

## **C.2 Application Regulatory Topics**

### **C.2.1 Pre-application Activities**

“Pre-application activities” is the term used to encompass all of the communications, correspondence, meetings, document submittals/reviews, and other interactions that occur between the NRC staff and a prospective applicant prior to the tendering of an application under Part 52. The NRC considers pre-application activities to be mutually beneficial to both the staff and prospective applicants and encourages prospective applicants to initiate interactions early in the application planning process. Pre-application activities, although encouraged and recommended by the NRC, are not required and are voluntary by prospective applicants. This section of the regulatory guide provides an explanatory overview of pre-application activities and provides guidance to prospective applicants for initiating and carrying out the varied activities.

#### **OVERVIEW**

##### **Commission Policy**

The NRC encourages interactions between the staff and those entities considering the submittal of an application under Part 52. As stated in the Commission’s Final Policy Statement on the Regulation of Advanced Reactors (73 FR 60616, October 14, 2008), the Commission encourages the earliest possible interaction with applicants, vendors, and other government agencies to provide for early identification of regulatory requirements and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of the designs. The Commission foresees that such interaction early in the design process will contribute towards adding stability and predictability in the licensing and regulation of new reactors. The Policy further states, “In the absence of a significant history of operating experience on an advanced concept reactor, plans for the innovative use of proven technology and/or new technology development programs should be presented to the NRC for review as early as possible, so that the NRC can assess how the proposed program might influence regulatory requirements.”

##### **NRC Staff Position**

Consistent with agency policy, the NRC staff encourages early and continuing communications and interactions with prospective applicants in varying type, scope, formality, and frequency as a prospective applicant progresses toward tendering an application. Pre-application activities support NRC readiness to conduct licensing reviews in a predictable timeframe; and, it is essential that major policy, technical, and licensing issues be identified and progress made in understanding how they can be resolved prior to receiving applications.

The NRC staff supports differing approaches for pre-application activities and the staff has no expectations for standardization of interactions with prospective applicants. Rather, the staff anticipates that the timing, extent, and frequency of interactions will be unique to specific prospective applicants. For example, a prospective applicant inexperienced with the NRC and considering a standard design certification (DC) application for a reactor design with innovative features may find it prudent to initiate interactions with the staff ten or more years prior to the intended application submittal. Alternatively, a prospective applicant with multiple operating nuclear plants considering a combined license (COL) application referencing a DC at a site with an early site permit (ESP) may elect to initiate interactions two to three years prior to the intended application submittal.

### **Public and Non-public Meetings**

To facilitate regulatory transparency and to ensure coordination between the NRC and its stakeholders, agency policy is to maximize the use of public meetings to address generic approaches for resolving the policy, licensing, and key technical issues for new reactor technologies. Also, consistent with the agency's mission, the NRC staff is precluded from performing – or being perceived as performing – the role of advisor or consultant to any prospective applicant or stakeholder. To this end, the staff will ensure that as many pre-application interactions as practicable are carried out in the public domain.

The NRC staff recognizes that certain information (e.g., applicable to innovative technologies) provided by prospective applicants includes proprietary information, pending patents, and other information not appropriate for release to the public. When such information is to be addressed, non-public (i.e., closed) meetings may be appropriate. However, the NRC intends to minimize closed meetings and, where feasible, arrange meeting agendas such that meetings can be divided into open and closed portions to allow public participation.

### **GUIDANCE**

The following paragraphs provide guidance to prospective applicants regarding: 1) familiarity with NRC's regulatory requirements and processes; 2) application-related plan and schedule information of interest to the NRC; 3) pre-application meetings with the NRC staff (public and non-public meetings); 4) application-related documents which may be submitted for NRC staff review; 5) application-related safety and environmental regulatory issues; 6) information requested by NRC Regulatory Issue Summaries; and, 7) the NRC staff's pre-application readiness assessment.

