C.2.6 COL Application Referencing DC and/or ESP

OVERVIEW

A COL application may, as allowed by 10 CFR 52.73, reference an ESP issued under 10 CFR 52, Subpart A–Early Site Permits, or a DC issued under Subpart B–Standard Design Certifications. By referencing an ESP, the COL applicant acquires the established level of regulatory finality regarding the site as provided by 10 CFR 52.39, "Finality of Early Site Permit Determinations." By referencing a DC, the COL applicant acquires the established level of regulatory finality associated with the design as provided by 10 CFR 52.63, "Finality of Standard Design Certifications."

The optimal use of the Part 52 licensing process is to reference both a DC and an ESP. COL applicants who reference both a DC and an ESP will have a significant portion of the facility reviewed by the NRC before applying for a COL. The remaining portions requiring safety and environmental review will constitute the information contained in the plant-specific FSAR and the environmental report. The guidance herein pertains to regulatory matters specific to a COL applicant referencing a DC and/or an ESP.

Final Safety Analysis Report
For a COL application referencing a DC, 10 CFR 52.79(d) provides that the FSAR need not contain information or analyses submitted to the Commission in connection with the DC provided, however, that the FSAR incorporates by reference the DC FSAR and contains, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the DC.

For a COL application referencing an ESP, 10 CFR 52.79(b) provides that the FSAR need not contain information or analyses submitted to the Commission in connection with the ESP provided, however, that the FSAR incorporates by reference the ESP SSAR and contains, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP.

Environmental report
For a COL application referencing a DC, 10 CFR 51.50(c)(2) provides that the COL environmental report may incorporate by reference the environmental assessment previously prepared by the NRC for the referenced DC. If the DC environmental assessment is referenced, then the COL environmental report must contain information to demonstrate that the site characteristics for the combined license site fall within the site parameters in the DC environmental assessment.

For a COL application referencing an ESP, 10 CFR 51.50(c)(1) provides that the COL environmental report need not contain information or analyses submitted to the Commission in the ESP environmental report or resolved in the Commission's ESP environmental impact statement but must contain, in addition to the environmental information and analyses otherwise required: (1) information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP; (2) information to resolve any significant environmental issue that was not resolved in the ESP proceeding; and, (3) any new and significant information for issues related to the impacts of construction and operation of the facility that were resolved in the ESP proceeding.

Sections C.1.3, “Environmental Report,” and C.2.15, “Environmental Issue Finality for COL Applicants,” of this regulatory guide contain guidance for information to be included in the environmental report.

GUIDANCE

Material Referenced

Applications under 10 CFR Part 52 may reference other documents as part of the provisions for the specific application. However, the application should clearly indicate whether these documents are (1) reference materials used to provide supplemental information, or (2) legally binding requirements necessary as part of the design or licensing description or bases in accordance with a specific requirement of 10 CFR Part 52.

A document which provides supplementary information on a topic and is not intended to provide a unique provision or approach describing the plant design or operation is a “reference document.” Conversely, a document “incorporated by reference” constitutes a requirement that is mandated as part of the design or operating provision or approach. The NRC may rely upon documents incorporated by reference in making determinations required by 10 CFR Part 52 for issuance of a certification or license. Deviations from documents incorporated by reference are controlled by the regulatory change processes set forth for the application. See Section C.2.14 within this guidance, “Information Change Processes for COL Applicants,” for additional guidance .

For example, in a DC application if a document is incorporated by reference then it could be either: (i) the actual description of the plant design; or (ii) information demonstrating that the design meets applicable NRC requirements and which is required by 10 CFR 52.47 to be in the DC FSAR or DCD. Such documents constitute requirements and must be listed in the DC rule as being approved for incorporation by reference. Documents incorporated by reference in the DC FSAR or DCD are considered by the NRC to apply as requirements to any COL applicant or licensee referencing the DC rule. Also, documents incorporated by reference are within the scope of issue resolution of the DC rule and are accorded issue finality protection under 10 CFR 52.63. The ESBWR DC rule (79 *Federal Register* 61944, 61955-61959) describes the difference between a document incorporated by reference and a reference document.

