

DRAFT Pre-application Engagement to Optimize Advanced Reactors Application Reviews May 2021

This draft staff white paper has been prepared and is being released to support ongoing public discussions.

This paper has not been subject to NRC management and legal reviews and approvals, and its contents are subject to change and should not be interpreted as official agency positions.

Purpose: The U.S. Nuclear Regulatory Commission (NRC) staff is publishing this paper to provide information to advanced reactor developers on the benefits of robust pre-application engagement in order to optimize both safety and environmental application reviews.

Background: In accordance with the Advanced Reactor Policy Statement,¹ the NRC encourages early interactions with advanced reactor developers and prospective applicants. The Policy states:

To provide for more timely and effective regulation of advanced reactors, the Commission encourages the earliest possible interaction of applicants, vendors, other government agencies, and the NRC to provide for early identification of regulatory requirements for advanced reactors and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of advanced reactor designs. Such licensing interaction and guidance early in the design process will contribute towards minimizing complexity and adding stability and predictability in the licensing and regulation of advanced reactors.

Further, Section 103 of the Nuclear Energy Innovation and Modernization Act (NEIMA) required the NRC to develop licensing strategies that (1) include the use of topical reports, standard design approval, and other appropriate mechanisms as tools to introduce stages into the commercial advanced nuclear reactor licensing process; (2) evaluate options for improving the efficiency, timeliness, and cost-effectiveness of licensing reviews of commercial advanced nuclear reactors, including opportunities to minimize the delays that may result from any necessary amendment or supplement to an application; and (3) options for improving the predictability of the commercial advanced nuclear reactor licensing process, including the evaluation of opportunities to improve the process by which application review milestones are established and met.

While pre-application interactions are not unique to advanced reactors, the NRC recognizes that such interactions may be particularly beneficial for advanced reactor developers because they allow early identification and resolution of technical and policy issues that could affect licensing. As such, the NRC staff is proposing a set of pre-application activities that, if fully executed, will enable staff to offer more predictable and shorter schedules and other benefits during the review of an advanced reactor license application. This proposal for pre-application activities is equivalent to a staged licensing approach, where some key elements of an advanced reactor design are reviewed, and the evaluation documented, before the license application is submitted. A staged licensing approach can provide the following advantages:

¹ Policy Statement on the Regulation of Advanced Reactors (73 FR 60612; October 14, 2008)

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Advantages for Applicants	Advantages for NRC
Enhanced regulatory predictability, reducing project risk	Greater review efficiency because NRC staff becomes familiar with the design and develops topical report safety evaluations that can be referenced by the application safety evaluation report
Greater review efficiency because NRC staff becomes familiar with design. Efficiency translates to lower costs and shorter review schedules	Early public engagement on the attributes of a design, increasing transparency and enhancing public awareness
Early interactions between the NRC, the applicant, and other agencies that have a role in the environmental review could shorten the licensing review schedule.	NRC staff becomes familiar with new approaches an applicant is considering and unique environmental aspects of a site
Early engagement with the Advisory Committee on Reactor Safeguards (ACRS) through the review of safety evaluations on topical reports. This early ACRS involvement will improve regulatory reliability and shorten application review times.	Early engagement with the ACRS through the review of safety evaluations on topical reports. This early ACRS involvement will reduce the number of issues addressed during the application review and lessen the effort of application review.

Program for Robust Pre-application engagement: In response to NEIMA, the NRC staff established generic milestone schedules for licensing reviews.² 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 licensee or applicant and the staff's resources. If an advanced reactor applicant completes the applicable items³ described in the following sections prior to submitting the application, the NRC staff will establish a review schedule at least 6 months shorter than the generic schedules depending on the complexity of the design.⁴ The NRC staff will complete the issuance of the final safety evaluation within this application-specific schedule as long as the following conditions are met:

- Applicants must submit responses to requests for additional information (RAIs) and other necessary information within agreed upon timeframes. Otherwise the schedule may be adversely affected.

