

**Final Interim Staff Guidance
Necessary Content of Plant-Specific Technical Specifications
When a Combined License Is Issued**

Purpose

The purpose of this interim staff guidance (ISG) is to clarify the U.S. Nuclear Regulatory Commission (NRC) position on what constitutes an acceptable set of plant-specific technical specifications (PTS) required for a combined license (COL) applicant to demonstrate compliance with Sections 182a and 185b of the Atomic Energy Act (the Act); Title 10 of the *Code of Federal Regulations*, Section 52.79 (a)(30) (10 CFR 52.79 (a)(30)); and paragraph IV.A.2.c of the referenced design certification (DC) rule appendix to 10 CFR Part 52, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants.” This ISG provides further clarification on the evaluation criteria that the NRC staff will use to determine whether the application contains sufficient information to support the issuance of a COL and the conclusion that there is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission’s rules and regulations. In particular, this ISG provides further clarification on the evaluation criteria that the NRC staff will use to determine whether the COL applicant has complied with the requirements of the Act and 10 CFR Part 52 concerning PTS.

Background

Section 182a of the Act requires that technical specifications (1) be a part of any license issued for operation of a utilization facility and (2) include information that the Commission may, by rule or regulation, deem necessary for it to find that the utilization of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. Section 185b of the Act requires the Commission to issue to the applicant a “combined construction and operating license” if, among other things, “the application contains sufficient information to support the issuance of a combined license” and “the Commission determines that there is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of this Act, and the Commission’s rules and regulations.” Rules that implement the provisions for technical specifications in Sections 182a and 185b of the Act appear in 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” and 10 CFR Part 52.

Specifically, 10 CFR 50.36, “Technical Specifications,” and 10 CFR 50.36a, “Technical Specifications on Effluents from Nuclear Power Reactors,” provide the Commission’s determination regarding the information that must be in the technical specifications issued as part of a license authorizing operation of a utilization facility. In addition, 10 CFR 52.79(a)(30) states that an application for a COL must contain a final safety analysis report (FSAR) that includes proposed technical specifications in accordance with the requirements of 10 CFR 50.36 and 10 CFR 50.36a. Paragraph IV.A.2.c of DC rule appendices to 10 CFR Part 52 requires that COL applications referencing a DC rule include PTS consisting of the generic and site-specific technical specifications that are required by 10 CFR 50.36 and 10 CFR 50.36a. The Statements of Consideration for the DC rulemakings make clear that the COL applicant must provide complete PTS, including the completion of bracketed items. For example, the Statements of Consideration in Volume 71 of the *Federal Register*, page 4464 (71 FR 4464), dated January 27, 2006, regarding Appendix D, “Design Certification Rule for the AP1000 Design,” to 10 CFR Part 52, state the following:

Enclosure

Paragraph IV.A.2.c requires submission of plant-specific TS [technical specifications] for the plant that consists of the generic TS from section 16.1 of the DCD [generic design control document], with any changes made under paragraph VIII.C of this appendix, and the TS for the site-specific portions of the plant that are either partially or wholly outside the scope of this design certification. The applicant must also provide the plant-specific information designated in the generic TS, such as bracketed values.

Paragraph IV.A.2.e of DC rule appendices to 10 CFR Part 52 requires that COL applications address COL action items. Chapter 16 of the generic design control document (DCD) of each DC rule has identified COL action items for providing site or plant-specific information in the PTS. However, the requirement that the PTS satisfy 10 CFR 50.36 and 10 CFR 50.36a when issued with the COL means that such action items must be resolved by the COL applicant and not by the COL holder or licensee.

In part, 10 CFR 52.97(a)(1) states that the Commission may issue a COL if the Commission finds, among other things, that (1) the applicable standards and requirements of the Act and the Commission's regulations have been met, (2) there is reasonable assurance that the facility will operate in conformity with the license, the provisions of the Act, and the Commission's regulations, and (3) issuance of the license will not be inimical to the common defense and security or to the health and safety of the public. In accordance with 10 CFR 52.97(c), a COL shall contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.