A COL application should include a discussion of reference material and material incorporated by reference. This discussion should be presented in Section 1.6 of the FSAR, consistent with NUREG-0800. Documents not intended to constitute requirements should be identified as references “for information only” and documents intended as requirements should be identified as “incorporated by reference.” Also, the applicant should make available public versions of referenced non-public documents.

FSAR Information

The requirements at 10 CFR 52.79(a) identify the scope and contents of the FSAR. NUREG-0800 addresses the technical information and level of detail to be included in the FSAR. The organization and format of the FSAR, for a COL application referencing a DC and/or ESP, should be consistent with NUREG-0800 and, additionally, should support clear understanding of that information which (1) is incorporated by reference from the DC or ESP, (2) is supplemental to the DC or ESP (e.g., conceptual design information, COL action items), or (3) constitutes a departure from the DC or variance from the ESP.

COL applicants should facilitate the NRC staff's review of the FSAR wherever possible. The NRC staff, as part of the review process, will verify that the information provided in the FSAR of a COL application is consistent with the referenced certified design and the referenced ESP. The applicant's use of the standardized format and clear and definitive presentation of information supports an effective and efficient review of the FSAR.

COL applicants should, in Chapter 1 of the FSAR, include administrative information, additional to the technical information identified in NUREG-0800, to address the organization and format of the FSAR and the information pertaining to the DC and ESP. Applicants should:

- Use an administrative scheme (e.g., "left-margin" annotation scheme analogous to that used by prior COL applicants) to identify FSAR information pertaining to the referenced DC or ESP. Such a scheme would designate that FSAR information which (1) is incorporated by reference from the DCD or SSAR; (2) replaces conceptual design information in the DCD; (3) supplements information in the DCD or SSAR; (4) addresses a COL action item in the DC or ESP; (5) is a departure from the DC or variance from the ESP; (6) involves an exemption from the regulations; (7) differentiates between a reference COL and subsequent COL; and, (8) should be annotated for clarity.
- Discuss the FSAR format consistency with this regulatory guide and NUREG-0800.
- Address compliance with Section IV of the appendix to 10 CFR Part 52 codifying the referenced certified design that requires COL applicants to follow the same organization and numbering as the certified design, as modified and supplemented by the applicant's exemptions and departures.
- Discuss pagination scheme and the format, content, and numbering for text, tables, and figures included in the FSAR.
- Discuss the method used to identify and reference proprietary information (see Section C.1.9, "Withheld Information," of this regulatory guide).
- List the acronyms used in the application. For consistency, applicants referencing a certified design and an ESP should use the acronyms provided in the DCD and ESP and should provide a supplemental list of acronyms for items not included in the DCD and ESP, as necessary.

Design Acceptance Criteria

The NRC implemented the policy of approving design acceptance criteria (DAC) in the design certification process in a limited number of design areas. Prior DCs have used DAC in the areas of radiation protection, instrumentation and controls, piping, and human factors engineering.

A COL applicant referencing a DC which used DAC should include detailed design information in the design areas where DAC were used. Alternatively, the COL applicant may justify the continued use of DAC in the COL application and provide implementation plans for design completion. Section C.2.8, "Design Acceptance Criteria," of this regulatory guide contains explanatory information and guidance on this topic.

COL Action Items

COL action items identify certain matters that shall be addressed in the FSAR by an applicant who submits a COL application that references a DC and/or an ESP. The appendices to Part 52 contain the design certification rules (DCRs) and each appendix requires a COL application referencing the DC to include information that addresses the identified COL action items. These COL action items (COL license information) are those regulatory matters that the DC vendor

deferred to the COL applicant to address in the COL application. For example, these items include (1) complete design information for the remainder of a proposed facility referencing a DC, (2) verification of site parameters, (3) completion of analyses and design reports for as-built plant systems, (4) development and implementation of operational programs, and (5) completion of designs included in DAC. Similarly, a COL applicant who references an ESP must address any COL action items pertaining to the ESP terms and conditions that were deferred to be addressed in the COL application.

