C.2.4 Application Acceptance Review

OVERVIEW

NRC regulations in 10 CFR Part 2 prescribe the requirements for applicants to file COL, ESP, and DC applications and, additionally, for NRC staff to determine whether a filed application is complete and acceptable for docketing. Applications for COLs and ESPs are filed in accordance with 10 CFR 2.101, "Filing of Application," and applications for DCs are filed in accordance with 10 CFR 2.811, "Filing of Standard Design Certification Application; Required Copies." Pursuant to 10 CFR 2.101 for COLs and ESPs and 10 CFR 2.815 for DCs, the NRC staff determines whether a tendered application is acceptable for docketing.

The acceptance review process is the means by which the staff determines the acceptability of an application. Consistent with Commission direction¹, the staff determines application acceptability on the basis of both completeness and technical sufficiency within a period of 60 days. The completeness review ensures that the applicant has submitted the information required by applicable requirements; and, the technical sufficiency review ensures that the application contains sufficient information in scope and depth for the staff to conduct its detailed technical review within a predictable timeframe. The goal is to determine with a high level of certainty that the staff can complete the detailed technical review within a predictable timeframe.

Although not part of the acceptance review, the pre-application interactions carried out between the applicant and the NRC staff prior to application submittal as well as the results of the pre-application readiness assessment support a more effective and efficient acceptance review. The staff's familiarity, prior to application submittal, with the applicant's approach to technical and regulatory issues and proposed new methodologies and/or innovative design features, enhances the staff's capabilities to evaluate both the application's completeness and its technical sufficiency. Guidance pertaining to pre-application interactions is contained in Section C.2.1, "Pre-application Activities," within this guidance.

NRO-REG-100²

The NRC staff's office instruction, NRO-REG-100, provides detailed guidance to the staff in preparing for and conducting acceptance reviews for ESP, DC, and COL applications. Although developed for use by the staff, this publicly-available document is a resource that is: 1) useful to all stakeholders for a general understanding of the acceptance review process,; and 2) valuable to applicants for a detailed understanding of the staff's acceptance review activities and schedule, the staff's expectations of applicants, and the docketing decision process.

¹Staff Requirements Memorandum for COMDEK-07-0001/COMJSM-07-0001, "Report of the Combined License Review Task Force," June 22, 2007 (ADAMS ML071090128)

² NRO-REG-100, Rev 2, "Acceptance Review Process for Early Site Permit, Design Certification, and Combined License Applications," December 18, 2014 (ADAMS ML14078A152)

GUIDANCE

Acceptance Review Process

The applicant should be familiar with the overall acceptance review process and the staff's approach for implementation of the process as documented in NRO-REG-100. Also, as discussed in NRO-REG-100, the applicant should anticipate interactions with the staff throughout the acceptance review process to include both oral and written communications and the potential need for submittal of documentation supplemental to the initial application.

Further, the applicant should be aware that the initial steps of the acceptance review process include the staff's actions to: 1) ensure the application adheres to the agency's guidelines for electronic submittal, and 2) make the application publicly available (less withheld information). Guidance pertaining to an application's electronic submittal and withheld information is contained, respectively, in Sections C.2.3, "Application Electronic Submittal," and C.1.9, "Withheld Information," within this guidance.

Completeness and Sufficiency

The applicant should understand that the acceptance review, although encompassing the entire application, is focused on the safety analysis report as well as the environmental report, and comprises both a "completeness" element and a "sufficiency" element. As prescribed in NRO-REG-100, the staff reviews and evaluates the application in terms of technical content identified in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition;" design-specific review standards (if applicable); NUREG-1555, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants;" RG 4.2, "Preparation of Environmental Reports for Nuclear Power Stations;" and other application-related guidance. For the environmental review, the staff has developed the Office of New Reactors Environmental Report Acceptance Review Tables (ML16085A019) as an aid in performing the acceptance review. The staff performs the completeness portion of the review to verify the application contains all of the information required by applicable regulations; and the technical sufficiency portion to verify the application contains sufficient technical information in scope and depth to conduct the detailed technical review of the application within a predicable timeframe.

During the review process, the applicant should understand that a key component of the staff's review is the identification of any technical deficiencies. As defined in NRO-REG-100, a technical deficiency is defined as missing, improper, inadequate, or incorrect technical information needed by the NRC staff to conduct the application detailed technical review. A <u>minor</u> technical deficiency is defined as missing, improper, inadequate, or incorrect technical information that can be addressed within a reasonable round of requests for additional information (RAIs) after the application is accepted for docketing without notably impacting the overall detailed technical review schedule (e.g., applicant possesses the relevant information but omitted the information in the application). A <u>significant</u> technical deficiency is defined as missing information that results in the staff being unable to evaluate detailed technical information against the acceptance criteria (e.g., NUREG-0800) or to conduct its review within a

predictable timeframe (e.g., applicant neglected to perform a required analysis that is critical to the staff's understanding of a safety system).

Communication

The applicant should be prepared to respond to any staff-initiated communications in a timely and accurate manner and to proactively initiate communication with the staff when warranted. The NRC staff, consistent with the agency's policy on transparency and openness (ML112510158), initiates and maintains communication with the applicant throughout the acceptance review process and these communications typically include a combination of teleconferences, meetings, and formal correspondence. The communications regarding application issues and deficiencies provide the applicant an opportunity to address, and potentially resolve, the acceptability-related items prior to the staff making a docketing decision.

Throughout the acceptance review process, the applicant should maintain an awareness of the staff's progress and acquire an understanding of any potential acceptance issues. The applicant should initiate communications with the staff as necessary to ensure a mutual understanding of potential issues and the appropriate path to resolution. When requested by the staff, the applicant should provide timely and substantive information to support the review and the docketing decision.

Results and Docketing Decision

As discussed in NRO-REG-100, the docketing decision has three possible outcomes: 1) application acceptable for docketing; 2) application not acceptable for docketing; or, 3) application acceptable for docketing contingent on specific supplemental information.

Following the guidance in NRO-REG-100, the NRC staff compiles the acceptance review results in a manner to clearly identify the significant deficiencies that the staff needs to consider in the decision to docket the application. For areas in which significant deficiencies are identified, the staff communicates the findings with the applicant for specific technical areas and describes the nature of the deficiencies. It is the responsibility of the applicant to have a clear understanding of the deficiencies in the application identified by the staff and the capability to address these deficiencies within an acceptable timeframe.

If the application is accepted for docketing, the staff issues a letter of acceptance to the applicant to include the staff's schedule for conducting the detailed technical review of the application. The applicant should support the staff's detailed technical review consistent with the agreed-upon schedule.

If the application is accepted with contingencies or is not accepted for docketing, the staff notifies the applicant and identifies the deficiencies and, additionally, the applicant's options concerning the application. If accepted with contingencies, the applicant should address the contingencies and submit supplemental information necessary to resolve the identified deficiencies. If not accepted for docketing, the applicant may withdraw the application and resubmit at a later date after the identified deficiencies are addressed by the applicant.