

C.3 Application Regulatory Topics

C.3.14 Information Change Processes for COL Applicants

[Record-keeping: This guidance updates RG 1.206 C.IV.3 *General Description of Change Processes* (2007)]

OVERVIEW

10 CFR Part 52 provides that a combined license (COL) application may reference an early site permit (ESP) and/or a design certification (DC). A COL applicant who intends to change portions of the information contained in the referenced ESP and/or the DC must comply with the Part 52 provisions which address the unique information change processes. A referenced ESP has regulatory finality regarding the site as provided by §52.39, “Finality of Early Site Permit Determinations,” and §52.39 describes processes for a COL applicant to request or to make changes to ESP information. A referenced DC has regulatory finality associated with the design as provided by §52.63, “Finality of Standard Design Certifications,” and §52.63(b) describes processes for a COL applicant to request or to make changes to DC information.

It is essential that the COL applicant referencing an ESP and/or DC maintain a clear distinction between the information contained in the COL application itself and that information formally incorporated by reference from the ESP and/or DC. Such distinction is necessary due to the different information change control and reporting requirements. The COL applicant has the responsibility to ensure that the information presented in the application is complete, through a combination of formal incorporation by reference and COL-application-specific material. The COL applicant also has the responsibility to ensure that the application is current and accurate. If information (e.g., site characteristics) have changed since the issuance of a referenced ESP or DC, changes to that referenced information may be necessary (e.g., an ESP variance).

The guidance provided herein addresses the processes to be followed when a COL applicant intends to change portions of the information contained in the referenced ESP and/or DC. This guidance is not applicable to a COL application that references neither a DC nor an ESP; and, the guidance is not applicable to an ESP or DC application.

GUIDANCE

COL Application Referencing an ESP

As required by §52.39, a COL applicant referencing an ESP shall demonstrate that the proposed facility falls within the site characteristics and design parameters specified in the ESP and must provide information to resolve any significant environmental issues not resolved in the ESP proceeding. Also, the COL applicant shall update the emergency preparedness information that was provided under §52.17(b) and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements. In addition, the information change processes in §52.39 provide that a COL applicant referencing an ESP may include in its application a request for a variance (i.e., change) in one or more site characteristics, design parameters, or terms and conditions of the ESP or the site safety analysis report (SSAR) associated with the ESP.

The COL applicant requesting a variance should clearly identify, evaluate, and justify each variance and include such explanatory documentation in Part 7 of the COL application. (See Section C.1, PART 7 – Exemptions, Departures, and Variances, of this regulatory guide).

COL Application Referencing a DC

A COL applicant referencing a DC shall comply with the Part 52 change process applicable to the type of information requested to be changed. §52.63(b) describes processes for a COL applicant to request or to make changes to DC information. In addition, the design certification rule (DCR) appendices to Part 52 are similarly structured and the information change processes are addressed at Section VIII, Processes for Changes and Departures. Although the DCRs are similarly structured, each DCR requires different technical information—under the same overall process—to be subject to review and approval by the NRC staff before changes are made.

The DCRs establish a three-tier hierarchy of design-related information. The COL applicant intending to change design information must either request an exemption or propose a departure depending on whether the information is defined as Tier 1, Tier 2, or Tier 2* or, alternatively, pertains to operational requirements. Further, as required by Section IV, Additional Requirements and Restrictions, of the DCRs, the COL applicant shall include as part of the application a plant-specific DCD, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of the DCRs. Table 1 below summarizes the process for COL applicants proposing to change information contained in the DC.

The COL applicant should identify, evaluate, and justify each exemption request and proposed departure. The applicant should include such explanatory documentation in Part 7 of the COL application. (See Section C.1, PART 7 – Exemptions, Departures, and Variances, of this guide.)

Changes to Tier 1 Information

As defined in Section II of the DCRs, **Tier 1** is the portion of the generic DCD that is approved and certified by the DCR. It includes definitions and general provisions; design descriptions; inspections, tests, analyses, and acceptance criteria (ITAAC); significant site parameters; and significant interface requirements. It is derived from the more-detailed information in Tier 2 (described below).

Because the information in Tier 1 represents the certified portion of the design, there are strict requirements for changes to this information. A COL applicant requesting an exemption should describe the basis for the change (grouped by topic where appropriate) and justify the regulatory acceptability, as well as provide the appropriate revisions to the generic DCD in the plant-specific DCD. When the exemption involves an underlying substantive requirement (e.g., a regulation in 10 CFR Part 50), the COL applicant must also show that the exemption from the underlying applicable requirement meets the criteria in 10 CFR 50.12.

Changes to Tier 2 Information

As defined in Section II of the DCRs, **Tier 2** is the portion of the generic DCD that is approved but not certified by the DCR. It includes the information required by subsections (a) and (c) of 10 CFR 52.47, except generic technical specifications, conceptual design information, supporting information on ITAAC, COL information items, and other items listed in the DCR.

