

DRAFT Preapplication Engagement to Optimize Application Reviews

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 NRC staff is publishing this paper to provide information to advanced reactor developers on the benefits of robust preapplication engagement in order to optimize both safety and environmental application reviews.

Background: In accordance with the Advanced Reactor Policy Statement¹, 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) included requirements that the NRC (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. Robust pre-application engagement is key to fulfilling these requirements.

NRC encourages pre-application interactions with advanced reactor developers to provide stability and predictability in the licensing process through early identification and resolution of technical and policy issues that would 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 essentially 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 has 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 business risk	Greater review efficiency because NRC staff becomes familiar with design
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
Regulatory requirements for the design are clarified	NRC staff become familiar with unique environmental aspects of a site and new approaches an applicant is considering
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.
Early interactions between the NRC, the applicant, and other agencies that have a role in the environmental review shorten the licensing review schedule.	

Program: As required by NEIMA the NRC staff established generic milestone schedules for licensing reviews². 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 design⁴. The NRC staff will complete the issuance of the final safety evaluation within the established 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 milestones. Otherwise the schedule may be adversely affected.
- There can be no substantive changes, other than those resulting from the RAI process, to the application after submittal as they may impact the schedule.

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 and would be determined on a case-by-case basis.

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- If the applicant participants 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 could impact the review schedule.

In addition to a substantially shorter overall application review, staff will complete the acceptance review in two weeks, only addressing administrative aspects including making the application publicly available and issuing notice of availability, if the activities described below are completed before submission of an application.

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 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 could invalidate the staff's prior approval in these areas and may result in significant changes to the review schedule. The key areas described below should be addressed.

1. Principle design criteria⁵

During the pre-application period, the applicant should submit proposed principal design criteria (PDC) for staff review and approval. As required by 10 CFR 50.34(a)(3)(i), 10 CFR 52.47(a)(3)(i), 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 establish the necessary design, fabrication, construction, testing, and performance of safety significant structures, systems, and components (SSCs). The NRC staff expects prospective non-light-water reactor (non-LWR) applicants will review the GDC pertaining to LWR provided in Appendix A to 10 CFR Part 50 and the guidance in 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. The 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 existing process such as the process described in Regulatory Guide 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."

⁵ Prospective applicant for small modular light-water reactor (SMR) designs are not required to submit PDC. SMR 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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b) The applicant should also 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

Applicants need to develop and execute fuel qualification plans that include fuel testing and validation and verification of associated engineering computer programs. The qualification plan needs to include fuel performance methodology and application. The applicant should submit the fuel qualification plan and associated methodologies to the NRC staff for review and approval. 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 (via topical report or an audit) of the testing to support qualification of the fuel for the associated reactor design.

4. Mechanistic or accident source term development⁶

Applicants need to 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 preapplication period to enable the NRC staff to provide the applicant with SGI information, as necessary, for the applicant to consider safeguards and security into the design of the facility and 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.

⁶ SMR developers 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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7. Safety and accident analysis methodologies and associated validation

Applicants need to develop and execute plans to perform safety and accident analyses that include testing of applicable SSCs and validation and verification of 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 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 will likely play an important role in the selection of Licensing Basis Events (LBEs); safety classification of SSCs and associated risk-informed special treatments; and determination of defense-in-depth (DID) adequacy, so early regulatory engagement on the PRA can avoid delays during the application review.

To facilitate a more efficient application review, the applicant should allow the NRC staff to audit the preliminary PRA and/or 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, event selection to support siting and 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 for PRA development. The NRC staff will audit 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 the 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 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 construction permit stage will be less than that available at the operating license stage. Similarly, for applications submitted

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under 10 CFR Part 52, the scope, degree of realism, and the level of detail represented in the PRA at the design certification stage will likely be less than that available at the combined license stage. The staff will adjust its PRA review and the PRA acceptability that is appropriate according to the maturity of the design. In the event that an applicant considers seeking finality on safety matters at the construction permit 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's decisions in these areas. Early pre-application discussion with the NRC staff is important in this area to receive timely feedback.

2. Regulatory Exemptions

Applicants may request exemptions from the NRC's regulations on a case-by-case basis. The applicant should submit a white paper providing a regulatory gap analysis listing the areas where the applicant plans to request exemptions from NRC requirements. This would allow the staff and the applicant to establish the list of the regulations that are applicable to the design to support an efficient acceptance review. It would also allow the NRC and the applicant to establish an efficient approach for reviewing proposed exemption requests. 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, the regulatory gap analysis should be informed by the staff's draft white paper titled "Analysis of Applicability of NRC Regulations for Non-LWRs," (ADAMS Accession No. ML20241A017)⁷.

3. Policy issues

The wide spectrum of designs and/or design features being contemplated by advanced reactor designers may present unique policy issues. These policy 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. If additional policy issues arise during the application review, the schedule may be affected.

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 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, security features, or novel approaches to operational programs.

⁷ 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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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.

6. Identification and justification of the use of engineering computer programs used in the application

The applicant should submit a white paper describing the anticipated list of the engineering computer codes and intended application during the pre-application phase. The validation and acceptability basis should be described as well as background and historical acceptance.

7. 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. 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 environmental report, referenced documentation, and applicant staff and contractors to assist the NRC staff during its readiness assessment.

C. Environmental Activities

As a Federal agency, the NRC follows National Environmental Policy Act requirements to 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 FAST-41 and Executive Order 13807 to streamline the environmental review process. As such, the staff expects that applicants would conduct meetings, support audits, and provide white papers beginning approximately 2 years in advance of the

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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 Regulatory Guide (RG) 1.206, "Combined License 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 (ERs) 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 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."

The early engagement is important for assuring that sufficient data is available in the application and 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 novel approaches to environmental topics, including the following key areas. 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 (in consultation with the staff if needed) any novel environmental methodology 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 for the project such as 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 the need for the project analysis and alternatives, including alternative sites and sources of energy.

2. Alternatives to the Proposed Project

A recurring issue on many of the previous COLs was the alternative site selection process. The applicant should support meetings to discuss the site selection process. In addition, a unique issue for advanced reactors could be energy alternatives, depending on the purpose and need for the project. The purpose

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could change the alternative energy analysis from what was previously considered for large LWRs.

3. Cooling Water Availability

The staff understands that for some advanced reactors the use of cooling water would likely be less than that of large LWRs; however, the necessary approvals by the permitting authorities for access to cooling water 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 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. Fishery and Wildlife Service (FWS), U.S. Army Corps of Engineers, National Marine Fisheries Service (NMFS), state and local officials. Staff will review the information and identify for the applicant any additional items that should be pursued.

Meetings and Audits

The staff expects the following topics to be discussed at meetings or audits during pre-application interactions:

- Information on 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.
- Identify 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.
- Discussion of severe accident mitigation analysis that uses the latest update to the plant's probabilistic risk assessment.
- Description of the fuel cycle and its impacts as related to the reactor design including the management of spent nuclear fuel.

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- Discussion of 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.