OFFICE OF NUCLEAR REACTOR REGULATION

LIC-117	Acceptance Review Process for New Nuclear Facility Licensing Applications	
Volume 100	Licensing Processes	
Approved By: Date Approved: Effective Date: Certification Date:	Anna Bradford January 28, 2021 January 28, 2021 January 28, 2026	
Responsible Organizations:	DANU and DNRL	
Primary Contacts:	Donna Williams Donna.Williams@nrc.gov 301-415-1322	Allen Fetter Allen.Fetter@nrc.gov 301-415-8556
Summary: The objective of this office instruction (OI) is to provide guidance to staff who perform acceptance reviews of new nuclear facility licensing applications. The OI was developed using information from NRO office instruction NRO-REG-100, "Acceptance Review Process for Early Site Permit, Design Certification, and Combined License Applications," (ML14078A152), which has been rescinded. This office instruction complements the acceptance review guidance for license amendment requests in LIC-109, Revision 3, "Acceptance Review Procedures for Licensing Basis Changes" (ML20036C829) for licensee-requested changes to a facility's licensing basis.		
Training:	None	
ADAMS Accession No.:	ML20283A188	

TABLE OF CONTENTS

Office Instruction: LIC-117, “Acceptance Review Process for New Nuclear Facility Licensing Applications”
Dated: 01/28/2021

ADAMS Accession No.: ML20283A188

OFFICE	NRR/DANU/D	NSIR/DPR/D	NRR/DRA/D	NRR/DEX/D
NAME	MShams	KBrock	MFranovich	EBenner
DATE	12/16/2020	12/15/2020	12/15/2020	12/16/2020
OFFICE	NRR/DRO/D	NRR/DSS/D	NMSS/REFS/DD	OGC
NAME	CMiller	JDonoghue	KCoyne	RWeisman
DATE	12/21/2020	01/07/2021	12/17/2020	12/31/2020
OFFICE	NRR/DNRL/D	NRR/DRMA	NRR/DNRL/D	
NAME	ABradford	TGorham	ABradford	
DATE	01/15/2021	01/28/2021	01/28/2021	

OFFICIAL RECORD

1. POLICY

It is the policy of the Office of Nuclear Reactor Regulation (NRR), as well as a regulatory requirement under Title 10 of the *Code of Federal Regulations* (10 CFR) 2.101(a)(2), to review applications for an early site permit (ESP), limited work authorization (LWA), construction permit (CP), operating license (OL), standard design approval (SDA), manufacturing license (ML), or combined license (COL) submitted under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," and Part 50 "Domestic Licensing of Production and Utilization Facilities," for completeness and acceptability for docketing. In accordance with 10 CFR 2.815, NRR applies the same policy to applications for design certification (DC). The regulations in 10 CFR Part 2, "Agency Rules of Practice and Procedure," prescribe the procedure for issuance of a license; amendment of a license at the request of the licensee; and transfer and renewal of a license. This Office Instruction (OI) covers applications for an ESP, LWA, CP, OL, DC, ML, SDA, and COL which will hereafter be referred to as licensing applications.

The regulations that are applicable to this OI are contained in 10 CFR 2.101, "Filing of Application," 10 CFR 2.102, "Administrative Review of Application," 10 CFR 2.107, "Withdrawal of Application," 10 CFR 2.108, "Denial of Application for Failure to Supply Information," and 10 CFR 2.815, "[Standard Design Certification] Docketing and acceptance review."

Section 2.101 of 10 CFR requires the U.S. Nuclear Regulatory Commission (NRC) staff to determine whether a request for a licensing action is complete and acceptable for docketing. In the Staff Requirements Memorandum (SRM) on COMDEK-07-0001/COMJSM-07-0001, "Report of the Combined License Review Task Force," dated June 22, 2007 (Agencywide Documents and Access Management System (ADAMS) Accession No. ML071090128), the Commission directed the staff to determine acceptability of COL applications on the basis of their technical sufficiency as well as their completeness and to do so within a period of 60 days of receipt. Both the completeness and technical sufficiency reviews ensure the application includes the information necessary for the NRC staff to make the findings required by the *Atomic Energy Act of 1954*, as amended, and the National Environmental Policy Act of 1969, as amended, and other applicable statutes. In particular, the technical sufficiency review should be conducted to ensure that the application contains sufficient information in scope and depth for the staff to conduct its detailed technical review within a predictable timeframe.[1] Although the SRM on COMDEK-07-0001/COMJSM-07-0001 was directed at COLs, the staff is applying the Commission's direction to all licensing applications under this OI.

An application is incomplete if it omits information required by the regulations governing the contents of applications. Similarly, in regard to technical sufficiency, if the information in the application: (1) does not clearly address the requirement it purports to address or (2) is incorrect and not easily correctable, the application does not satisfy the "technical sufficiency" test. The staff may gauge whether an application addresses the applicable regulatory requirements based on engineering judgment and/or whether or not the supplied information conforms to applicable regulatory guidance or industry codes and standards. Both the administrative completeness and technical sufficiency tests apply to information required for regulatory purposes and information required for substantive technical safety or environmental purposes. This OI will refer to areas in which the staff has determined that the information provided fails one of these tests as "gaps" in the application or

[1] The term "predictable timeframe" refers to the applicable generic review schedule (https://www.nrc.gov/about-nrc/generic-schedules.html) for each type of application deemed acceptable for docketing, as modified to account for complexity and uniqueness of the application (See Section 5 of this OI).

"information gaps." While this OI provides criteria for an acceptable application, the staff has flexibility in deciding whether to accept an application for docketing based on consideration of other factors and circumstances. However, consideration of other factors and circumstances for a flexible approach must be done in coordination and agreement with NRR management and the Office of General Counsel (OGC). The other considerations upon which a determination is made to accept an application should be clearly documented and communicated, and these factors should be considered in establishing the schedule for the technical review.

If an application is deemed acceptable for docketing and detailed technical review, the NRC staff will send an acceptance letter to the applicant, which will include a review schedule and could include an estimated level of resources necessary to complete the review. The schedule and resource estimates may be provided separately but should be sent within a defined timeframe or specified milestones stated in the application acceptance letter (usually within about 60 days of staff having received all information deemed necessary to set the schedule).

If, however, the NRC staff finds an application to be materially incomplete or not technically sufficient, as discussed above, and therefore not acceptable for docketing, it is the staff's policy to inform the applicant by letter of all the specific gaps in the application that preclude docketing of the application. In cases where an application is not accepted for docketing, but can be remedied (i.e., the applicant can provide the needed supplementary information within 6 months), NRC should consider including a comprehensive list of Requests for Supplemental Information (RSIs) as an attachment to the acceptance review status letter. This will help ensure that additional information will be provided for subsequent acceptance of the application for docketing. If the NRC staff determines that an application is not acceptable for docketing, it will remain in a tendered state until the applicant addresses the identified information gaps, but generally not longer than six months from the date of the NRC letter informing the applicant of the identified information gaps. If an applicant cannot address the information gaps in a timely manner, the applicant will be given the opportunity to withdraw the application or have NRC reject it via letter.

Section 2.102 of the NRC's regulations allows the NRC staff to request that the licensee supply additional information in the course of the review of the proposed action. NRR will consider an application to be acceptable for docketing upon the NRC staff's conclusion that the application appears to contain sufficient technical information, both in scope and depth, for the NRC staff to complete the detailed technical review using a reasonable number of rounds of Request for Additional Information (RAIs) (generally one or two), or through audits (see LIC-111, Revision 1 "Regulatory Audit," and examples of audit plan ADAMS Accession No. ML17108A822 and audit summary report ADAMS Accession No. ML17223A428) and public meeting interactions as supported by subsequently docketed information (see example meeting summary ADAMS Accession No. ML17054D545 and subsequent information provided by applicant ADAMS Accession No. ML17107A080). Such a conclusion means that the staff anticipates it will be able to determine, in an appropriate time frame for the requested action, whether the application complies with applicable NRC requirements.

While the goal of the acceptance review process is to facilitate the staff's review of applications, the acceptance of an application does not imply that RAIs will not be issued during the detailed review process. Such RAIs may identify serious technical issues in the application (possibly resulting in denial of the application). Docketing of an application does not imply that the application will be approved. Rather, the acceptance review is a tool used by the NRC staff to identify clearly unacceptable applications early in the review process, so that information in the application that is incomplete or not technically sufficient can be addressed by the applicant or the applicant may choose to withdraw the application.

2. OBJECTIVES

This OI provides NRR staff (and other NRC staff supporting NRR licensing activities) a basic framework for performing an acceptance review upon receipt of a licensing application. This OI builds upon the framework for conducting acceptance reviews established in LIC-109, Revision 3 "Acceptance Review Procedures for Licensing Basis Changes," (ADAMS Accession No. ML20036C829). This guidance expands on the concepts presented in LIC-109 to account for differences between applications for licensee-requested changes to an existing facility's licensing basis and an initial license application. Examples of additional considerations accounted for in this OI include increased technical complexity; expanded regulatory and technical scope; and greater volume of information to review for initial license applications compared to typical license amendment requests.