Section VIII.B of the DCRs describes the process for making changes, some of which may be made without prior NRC approval. The criteria for determining whether prior approval is required are provided in VIII.B.5.b (for most Tier 2 information), VIII.B.5.c (for severe accident

features), and VIII.B.5.d (for the aircraft impact assessment). The criteria in VIII.B.5.b are similar to those in 10 CFR 50.59 and relate to accident analysis, function of structures, systems, and components, design basis limits, and methods of evaluation. An exemption is not automatically required since the material is approved but not certified; however, an applicant may determine that an exemption from Tier 2 material is appropriate in certain cases.

A COL applicant departing from Tier 2 of the generic DCD should describe the basis for the change (grouped by topic where appropriate) and justify the regulatory acceptability, as well as provide the appropriate revisions to the generic DCD in the plant-specific DCD. This information should be provided regardless of whether the individual change requires prior NRC approval. In determining that a change does not require prior NRC approval, the applicant should verify that the Tier 2 change does not affect Tier 1, Tier 2*, or the technical specifications. The applicant's evaluation of a proposed change should consider matters resolved in the DCD, such as generic issue resolutions that are relevant to the proposed departure, to ensure appropriate standardization and resolution of safety issues. The evaluation also needs to consider the full range of operation from startup to shutdown, as it relates to anticipated operational occurrences, transients, design-basis accidents, and severe accidents. The evaluation should also include a review of all relevant references in the DCD that are intended to be treated as a requirement equivalent to material in the DCD (e.g., through formal incorporation by reference in the DCR). Departures from Tier 2 made in compliance with Section VIII.B.5 of the DCRs that do not require prior NRC approval will be considered resolved. The NRC staff will not re-review these departures in the COL proceeding, as described in Section VI.B of the DCRs.

Changes to Tier 2* Information

Tier 2* is different from the remainder of Tier 2 because NRC approval is required for any change, as described in Section VIII.B.6 of the DCRs. The category of Tier 2* information was established during the NRC's initial DC reviews. During this development process, these applicants requested that the agency minimize the amount of information in Tier 1 to allow additional flexibility for a COL applicant or licensee who references a DCR. Tier 2 also specified many codes, standards, and design processes that Tier 1 does not specify, but that the staff found acceptable for meeting ITAAC. As a result, Tier 2 contains certain significant information that must not be changed without prior NRC approval. This information is designated Tier 2* (generally marked with italics or brackets and an asterisk in the generic DCD). A portion of this information retains its Tier 2* designation throughout the duration of a COL license, including any license renewal, because of the need for NRC review of any changes. The remainder is associated primarily with construction detail and therefore reverts to the standard process for Tier 2 information after the Commission makes its finding in accordance with 10 CFR 52.103(g) that the acceptance criteria in the COL are met. Examples of these two groups of information for the AP1000 DCR can be found in 10 CFR Part 52, Appendix D, Section VIII.B.6.b (e.g., fuel information) and Section VIII.B.6.c (e.g., structural dimensions of the nuclear island).

A COL applicant proposing to depart from Tier 2* information in the generic DCD should describe the basis for the change (grouped by topic as appropriate) and justify the regulatory acceptability, as well as provide appropriate revisions to the plant-specific DCD. Requests for departures from Tier 2* information that affect Tier 1 must also follow the Tier 1 change procedures described above.

Changes to Operational Requirements

As stated in Section VI, Issue Resolution, of the DCRs, the Commission does not consider the

operational requirements addressed in a DC to be resolved within the meaning of §52.63(a)(5) for a COL applicant who references the DC. Therefore, a COL applicant must provide additional detail to complete the information needed to resolve the operational requirements (e.g., identified in COL action items). A COL applicant also must provide plant-specific values for the generic technical specifications.

A COL applicant intending to change information pertaining to operational requirements may request an exemption from the generic technical specifications or other operational requirements contained in the DC. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7.

Guidance regarding COL action items and technical specifications is provided, respectively, in Section C.2.11, COL Action Items and License Commitments, and Section C.1, PART 4 – Technical Specifications, of this regulatory guide.

Table 1: COL Applicant Change Process for DC Information

Type of Information	Type of Change	Requirements for Change
Tier 1	Exemption	DCR Section VIII, Processes for Changes and Departures – VIII.A.4 10 CFR 52.63, Finality of standard design certifications – § 52.63(b)(1) 10 CFR 52.7, Specific exemptions 10 CFR 50.12, Specific exemptions – § 50.12(a)
Tier 2 or 2*	Exemption	DCR Section VIII.B.4 10 CFR 50.12(a)
Operational Requirements	Exemption	DCR Section VIII.C.4 10 CFR 52.7 10 CFR 50.12(a)
Tier 2*	Departure (Prior NRC approval required)	DCR Section VIII.B.6.a
Tier 2	Departure (Prior NRC approval required)	DCR Section VIII.B.5
Tier 2	Departure (Prior NRC approval not required)	DCR Section VIII.B.5 [Note: Departure must not involve a change to or departure from Tier 1, Tier 2*, or the generic TS, or otherwise require prior NRC approval]