

C.2 Application Regulatory Topics

C.2.2 Pre-application Readiness Assessment

OVERVIEW

The voluntary pre-application readiness assessment is a unique form of pre-application activity which is intended to inform and benefit both the prospective applicant and the staff. The NRC staff anticipates conducting an assessment of each prospective applicant's readiness to tender an application under Part 52 for a combined license (COL), standard design certification (DC) or early site permit (ESP) approximately six months prior to the planned submittal date. Although voluntary, the readiness assessment was identified in the "New Reactor Licensing Process Lessons Learned Report," April 2013 (ML13059A239), as one of the means of enhancing the quality of applications; and, the NRC staff highly recommends a readiness assessment for each prospective applicant.

The readiness assessment allows the NRC staff to 1) identify information gaps between the draft application and the technical content expected to be included in the application submitted to the NRC, 2) identify major technical or policy issues that may adversely impact the acceptance or technical review of the application, and 3) become familiar with the application, particularly in areas involving proposed new concepts or novel design features.

The readiness assessment allows the prospective applicant an opportunity to interface directly with NRC staff regarding application-specific regulatory and technical issues and gain a better understanding of NRC requirements and guidance. For example, the prospective applicant may 1) discuss a planned request for an exemption from the regulations, 2) discuss potential departures from the certified design, 3) better understand the need for a variance from the ESP, 4) discuss the significance of a site-specific environmental issue, 5) better understand the necessary coordination between the NRC as lead federal agency and cooperating federal agencies, and/or 6) develop an effective approach for facilitating cooperation between state and federal agencies involved in the review.

The assessment results 1) inform the prospective applicant in finalizing the application and 2) support the NRC's process for planning, budgeting, and resource allocations by providing the staff with better clarity regarding the application's content and schedule. . The assessment results are documented in an NRC staff report which is issued to the prospective applicant and made publicly available.

GUIDANCE

Each prospective applicant should support the NRC staff's planning, preparations, and conduct of the pre-application readiness assessment. The staff will plan and schedule the readiness assessment in coordination with and consistent with the application development schedule of the prospective applicant.

The staff typically engages with prospective applicants to conduct the assessment at least six months prior to the planned application submittal date and each prospective applicant should support this timeframe. The staff coordinates both the schedule and scope of the assessment

with the prospective applicant. Ideally, the scope of the assessment should include the overall application. Alternatively, the assessment scope may be limited to selected parts of the application such as those topics identified as challenging areas in prior application reviews (e.g., instrumentation and controls, seismic analysis, long-term cooling, human factors engineering). The prospective applicant should support the staff's assessment preparations (e.g., availability of appropriate documentation) and the conduct of the assessment (e.g., availability of appropriate personnel and subject matter experts). Further, the prospective applicant should support, as requested, the staff's preparation of the assessment report, to ensure the report's accuracy and clarity.

The prospective applicant should consider the results of the readiness assessment while finalizing the application and should re-evaluate, as appropriate, the application submittal date based on the time required to address the readiness assessment observations. Prospective applicants should be aware that the readiness assessment neither conforms to, nor is part of, the NRC's acceptance review process. The readiness assessment does not predetermine whether the application will be accepted and docketed.

NRO-REG-104 "Pre-application Readiness Assessment"

Prospective applicants should have familiarity with the NRC's Office of New Reactors (NRO) Office Instruction NRO-REG-104, "Pre-application Readiness Assessment," (ML14079A197) which provides guidance to the NRC staff in preparing for and conducting pre-application readiness assessments. This office instruction is publicly available and, although developed for staff use, provides information and insights useful to prospective applicants.