#### **Regulatory Familiarity**

Prospective applicants may initiate communications (e.g., telephone, written correspondence, e-mail) with the NRC staff at their discretion. However, early in the application planning process, a prospective applicant should become familiar with the NRC's regulatory structure, policies, requirements, and processes. The NRC public website (<http://www.nrc.gov/>) is a resource for such information. The Office of New Reactors (NRO) site <http://www.nrc.gov/reactors/new-reactors.html> is the source for current requirements, guidance, and information pertaining to new reactors and applications. In addition, the NRO site provides extensive information regarding applications currently undergoing staff review and the licenses/certifications/permits recently issued. The advanced reactors website <http://www.nrc.gov/reactors/advanced.html> is the source for current regulatory and technical issues pertaining to advanced reactors and small modular reactors. In addition, the advanced reactor website provides specific information regarding the business entities currently engaged in pre-application activities – and the respective reactor designs.

Prospective applicants should be familiar with the identification and resolution of regulatory and technical issues encountered by prior applicants/pre-applicants. The NRO and advanced reactor websites provide e-links to the comprehensive publicly-available information authored by both applicants/pre-applicants and the staff throughout the application submittal/review process (e.g., pre-application public meetings, applicant-authored topical reports and final safety analysis reports, staff requests for additional information (RAIs) and applicant responses, staff safety evaluation reports). The NRC staff recommends prospective applicants review relevant information for insights regarding policy, regulatory and technical issues.

Prospective applicants should attend several NRC public meetings. The varied public meetings

held with both applicants and pre-applicants provide an additional source of insights to prospective applicants regarding regulatory and technical issues. The NRC website provides a comprehensive list of recent and upcoming public meetings – to include the meeting topic(s), participants, and agenda. The NRC staff recommends prospective applicants attend public meetings held with applicants/pre-applicants which address regulatory and technical issues relevant to the prospective applicant's design/application to gain insights helpful in preparing the application.

### **Plans and Schedules**

Prospective applicants should determine the appropriate pre-application activities relative to their respective plans, needs and schedules and should initiate those activities and provide follow-through with the NRC staff. The pre-application activities should focus on what would be most beneficial both to the preparation and submittal of the application and to the NRC's acceptance and detailed review of the application. Further, the activities should focus on what would achieve the most efficient use of both staff and applicant resources.

Pre-application activities should address information regarding plans and schedules (see below discussion of NRC Information Requests – Regulatory Issue Summaries), as well as the specific design and application-specific regulatory issues. Early in the planning process, information will be preliminary; however, the information will become more defined and detailed as the design and planning progress. During the pre-application timeframe, the NRC will seek information such as the following:

- What applications (e.g., ESP, DC, COL) are planned and when?
- What is the status of the plant design?
- What is the status for the qualification of fuel and other major systems and components?
- What is the status of computer codes and models for design and licensing analyses?
- What is the status of a quality-assurance program?
- What is the status of probabilistic risk assessment (PRA) models?
- What is the status of a control room simulator?
- What are the plans for submittal of white papers, technical reports, and topical reports?

### **Meetings**

The prospective applicant should request an initial meeting with the NRC staff early in the application planning process and should continue to initiate and/or support appropriate subsequent meetings. The meetings (depending on the purpose, scope, and subject matter) may or may not include attendance by external stakeholders and the public (i.e., public or non-public); and, NRC staff participation may or may not be fee billable to the prospective applicant.

#### Introductory Meetings

Typically, the initial meeting is introductory in nature and intended to provide overview information to the NRC staff. Topics include the prospective applicant's business structure, reactor design features, siting considerations, preliminary application plans/schedules, and potential regulatory issues. The prospective applicant and NRC staff may agree to one or two follow-on meetings to address preliminary information.

For example, the initial meeting may be a planning/scheduling "drop-in" meeting. The prospective applicant's management requests the opportunity for a "drop-in" with NRC staff management to share information regarding the design and application intentions. The meeting is limited to a general exchange of information not directly related to any regulatory action or decision. The meeting is not a public meeting and is not billable to the prospective applicant. A

follow-on second meeting, perhaps months or a year later is similar but the scope includes information of increased detail and more certainty is expressed regarding the design and application intentions. This meeting is also non-public and non-billable.