² <https://www.nrc.gov/about-nrc/generic-schedules.html>

³ For a design certification, only the safety review items would be applicable. For a combined license application referencing a certified design, the environmental review items would be applicable in addition to safety topics associated with site specific features and any departures to the certified design. For a combined license not referencing a certified design, all the review topics listed would be applicable.

⁴ Substantive pre-application engagement of a lesser extent than that described in this paper may result in a shorter review schedule than the NEIMA generic schedules, which would be determined on a case-by-case basis.

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- If the applicant makes substantive changes to the application after submittal, those changes may impact the schedule.
- If the applicant participates in pre-application activities, the design should not change significantly between pre-application and the time the application is submitted so that matters resolved in pre-application are not adversely impacted; significant design changes may impact the review schedule.

In addition to a substantially shorter overall application review, the acceptance review could be shorter if the activities described below are completed before submission of an application. The staff could complete the acceptance review in as little as two weeks⁵ if only administrative aspects, such as making the application publicly available and issuing a notice of availability, need to be addressed at that time.

A. Topical reports

The applicant should submit topical reports on key topics for review during the pre-application phase. The NRC staff will review these topical reports and prepare safety evaluations with findings that can be relied on for the application review. These topical reports should be submitted early enough to support staff issuance of final staff safety evaluations prior to submittal of an application. It should be noted that any substantive changes to the design between submission of a topical report and submission of the application could require additional staff review and result in significant changes to the review schedule. The key areas described below should be addressed. The staff notes that at the construction permit stage, the level of design completeness would not typically support reaching conclusive staff findings on some safety and security topics during the preapplication or permit application review⁶. However, most of the topics below address methods or design fundamentals, and pre-application engagement in these areas is encouraged for prospective construction permit applicants to manage project risk as well as produce schedule efficiencies.

1. Principal design criteria for non-light-water reactors⁷

During the pre-application period, prospective non-light-water reactor (non-LWR) applicants should submit proposed principal design criteria (PDC) for staff review and approval. As required by Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34(a)(3)(i), 10 CFR 52.47(a)(3)(i), and 10 CFR 52.79(a)(4)(i), proposed PDC must be included in an application for a construction permit (CP), design certification (DC), or combined license (COL). The PDC establishes the necessary design, fabrication, construction, testing, and performance of safety significant structures, systems, and components (SSCs). The NRC staff expects non-LWR applicants will review the

⁵ This assumes that applicant's submittal meets NRC's SUNSI and electronic submittal requirements to facilitate release of public version of the application.

⁶ With regard to application files under 10 CFR Part 50, the staff notes that in accordance with 10 CFR 50.35(b) a construction permit will constitute an authorization to the applicant to proceed with construction but will not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit.

⁷ Prospective applicants for LWR designs are not required to submit PDC. LWR developers should instead discuss how the General Design Criteria (GDC) in Appendix A to 10 CFR Part 50 will be applied to their design and discuss any proposed exemptions to the GDC.

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GDC in Appendix A to 10 CFR Part 50 and the guidance in Regulatory Guide (RG) 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors," to develop their PDC and ensure that necessary safety functions and SSCs are covered under the selected PDC. For the applications that follow the risk-informed and performance-based (RIPB) approach in Nuclear Energy Institute (NEI) 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," the design-specific criteria identified by the RIPB approach may be used to supplement or modify the applicable GDC or Advanced Reactor Design Criteria in RG 1.232 in the formulation of PDC. The NRC staff will review the applicant's proposed PDC to determine if they are acceptable.

2. Selection of licensing basis events and classification and treatment of structures, systems, and components

a) The applicant should request staff review and approval of their proposed process for selection of licensing basis events and classification and treatment of SSCs, or indicate that they plan to use an approved process such as the process described in NEI 18-04 and 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."

b) The applicant should submit, for NRC information, the anticipated list of licensing basis events and the associated list of safety-related and risk-significant SSCs. This will help the staff understand the design and would support discussions on the preliminary SSC classifications, as needed, in preparation for an efficient and effective application review.