Section C.2.11, "COL Action Items & Post-License Commitments," of this regulatory guide contains explanatory information and guidance on this topic. Applicants should note that the terms "COL action item" and "COL information item" have been used interchangeably; however, the term "COL action item" is used for consistency throughout this regulatory guide.

Design Interfaces – DC and ESP

The DC FSAR is required by 10 CFR 52.47(a)(25) to contain the interface requirements to be met for those portions of the nuclear power plant for which the DC application does not seek certification. Further, 10 CFR 52.47(a)(26) requires the DC FSAR to contain justification that compliance with the interface requirements is verifiable through inspections, tests, or analyses.

COL applications referencing a DC are required by 10 CFR 52.79(d) to contain information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the DC and, additionally, must contain information sufficient to demonstrate that the interface requirements established for the design under 10 CFR 52.47 have been met. If not demonstrated in the application, the COL applicant shall include a request for departure that complies with the requirements of 10 CFR 52.63, 10 CFR 52.93, and/or Section VIII of the referenced DC rule appendix to Part 52.

COL applications referencing an ESP are required by 10 CFR 52.79(b) to contain information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP. For an ESP that uses a plant parameter envelope (PPE) approach, the COL application must contain information sufficient to demonstrate that the design of the facility falls within the site characteristics enveloped in the PPE. (A PPE sets forth postulated values of design parameters that provide design details to support the NRC staff's review of an ESP application. A controlling PPE value, or bounding parameter value, is one that necessarily controls the value of a site characteristic. As the PPE is intended to bound multiple reactor designs, the actual design selected in a COL application referencing an ESP must fit within the bounding parameter values.) If not demonstrated in the application, the COL applicant shall include a request for variance that complies with the requirements of 10 CFR 52.39 and 10 CFR 52.93.

The COL applicant should provide information sufficient to demonstrate compliance with the requirements of 10 CFR 52.79(b) and 10 CFR 52.79(d) in Chapter 1 of the FSAR. The information should be included in Section 1.8 and/or a cross-referenced tabulation highlighting the specific FSAR sections that contain the sufficient information.

Conceptual Design Information – DC

10 CFR 52.47(a)(24) requires the DC application to contain a representative conceptual design for those portions of the nuclear power plant for which the application does not seek certification, to aid the NRC in its review of the DCD and to permit assessment of the

adequacy of the interface requirements in paragraph (a)(25) of 10 CFR 52.47.

COL applicants who reference a DC should provide a complete design for the entire facility, including appropriate site-specific design information to replace any conceptual design portions for the referenced certified design. DC applicants facilitated the NRC staff review of applications by including conceptual designs in the DCDs that offered a more comprehensive design perspective and these conceptual designs typically included portions of the balance-of-plant of the nuclear facility. However, the conceptual portions of the design were not certified and need to be addressed by the COL applicant. The NRC does not consider replacement of the conceptual design information with actual design information to be a departure from the DC because the conceptual design was not certified. However, for those instances in which the actual design information differs from the conceptual design information, the COL applicant should address the impact of these differences on the NRC's evaluation of the certified design and the design probabilistic risk assessment, as applicable.

The COL applicant should provide information to address the conceptual design information from the referenced DC in Chapter 1 (Section 1.8) of the FSAR and applicable FSAR sections. The level of detail needed for the site-specific designs that replace conceptual designs should be consistent with the level of detail provided in the DCD for the non-conceptual (or specific) designs and should be sufficient to resolve all safety issues.

Departures from the DC

A departure is a plant-specific deviation from design information in a DC rule. Section IV of the appendices to 10 CFR Part 52 codifying the certified designs requires a COL applicant referencing a certified design to incorporate by reference, as part of its application, the applicable appendix. A COL applicant referencing a DC may make departures from the design as provided in 10 CFR 52.63 and 52.93 and Section VIII, "Processes for Changes and Departures," of the referenced DC rule appendix to Part 52.

The COL applicant requesting a departure that requires Commission approval should identify and discuss the departure in Part 7 of the application, and should provide appropriate information in the FSAR to justify the departure as needed. The applicant should discuss the departure in the FSAR section that corresponds to the DCD section in which the topic is presented and should include in Chapter 1 of the FSAR a tabular list of departures with reference to applicable FSAR sections. The applicant should provide sufficient information for the NRC staff to resolve all safety and security issues in its review of the departure.