The staff conducts a regulatory completeness review to ensure that the applicant has submitted the information required by the applicable regulations in 10 CFR Parts 50, 51, and 52, such that the staff can conduct its detailed technical review. While conformance with NRC guidance is not required, it facilitates both the preparation of an application by the applicant and the timely review of the application by the NRC staff. These procedures should enhance NRR's efficiency in responding to the needs of the applicants and the public. Specific objectives include the following:

- Provide general guidance to NRC staff that defines the attributes of an acceptable application;
- Promote the submittal of high-quality applications;
- Promote an effective and consistent use of NRC resources in performing acceptance reviews;
- Establish the acceptance review process as an integral part of an effective licensing review, thus reducing unnecessary delays in the review of applications;
- Establish the priority of acceptance reviews and schedule for completion; and
- Ensure effective internal and external communications.

NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants; LWR Edition," (SRP); NUREG-1555, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants," (ESRP); and NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," for licensing radioisotope production facilities and aqueous homogeneous reactors (ADAMS Accession Nos. ML12156A069 and ML12145A075) provide guidance to the technical staff on performing the safety and environmental reviews of 10 CFR Parts 50 and 52 applications. NUREG-0800 and NUREG-1555 were written for light water reactors (LWRs). For non-LWR applications there are several efforts underway to provide guidance and the status of these activities is available on the NRC Advanced Reactors public Web site (https://www.nrc.gov/reactors/new-reactors/advanced.html). These efforts have resulted in documents that are in various stages of maturity and availability. Examples include COL-ISG-029 "Environmental Considerations Associated with Micro-reactors" (ADAMS Accession No. ML20252A076) dated October 2020; and Regulatory Guide (RG) 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors" (ADAMS Accession No. ML20091L698). Because there is less guidance available for non-LWRs and these designs feature new technologies, an acceptance review for a non-LWR may deviate from the standard criteria and process.

The documents listed above should be used to evaluate and determine the completeness and technical sufficiency of an application. RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)," and RG 1.206, "Applications for Nuclear Power Plants," Revision 1, October 2018, Section C.1.11.b, "Supplemental Information," are formal guidance documents on contents applications and can be used by staff as part of the acceptance review process. Other application-specific guidance is available in ADAMS Package Accession No. ML20283A182, which can be used for performing acceptance reviews for several types of new licensing applications (COLs, DCs, and SDAs).[2] For acceptance reviews of applications for CPs and OLs related to non-power production and utilization facilities, NUREG-1537 and its associated interim staff guidance have been used as a general technical guide for the acceptance review process.

3. BACKGROUND

The NRC staff is expected to determine the acceptability of licensing applications for new production and utilization facilities within a period of 60 days.[3] The acceptability of an application for docketing and detailed technical review is based on its technical sufficiency as well as its regulatory completeness. The technical sufficiency review is conducted to ensure that the application contains sufficient information in scope and depth for the staff to conduct its detailed technical review within a predictable timeframe. The acceptance review commences when the application is successfully processed into ADAMS.

4. BASIC REQUIREMENTS

The acceptance review consists of the following high-level processes:

- Planning the acceptance review;
- Application receipt and processing;
- Reviewing the application for regulatory completeness and technical sufficiency;
- Documenting the decision; and
- Developing the review schedule and resources.

Early and frequent communication is essential for meeting the Agency's objective for openness with all stakeholders. Throughout the acceptance review, the Lead Project Manager (PM) should encourage and maintain routine communications with the applicant, the Environmental PM (EnvPM), and the NRC review team regarding identified acceptance review issues, and document pertinent interactions in accordance with COM-101, "NRR Interfaces with NMSS," and COM-203, "Informal Interfacing and Exchange of Information with Licensees and Applicants."

[2] Guidance applicable to COL and DC applications also applies, in part, to ML applications. In deciding what guidance to apply to an ML application, a reviewer should consider whether the regulation governing MLs for the subject area of interest more closely parallels the COL or DC regulations.
[3] SRM on COMDEK-07-0001/COMJSM-07-0001: Acceptance review in a very short timeframe might be considered (on the order of 30 days or less), but this would be a rare circumstance involving advance discussions with NRR management and OGC.

5. RESPONSIBILITIES AND AUTHORITIES

All NRC staff who support the review of new licensing applications are responsible for understanding and applying the guidance contained in Enclosure 1. They are also responsible for identifying possible improvements to the guidance and submitting suggestions for such improvements to their management or to the assigned contact for this OI. The responsibilities listed below are applicable to NRC staff from other offices performing all or part of the review. OGC involvement is dependent on the acceptance review process and whether there are any issues that preclude docketing. If a decision other than acceptance is being considered, OGC consultation might be needed.

Throughout the process, NRR management is responsible for ensuring the consistent application of the process, communicating the process objectives, and providing the status to internal and external stakeholders. NRR management is responsible for clearly communicating the rationale for decisions on applications to stakeholders, as appropriate.

5.1 Project Management

Project Manager

The Lead PM within NRR, as supported by other PMs:

- Communicates with the applicant;
- Coordinates and manages activities (with EnvPM, and management) of staff review team during the acceptance review;
- Performs administrative activities associated with the acceptance review, including confirming that the application has been processed into ADAMS and coordinating the Sensitive Unclassified Non-Safeguards Information (SUNSI) review and public release. For applications that are docketed, ensure the creation of a project Web site on the NRC public Web site and update it in a timely manner;
- Reviews assigned sections to evaluate the completeness and acceptability of the application for docketing;
- Performs and documents interactions with stakeholders in accordance with the applicable NRR OI, COM-203;
- Plans, manages, and schedules acceptance review activities within the current system in use by NRR (e.g., RRPS, EPM, etc.);
- Compiles documented inputs provided by all technical branches and contractors, and, as necessary, conducts teleconferences/meetings with applicant to discuss information gaps identified by the staff;
- Refers technical staff to the pre-application readiness assessment report, if available;
- Refers technical staff to other pre-application documents (technical reports, white papers, meeting slides, etc.);

- Briefs management on review team results of acceptance review and makes a docketing recommendation to division management (NRR, NMSS, and NSIR);

- Prepares and signs letter to the applicant (Enclosure 2) describing the results of the NRC staff review and the docketing decision. If a review schedule is not included in this letter, the PM will subsequently prepare and sign a schedule letter after a schedule is established; and

- Prepares and issues in the *Federal Register* the Notice of Receipt and a Notice of Acceptance, if the application is docketed, if applicable. (A Notice of Hearing should be published in the *Federal Register* as soon as practicable after the application is docketed).

Projects Branch Chief

- Confers with the PM on the overall application acceptability for docketing based upon the results of the technical staff's review for completeness and technical sufficiency and the PM's recommendation;

- Supports management briefings of acceptance review results;

- As necessary, participates in meetings/teleconferences with applicant to better characterize nature of any information gaps;

- Obtains alignment from Technical BC's and senior management regarding the review scope and proposed schedule; and

- Facilitates the division issuing the *Federal Register* Notice of Receipt and a Notice of Acceptance, if the application is docketed. (A Notice of Hearing should be published in the *Federal Register* as soon as practicable after the application is docketed).

Environmental Project Manager

Environmental PM (EnvPM) in the Environmental Center of Expertise (COE) within NMSS:

- Coordinates activities associated with the environmental acceptance review for an ESP, DC,[4] ML,[5] COL, CP, or OL application;

- Supports the Lead PM in performing administrative activities associated with the acceptance review;

[4] The scope of the environmental review for a DC application is limited to the analysis of severe accident mitigation design alternatives (SAMDAS).
[5] The scope of the environmental review for an ML application is limited to the analysis of SAMDAs. The environmental report for an ML application need not address the environmental impacts associated with manufacturing the reactor under the ML. *See* 10 CFR 51.32(b)(3).

- Leads the completeness and technical sufficiency review of the Environmental Report (ER);
- Compiles environmental inputs from assigned technical branches and contractors, if applicable, and if necessary, conducts teleconferences/meetings with the applicant to discuss technical gaps identified by the staff;
- Immediately communicates potential issues to the Lead PM, the Environmental BC, and EnvCOE management, in the initial stage of the acceptance review;
- Provides results of environmental report acceptance review to Lead PM; and
- Supports management briefings of acceptance review results.