3. Fuel qualification and testing

Preapplication engagement on fuel qualification should include the following steps: staff approval of the fuel qualification plan and associated methodologies, potential staff observation of execution of the testing, and verification of the results of the testing to support qualification of the fuel for the associated reactor design. Applicants need to demonstrate that the fuel is qualified for use in their reactor design (i.e., demonstrate that fuel manufactured in accordance with a specification will perform as described in the licensing safety case). Sufficient information should be provided to support reasonable assurance findings that:

- a. The role of the fuel in the safety case is adequately described. This can be addressed by providing fuel performance requirements during (1) normal operation, including the effects of anticipated operational occurrences, and (2) accident conditions. Sufficient information should be provided to describe the safety limits of the fuel and the fuel contribution in the accident source term. Understanding of the safety limits and source term should address uncertainty associated with any limitations on data available during the pre-application stage.

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- b. The fuel qualification plan is adequate. Information should be provided in the fuel qualification plan that describes proposed analysis methodologies (e.g., fuel performance codes), the use of existing data, and any ongoing testing or plans to utilize lead test specimens. Where legacy data is used, a justification for the applicability of the data to the current application (e.g., data was collected for a fuel fabricated consistent with the proposed fuel design and irradiated in an applicable environment) and justification that the data was collected under an appropriate quality assurance program commensurate with the safety significance and in conformance with NRC quality assurance requirements should be provided.

4. Mechanistic or accident source term development⁸

Applicants should develop a source term methodology that includes validation and verification of associated engineering computer programs. The source term development needs to include radiological source terms for effluents, radwaste system design, shielding design, and equipment qualification. The applicant should submit the source term methodologies to the NRC staff for review and approval.

5. Quality assurance program

Applicants should submit a quality assurance program description (QAPD) for NRC review and approval during the pre-application phase to ensure that the design and the application have been developed in accordance with 10 CFR Part 50 Appendix B. The QAPD should cover the scope of the planned type of license application (e.g., 10 CFR 52.47(a)(19) discusses the QAP requirements for DC applications and 10 CFR 52.79(a)(25) discusses the QAP requirements for COL applications) as applied to the fabrication, construction, and testing, of the SSCs of the facility. The description of the QAP must include a discussion of how the applicable requirements of Appendix B to 10 CFR part 50 have been and will be satisfied, including a discussion of how the QAP will be implemented.

6. Safeguards Information Plan

The applicant should submit a plan for the protection of safeguards information (SGI) for NRC review and approval during the pre-application period. Approval of the SGI plan will enable the NRC staff to provide the applicant with SGI information, as necessary, for the applicant to consider safeguards and security in the design of the facility and development of the physical security program in order for the applicant to address the requirements of 10 CFR Part 73, "Physical Protection of Plants and Materials," and 10 CFR 50.150, "Aircraft impact assessment," in their application.

7. Safety and accident analysis methodologies and associated validation

Applicants should develop and execute plans to perform safety and accident analyses that include testing of applicable SSCs and validation and verification of

⁸ Developers of light-water small modular reactors may use the accident source term in NUREG-1465, "Accident Source Terms for Light-Water Nuclear Power Plants," or propose a design-specific accident source term.

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associated engineering computer programs. The analysis plans need to include development of associated methodologies and applications of those methods, which include but are not limited to event specific analysis methodologies, scaling methodology, setpoint methodology, reactor coolant analysis methodology, core design methodology, and reactivity control methods. The analysis plans need to include a test plan and test program as well as equipment qualification methodology to ensure appropriate verification and validation of the engineering computer programs. The test program should satisfy 10 CFR 50.43(e), which requires applicants to demonstrate that sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions. The applicant should submit the safety analysis methodologies and application of those methods to the NRC staff for review and approval.

B. Meetings, audits and white papers:

In addition to the topical reports discussed above, applicants should engage in pre-application interactions on the key topics below. The NRC staff will review the information submitted or discussed and will provide feedback to the applicant which will be useful in preparation of the application.

