POLICY ISSUE
(Information)

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FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: CHANGE IN STAFF POSITION CONCERNING INFORMATION IN PLANT-SPECIFIC TECHNICAL SPECIFICATIONS THAT COMBINED LICENSE APPLICANTS MUST PROVIDE TO SUPPORT ISSUANCE OF COMBINED LICENSES

PURPOSE:

To describe a change in position that the U.S. Nuclear Regulatory Commission (NRC) staff has determined is essential to ensure that plant-specific technical specifications in combined license applications contain sufficient information to support the issuance of combined licenses. Also, to describe the options available to combined license applicants to complete proposed technical specifications in response to this change in staff position.

SUMMARY:

The staff, after extensive discussion with the NRC Office of the General Counsel (OGC), has concluded that the plant-specific technical specifications issued with a combined license must be complete, implementable, and provide a basis for the Commission to conclude that the plant will operate in accordance with the relevant requirements. This discussion has resulted in a change of staff position on the use of license conditions to address combined license information items related to technical specifications. The previous staff position is included in NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” Section 16.0, “Technical Specifications,” Revision 2. The change will affect those technical specification items for which neither a plant-specific value nor a useable bounding value is available at the time of issuance of the combined license. This decision means that any process or methodology used to develop such necessary operational limits must be within the technical specifications (for example, in the technical specification

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administrative controls section) rather than external to the technical specifications, as would be the case with the previously envisioned use of a condition in the combined license. This paper also describes how the staff plans to continue working with applicants and stakeholders on the scope, format, and content of associated conforming changes to plant-specific technical specifications. Additionally, this paper discusses the schedule and resource implications the revised guidance may have on the staff's current and future reviews of combined license applications.

BACKGROUND:

Under Section 182a of the Atomic Energy Act, technical specifications have the statutory function of allowing the Commission to make its operational safety finding. Section 182a also requires the issued license to include technical specifications. Section 185b of the Atomic Energy Act governs the issuance of combined licenses and requires the Commission to find, before issuing the license 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." In Title 10, Section 50.36, "Technical Specifications," of the *Code of Federal Regulations* (10 CFR 50.36) and 10 CFR 50.36a, "Technical Specifications on Effluents from Nuclear Power Reactors," the NRC has defined by regulation the information that must be contained in technical specifications. The NRC includes technical specifications in the combined license under 10 CFR 52.97, "Issuance of Combined Licenses."

Paragraph IV.A.2.c of each design certification rule appendix to 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," requires combined license applicants referencing a certified design to include plant-specific technical specifications with their applications. Plant-specific technical specifications include both the generic technical specifications, contained in Chapter 16 of the generic design control document (DCD) of the referenced design certification rule, and the site-specific technical specifications. Paragraph IV.A.2.e of each design certification rule appendix requires a combined license applicant to address in its application the combined license action (or information) items. Paragraph II.E.3 of each design certification rule states that Tier 2 information includes combined license 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 design certification rule.

DISCUSSION:

Recognizing that some combined license action items in the generic DCD cannot be fully addressed by the time of issuance of the combined license, the staff identified options that it considered acceptable for addressing such action items by the time the combined license is issued. Section C.III.4.3, "Combined License Information Items That Cannot Be Resolved before the Issuance of a License," of Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," issued June 2007, describes one of the optional approaches as follows:

> (3) The COL [combined license] 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 Section 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 NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 16.0, "Technical Specifications," Revision 2, issued March 2007. In particular, this guidance discusses providing a condition in the combined license requiring the licensee to update the plant-specific technical specifications before initial fuel load with any information that was unavailable when the combined license was issued.

The staff reasoned that this guidance was acceptable because the license condition would preclude plant operation, including initial fuel load, until plant-specific technical specifications contained all the site-specific information necessary to ensure the safe operation of the facility.