Environmental Branch Chief

- Confers with the EnvPM on the overall application acceptability for docketing based upon the results of the technical staff's review for completeness and technical sufficiency and the EnvPM's recommendation;
- Concurs on the FRN Notice of Hearing and on Notice of Acceptance;
- Supports management briefings of acceptance review results;
- As necessary, participates in meetings/teleconferences with applicant to better characterize nature of any environmental information gaps; and
- Ensures consensus with NRR and NMSS senior management regarding the environmental review scope and proposed environmental schedule.

5.2 Technical Branches

Technical Staff – NRR, NMSS, and other offices as assigned:

- Before beginning the acceptance review, becomes familiar with the anticipated scope of review (e.g., applicable sections of the SRP, the ESRP, or other applicable review guidance);
- Reviews assigned sections to evaluate the completeness and technical sufficiency of the application;
- Becomes familiar with other sections of the application that may have an impact on the assigned area of responsibility (e.g., Chapter 1 and risk insights) to assist in specific technical acceptance reviews;
- As necessary, participates in meetings/teleconferences with applicant to better characterize nature of any information gaps;
- Obtains (in coordination with the PM), as necessary, input and support from outside entities (e.g., Federal Emergency Management Agency, Department of Homeland Security, Corp of Engineers, Environmental Protection Agency, United States

Geological Survey, etc.) to support the completeness and technical sufficiency review of applicable sections and for the development of the baseline review schedule;

- Estimates hours to be factored into the review schedule;
- Identifies any known dependencies among concurrent review efforts (e.g., review of a DC application in parallel with the review of a COL application);
- Communicates results of acceptance review and estimated staff-hours to PMs; and
- Update schedule and resources in the current system in use by NRR (e.g., RRPS, EPM, etc.) upon completion of the acceptance review.

Technical Branch Chief

- Reviews and evaluates the significance of technical issues and the results of the staff's acceptance review and confirms that any identified technical gaps fall into the scope of the acceptance review (rather than in the scope of the detailed technical review);
- Communicates potential issues to the projects branch PM, BC, and upper management, as they are identified during the staff's acceptance review;
- Forwards acceptance review results and estimated staff hours (example in Enclosure 2) to the lead PM; and
- Supports management briefings of acceptance review results.

5.3 NSIR/NRR/NMSS Management

- Receives briefing(s) on results of the acceptance review; and
- Reviews results of acceptance review (identified information gaps and resolution strategies) and reaches a decision about docketing the application.

5.4 OGC

- Provides guidance to staff on the docketing decision for applications that may not be accepted; and
- May review potential RSIs.

6. PERFORMANCE MEASURES

Section 2.101 of 10 CFR states that the determination of acceptability will be made generally within a period of 60 days if the Commission decides to determine acceptability based on the technical adequacy of the application as well as its completeness. In the SRM for COMDEK-07-0001/ COMJSM-07-0001 the Commission approved expansion of the scope and duration of the COL application acceptance review to include completeness and technical sufficiency reviews, and the extension of the acceptance review from 30 to 60 days. For the purposes of this Office Instruction, the staff applies this direction to other new reactor licensing applications. The established

performance timeliness goal for NRR is to complete acceptance reviews for DCs, COLs, CPs, OLs, ESPs, MLs, and SDAs, within 75 calendar days of receipt of an application. This 75-day period includes a 15-day allowance for administrative processing and SUNSI review. The application will be considered received by the NRC the day that it is declared an official agency record in ADAMS.

7. PRIMARY CONTACTS

Donna Williams
Donna.Williams@nrc.gov
301-415-1322

Allen Fetter
Allen.Fetter@nrc.gov
301-415-8556

8. RESPONSIBLE ORGANIZATIONS

DANU and DNRL

9. EFFECTIVE DATE

January 28, 2021

10. CERTIFICATION DATE

January 28, 2026

11. REFERENCES

1. Title 10, *Energy*, Part 52, of the *Code of Federal Regulations* (10 CFR Part 52), "Licenses, Certifications, and Approvals for Nuclear Power Plants."

2. Title 10, *Energy*, Part 50, of the *Code of Federal Regulations* (10 CFR Part 50), "Domestic Licensing of Production and Utilization Facilities."

3. Title 10, *Energy*, Part 2, "Agency Rules of Practice and Procedure."

4. Title 10, *Energy*, § 2.101, "Filing of Application."

5. Title 10, *Energy*, § 2.102, "Administrative Review of Application."

6. Title 10, *Energy*, § 2.107, "Withdrawal of Application."

7. Title 10, *Energy*, § 2.108, "Denial of Application for Failure to Supply Information."

8. Title 10, *Energy*, § 2.815, "[Standard Design Certification] Docketing and acceptance review."

9. COMDEK-07-0001/COMJSM-07-0001, “Report of the Combined License Review Task Force,” (ADAMS Accession No. ML071090128).

10. LIC-111, Revision 1 “Regulatory Audit,” (ADAMS Accession No. ML19226A274).

11. NRC Audit Plan, to Tennessee Valley Authority, from Allen Fetter, Division of New Reactor Licensing, Office of New Reactors, “Audit Plan for Areas Covered in Section 2.5 of the Site Safety Analysis Report, Clinch River Nuclear Site Early Site Permit Application,” (ADAMS Accession No. ML17108A822).

12. NRC Memorandum to Joseph Colaccino, Division of New Reactor Licensing, Office of New Reactors, from Allen Fetter, Division of New Reactor Licensing, Office of New Reactors, “Summary Report for the May 8-9, 2017, Geology, Seismology, and Geotechnical Engineering Information Audit (Section 2.5 of the Site Safety Analysis Report), Tennessee Valley Authority, Early Site Permit Application, Clinch River Nuclear Site,” (ADAMS Accession No. ML17223A428).

13. NRC Memorandum to Joseph E. Donoghue, Division of New Reactor Licensing, Office of New Reactors, from Allen Fetter, Division of New Reactor Licensing, Office of New Reactors, “Summary of Meeting Between the U.S. Nuclear Regulatory Commission and Tennessee Valley Authority to Discuss Topics Associated with Sections 2.1, 2.2, And 2.3 In Part 2, Site Safety Analysis Report of Tennessee Valley Authority's Early Site Permit Application for the Clinch River Nuclear Site,” (ADAMS Accession No. ML17054D545).

14. Letter from J.W. Shea, Tennessee Valley Authority to Document Control Desk, NRC, “Submittal of Supplemental Information Related to the Exclusion Area Boundary and Population Distribution Around the Clinch River Nuclear Site in Support of the Early Site Permit Application,” (ADAMS Accession No. ML17107A080).

15. LIC-109, Revision 3 “Acceptance Review Procedures for Licensing Basis Changes,” (ADAMS Accession No. ML20036C829).

16. NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants; LWR Edition,” (ADAMS Accession No. ML070660036).

17. NUREG-1555, “Standard Review Plans for Environmental Reviews for Nuclear Power Plants.”

18. NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors,” for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors (ADAMS Accession Nos. ML12156A069 and ML12145A075).

19. COL-ISG-029, “Environmental Considerations Associated with Micro-reactors,” (ADAMS Accession No. ML20252A076).

20. RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” (ADAMS Accession No. ML20091L698).

21. RG 1.70, “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition),” (ADAMS Accession No. ML14272A331).

22. RG 1.206, “Applications for Nuclear Power Plants,” Revision 1, Section C.1.11.b, “Supplemental Information,” (ADAMS Accession No. ML18131A181).

23. LIC-117, “Supporting Guidance Documents, (ADAMS Package No. ML20283A182).

24. COM-101, “NRR Interfaces with NMSS,” (ADAMS Accession ML20941D873).

25. COM-203, Revision 2, “Informal Interfacing and Exchange of Information with Licensees and Applicants,” (ADAMS Accession No. ML082940232).

26. LIC-116, “Pre-application Readiness Assessment,” ADAMS Accession No. ML ML20104B698).

27. NRC/OIS, “Guidance for Electronic Submissions to the NRC,” (ADAMS Accession No. ML13031A056).

28. SECY-04-191, “Withholding Sensitive Unclassified Information Concerning Nuclear Power Reactors from Public Disclosure,” (ADAMS Accession No. ML042310663).

29. LIC-204, Revision 4, "Handling Requests to Withhold Proprietary Information from Public Disclosure" (ADAMS Accession No ML20049A139).

30. 10 Title 10, *Energy* 810, https://drupal.nrc.gov/sunsi

31. “Acknowledgement of the Receipt of the Custom Combined License Application Aurora Powerhouse and Associated Federal Register Notice,” (ADAMS Accession No. ML20083G75).

32. “Review Guide for COL Application Acceptance Review,” (ADAMS Accession No. ML20283A183).

33. “Review Guide for DC and SDA Application Acceptance Review,” (ADAMS Accession No. ML20283A185).

34. RG 4.2, “Preparation of Environmental Reports for Nuclear Power Stations,” (ADAMS Accession No. ML18071A400).

35. Micro-Reactor License Application COL-ISG-029, “Environmental Considerations Associated with Micro-Reactors, Interim Staff Guidance – Draft,” (ADAMS Accession No. ML19234A216).