COL applicants referencing a certified design are required by the applicable DCR appendix to 10 CFR Part 52 to provide a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. The DCR also requires each applicant to maintain and submit updates to its plant-specific DCD, which consists of the generic DCD and plant-specific departures. Applicants may fulfill these requirements by providing a report separate from the FSAR with the description and evaluation for each departure and include a summary table in this section of the FSAR providing a list of each departure and the FSAR section(s) in which each departure is addressed.

Sections C.1.7 and C.2.14 of this regulatory guide contain explanatory information and guidance on this topic.

Variances from the ESP

A variance is a plant-specific deviation from one or more of the site characteristics, design parameters, or terms and conditions of an ESP or from the SSAR. As required by 10 CFR 52.79(b), if the application's FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters of the ESP, the COL application shall include a request for a variance that complies with the requirements of 10 CFR 52.39 and 52.93. In addition, the COL applicant may, at its option, request a variance from the permit terms and conditions or from the SSAR.

The COL applicant requesting a variance should identify and discuss the variance in Part 7 of the application and should provide detailed and sufficient information in the FSAR to justify the variance and enable the NRC staff to resolve all safety issues pertaining to the variance. Further, the applicant should identify or uniquely designate the information provided in the application, including the FSAR, that is a variance from the ESP. In addition, 10 CFR 51.50(c)(1)(i) requires the environmental report (ER) to contain information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP. Therefore, the ER must analyze the environmental impact of the variance.

Sections C.1.7 and C.2.14 of this regulatory guide contain explanatory information and guidance on this topic.

Exemptions from the regulations

A COL applicant's intended departure from the referenced DC may constitute an exemption from NRC regulations as discussed in the DCR appendices to 10 CFR Part 52 that would require an exemption request. In addition, a COL applicant may request an exemption from one or more of the requirements of 10 CFR Part 52 as provided in 10 CFR 52.7.

COL applicants should discuss any departure from the referenced certified design that requires an exemption in the section of the FSAR that corresponds to the DCD section in which the topic is presented. The COL applicant should include sufficient information for the NRC staff to resolve all safety and security issues related to the exemption and to determine the regulatory basis for the exemption as described in 10 CFR 52.93.

Further, COL applicants should understand that the NRC staff regards an exemption from the referenced certified design as a potential critical path item in the review of a COL application. Accordingly, the COL applicant should inform the NRC of its intent to request exemptions, including the number and nature of these exemptions, during pre-application interactions.

Sections C.1.7 and C.2.14 of this regulatory guide contain explanatory information and guidance on this topic.

Conformance with NUREG-0800 and Regulatory Guides

NUREG-0800

The requirements of 10 CFR 52.79(a)(41) specify that COL applicants evaluate the facility against the NUREG-0800 revision that is in effect 6 months before the docket date of the application. The evaluation shall identify and describe all differences in design features, analytical techniques, and procedural measures proposed for the facility and those corresponding features, techniques, and measures given in the acceptance criteria in the application and review guidance.

In accordance with 10 CFR 52.47(a)(9), DC applicants provided information addressing conformance with NUREG-0800 that was in effect 6 months before the docket date of the DC application. In accordance with 10 CFR 52.63, COL applicants who reference a DC are not required to re-address conformance with NUREG-0800 for those portions of the facility design included in the referenced DC. However, a COL applicant should address conformance with the NUREG-0800 revision in effect 6 months before the submittal date of the COL application for the site-specific portions of the facility design that are not included in the referenced DC. In addition, the COL applicant should address conformance with NUREG-0800 insofar as it pertains to operational aspects of the facility. COL applicants who include departures from the referenced DC should evaluate these departures for conformance with the NUREG-0800 revision in effect 6 months before the submittal date of the COL application.