### Subsequent Meetings

Typically, after a few (e.g., three) introductory-type meetings, the prospective applicant and NRC staff agree to engage in follow-on pre-application activities intended to result in the submittal of an application. At this time, the staff establishes a project designation for the prospective applicant that initiates the agency's administrative and business process (e.g., correspondence control, fee-billable account) for subsequent pre-application activities. NRC staff participation in subsequent activities specifically in support of the prospective applicant is billable to the prospective applicant.

The purpose, subject matter, and frequency of subsequent meetings are primarily determined by the needs of the prospective applicant as the application is developed and prepared for application submittal. Topics include, for example, application-specific approaches for resolution of generic regulatory issues and application-specific submittal issues. The meetings typically address, in increasing level of detail, application-specific regulatory and technical issues and the prospective applicant's plans/schedules. Whenever practicable, the meetings include participation by external stakeholders and the public.

For example, a prospective design certification applicant may elect to engage with the NRC staff in development of a design-specific review standard (DSRS). The DSRS process (see Section C.2.3, Small Modular Reactors and Design-Specific Review Standards, of this regulatory guide) includes extensive interactions with the staff, typically fee-billable, over a timeframe of approximately two years and includes a number of both closed and public meetings.

In addition to meetings initiated by the prospective applicant, the prospective applicant should support NRC-requested meetings. The NRC staff may find it appropriate to conduct meetings in support of the staff's preparations for acceptance and technical review of the anticipated application. Such meeting requests would typically be based on the staff's need for clarification of certain application-specific information (e.g., proposed resolution of generic regulatory or technical issues, revised application plans/schedules, DSRS-related issues, and proprietary or security-related information issues).

### **Documents**

During the pre-application timeframe, the prospective applicant should determine both the type of documents and the schedule for submittal to the NRC staff. Pre-application documents vary in both purpose and formality; and they may or may not be made publicly available. For example, a prospective applicant may request, under 10 CFR 2.390, that preliminary application plans and schedules intended to inform the NRC staff which include proprietary information (including trade secrets and privileged or confidential commercial or financial information) be withheld from public availability. Alternatively, a topical report which addresses the approach for regulatory resolution of design technical issues and which is submitted for formal staff review and preparation of a staff safety evaluation report would be fee-billable and likely be made publicly available.

The NRC staff identifies three types of formal documents (topical reports, technical reports and white papers) which the prospective applicant may author and submit for staff consideration. The intended purpose of these documents is to address application-related regulatory and/or technical issues. As determined by the prospective applicant, the documents may be submitted

during the pre-application timeframe, in parallel with, and/or subsequent to application submittal.

### Topical reports

A prospective applicant may, at its option, submit topical reports for NRC staff review. The NRC sponsors a topical report program to increase the efficiency of the licensing process and reduce the burden on applicants/licensees. Details of the program, including NRC requirements and the administrative process, are available at the NRC website <http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html>.

A topical report addresses a technical topic related to nuclear plant safety that may apply to multiple applicants/licensees. For example, a topical report may address the quality assurance program, instrument set-point methodology, or severe accident evaluation for the design certification. Submittal of a topical report allows for a single review by NRC staff and (if appropriate) approval of a safety-related topic, thereby, increasing the efficiency of the licensing process by minimizing the time and resources that both industry and the NRC staff could expend on serial reviews of the same topic in multiple applications. The schedule for the staff's review is dependent on the scope and complexity of the topical report; and, the review may require one or more years. The staff typically documents and publishes its evaluation in a topic-specific safety evaluation report.

Applicants may incorporate topical reports, for which safety evaluation reports have been published, by reference into an application. Non-proprietary topical reports, non-proprietary versions of proprietary topical reports and non-proprietary correspondence regarding the review of topical reports are made publicly available.