36. “New Reactor Licensing Process Lessons Learned Report,” (ADAMS Accession No. ML13059A239).

37. “Commission’s Final Policy Statement on the Use of PRA Methods in Nuclear Regulatory Activities,” (60 FR 42622, August 16, 1995).

38. “List of SAR Review Areas Potentially Involving More Detailed Review,” (ADAMS Accession No. ML072430683).

39. “Environmental Review Acceptance Checklist for Early Site Permit and Combined License Applications,” (ADAMS Accession No. ML16085A014).

40. Section 102(c) of the Nuclear Energy Innovation and Modernization Act (NEIMA), January 14, 2019

41. “Generic Communication Plan for Review for the Review of Combined License Applications,” Revision 1, (ADAMS Accession No. ML091470473).

Enclosures:
1. Guide for Performing Acceptance Reviews for New Reactor Licensing Applications
2. Template of Branch Memo and Letter to Applicant Documenting Acceptance Review Results
3. Timeline for Application Readiness and Acceptance Review
4. Appendix A – Change History

ENCLOSURE 1

Guide to Performing Acceptance Reviews for New Reactor Licensing Applications

INTRODUCTION

This guide provides staff in the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Reactor Regulation (NRR) with a basic framework and process to follow for performing an acceptance review of an application for a design certification, standard design approval, manufacturing license, early site permit, construction permit, limited work authorization, operating license, or combined license. The guide is for use by project managers (PMs), technical staff, and their respective management. Additionally, this guide is for use by NRC staff in other offices when they are performing an acceptance review of an application at the request of NRR (e.g., emergency plan review, environmental review, etc.). The NRR PM should follow the appropriate procedure for requesting work from another office.

While this guide is intended to be comprehensive, there may be some unique applications and circumstances that may not be covered in this guidance, and reasonable flexibility should be considered, as needed. Consideration of departures from this guidance should be discussed with management and documented.

Process Overview

The NRR process for the review of new licensing applications begins with the acceptance review. The performance of an acceptance review is an important part of the NRC's overall review process. When properly implemented, acceptance reviews allow for a more efficient use of NRC staff resources and foster the submittal of applications that are acceptable for NRC's review.

Frequent and early communications between the NRC staff and the applicant can help avoid unnecessary delays in the processing of submittals. Pre-application review meetings or conference calls (discussions regarding future applications prior to the request being submitted) between the applicant and NRC staff members can be beneficial and are encouraged.

The acceptance review is described in detail in the following sections:

Section 1.0 – Planning the Acceptance Review
Section 2.0 – Application Receipt and Processing
Section 3.0 – Regulatory Completeness and Technical Sufficiency Review
Section 4.0 – Docketing Decision
Section 5.0 – Developing the Review Schedule and Resource Estimates

1.0 Planning the Acceptance Review

Pre-application Interactions

An applicant's early interaction with the NRC, as described in a Regulatory Engagement Plan, is a critical first step. Applicants are also encouraged to provide early identification of regulatory requirements for a given application and to provide the staff with the opportunity to have an advance look at the environmental, safety, and security characteristics of the site and/or design described in the draft application. Such licensing interaction and guidance early in the application development process will contribute towards minimizing complexity and adding stability and predictability in the licensing and regulation of production and utilization facilities.

On a voluntary basis, a prospective applicant may engage the NRC in the following areas: administrative, planning, application organization, a preview of the draft application, technical issues, and pre-application readiness assessment (see LIC-116, "Pre-application Readiness Assessment," ADAMS Accession No. ML20104B698). The purpose of interactions on technical issues is for the staff to become familiar with the application (or new facility design), particularly in areas where prospective applicants are proposing new technologies, design concepts, or analysis methodologies. Such interactions will help identify policy or technical issues early in the process to enable the NRC to effectively and efficiently plan its review work and address NRC infrastructure needs.

For applications that may raise potentially challenging and complex technical and regulatory issues, early pre-application engagement (that includes NRC management, PMs, and associated technical reviewers) is recommended (18 to 24 months before submission). This early engagement might include the submission of topical reports and white papers. While pre-application engagement activities are not part of the NRCs official acceptance review process and does not predetermine whether the application will be docketed, those activities can result in significant savings of both time and resources for both the acceptance review and subsequent application review by familiarizing the NRC staff with the technical aspects of the application and providing the prospective applicant insights on NRC processes.

Pre-application Readiness Assessment

The pre-application readiness assessment (see LIC-116) allows the NRC staff to: (1) identify information gaps between the draft application and the technical content required to be included in the final application submitted to the NRC, (2) identify major technical and/or policy issues that may adversely impact the docketing or technical review of the application, and (3) become familiar with the application, particularly in areas where prospective applicants are proposing new concepts or novel design features. The results of the readiness assessment will inform a prospective applicant in finalizing its application and assist the NRC staff in planning its resources for the review once the application is formally submitted. The staff should plan to engage prospective applicants to schedule a pre-application readiness assessment at least 6 months prior to the expected date of application submittal. The readiness assessment is optional and highly recommended but is not part of the NRC's official acceptance review process and does not predetermine whether the application will be docketed.

Declaration of the Expected Application Submission Date

The NRC encourages each prospective applicant to declare its intent to submit an application, via letter, including its anticipated application submission date, no later than 90 days in advance of the arrival of the submission. This helps NRC management prepare for and allocate staff resources for both a timely application acceptance review and, if docketed, a timely and predictable application review.

Planning the Acceptance Review

In anticipation of an application submission, the PM and management should ensure that the staff resources are in place to perform a timely acceptance review consistent with application-specific expectations. The lead PM should identify the review team members and develop a proposed schedule for the acceptance review, and set up the necessary CAC/EPID numbers, before receipt of the application. The acceptance review should be completed, and a letter provided to the applicant

within 60 calendar days from when the application is available in ADAMS. At the first review team meeting after the application is received, the acceptance review schedule will be discussed to determine if the review can be completed in accordance with the 60-day timeframe. A proposed acceptance review schedule is included in Enclosure 3 of this OI. Other preparatory actions that should be completed by the PM in anticipation of receipt of the application, such as developing a communication plan, are listed in Enclosure 3.

2.0 Application Receipt and Processing

Electronic Submission

The lead PM, supported by the Office of the Chief Information Officer, ensures the application follows the guidelines provided in "Guidance for Electronic Submissions to the NRC," (ADAMS Accession No. ML13031A056) and coordinates with the Document Processing Center for processing the application into ADAMS. The application will initially be treated as tendered.

SUNSI Review

The lead PM as supported by the Environmental PM (EnvPM) performs a SUNSI[6] review in accordance with the guidance in SECY-04-191, "Withholding Sensitive Unclassified Information Concerning Nuclear Power Reactors from Public Disclosure," (ADAMS Accession No. ML042310663). As applicable, the Lead PM reviews the applicant's request to withhold proprietary information from public disclosure in accordance with NRR Office Instruction LIC-204, Revision 4, "Handling Requests to Withhold Proprietary Information from Public Disclosure" (ADAMS Accession No. ML20049A139), Security-related information should also be withheld from public disclosure by the applicant in accordance with 10 CFR 2.390(d). Information withheld as Export Controlled Information under 10 CFR Part 810 should be handled with additional precautions described in https://drupal.nrc.gov/sunsi on protecting proprietary and export controlled information (ECI). Additional information on the requirements for marking, handling, and disposing of SUNSI is available through https://drupal.nrc.gov/sunsi. *Note: An affidavit is not required to be prepared to withhold security-related information and ECI from public disclosure. Additionally, the NRC staff does not make a determination on whether or not information marked as ECI is to be withheld. Applicants should align with the U.S. Department of Energy on information to be withheld as ECI prior to submission.* The tendered application should be made publicly available after the SUNSI review is completed. The proprietary review should be completed as soon as practicable (usually within 10 days). Administrative templates are located as an enclosure to LIC-204.

Notifications and Publication

The NRC recognizes the public's interest in the proper regulation of nuclear activities and provides opportunities for citizens to be heard. Therefore, once the SUNSI review is competed and the application is processed into ADAMS, the lead PM should publish the Notice of Receipt and Availability of the application and send a letter to the applicant acknowledging its receipt

[6] Note that the term "SUNSI" will be replaced by the term "CUI" (Controlled Unclassified Information) in the future and staff will need to conduct the CUI review in accordance with the associated guidance.

(see example letter – "Acknowledgement of the Receipt of the Custom Combined License Application Aurora Powerhouse and Associated Federal Register Notice (ADAMS Accession No. ML20083G752). If the application is docketed, the PM should issue a *Federal Register* Notice and create a Web page on the NRC public Web site providing application and licensing information.