Similarly, the requirements of 10 CFR 52.17(a)(1)(xii) specify that ESP applicants evaluate the site against applicable sections of NUREG-0800 in effect 6 months before the docket date of the ESP application. In accordance with 10 CFR 52.39, COL applicants who reference an ESP are not required to re-address conformance with the applicable NUREG-0800 sections included in the referenced ESP. COL applicants who include variances from the ESP should evaluate these variances for conformance with the NUREG-0800 revision in effect 6 months before the submittal of the COL application.

Regulatory Guides

DC applicants should provide information addressing conformance with regulatory guides that were in effect 6 months before the submittal date of the DC application. In accordance with the provisions of 10 CFR 52.63, COL applicants who reference a DC are not required to re-address conformance with regulatory guides for the portions of the facility design included in the referenced DC. However, for the site-specific portions of the facility design that are not included in the referenced DC, a COL applicant should address conformance with regulatory guides in effect 6 months before the submittal date of the COL application. In addition, the COL applicant should address conformance with regulatory guides in effect 6 months before the submittal date of the COL application insofar as they pertain to operational aspects of the facility. COL applicants who include departures that require NRC approval from the referenced DC should evaluate these departures for conformance with the regulatory guides in effect 6 months before the submittal date of the COL application.

ESP applicants should provide information addressing conformance with applicable regulatory guides that were in effect 6 months before the submittal date of the ESP application. In accordance with the provisions of 10 CFR 52.39, COL applicants who reference an ESP are not required to re-address conformance with the applicable regulatory guides included in the ESP. COL applicants who include variances from the ESP should evaluate these variances for conformance with the regulatory guides in effect 6 months before the submittal of the COL applications.

COL Application Timing

A COL application submittal date may differ considerably from the submittal date of the referenced DC or ESP (i.e., a DC is valid for 15 years and an ESP may be issued for up to 20 years, and COL applications that reference a DC or ESP may do so at any point during the valid life of the DC or ESP). Therefore, the revision number of NUREG-0800 and regulatory guides that a COL applicant should address might also differ considerably from those considered in the referenced DC. However, the COL applicant should address those NUREG-

0800 and regulatory guide revisions issued after the NUREG-0800 and regulatory guides that were evaluated for the referenced DC only insofar as they may impact site-specific portions of the facility design not included in the referenced DC. In addition, the COL applicant should address operational aspects of the facility and any departures and variances consistent with the aforementioned guidance.

Completeness and Accuracy of Referenced DC and ESP

A COL applicant referencing a DC and/or ESP is not required to revise the information included in the DC and ESP. However, pursuant to 10 CFR 52.6, each applicant who identifies information suggesting that the regulated activity has a significant implication for public health and safety or common defense and security shall notify the Commission of this information. An applicant referencing an ESP is required to submit the information specified in 10 CFR 51.50(c)(1).

DC and/or ESP applications under review

Part 52 allows a COL applicant, at its own risk, to submit a COL application which references a DC and/or an ESP application that has been docketed and is undergoing review by the NRC staff, as follows:

- 10 CFR 52.26(c) provides that an applicant for a COL may, at its own risk, reference in its application a site for which an ESP application has been docketed, but not granted. However, the terms of 10 CFR 51.50(c)(1) dictate that the environmental review for a COL application referencing an ESP cannot begin until an ESP has been issued, given that the COL environmental report must reference the (issued) permit and its proceeding. The applicant should discuss with the staff the impact to the environmental review schedule.
- 10 CFR 52.55(c) provides that an applicant for a COL may, at its own risk, reference in its application a design for which a DC application has been docketed, but not granted.

This regulatory guide does not include guidance specific to the “concurrent review” approach allowed by 10 CFR 52.26(c) and 52.55(c) due to the numerous “what if” scenarios involving regulatory issues and schedule interactions associated with concurrent application reviews. In general, the NRC staff recommends that the COL applicant who elects to reference a DC and/or ESP application undergoing staff review should ensure timely synchronization of information contained in the COL application with that in the DC/ESP application. It is incumbent upon the COL applicant to synchronize the update and revision of the COL application in a timely manner consistent with DC/ESP application information undergoing review. For example, the COL application may need to be revised to reflect updated information in topical reports and technical reports and responses to RAIs related to the COL/ESP application. In addition, the COL application will need to be updated once the ESP is issued.