A topical report should meet all of the following criteria:

- 1) Address a specific safety-related subject that requires a safety assessment by the NRC staff that can be evaluated independently of a specific license application.
- 2) Be referenced by multiple applicants/licensees.
- 3) Contain complete and detailed information on the specific subject presented.
- 4) Use of the NRC-approved topical report will increase the efficiency of the review process for those applications referencing the report.

### Technical Reports

A prospective applicant may, at its option, submit technical reports for NRC staff review in advance of the application submittal; and, additionally, may submit technical reports in parallel with, or subsequent to, the application submittal. Technical reports address application-specific technical safety topics and are generally intended to support and augment information contained in the application – typically the final safety analysis report. Technical reports may contain a level of detail (e.g., test data) beyond that considered appropriate for inclusion in the application and, to support application completeness, may be incorporated by reference into the application. A technical report may address, for example, design-specific features to address a regulatory issue, design-specific features to address the safety-security interface, and the design-specific vibration assessment program.

The NRC staff will typically review technical reports submitted by a prospective applicant as part of the pre-application process. The staff may issue RAIs, but the staff will not publish issue-specific safety evaluation reports. Rather, the staff will incorporate the technical reports and the staff's associated evaluation into the overall review/evaluation of the application. Similarly, the NRC staff will review technical reports submitted in parallel with, or subsequent to, the application as part of the overall review/evaluation of the application.

### White Papers

A prospective applicant may, at its option, submit white papers in advance of the application submittal. White papers are “information” reports which address application-specific regulatory and/or technical issues and may document a prospective applicant’s proposed “position” regarding a regulatory issue. White papers are intended to provide explanatory information to enhance the understanding of the NRC staff; and, as such, are not formally incorporated into the Part 52 application. A white paper may, for example, address 1) a proposed alternative for compliance with a requirement considered not applicable due to the innovative features of the design 2) an approach for risk-informing plant systems/components 3) an approach for using PRA to enhance the design 4) methodology for a design-specific emergency planning zone or 5) the prospective applicant’s perspective on the industry position on a generic regulatory issue (e.g., Nuclear Energy Institute (NEI) template).

The NRC staff will typically review submitted white papers for familiarization and enhanced understanding. Further, the staff may informally request clarification and/or supplemental information. However, the staff will not issue formal RAIs and will not perform a formal review and evaluation of white papers.

### **Safety and Environmental Issues**

The NRC’s application acceptance review and detailed technical review are focused on the regulatory issues pertaining to safety and the environment. The prospective applicant should ensure that pre-application activities encompass the identification and proposed resolution of issues necessary to support an effective and efficient safety review and environmental review.

As development of the application progresses, the prospective applicant should take steps to address application-specific safety and environmental issues. For example, the prospective applicant may discuss the potential resolution of issues in meetings with the NRC staff and, subsequently, document the proposed resolution in a technical report. The NRC staff will seek information, in increasing level of detail, in support of its anticipated reviews on issues such as the following:

- Proposed exemptions from the regulations
- For a DC application
  - Innovative and/or advanced reactor design features
  - Decision regarding development of a DSRS
- For COL application referencing a DC
  - Potential departures from the certified design
  - Plans to address COL action/information items
- For COL application referencing an ESP
  - Potential variances from the ESP
  - Plans for addressing COL action items and conditions in the permit
- Quality assurance program
- Probabilistic risk assessment
- Reliability assurance program

### **Environmental Pre-application Activities**

Prospective applicants are encouraged to participate in environmental pre-application activities so as to ensure the staff’s effective and timely review of the application’s environmental report. It is recommended that the prospective applicant and staff begin discussions on environmental pre-application activities soon after the introductory meetings are completed. A site tour and

discussions concerning design features that will directly impact environmental resources such as rivers, wetlands, ecological habitats, and groundwater should be completed early in the pre-application process. Environmental guidance documents available on the NRC and NRO websites address information that must be included in the environmental report.