Notifications to Review Team

The lead PM, in coordination with the EnvPM, will provide notification to the review team when the application is available in ADAMS and provide the CAC number under which the acceptance review resource expenditures will be captured. If an advance copy of the application is available, the lead PM will distribute this to the review team. Throughout the acceptance review process, the lead PM, EnvPM and Technical Leads should inform their respective Branch and Division level management of issues identified during the acceptance review and provide status updates on the acceptance review progress on a weekly basis.

3.0 Regulatory Completeness and Technical Sufficiency Review

Once the application is available in ADAMS,[7] the completeness and technical sufficiency review will be initiated by the technical staff in parallel with the administrative processing steps.

During the acceptance review, the review team should look for the following:

- Use of unapproved information. Such information may include: guidance that the NRC has not approved or issued in final form, computational codes or methodologies that the NRC has not reviewed and approved for the proposed application, or any codes or standards that the NRC has not reviewed and endorsed in the regulations or regulatory guides (RGs). Use of such information may involve added resources for the staff during the technical review;

- Exemptions that are requested. Also look for cases where exemptions may be needed but have not been requested;

- Completeness of the application to conform with the requirements for the contents of applications in the following sections of 10 CFR Part 50, 10 CFR Part 51, and 10 CFR Part 52, Section 51.45 (General), Sections 50.33, 50.34, and 51.50 (CPs and OLs), 51.50, 52.16 and 52.17 (ESPs); 51.55, 52.46 and 52.47 (DCs); 51.50, 52.77, 52.79, and 52.80 (COLs); 52.136 and 52.137 (SDAs); 10 CFR 2.643 and 50.10(d) (LWAs); and 51.54, 52.156, 52.157, and 52.158 (MLs). Look for analyses (or summaries of analyses) that may be missing from the application;

- Sufficiency of information to support conclusions. Look for references that support conclusions made in the application. If there are no references or indications of how the information was developed, is correct, applicable, etc., identify this during the acceptance review. If the referenced information, or portions of it, is necessary to demonstrate the application is technically sufficient because the application does not summarize that information, then the referenced information or a summary of it must be submitted as part of the application. If the information merely confirms the validity of information submitted in the application, then the referenced information may need to be audited during the detailed review following acceptance; and

[7] The timeframe associated with availability in ADAMS is approximately 5 days, if there are no processing problems requiring an electronic re-submission.

- Regulatory basis/approved guidance. Look to see if the applicant has adequately identified the regulatory criteria/guidance used to write the application. In areas where the applicant has determined the existing regulatory criteria/guidance is not applicable for a non-LWR, advanced LWR or other technology, verify that alternate criteria/guidance has been proposed and justified.

To perform the acceptance review, the staff has developed application-specific guidance for certain types of licensing applications, as follows:

- Review guide for COL application acceptance review (ADAMS Accession No. ML20283A183)

- Review guide for DC and SDA application acceptance review (ADAMS Accession No. ML20283A185)

- RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants," applicable for CP applications.

- RG 1.206, "Applications for Nuclear Power Plants,"

- Environmental guidance for reactor licensing as described in RG 4.2, "Preparation of Environmental Reports for Nuclear Power Stations" (ADAMS Accession No. ML18071A400), and Micro-Reactor License Application COL-ISG-029, "Environmental Considerations Associated with Micro-Reactors, Interim Staff Guidance - Draft" (ADAMS Accession No. ML19234A216)

- Interim Staff Guidance Augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors (ADAMS Accession Nos. ML12156A069 and ML12145A075).

During the completeness and technical sufficiency reviews (prior to the acceptance review decision), technical staff should discuss identified information gaps with branch chiefs and also notify the lead PM of the significant gaps as soon as they are identified. Significant information gaps should be shared with division management and be discussed with the applicant in order to convey the nature of the gaps and the timeframe for the applicant to address the gap. The staff may also choose to issue management-approved requests for supplemental information (RSIs) to the applicant (prior to the acceptance review decision) as a means to ensure timely receipt of information submitted by the applicant in response to the RSIs prior to docketing of the application or issuance of the review schedule (for cases where a decision is made to docket the application before receipt of the RSI responses).

Completeness Review

The completeness portion of the acceptance review verifies that the application contains all of the information required by applicable regulations set forth in 10 CFR Parts 50 and 52. For licensing applications, the completeness review is conducted by the PMs and technical staff

by comparing the information in the application against applicable checklists and guidance documents available for the particular type of license application. ADAMS accession numbers to guidance documents and checklists are listed above.

As part of the determination of completeness, the staff should review introductory information in an application. This material can provide useful information addressing general regulatory considerations including conformance with the Standard Review Plan (SRP) and Environmental SRP (ESRP), and identification of new safety features. The staff should consider whether the application identifies and describes the differences between the design, analysis, and procedures proposed for a facility and the corresponding SRP acceptance criteria. For a COL application referencing an ESP or design certification, the introductory material should also identify any action items and permit conditions from previous licensing actions (design certifications and ESPs) as well as any proposed variances from an ESP or departures from a DC in the application. The appropriate staff should also review parts of the application that are required to provide information on whether site characteristics fall within site parameters, including any departures or variances.

Technical Sufficiency Review

For the technical sufficiency portion of the acceptance review, the staff evaluates the application in terms of expected technical content identified in the SRP, ESRP, design specific review standard (DSRS) or other guidance documents and identifies significant technical gaps. Thus, the staff verifies that the application contains sufficient technical information in scope and depth to conduct the detailed technical review within a predicable timeframe.

The minimum criteria that the staff should consider when deciding whether or not an application contains enough information to conduct the review, complete it within a predictable timeframe, and docket the application are:

- Is the level of detail sufficient for the staff to make a regulatory determination with no more than two rounds of requests for additional information (RAI)?

- Does the application introduce a new methodology or safety feature?

    - Does the regulatory framework, including the principle design criteria, adequately address the methodology or safety feature;

    - Does the new methodology or safety feature create a knowledge gap; and

    - Has all of the information necessary to review the new methodology or safety feature been submitted for review?

- Are the applicable regulations and acceptance criteria properly addressed?

    - Does the applicant provide justification for exceptions or differences with the applicable guidance documents; and

    - Does the justification seem adequate?

- Has all needed testing been completed by the applicant? Are there significant analyses or evaluations missing? Are sufficient data available to support the staff's independent modeling?

A "technical gap" (safety or environmental) is defined as technical information needed by the NRC staff to conduct the assigned review, but which is missing from the application or is unsupported, inadequate, or incorrect. A minor technical gap can be addressed in reasonable rounds of RAIs and without impacting the overall review schedule for the application. As stated in the Lessons Learned Report (ADAMS Accession No. ML13059A239), the term "reasonable rounds of RAIs" generally means two rounds of RAIs while precluding any adverse impact on the review schedule. A significant technical gap is missing or has incorrect information that results in the staff being unable to conduct its review of the application against the acceptance criteria in the applicable guidance (i.e., SRP, DSRS, etc.) and make the necessary regulatory finding within a predictable timeframe. The technical staff, in coordination with the PM, should discuss significant technical gaps with the applicant to ensure a common understanding of the issue. If supplemental information is necessary, the timeframe and schedule for submitting the information should be established and the supplemental information should be received prior to docketing the application (or, at a minimum, prior to establishing a review schedule for the application for cases where management has decided to docket the application despite the need for RSIs). Supplemental information should be received within 6 months after the initial docketing decision.

The following are some of the tools available to assist the staff in performing its technical sufficiency review.

- Risk insights from an ongoing or completed DC application review should be available for a COLA that references a DC. The timeframe in which the risk insights are reviewed and distributed among the staff will determine the extent to which risk insights can inform the scope of the acceptance review. Consistent with the Commission's Final Policy Statement on the Use of PRA Methods in Nuclear Regulatory Activities (60 FR 42622, August 16, 1995), risk insights should be used during the acceptance review to help determine the scope of the technical sufficiency review. The staff should focus its technical sufficiency review on systems, structures, and components (SSCs) that have been identified as risk-significant;

- A list of review areas identified in the SRP that may potentially involve more detailed technical review (e.g., involve computer code evaluation, detailed data analysis, new safety feature, or emerging operating experience) has been developed for use by staff (ADAMS Accession No. ML072430683). Note that not all SRP sections are represented in the list. The time it will take to review these areas should be factored into the technical sufficiency review and confirmation of planning assumptions, development of the baseline schedule, and adjusted staff-hours;
- An Environmental Acceptance Review Checklist for ESP and COL applications has been developed for use by staff (ADAMS Accession No. ML16085A014). This list should be used to help determine technical sufficiency for the environmental review areas of large light water reactors and is a comprehensive set of review issues based on RG 4.2 and NUREG-1555 applicable to ESP and COL applications. For reviews other than large light water reactors, see the environmental guidance documents previously described in this OI; and

- The staff may use an audit (or audits) to support its technical sufficiency review. Guidance for audits is described in LIC-111.

