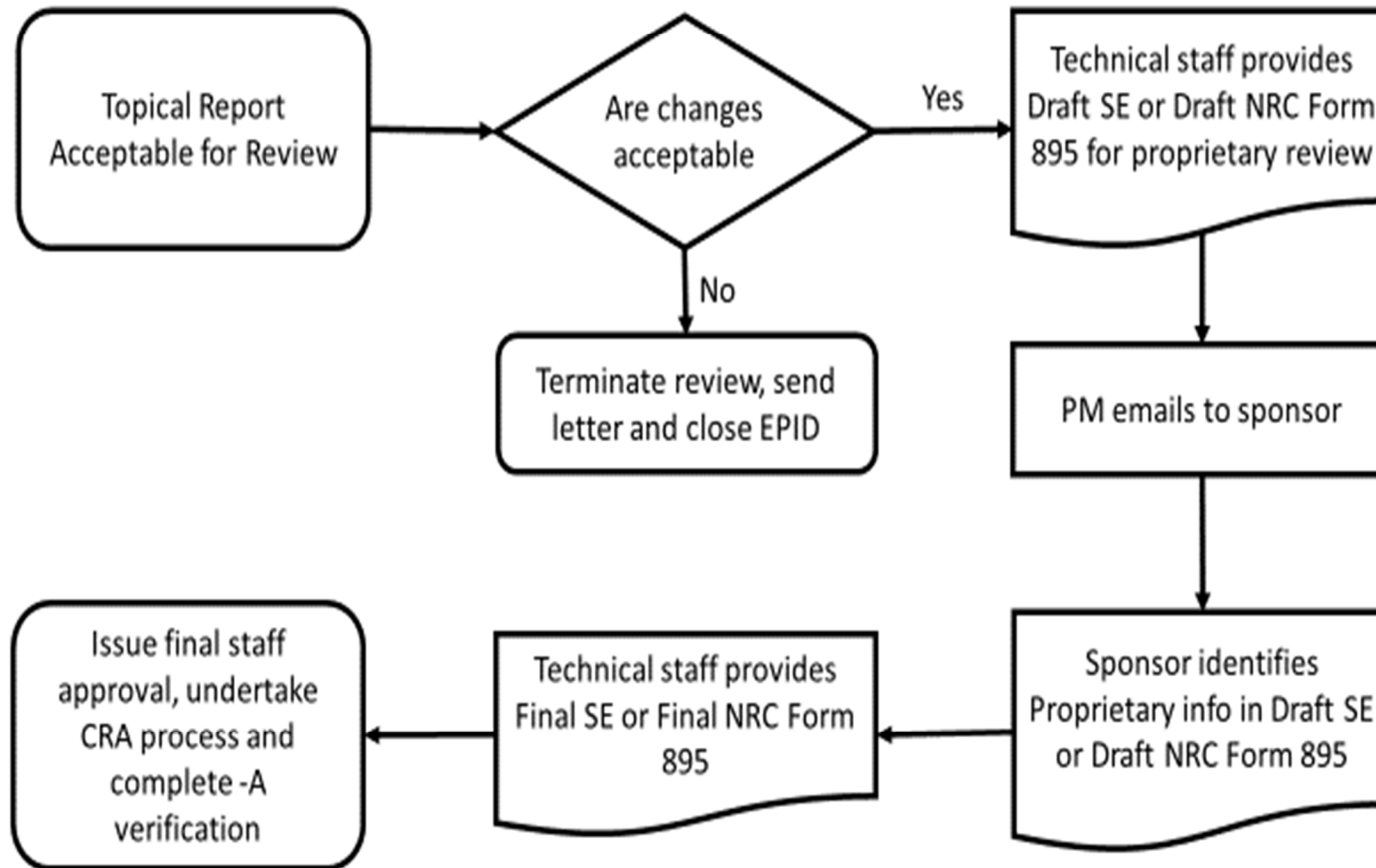
Figure 2: Compressed Review (One-year Schedule)

Figure 3: Uncomplicated TR Revision Review (Six Months to One Year Schedule) or SE Confirmation Review (Three to Six Months Schedule)



Types of Review Processes and Attributes				
Process Attribute	Standard Review	Compressed Review	Uncomplicated Review	Safety Evaluation Confirmation Review
Application	New or revised complex Topical Report (TR).	Less complicated new or revised TR.	TR having minimal revisions with no need for Request for Additional Information (RAI) questions and no open items anticipated.	Used for TR revisions, and in rare instances new TRs, where the subject matter of the TR has already been evaluated and documented in an existing Safety Evaluation (SE). The U.S. Nuclear Regulatory Commission (NRC) staff review confirms the existing SE.
Acceptance Review	Conducted with completeness determination of: 1) acceptable, 2) unacceptable with opportunity to supplement, or 3) unacceptable. Documented on NRC Form 898, "Topical Report Completeness Determination."	Conducted with completeness determination of acceptable or unacceptable. Because of the one-year schedule, unacceptable with opportunity to supplement is not a completeness determination finding. Documented on NRC Form 898.	If the NRC staff agrees that an Uncomplicated Review is appropriate, no acceptance review is done.	If the NRC staff agrees that a SE Confirmation Review is appropriate, no acceptance review is done.
Information Insufficiency Process	RAI questions or other options to get the desired information efficiently (e.g., audits, public meeting/conference call, requests for confirmation of information).	Detailed RAI questions not expected to be necessary but some minor RAI questions for clarification may be necessary to place information on docket.	None expected	None expected
Review Documentation	Draft SE, Final SE, and a -A TR with verification on NRC Form 896, "Office of Nuclear Reactor Regulation -A Topical Report Verification Review Determination."	Draft SE, Final SE, and a -A TR with verification on NRC Form 896.	Draft SE, Final SE, and a -A TR with verification on NRC Form 896.	Draft and Final NRC Form 895, "Topical Report Safety Evaluation," and a -A TR with verification on NRC Form 896.
Nominal Review Time	Two Years	One Year	Six months but may extend to 12 months.	Three months but may extend to six months.