As noted previously, 10 CFR 52.79(a)(30) states that the FSAR submitted as part of a COL application shall include proposed technical specifications. Under 10 CFR 52.79(d)(3), the FSAR "must demonstrate that all requirements and restrictions set forth in the referenced DC rule, other than those imposed under § 50.36b, must be satisfied by the date of issuance of the COL. Any requirements and restrictions set forth in the referenced DC rule that could not be satisfied by the time of issuance of the COL, must be set forth as terms or conditions of the COL." The August 28, 2007, Statements of Consideration for the final rule revising 10 CFR Part 52 (72 FR 49352 [specifically page 49387]) discuss 10 CFR 52.79(d)(3) together with 10 CFR 52.79(b)(3):

In addition, the Commission is revising this paragraph [52.79(b)(3)] to add a provision that any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license must be set forth as terms or conditions of the combined license. This provision is needed to address terms or conditions of the early site permit that are related to activities that will not take place until after issuance of the combined license, such as construction activities. A similar change is being made to §§ 52.79(d)(3) and (e)(3) for referenced design certifications and manufacturing licenses.

Generic technical specifications for standard plant designs, either those previously certified or being reviewed for certification, contain COL action items to include site-specific information in the PTS. Previously, the staff did not expect COL applicants to resolve all of these action items by the time of COL issuance because of the impracticality of obtaining the information needed to obtain final technical specification values for certain items. This supporting information includes system design details, equipment selections, manufacturer recommendations, instrumentation

setting uncertainties, system as-built information, and the results of system testing, including startup testing. Therefore, the staff incorporated into its COL application and review guidance the position that a COL applicant could propose a COL condition in accordance with 10 CFR 52.79(d)(3) as a means of resolving any COL action items in the generic technical specifications that the applicant could not otherwise address before issuance of the COL. The staff guidance appears in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" (hereafter referred to as the Standard Review Plan (SRP)), Section 16.0, "Technical Specifications," Revision 2, issued March 2007; and Regulatory Guide (RG) 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," issued June 2007, Section C.III.4.3, "Combined license information items that cannot be resolved before the issuance of a license."

On October 8, 2008, the staff issued the proposed ISG "Interim Staff Guidance on the Necessary Content of Plant-Specific Technical Specifications for a Combined License," (COL/DC-ISG-008) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML082520707) to solicit public and industry comment. The staff did not receive any comments on the draft ISG. Therefore, the ISG is now being issued for use.

Issue Discussion

Paragraph IV.A.2.e of each DC rule appendix to 10 CFR Part 52 requires a COL applicant to address in its application the COL action (or information) items. Paragraph II.E.3 of each DC rule states that Tier 2 information includes COL action items, which identify "certain matters that must be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references" the DC rule. Although generic technical specifications are a part of the DC rule, they are not Tier 2 information. However, in practice, the NRC staff and industry have used the term "COL action item" to describe preliminary or missing site-specific technical specification information. Such information is denoted by brackets, reviewer's notes, or other placeholders in the generic technical specifications, which are in Chapter 16 of the generic DCD of the referenced DC rule. For example, NRC final safety evaluation reports for previous standard DCs enumerate one or more COL action items in the evaluation of the generic technical specifications; and these items correspond to the description of such action items in the Tier 2 information of Chapter 16 of the generic DCD.

Recognizing that some COL action items in the generic DCD cannot be fully addressed by the time of issuance of the COL, the staff identified four options that it considered acceptable to address such action items by the time the COL is issued. Section C.III.4.3 of RG 1.206 describes one of the four optional approaches as follows:

- (3) The COL applicant proposes a condition to the license or identifies an existing license condition (e.g., TS [technical specifications]) for COL information items (e.g., the operational programs discussed in Section C.IV.4). The license condition should include implementation schedules to allow the coordination of activities with the NRC construction inspection program.