Combined license applicants are following this guidance. The staff knows from past experience in reviewing standard design certification applications that design certification applicants had proposed combined license action items in generic technical specifications because determining some of the technical specification information, generally numerical values, required having other supporting information that was not available during the review of the design certification application. Some of this supporting information also remains unavailable during combined license application reviews. Such information includes system design details, equipment selections, manufacturer recommendations, as-built system configurations, and the results of system testing, including prestartup testing. Without exception, combined license applications that have been docketed include proposed plant-specific technical specifications containing placeholders for site-specific information that the licensee proposed to provide when practicable after issuance of the combined license and on a schedule specified in an associated license condition.

In November 2007, the staff sent a combined license applicant a letter containing the results of the staff's acceptance review of the application and raising the issue of technical specification completeness. Since then, the staff has communicated to the industry that it would require resolution of combined license action items in the technical specifications before issuance of the combined license, except for those items related to design acceptance criteria. For example, because plant-specific instrumentation setting values would ordinarily not be determined until after completing the detailed design, which includes closing out design acceptance criteria for instrumentation and control systems, the combined license holder would insert these instrumentation settings into plant-specific technical specifications when practicable (through a license amendment under 10 CFR 52.98, "Finality of Combined Licenses; Information Requests"), but before plant operation, to satisfy an associated condition of the combined license.

At the May 2008 Joint Design Center Working Group meeting, during a discussion of the limited use of placeholder items in plant-specific technical specifications, OGC staff expressed concern that the Atomic Energy Act and 10 CFR Part 52 may not permit such items to be left pending in the plant-specific technical specifications issued with a combined license. Subsequently, OGC

and the Office of New Reactors (NRO) staff began working together to fully evaluate the staff guidance in this area. By mid-August 2008, this activity led the staff to conclude, based on OGC's advice, that the plant-specific technical specifications issued with a combined license must be complete, implementable, and provide a basis for the Commission to conclude that the plant will operate in accordance with the relevant requirements. That is, technical specifications are deemed acceptable for ensuring safe operation of the facility if they satisfy 10 CFR 50.36 and 10 CFR 50.36a. Accordingly, unless the staff concludes that the plant-specific technical specifications satisfy 10 CFR 50.36 and 10 CFR 50.36a, it would not be able to provide the Commission with a necessary portion of the basis for making the required reasonable assurance finding regarding facility operation.

The need to include a complete and implementable set of technical specifications with the combined license when it is issued fundamentally derives from the Act. As stated above, Section 182a of the Act ties technical specifications to the NRC's operational safety finding and requires technical specifications to be included in the issued license. Section 185b requires the NRC to make its finding of safe operation when issuing the combined license. Therefore, compliance with these statutory provisions requires including a complete set of technical specifications in the combined license to support the Commission's safety findings for granting a combined license. The enclosure to this paper provides more extensive background on the regulatory basis for this change in staff position.

The staff plans to communicate this change in staff position to current and potential combined license applicants and other stakeholders through the issuance of interim staff guidance (ISG) and requests for additional information. The staff plans to issue the ISG, included in the enclosure to this paper, during the last week of September 2008.

In the ISG, the NRO staff has identified options that combined license applicants may use to resolve all generic technical specification combined license action items. These options would allow applicants to finalize the plant-specific technical specifications by replacing plant-specific values with useable bounding values or administrative control technical specifications that require use of NRC-approved methodologies to determine plant-specific values. The staff would prefer the useable bounding value approach over the methodology approach in order to maintain the standard presentation of technical specification information. These options do not rely on supporting information, as described above, which is impractical to obtain before the time of combined license issuance. Once the applicant has resolved all combined license action items, as well as all other issues related to the technical specifications, the staff would consider plant-specific technical specifications to be sufficient to support combined license issuance.

The staff plans to request additional information from combined license applicants regarding which of these options they will use to resolve each of the action items that they previously had designated in their applications as placeholder items for finalization by the combined license holder. The staff will send the applicants these requests shortly after it publishes the ISG for public comment.