The NRC staff will seek information, in increasing level of detail, in support of its anticipated reviews on issues such as the following:

- Historical site information for land use, cultural/historic resources, hydrology, hydrogeology, geology, meteorology, and socioeconomic data
- Site-specific information needed for the environmental review – e.g.,
  - Alternative site selection process and narrowing of the selection of the alternative sites and the proposed site.
  - Information regarding the applicant's monitoring-related plans such as one year of aquatic ecology surveys in waterways adjacent to the site (reviewed during NRC staff visits)
  - Pre-application interactions with other state and federal Agencies
  - Information pertaining to socioeconomic characteristics of the site and surrounding area, cultural/historic resources, hydrology and geohydrology, and aquatic and terrestrial threatened and endangered species, meteorology, and other resource areas (reviewed during NRC staff visits)

For prospective COL and ESP applicants, the NRC typically will request that the U.S. Army Corps of Engineers (USACE) be a cooperating agency in the preparation of the environmental impact statement (EIS) for the application. For construction activities detailed in COL and ESP applications, the USACE develops an EIS for the issuance of licenses that cover those construction activities in waters of the U.S. and to address potential impacts to wetlands. To be cost effective, the NRC and USACE work together on the NRC's EIS and the USACE adopts the EIS for their action. The prospective applicant needs to brief the USACE on their planned activities so that the USACE can begin their work planning and funding activities. Additionally, the NRC staff will brief other federal, state, and local government agencies on the NRC's scope and schedule for the license application no later than one year prior to application submittal. It is recommended that the prospective applicant brief these federal, state, and local agencies prior to the NRC as the prospective applicant knows more about the site and the surrounding environs, the reactor design, and the application schedule.

The NRC staff may request a tour of the proposed site and proposed alternative sites, and the opportunity to review nearly-completed sections of the environmental report. The tours and meetings may begin as early as two years prior to submission of the application. Other federal, state, and local government agencies who have a regulatory or enforcement interest in the project may attend some or all of these tours and meetings. It is beneficial to the prospective applicant to maintain open communications with all government entities that may have an interest and/or regulatory responsibility associated with the project.

### **NRC Information Requests – Regulatory Issue Summaries**

To support the agency's process for planning, budgeting, and resource allocations, the NRC requests that prospective applicants provide application-related planning and scheduling information commencing approximately three years prior to the intended application submittal date. As a federal agency, the NRC must prepare its budget, to include plans for application reviews and associated resource estimates, several years in advance. To support this effort, the NRC seeks planning information such as the intended use of topical reports to resolve regulatory issues and the schedules for application submittals as well as preliminary technical

design information. The NRC issues updated information requests annually, in the form of a Regulatory Issue Summary (RIS) (e.g., RIS 2014-13, "Planned Licensing Action Submittals for All Power Reactor Licensees," December 17, 2014 (ADAMS ML14329A165)). Prospective applicants should be responsive to these information requests.

In addition to application plan/schedule information, the NRC is especially interested in the extent of standardization related to the application. The NRC promotes the standardization of applications to enhance the safety, reliability, and availability of nuclear power plants, and facilitate a predictable and consistent method for application review. The agency's design-centered review approach (DCRA) is a strategy based on industry standardization of COL applications referencing a particular reactor design. When such standardization is achieved, the staff intends to conduct one technical review for each reactor design issue and use this one decision to support the decision on the DC application and on multiple COL applications. The DCRA strategy was initially addressed in RIS 2006-06, "New Reactor Standardization Needed to Support the Design-Centered Licensing Review Approach," May 31, 2006 (ADAMS ML053540251) and the strategy continues to be a subject of the annual RIS information requests.

#### **NRC Pre-application Readiness Assessment**

The NRC staff anticipates conducting an assessment of each prospective applicant's readiness to tender an application under Part 52 approximately six months prior to the planned application submittal date. The assessment is a unique pre-application activity which is intended to inform and benefit both the prospective applicant and the staff. The staff plans and schedules the assessment in coordination with the prospective applicant.

A prospective applicant should support the NRC staff's request for, and conduct of, the pre-application readiness assessment. The pre-application readiness assessment is addressed in detail as a separate, stand-alone topic in Section C.2.2 of this regulatory guide.