The staff believed that this guidance was consistent with the 2007 revision to 10 CFR Part 52, which states in 10 CFR 52.79(d)(3) that "any requirements and restrictions set forth in the referenced design certification rule that could not be satisfied by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license." The staff

also incorporated this option, along with other guidance related to 10 CFR Part 52 requirements, in SRP Section 16.0. In particular, the SRP discusses providing a condition in the COL requiring the licensee to update the PTS before initial fuel load with any information that was unavailable when the COL was issued.

The staff reasoned that this guidance was acceptable because the license condition would preclude plant operation, including initial fuel load, until the PTS contained all the site-specific information necessary to ensure the safe operation of the facility. However, the staff has determined that the approach in this guidance cannot be used for technical specifications because the Act requires technical specifications issued with the COL to contain all the information mandated by 10 CFR 50.36 and 10 CFR 50.36a. As stated above, technical specifications serve the purpose, under Section 182a of the Act, of allowing the NRC to make its operational safety finding. Section 182a also requires the issued license to include technical specifications. Moreover, Section 185b specifically requires the NRC to make its finding of safe operation when issuing the COL. Therefore, compliance with these statutory provisions requires including a complete set of technical specifications in the COL to support the Commission's safety findings for granting a COL.

Final Interim Staff Guidance

Present and future applicants for standard plant DCs shall identify resolution of all generic technical specification COL action items by the time of COL issuance as the responsibility of the COL applicant; DC applicants may not identify resolution of generic technical specification COL action items as the responsibility of the COL holder following issuance of the COL.

To comply with the Act and the regulations applicable to PTS issued with a COL referencing a standard DC rule, present and future COL applicants shall propose PTS containing all site-specific information that is necessary to ensure plant operation within its design basis. The COL applicant shall confirm all preliminary information and provide all missing information that is denoted in the generic technical specifications by bracketed values, reviewer's notes, or any other placeholder. The PTS issued with the COL will be complete and will contain no COL action (or information) items for the COL holder to resolve (i.e., completing the PTS). The COL will contain no license condition on completing the PTS.

Present and future COL applicants shall resolve all generic technical specification COL action (or information) items before COL issuance. The COL applicant may propose to resolve each such item using one of the following three options, listed in order of preference:

- (1) Provide a plant-specific value.
- (2) Provide a value that bounds the plant-specific value, but by which the plant may be safely operated (i.e., a useable bounding value).
- (3) Establish a PTS Section 5.5 or 5.6 administrative controls program or report.

Such an administrative controls technical specification as described in option (3) shall require (a) use of an NRC-reviewed and -approved methodology for determining the plant-specific value, (b) establishment of an associated document, outside the PTS, in which the relocated plant-specific value shall be recorded and maintained, and (c) any other information or

restrictions the NRC staff deems necessary and appropriate to satisfy 10 CFR 50.36. For example, some COL applicants have proposed an administrative controls technical specification for a set point control program to satisfy 10 CFR 50.36(c)(1)(ii)(A) in lieu of specifying explicit values for the limiting safety system settings in the PTS.

Options (2) and (3) should allow an applicant to provide the necessary information without relying on information that is impractical to obtain before the time of COL issuance (i.e., information such as design detail, equipment selection, as-built system configuration, and system test results). Option (2) may be the most time-efficient approach to provide to the NRC staff for review.

Final Resolution Method

Upcoming updates of RG 1.206 and SRP Section 16.0 will address the change in staff position presented in this ISG. The updates will either clarify or correct affected sections of these documents dealing with the resolution of generic technical specification COL action items, which are described in Chapter 16 of the DCD of the DC rule (or DC application) referenced by the COL applicant. The NRC final safety evaluation report for the referenced standard certified design also describes the generic technical specification COL action items.

Applicability

This ISG is applicable to all DC and COL applications submitted under 10 CFR Part 52. It shall remain in effect until it has been superseded, withdrawn, or incorporated into a revision of SRP Section 16.0 and RG 1.206.