Documenting Technical Staff Results

Once the technical staff completes the acceptance review, each technical Branch Chief documents the acceptance review findings by memorandum or email to the appropriate Projects Branch Chief. Enclosure 2 contains a template memorandum that can be used by the Technical Branch Chiefs to transmit their acceptance review results to the appropriate licensing or projects branch.

The lead PM, in coordination with the EnvPM, will compile the results of the acceptance reviews that are documented in the technical branch memoranda and clearly identify any significant information gaps that have implications for the acceptance review decision.

Communicating Gaps to Applicant

For areas in which significant administrative completeness and technical gaps were identified, the technical areas and nature of the gaps should be shared with the applicant before an acceptance review decision is made. The lead PM and EnvPM should arrange public meetings or teleconference(s) with the applicant, as necessary, to discuss these information gaps (meetings may have a closed portion for proprietary information). The objective of these interactions is to allow the staff and applicant to have a mutual understanding of the information gaps and the timing/ability of the applicant to address them. In certain cases, the applicant may be able to point the staff to other areas of the application where the gaps may be addressed. The PMs should document interactions as an official agency record by creating a summary of each call and adding it to ADAMS. The results of these discussions will be used by NRC management to support its decision on docketing of the application.

4.0 Docketing Decision

The review team will confer during team meetings and make a recommendation regarding acceptance of the application. The lead PM, EnvPM, and lead technical reviewers will present and discuss the recommendation with the Branch and Division level management.

The following factors should be considered in reaching this decision:

- The number of administrative completeness and technical gaps;
- The safety significance of the gaps in substantive safety information; and
- The time the applicant will need to develop or prepare the supplemental information (Generally, within 6 months if the application is not acceptable for docketing).

These factors should be considered for each application. Ultimately, the goal of the acceptance review is to determine with a high level of confidence that the application review can be completed within a predictable timeframe, but there may be other factors that management might take into consideration in making a decision on whether to docket or not (e.g., rare circumstances, first of a kind application, etc.). In either case, a review schedule should not be issued until receipt of technically sufficient information needed to support the application review (such as adequate responses to any RSIs issued).

The lead PM, with support from the EnvPM and technical staff, presents to senior management the results of the technical staff review of the application, and any supplemental information obtained through communications with the applicant that is submitted to the NRC document control desk.

The possible outcomes of the completeness and technical sufficiency portions of the acceptance review are as follows:[8]

A. Application Acceptable for Docketing

The staff has determined that the application contains sufficient information to conduct its detailed technical review within a predictable timeframe for the following reasons:

- The number of administrative or technical (safety and environmental) gaps is small and none is significant (e.g., level or depth of deficiency);

- If there are any information gaps identified, these can likely be resolved in the detailed technical review on a predictable schedule.

If management agrees with the staff's determination, the application is accepted for docketing. The lead PM communicates the status and results of the acceptance review internally and externally in accordance with the guidance provided below.

Note that the docketing of the application does not guarantee a fixed review schedule. Schedule changes could arise due to the risk associated with the complex aspects of nuclear plant licensing.

The schedule and resource estimates may be provided in a separate letter but should be sent within a defined timeframe or specified milestones stated in the application acceptance letter (usually within about 60 days of staff having received all information deemed necessary to set the schedule). The staff may determine that it needs additional information on specific areas of the application to set a review schedule. In this case, RSIs may be included in the acceptance letter and the staff will provide a review schedule upon receipt of acceptable responses.

[8] The acceptance review outcomes presented in this OI correspond to the acceptance review results described in Section 3.2 of LIC-109: Acceptable for Review; Unacceptable with Opportunity to Supplement; Unacceptable with No Opportunity to Supplement, respectively. The descriptions of review outcomes in this OI provide staff with more detailed guidance for determining the acceptability of complex initial license applications where increased coordination may be necessary among technical staff, project managers, management, and licensee personnel may be needed to reach a determination on the ultimate acceptability of an application.

B. Application Not Initially Acceptable for Docketing – Acceptance Contingent on Receipt of Specific Supplemental Information

The staff has determined that the application does not contain sufficient information to conduct its technical review or does not contain sufficient information to develop a schedule. For example:

- The number of administrative or technical (safety and environmental) gaps is moderate and resolving these gaps during the detailed technical review would likely create a schedule risk unless they are remedied before the detailed review starts; and
- The application completely omits information required by applicable regulations or includes incorrect information that can be remedied by the applicant within 6 months or less.

If the staff determines that the applicant could likely address the missing or incorrect information within 6 months, and management agrees, the staff may issue a letter with a request for supplemental information (RSI). During this period of time, the application will be considered to be tendered but not docketed. Any decision to pursue technical review of parts of the application that have no gaps would need to be made by NRR management, in consultation with OGC, and in coordination with the applicant. The application will be docketed, and a review schedule will be transmitted to the applicant only if the staff has reviewed the RSI responses and concluded that the application is sufficiently complete to complete the detailed technical review within a predictable timeframe.

If the applicant does not respond to the RSIs on the designated schedule or the staff determines that the responses to the RSI are inadequate, the staff will communicate with the applicant (via public meetings or clarification call) and recommend to management that the application not be docketed. Management will communicate this to the applicant who may choose to withdraw its application before the staff issues the letter informing the applicant of the staff decision to refuse to docket the application. If the applicant withdraws the application and then resubmits it with the deficiencies corrected, the NRC will conduct a limited acceptance review of the new or modified information (This limited acceptance review should be completed in less than 60 days).

C. Application Not Acceptable for Docketing

The staff has determined that the application does not contain sufficient information to conduct its detailed technical review within a predictable timeframe if any of the following reasons is true:

- There are multiple administrative completeness and technical (safety and/or environmental) gaps in the application of which several are significant and cannot be resolved through a reasonable number of rounds of RAIs;
- Complete omission of information required by applicable regulations and a significant effort or amount of time would be necessary to develop the information (more than 6 months); and
- One or more instances of incorrect information that does not have a clear resolution path (in 6 months or less) and would likely have a significant impact to the review schedule.

If management agrees with the staff's determination, the application is not accepted for docketing. The staff should communicate the information gaps to the applicant in accordance with COM-203. The staff can either issue a letter of non-acceptance or the applicant can choose to withdraw its application before a non-acceptance letter is issued. The applicant can choose to resubmit its application once the information gaps are corrected. Subsequent to the revised submission, the NRC may conduct a limited acceptance review of the new or modified submitted information (This limited acceptance review should be completed in less than 60 days).

Internal Communication of Acceptance Decision

Once a determination is made on the acceptability of an application for docketing, the lead PM and the Projects Branch Chief should promptly communicate the decision to internal stakeholders. If an application is not acceptable for docketing, the PM should communicate promptly to the technical staff to ensure that no resources will be expended on the technical review of the application. In addition, the lead PM, should (1) develop a Communication Plan, (2) inform the Office of the Executive Director of Operations (EDO) via an EDO daily note and conduct an EDO briefing, and (3) inform the Commission via a Commissioner's Assistant note and may conduct a Commissioner's Technical Assistant briefing.

Communications with Applicant

During the acceptance review period, the Lead PM, supported by the appropriate staff, branch chiefs and senior management, should regularly communicate the status of the staff's review with the applicant in accordance with COM-203. Early communication with the applicant by management is especially important if significant information gaps are identified by staff. This allows for earlier discussion and implementation of corrective actions needed to supplement an application prior to docketing.

Once the lead PM and management have made a determination on the acceptability of the application, the Lead PM will prepare the official letter (see Enclosure 2) communicating to the applicant the result of the acceptance review.

If the application is accepted, the review team with input from the Branch and Division level management will recommend if a review schedule will be provided in the acceptance review letter. If the acceptance review letter to the applicant does not contain the application review schedule, it should include a date or milestone by which the schedule will be provided. Generally, this will be within about 60 days of the acceptance review letter or following receipt of technically sufficient responses to any RSIs issued, whichever is later. This letter will include the application review schedule and the key milestones in the project and could include resource estimates for the review.

5.0 Developing the Review Schedule and Resources

The lead project manager develops the review schedule. The NRC has established generic schedules for licensing reviews in response to Section 102(c) of the Nuclear Energy Innovation and Modernization Act (NEIMA), which requires the NRC to develop performance metrics and milestone schedules for "requested activities of the Commission," including new reactor licensing applications. When the generic milestone schedules were established, the NRC staff noted that it will work with each licensee or applicant to establish a specific schedule for each request, which may be shorter or longer than the generic milestone schedule based on the specific needs of the applicant and the staff's availability.

A. Generic Milestone Schedule - The application is sufficiently complete to conduct a detailed technical review and complete it on a predictable schedule. For these applications, the staff should use the generic schedule for issuance of the final safety evaluation published on the NRC Web site. This does not preclude staff's use of reasonable rounds of RAIs (normally one or two rounds) during the evaluation.