1. Probabilistic risk assessment (PRA)

The PRA provides important insights in the selection of licensing basis events, safety classification of SSCs and associated risk-informed special treatments, and determination of defense-in-depth (DID) adequacy. As such, early regulatory engagement on the PRA can make the review of an application more effective and efficient.

The applicant should facilitate the NRC staff's audit of the PRA peer review prior to submitting an application. The applicant should explain how the PRA will be used to support their application (e.g., risk-informed licensing, licensing basis event selection, siting, emergency preparedness, use of maintenance rule, etc.) to determine acceptability of the PRA for its planned use. The applicant should describe the development of its PRA, highlighting the use of any approaches that differ significantly from endorsed consensus codes and standards and NRC staff-approved guidance. The NRC staff will audit the resolution of the peer review findings and observations if a peer review has been completed. The NRC staff will provide feedback on these topics during the pre-application interactions. The applicant should address any issues identified before submittal of the application. Pre-application interactions on the PRA and its results should also assist the NRC staff in gaining valuable risk insights on the plant design. These risk insights will help the NRC staff conduct the application review by enabling the use of such risk insights in determining the depth and scope of the review, as well as by facilitating the use of risk-informed decision-making.

For applications submitted under 10 CFR Part 50, the degree of realism and the level of detail represented in the PRA at the CP stage will be less than that available at the

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operating license stage. Similarly, for applications submitted under 10 CFR Part 52, the scope represented in the PRA at the design certification stage will likely be less than that available at the COL stage. The NRC staff will adjust the depth and scope of its review, including consideration of the PRA acceptability appropriate to the maturity of the design. If an applicant considers seeking finality on safety matters at the CP stage, such as risk-informed licensing basis event selection or SSCs classification, the PRA would need to be at a state of development that would support NRC staff's decisions in these areas. Early pre-application discussion with the NRC staff is important in this area to receive timely feedback.

2. Regulatory gap analysis

The applicant should submit a regulatory gap analysis report listing those 10 CFR Part 50 or Part 52 requirements for which the applicant plans to request an exemption or seek a case-specific order or rule of particular applicability.⁹ This would allow the NRC staff and the applicant to establish an efficient approach for reviewing proposed exemption requests or developing a case-specific order or rule of particular applicability for the Commission's consideration. Case-specific orders have been used to license new facilities and technologies (e.g., Louisiana Energy Services, L.P., enrichment facility application). Examples of potential exemption requests may include emergency planning zone size and number of armed responders for physical security in advance of completion of ongoing rulemakings.

For non-LWR applicants submitted under 10 CFR Part 50 or 52, the regulatory gap analysis and decision to seek a case-specific order, rule of particular applicability, and/or exemptions should be informed by the NRC staff's draft white paper titled "Analysis of Applicability of NRC Regulations for Non-Light Water Reactors" and the draft appendix providing examples for demonstrating compliance or exemption (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML20241A017 and ML21049A098, respectively).¹⁰

3. Policy issues

The wide range of designs and/or design features being contemplated by advanced reactor designers may present unique regulatory issues. These issues need to be brought forward, through white papers or meetings, to the NRC staff as early as possible so that they can be properly considered and addressed by the NRC before the application is submitted. Early engagement will allow NRC staff time to pursue a Commission decision for those issues that rise to the level of policy matters. If additional policy issues arise during the application review, the schedule may be affected.

⁹ In lieu of exemptions, applicants may request alternate licensing approaches such as case-specific orders and rules of particular applicability. These are discussed further in Enclosure 2 to SECY 20-0093, Policy and Licensing Considerations Related to Micro-Reactors (ADAMS Accession No. ML20254A366).

¹⁰ Note that the staff plans to update this white paper to incorporate stakeholder feedback and applicants should refer to the most current staff guidance on this topic.