In accordance with a communications plan that the staff has prepared for coordinating actions related to developing the ISG, the staff will continue working with applicants and stakeholders on the scope, format, and content of changes to plant-specific technical specifications associated with implementation of this change in staff position. At the September 2008 Joint

Design Center Working Group meeting, the staff informed industry of this change in staff position on plant-specific technical specifications that are issued with a combined license.

License conditions have also been proposed to address other areas of combined license application review that are impacted by a lack of detailed design information. In light of the changing staff position on the use of license conditions to address combined license action items in the generic technical specifications, the staff is examining the extent to which license conditions proposed by combined license applicants are appropriate for addressing these other areas of combined license application review.

RESOURCES:

This change in staff position will impact the current schedules for combined license applications that have been docketed and are under review. The impact on each design center and reference combined license applicant will vary. Once this has been addressed for the reference combined license application, the subsequent combined license applicants can use the same solution and thus minimize the resource impacts on subsequent combined license application reviews for each design center.

The ISG provides three options for addressing combined license action items in the generic technical specifications; each option has different resource implications. Addressing a combined license action item by providing the necessary plant-specific information, such as a numerical limit, would have little or no effect on both schedule and resources, beyond the effort expended by the applicant in determining that information. Addressing an action item by providing information that is bounding to the plant-specific information could require additional resources and schedule delays stemming from a need for the staff to review and approve the basis for the bounding information and to determine that the bounding information could be used for plant operation. Addressing an action item by providing an administrative control technical specification that requires using an NRC-approved methodology to determine the information, which will be kept outside the technical specifications in a specified document, would have the greatest impact on schedule and resources. This is because of the challenges associated with the staff's review and approval of a methodology, and to a lesser extent with reaching agreement with the applicant on the administrative control technical specification format and content.

NRO does not have resources for this work in the Fiscal Year (FY) 2009 budget request and the resource needs were not addressed in the FY 2010 Planning, Budgeting, and Performance Monitoring (PBPM) process. The staff will work with each of the design centers to learn which option will be used to resolve each of the combined license action items during the combined license application review. The staff will conduct a review to identify funding for reallocation and will inform the Commission of any impacts of the reallocation. Future planning, budgeting, and performance monitoring processes will address the required funding for FY 2011 and beyond.

COORDINATION:

The Office of the General Counsel reviewed this package and agrees that it is consistent with OGC's legal advice to the staff. The Chief Financial Officer reviewed this package and determined that it has financial impact.

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Enclosure:
Interim Staff Guidance

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, Section 52.79(a)(30), of the *Code of Federal Regulations* (10 CFR 52.79(a)(30)); and paragraph IV.A.2.c of the referenced design certification 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 design certification rule appendices to 10 CFR Part 52 requires that COL applications referencing a design certification 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 design certification 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:

> 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 design certification 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 design certification 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 design certification rule, other than those imposed under § 50.36b, must be satisfied by the date of issuance of the combined license. 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 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 SRP), Section 16.0, "Technical Specifications," Revision 2, issued March 2007; and Regulatory Guide 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."

Issue Discussion

Paragraph IV.A.2.e of each design certification 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 design certification 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 design certification rule. Although generic technical specifications are a part of the design certification 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 design certification rule. For example, NRC final safety evaluation reports for previous standard design certifications 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 Regulatory Guide 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.

Proposed Interim Staff Guidance

Present and future applicants for standard plant design certifications shall identify resolution of all generic technical specification COL action items by the time of COL issuance as the responsibility of the COL applicant; design certification 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 design certification 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 setpoint control program to satisfy 10 CFR 50.36(d)(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 Regulatory Guide 1.206 and SRP Section 16.0 will address the change in staff position presented in this ISG, and the NRC staff is specifically requesting comments on revising these NRC guidance documents. 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 design certification rule (or design certification 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.

After resolution of public comments, the staff will issue this ISG in final form and incorporate its contents into SRP Section 16.0 and the appropriate sections of Regulatory Guide 1.206.

Applicability

This ISG is applicable to all design certification 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 Regulatory Guide 1.206.