B. Adjusted Milestone Schedule – For some applications, additional time beyond the generic milestone schedule will be needed to reach the required regulatory findings. An application should contain sufficient technical detail for the staff to estimate this additional time. A schedule that accounts for the complexity or uniqueness of the review will be transmitted to the applicant with the acceptance letter.

   An adjusted milestone schedule may also be shorter than the generic milestone schedule if the NRC staff determines one or more of the following:

   1) there are minimal administrative and technical gaps identified during the acceptance review;

   2) the application is of low technical, licensing, and/or policy complexity;

   3) the review of the application may be completed with limited anticipated need for requests for additional information, regulatory audits, public meetings, or other engagement between the NRC staff and the applicant to resolve information gaps; or

   4) external factors exist (e.g., public need or legislative directive).

Another factor to consider in establishing the review schedule are dependencies among concurrent reviews. Dependencies may include a COL referencing a DC, an application referencing an unapproved topical report, or interagency consultations and approvals associated with the environmental review. These dependencies should be identified by the technical staff to assist the integrated management of any concurrent reviews.

The staff should communicate to the applicant that completion of the final safety evaluation and final environmental impact statement within the established schedule is dependent, in part, on the following:

- The applicant submits adequate responses to requests for additional information (RAIs) and other necessary information within agreed upon milestones.

- There are no significant substantive changes to the application after submittal.

Resources

The technical branch chiefs (In NRR and other supporting offices) and EnvPM should provide estimates in terms of total staff resource hours needed for the branch assigned task(s) to the lead PM. The lead PM will consolidate the inputs from the technical branches and recommend a total number of staff hours that is expected to complete the review of the application. The input should also include resources needed for contract support [dollar amount] as a contingency for technical support for the safety review and/or preparation of the environmental impact statement.

ENCLOSURE 2

Template of Branch Memo and Letter to Applicant Documenting Acceptance Review Results

EXAMPLE 1: BRANCH MEMO

[DATE]

MEMORANDUM TO: [Branch Chief Name], Chief
[Name of PM Branch]
[Name of Division]
Office of Nuclear Reactor Regulation

FROM: [Branch Chief Name], Chief
[Name of Technical Branch]
[Name of Division]
[Name of Office, if outside NRR]

SUBJECT: ACCEPTANCE REVIEW RESULTS FOR THE [NAME OF APPLICATION] [Application type] APPLICATION

[Name of branch (branch acronym)] has completed its acceptance review of the [XXXX] [application type: submitted by [Applicant XXX (applicant acronym)]. This review covered the following Section[s] of the application for which [branch acronym] has [primary/secondary] review responsibilities.

Based on our review, the XXX Branch have concluded that the application contains the information required by applicable regulations and that the submitted information is technically sufficient for [branch acronym] to conduct the detailed technical review of the [XXXX application].

[***Alternate paragraph to be used when a section(s) is not technically sufficient***] Based on our review, we have concluded that the application includes information to address the applicable regulations. However, that information is not technically sufficient to address the regulations, which precludes the staff from conducting an effective and efficient technical review and, therefore, precludes the development of a specific review schedule at this time. [Branch acronym] cannot commence the detailed technical review of the [Name of Application] without the information identified in Enclosure 1.

Header Information: First initial of Branch Chief's name. Last name

The significant technical information gaps are as follows. [List as appropriate]

(Optional) Prepare Request for Supplemental Information (RSIs) for the applicant to address significant technical information gaps or remedy missing or incorrect information.

Schedule

The [XXX Branch] is establishing a detailed review schedule of [xx months] from the time of docketing the application to issuance of the final safety evaluation report which will support making a final determination on the applicant's request. The [XXX Branch] anticipates that the total level of effort needed to complete the milestones detailed in the technical review schedule will be up to [number] staff hours. The NRC staff has also budgeted for up to [dollar amount] in contract support [as a contingency for technical support for the safety review and/or preparation of the environmental impact statement].

Review Dependencies.

[Branch acronym]'s detailed technical review of the [Name of Application], is dependent on [Name of Agency] completing its respective review task and providing input to [Branch acronym].

[Alternate paragraph: [Branch acronym]'s detailed technical review of the [Name of Application] is independent of other ongoing application reviews by the staff.]

Enclosures: (if applicable - *this format is used when document contains two or more enclosures*)
1. Title
2. Title

DISTRIBUTION:
NRR/Division [Lead PM] [Supporting PM] [EnvPM] [Other Technical Branches that have primary/secondary review]

ADAMS Accession No.:

OFFICE			
NAME			
DATE			

OFFICIAL RECORD COPY

EXAMPLE 2: ACCEPTANCE REVIEW RESULTS OF AN APPLICATION

[DATE]

[ADDRESSEE]

SUBJECT: ACCEPTANCE OF THE [NAME OF APPLICATION] [TYPE OF APPLICATION] APPLICATION – [NAME OF APPLICANT]

Dear [Addressee]:

By letter to the U.S. Nuclear Regulatory Commission (NRC) dated [Date], [Name of Applicant] submitted an application for a [type of application] for the [Name of Application or Proposed Facility], pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) [Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." [OR] Part 50, "Domestic Licensing of Production and Utilization Facilities."] The purpose of this letter is to inform you of the results of the NRC staff's acceptance review of this application.

[FOR COMPLETE APPLICATION USE THESE PARAGRAPHS]
In accordance with 10 CFR 2.101 and [10 CFR 50.33, 50.34, and other Part 50 substantive requirements for CPs and OLs, 10 CFR 52.46 and 52.47 for DCs, 10 CFR 52.77, 52.79, and 52.80 for COLs, 10 CFR 52.16 and 52.17 for ESPs, 10 CFR 52.136 and 52.137 for SDAs, 10 CFR 52.156, 52.157 and 52.158 for MLs] or [10 CFR 2.643 and 50.10(d) for LWAs], the NRC staff performed an acceptance review to determine if the [Type of Application] application for the [Name of Application or Proposed Facility] contains sufficient technical information in scope and depth to allow the NRC staff to conduct its detailed technical review and complete it on a predictable schedule.

In accordance with 10 CFR Part 2, "Agency Rules of Practice and Procedure," [Part 50/Part 52], and agency procedures, the NRC staff performed an acceptance review of the [xxx] application, assessed the various criteria and considerations specified in agency procedures associated with accepting an application, and concluded that the application is acceptable for docketing. The docket number established for the xxx is xx.

The NRC staff is establishing a detailed review schedule of [xx months] from the time of docketing the application to issuance of the final safety evaluation report, which will support making a final determination on your request. [The following text is at the discretion of management] The NRC staff anticipates that the total level of effort needed to complete the milestones detailed in the technical review schedule will be up to [number] staff hours. The NRC staff has also budgeted for up to [dollar amount] in contract support [as a contingency for technical support for the safety review and/or preparation of the environmental impact statement]. If there are emergent complexities or challenges in our review that would cause changes to the initial forecasted completion date or significant changes in the forecasted hours, the reasons for the changes, along with the new estimates, will be communicated during the routine interactions with the assigned project manager.

[insert the following if the generic milestone schedule is to be used] This review schedule is consistent with the [*insert appropriate review schedule length established here:* *https://www.nrc.gov/about-nrc/generic-schedules.html*] generic milestone schedule for [*insert type of facility and type of application here*] reviews established as part of the NRC's implementation of Section 102(c) of the Nuclear Energy Innovation and Modernization Act.

The enclosed notice of acceptance for docketing has been forwarded to the Office of the Federal Register.

[FOR APPLICATION CONTINGENT TO SPECIFIC SUPPLEMENTAL INFORMATION USE THESE PARAGRAPHS]
In accordance with 10 CFR 2.101 and [10 CFR 50.33, 50.34, and other Part 50 substantive requirements for CPs and OLs, 10 CFR 52.46 and 52.47 for DCs, 10 CFR 52.77, 52.79, and 52.80 for COLs, 10 CFR 52.16 and 52.17 for ESPs, 10 CFR 52.136 and 52.137 for SDAs, 10 CFR 52.156, 52.157 and 52.158 for MLs] or [10 CFR 2.643 and 50.10(d) for LWAs], the NRC staff performed an acceptance review to determine if the [Type of Application] application for the [Name of Application or Proposed Facility] contains sufficient technical information in scope and depth to allow the NRC staff to conduct its detailed technical review and complete it on a predictable schedule.