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4. Novel design features or approaches

The applicant should identify any novel design features, through white papers or meetings, during the pre-application review to allow staff familiarization so staff can develop a review strategy and review guidance, if needed. If the applicant intends to use novel design features (such as passive systems, inherent safety features, or simplified control features), early identification of these features or approaches to the NRC staff will facilitate timely identification and resolution of any unique regulatory topics. Topics to be considered beyond the reactor system include unique features such as seismic isolators, novel digital instrumentation and control systems, physical and cyber security features, safeguards features, or novel approaches to operational programs. Applicants should be aware that in accordance with 10 CFR 50.43(e) the performance of each safety feature must be demonstrated, and it must be demonstrated that the interdependent effects among the safety features of the design is acceptable. The applicant should inform the NRC how this demonstration will be made in their application.

5. Consensus codes and standards and code cases

During the pre-application stage the applicant should use a white paper to identify any consensus codes and standards or code cases they intend to use and specifically identify any standards or code cases that have not been endorsed or previously accepted by the staff. For any such standards or code cases, the applicant should engage in pre-application discussions to identify any areas where additional information may be needed in the application to support the proposed approach.

C. Environmental activities

The NRC conducts its environmental review in accordance with the National Environmental Policy Act's requirement that Federal agencies assess the environmental effects of proposed actions prior to making decisions. Therefore, the environmental review is an integral but distinct part of the NRC's licensing review.

Early and frequent pre-application interactions is a key component of federal directives outlined in Title 41 of the Fixing America's Surface Transportation Act (FAST-41) to streamline the environmental review process. As part of these pre-application interactions, the NRC staff expects that applicants would conduct meetings, support audits, and provide white papers beginning approximately 2 years in advance of the application submittal. An applicant seeking a predictable review schedule should engage in substantive pre-application interactions with the NRC staff as early as possible in the planning process in accordance with 10 CFR 51.40, "Consultation with NRC staff," and as discussed in RG 1.206, "Applications for Nuclear Power Plants." In addition, an applicant is expected to address the environmental issues described in RG 4.2, "Preparation of Environmental Reports for Nuclear Power Stations," which provides guidance to applicants for the format and content of environmental reports that are submitted as part of an application for a permit, license, or other authorization to site, construct, and/or operate a new nuclear power plant, or provide a justification for any

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issues that do not need to be analyzed. In addition, an applicant should also consider following the guidance:

- NEI 10-07, “Industry Guideline for Effective Pre-Application Interactions with Agencies Other Than NRC During the Early Site Permit Process”
- COL/ESP-ISG-026 Combined License and Early Site Permit Environmental Issues Associated with New Reactors
- COL/ESP-ISG-027 Combined License and Early Site Permit Specific Environmental Guidance for Light Water Small Modular Reactor Reviews
- Interim Staff Guidance (ISG)-29, “Environmental Considerations Associated with Micro-reactors.”

Early engagement is important for assuring that sufficient data is available in the application and that appropriate engagement with other Federal and State agencies has begun. For example, a project may affect a threatened or endangered species, necessitating consultation with the U.S. Fish and Wildlife Service. If the service or the NRC need data on the species, seasonal lifecycles could affect the ability to collect the data, which in turn could delay a project.

White Papers

The applicant should submit white papers on the following key areas and on any novel approaches to environmental topics. The NRC staff will assess the approaches, document a position, and provide feedback to the applicant during the pre-application phase.

1. Unique or Novel Methodologies and Issues

The applicant should identify any novel environmental methodology or issue to allow staff familiarization so it can develop a review strategy and review guidance, if needed. An example of a unique issue would be a purpose and need statement for the project that specifies uses other than electricity production. The purpose and need for the project is the foundation on which the environmental review is based. The purpose and need statement informs analyses of the need for the project and of alternatives, including alternative sites and alternative sources of energy.