The NRC staff has reviewed your application and concluded that the information delineated in the enclosure to this letter is necessary to enable the NRC staff to conduct its detailed technical review. In accordance with 10 CFR 2.101, the application will be considered tendered but will not be docketed until the requested information is submitted and the acceptance review process can be re-initiated to determine if the application is acceptable for docketing. The NRC staff requests that [Name of Applicant] address the Requests for Supplemental Information (RSIs) identified in the enclosure by [Date]. If the information requested by the NRC staff is not received by the above date, the application will not be docketed for review pursuant to 10 CFR 2.101. If the application is subsequently accepted for review, you will be advised of any further information needed to support the NRC staff's detailed technical review by separate correspondence.

Following receipt of the identified supplemental information, the NRC staff will establish 1) a detailed review schedule, which may be longer or shorter than the generic review schedule, and 2) a projected level of effort to complete the detailed technical review (at the discretion of management).

[FOR NON-ACCEPTANCE OF THE APPLICATION USE THESE PARAGRAPHS]
In accordance with 10 CFR 2.101 and [10 CFR 50.33, 50.34, and other Part 50 substantive requirements for CPs and OLs, 10 CFR 52.46 and 52.47 for DCs, 10 CFR 52.77, 52.79, and 52.80 for COLs, 10 CFR 52.16 and 52.17 for ESPs, 10 CFR 52.136 and 52.137 for SDAs, 10 CFR 52.156, 52.157 and 52.158 for MLs] or [10 CFR 2.643 and 50.10(d) for LWAs], the NRC staff performed an acceptance review to determine if the [Type of Application] application for the [Name of Application or Proposed Facility] contains sufficient technical information in scope and depth to allow the NRC staff to conduct its detailed technical review and complete it on a predictable schedule.

The NRC staff has decided not to accept the [Name of Application] [Type of Application] application for docketing at this time. [Describe interactions with the applicant where significant information gaps were communicated and provide the reasons why the application is not being docketed.]

The NRC staff plans to continue interactions with your staff to support your efforts at resolving the staff's concerns and in developing the necessary information to support a complete application.

[IF THE APPLICANT WITHDRAWS THE APPLICATION, USE THIS PARAGRAPH]
By letter dated [DATE], you requested to withdraw the application from NRC review. The NRC staff acknowledges your request to withdraw the application. The NRC staff activities on the review have ceased and the associated CAC number has been closed.

The NRC staff notes that its review to date has identified that your application did not provide the following technical information in sufficient detail to enable the NRC staff to complete its detailed review. Therefore, if you decide to re-submit the request, please include the information described in the letter dated [DATE] (Agencywide Documents Access and Management System [ADAMS] Accession No. MLXXXXXXXX). Otherwise, the re-submitted application will not satisfy NRC standards for docketing. In this letter, the NRC staff identified the following information needed to conduct its technical review: [List the information needed if not previously described in a letter]

If you have any questions, please contact me at (301) 415-XXXX or email.

Sincerely,

[Name], Project Manager
[Branch]
[Division]
Office of Nuclear Reactor Regulation

Docket No(s).

Enclosure:

cc w/encl:

DISTRIBUTION: via Listserv

ADAMS Accession No.:

OFFICE	PM:Division/Branch	TR:Division/Branch	TBC:Division/Branch	OGC (if application will not be docketed)	PBC:Division/Branch
NAME					
DATE					

OFFICIAL RECORD COPY

ENCLOSURE 3

Timeline for Application Readiness and Acceptance Review

The following milestones for application readiness and conducting an acceptance review are provided as an example. Adjustments to these milestones may be made to accommodate individual applications that may have unique considerations. In addition, some of the pre-application steps below are optional and may not apply to each application.

Milestone	Notes	Schedule
Application-specific review team members identified	Core Team might be utilized with targeted use of SMEs	T minus 180 days
Application readiness review	LIC-116	T minus 180 days
Develop Packing Slip Wizard structure for electronic submittal	Work with OCIO, as needed	T minus 180 days
Baseline schedule and resource estimates developed for both acceptance review and full review	RRPS template or other	T minus 120 days
Review team trained on technology, design, advanced reactor policy issues, etc.	Licensing Modernization Project (LMP) process or other	T minus 120 days
CAC/EPID numbers for acceptance review are available		T minus 90 days
PRA audit	If applicable	T minus 90 days
Create folder on SharePoint, Teams or shared drive for communications required documents: FRN, letters, emails and so forth		T minus 60 days
Set up email and document capture with OCIO to support project and hearing file	Include project folder structure in ADAMS for automatic filing of documents and emails	T minus 60 days
Set up ListServ for distribution of correspondence to interested stakeholders	Consult with LA trained on ListServ setup and management	T minus 60 days
Send electronic reading room MOU to applicant	For applicant review and signature (See example ML19291B640)	T minus 60 days
Prepare and place in folder on SharePoint: -Communication Plan -Emails -EDO Daily -Press Release	Generic Communication Plan Enclosure 2 (ML091470473)	T minus 45 days
Technical Branch Contracts in Place		T minus 45 days
SE Template	Define format; include principles of good regulation, enhanced safety focused review changes.	T minus 30 days
Prepare Letter to Applicant for Receipt of Application	Generic Communication Plan Enclosure 6 (ML091470473)	T minus 30 days
Prepare Draft Letter to Applicant for Acceptance of Application	LIC-117 (This OI) Enclosure 2	T minus 30 days

Milestone	Notes	Schedule
Prepare and get preliminary review from ADM and OGC: - Receipt FRN - Docketing FRN	Generic Communication Plan Enclosure 2 (ML091470473)	T minus 30 days
Page turn/preview of application (with applicant)	See LIC-116	T minus 30 days
Day before receipt of application, Initiate Communication Plan notifications required.	Generic Communication Plan (ML091470473)	T minus 1 day
Electronic application submitted		T = 0 days
Photo Op		T = 0 days
Send Receipt Acknowledgement Letter to applicant	Generic Communication Plan Enclosure 6 (ML091470473)	T = 0 days
Initiate Communication Plan notifications upon receipt of application. -Communication Plan -Emails -EDO Daily -Press Release	Generic Communication Plan (ML091470473)	T = 0 days
Application processed into ADAMS		T = 0 to T = 5 days
Upon availability in ADAMS, Lead PM issues email to tech staff to initiate acceptance review, CAC, resources and so forth.		T = 0 days
PMs distribute Non-Public DVDs as needed to tech staff (hold public DVDs till prop review is complete).		T = 5 days
PMs perform 5-day SUNSI (CUI) Review on public version of application	Generic Communication Plan: Enclosure 2 and 4 (ML091470473)	T = 5+ calendar days
Upon completion of getting the application into ADAMS, and SUNSI (CUI) review completion: • Issue FRN for Notice of Receipt of Application, Issue Press Release	Generic Communication Plan: Enclosure 2 and 4 (ML091470473)	After SUNSI is complete.
Upon completion of getting the application into ADAMS, and SUNSI (CUI)review completion: • Place public version of application on public Web site and update as needed Place public and non-public version of application on internal web/SharePoint pages		After SUNSI is complete.
PM issues proprietary response letter		Before T = 60 days
PMs communicate with staff and applicant to clarify if information is unclear or missing.		25-day duration ending at T= 30 days
PM Compiles Results of Tech Staff BC letters		25-day duration ending at T = 55 days

Milestone	Notes	Schedule
PM completes building schedule for Tech Review based on BC input for use in docketing letter with schedule.		Before T = 55 days
PM initiates process for obtaining docket number for the review		Before T = 55 days
Safety PM and Environmental PM lead meeting with management for docketing decision after updating draft docketing acceptance letter.		5-day duration ending at T = 60 days
PM finalizes docketing acceptance decision letter based on management decision.		60 calendar days after receipt
PM issues signed docketing letter	Generic communication Plan, Enclosure 2 (ML091470473)	60 calendar days after receipt
Upon completion of AR decision: • Issue FRN for Docketing (if appropriate), • Issue Press Release • Issue EDO Daily Note	Generic Communication Plan, Enclosure 2 (ML091470473)	60 calendar days after receipt
Initiate communications plan notifications for acceptance decision.	Generic Communication Plan, Enclosure 2 (ML091470473)	60 calendar days after receipt
Update public Web site for docketing decision	Generic Communication Plan, Enclosure 5 (ML091470473)	60 calendar days after receipt

Appendix A – Change History
Office Instruction LIC-117

LIC-117 - Change History			
Date	**Description of Changes**	**Method Used to Announce & Distribute**	**Training**
01/28/2021	The objective of this office instruction (OI) is to provide guidance to staff who perform acceptance reviews of new nuclear facility licensing applications. The OI was developed using information from NRO office instruction NRO-REG-100, "Acceptance Review Process for Early Site Permit, Design Certification, and Combined License Applications," (ML14078A152), which has been rescinded. This office instruction complements the acceptance review guidance for license amendment requests in LIC-109, Revision 3, "Acceptance Review Procedures for Licensing Basis Changes" (ML20036C829) for licensee-requested changes to a facility's licensing basis.	E-mail to All NRR staff	None