2. Alternatives to the Proposed Project

A recurring issue on many of the previous COLs and ESPs was the alternative site selection process. The applicant should support meetings to discuss the site selection process. In addition, energy alternatives could be a unique issue for an advanced reactor application, depending on the purpose and need statement for the project. A purpose other than generating baseload electricity could change the alternative energy analysis, relative to what was previously considered for large LWRs.

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3. Cooling Water Availability

The NRC staff understands that advanced reactors may use less cooling water than the operating reactor fleet; however, access to cooling water and approvals by the relevant permitting authorities have proved to be a challenge for many previous projects. Therefore, the staff expects an applicant to provide information on the proposed facility's water consumption so the staff can gain an understanding of the facility's water needs and assess the appropriateness of the permits being sought. The staff also recommends that the applicant, the NRC staff, and the water permitting agencies meet at least once during the pre-application activities.

4. Status of Permits and Authorizations for the Proposed Project

The NRC staff recommends that the applicant interact with other permitting agencies as discussed in NEI 10-07, "Industry Guideline for Effective Pre-Application Interactions With Agencies Other Than NRC During the Early Site Permit Process," and provide a list of the needed authorizations, permits, licenses, and approvals for the project. This documentation should also contain a timeline for obtaining the necessary permits and the current status. The applicant should also provide copies of available correspondence between the applicant and State Historic Preservation Office (SHPO), Tribes, U.S. Fish and Wildlife Service, U.S. Army Corps of Engineers, National Marine Fisheries Service (NMFS), and state and local officials. The NRC staff will review the information and identify for the applicant any additional items that should be pursued, such as a consistency determination under the Coastal Zone Management Act.

Meetings

Based on recent experience, the following topics are critical components of environmental reviews that have caused schedule challenges during past reviews. Both the prospective applicant and the NRC staff would benefit from early discussion of any special aspects of these topics and a description of the applicant activities in these areas.

- Socioeconomic characteristics of the community
- Aquatic or terrestrial ecology studies that have been performed (if any).
- Federally listed species and critical habitats present, and potential impacts on those species and habitats
- Potential impacts on Essential Fish Habitat, including prey of Federally managed species.
- Historic properties and other cultural resources within the direct and indirect areas of potential effect (APE). Summarize cultural resource investigations conducted in the APE (all past and current historic and cultural resource investigations), and outreach conducted with the SHPO, Tribal Historic Preservation Officer, American Indian Tribes, and interested parties.

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- The fuel cycle and its impacts as related to the reactor design including the management of spent nuclear fuel.
- The environmental impacts from the transportation of fuels and wastes.
- Design-specific information needed for the environmental review including:
 - radiological health impacts (10 CFR Part 20 exposure analysis, annual population dose, non-human biota dose),
 - radiological waste management including effluent releases and solid wastes, as applicable,
 - non-radiological waste management, and
 - postulated accidents and severe accident mitigation design alternatives, as applicable.

D. Pre-application Readiness Assessment

In addition to the above pre-application activities, the applicant should allow the staff to conduct a pre-application readiness assessment (see Office instruction LIC-116, "Pre-application Readiness Assessment," ADAMS Accession No. ML20104B698) of both safety and environmental topics. In accordance with the Office Instruction, the readiness assessment may focus on either the whole application or selected parts identified in early interactions between the staff and prospective applicant. Depending upon the type of application to be submitted and the extent of pre-application activities leading up to this point, the staff will propose a right-sized scope for the readiness assessment.

The readiness assessment would allow the NRC staff to: (1) identify information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC, (2) identify major technical and/or policy issues not previously identified 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 not previously identified. The results of the readiness assessment will inform prospective applicants in finalizing their application and assist the NRC staff in planning its resources for the review once the application is formally submitted. The staff plans to engage prospective applicants to schedule a pre-application readiness assessment at least 6 months prior to the expected date of submittal. The readiness assessment is not part of the NRC's official acceptance review process and does not predetermine whether the application will be docketed. An applicant should provide the most current draft of the safety analysis report and environmental report, referenced documentation, and applicant staff and contractors to assist the NRC staff during its readiness assessment.