

### **C.IV.3 General Description of Change Processes**

This section describes the unique change processes associated with the licensing process set forth in Title 10, Part 52, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants,” of the *Code of Federal Regulations* (10 CFR Part 52). Combined license (COL) applications introduce a unique set of change processes during licensing because of the likelihood that these applications will reference previously approved design documentation for a certified standard design or an approved safety analysis for an early site permit (ESP). It is essential that a COL application referencing a certified design and/or ESP site maintains a clear distinction between the material in the COL application itself and the portions of the application that are incorporated by reference, which may be subject to different change control and reporting requirements.

The guidance included in this section is based on the statements of consideration in each of the four design certification rules (DCRs) that have been codified at the time of issuance of this guide. COL applicants should consult the DCR for the design they are referencing for specific requirements for their particular certified design.

#### ***C.IV.3.1 Custom Combined License Applications***

For a COL application referencing neither a certified design nor an ESP, the information in the application does not have the finality associated with other parts of the 10 CFR Part 52 licensing process. The U.S. Nuclear Regulatory Commission (NRC) refers to this application as one referencing a custom design with none of the siting issues resolved. Therefore, none of the unique 10 CFR Part 52 change processes apply to this type of COL application scenario.

When the agency issues a COL in this scenario, the change processes established in 10 CFR Part 2, “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders,” 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” and 10 CFR Part 52 apply to the entire final safety analysis report. These include, but are not limited to, the following regulations:

- 10 CFR 2.309, “Hearing Requests, Petitions to Intervene, Requirements for Standing, and Contentions”
- 10 CFR 2.335, “Consideration of Commission Rules and Regulations in Adjudicatory Proceedings”
- 10 CFR 50.12, “Specific Exemptions”
- 10 CFR 50.59, “Changes, Tests, and Experiments”
- 10 CFR 50.109, “Backfitting”
- 10 CFR 50.90, “Application for amendment of license or construction permit”
- 10 CFR 52.97, “Issuance of Combined Licenses”

#### ***C.IV.3.2 Combined License Applications Referencing an Early Site Permit***

The change processes related to an ESP or a COL application referencing an ESP are defined in 10 CFR 52.39, “Finality of early site permit determinations.” This regulation prohibits the NRC from imposing new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on an ESP unless:

- a modification is necessary to bring the ESP or the site into compliance with the NRC regulations and orders applicable and in effect at the time the permit was issued, or
- a modification is necessary to assure adequate protection of the public health and safety or the common defense and security.

For cases where an ESP emergency plan (or major features thereof) is the same as the emergency plan in use by a licensee for a nuclear power plant, the holder of the ESP may make changes to the ESP emergency plan that correspond identically to changes made to the emergency plan for the licensed nuclear power plant in compliance with 10 CFR 50.54(q). If the ESP emergency plan is not also used by a licensee for a nuclear power plant, the holder of the ESP may make changes equivalent to those that could be made under 10 CFR 50.54(q) without prior NRC approval had the emergency plan been in use by a licensee. The COL application shall include an update to the emergency preparedness information provided during the ESP review and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements.

The holder of an ESP may not make changes to the ESP, including the site safety analysis report (SSAR), without prior NRC approval. A request for a change to an ESP must be in the form of a license amendment in accordance with 10 CFR 50.90, "Application for amendment of license or construction permit," and 10 CFR 50.92, "Issuance of amendment." An applicant for a COL referencing an ESP may include in its application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the ESP or the SSAR. The NRC shall use the same technically relevant criteria applicable to the original or renewed ESP when making its finding on a variance included in a COL application. Contentions on whether a requested variance is unwarranted or should be modified may be litigated in the same manner as other issues material to the COL proceeding.

#### C.IV.3.3 *Combined License Applications Referencing a Certified Design*

This section describes the processes associated with generic changes to, or plant-specific departures (including exemptions) from, the certified design control document (DCD). The agency adopted this change process to achieve a more stable licensing process for applicants and licensees who reference a DCR. As illustrated by Table C.IV.3-1, the design certification change process, and this section of the guidance, is divided into three subsections, which correspond to Tier 1, Tier 2, and operational requirements. Definitions for the various categories and terms are provided in the DCR appendices to 10 CFR Part 52.

**Table C.IV.3-1 Design Certification Change Process:  
Changes to, and Departures from, DCDs**

DCD	Applicability		DCR Section	Change Standard
	Generic	All		
Tier 1	Generic	All	VIII.A.1 (10 CFR 52.63(a)(1))	Adequate protection backfit or compliance exception, reduces unnecessary regulatory burden, provides detailed design information, corrects errors, or contributes to standardization
	Plant-specific	NRC	VIII.A.3 (10 CFR 52.63(a)(3))	Adequate protection backfit or compliance exception, special circumstances, and standardization
		Applicant/ licensee	VIII.A.4 (10 CFR 52.63(b)(1)) (10 CFR 52.97(b))	10 CFR 50.12(a), special circumstances, and standardization
Tier 2	Generic	All	VIII.B.1 (10 CFR 52.63(a)(1))	Adequate protection backfit or compliance exception, reduces unnecessary regulatory burden, provides detailed design information, corrects errors, or contributes to standardization
	Plant-specific	NRC	VIII.B.3	Adequate protection backfit or compliance exception, and special circumstances
		Applicant/ licensee	VIII.B.4 (10 CFR 50.12(a))	No significant decrease in safety
		Applicant/ licensee	VIII.B.5 (~ 10 CFR 50.59)	Not Tier 1, 2*, TS, or require license amendment
		Applicant/ licensee	VIII.B.6	Tier 2* requires NRC approval
Generic technical specifications or other operational requirements	Generic	All	VIII.C.1	10 CFR 50.109, VIII.A, VIII.B
	Plant-specific	NRC	VIII.C.3	Special circumstances
		Applicant	VIII.C.4	10 CFR 50.12(a)
		Party	VIII.C.5	10 CFR 2.309 and special circumstances
		Licensee	VIII.C.6	Generic TSs have no further effect

The language distinguishes between generic *changes to* the DCD and plant-specific *departures from* the DCD. Generic *changes* must be accomplished by rulemaking because the intended subject of the change is the DCR itself, as contemplated by 10 CFR 52.63(a)(1). Consistent with 10 CFR 52.63(a)(2), any generic rulemaking changes apply to all plants, absent circumstances that render

the change technically irrelevant. By contrast, a plant-specific *departure* could be either a Commission-issued order to one or more applicants or licensees or could be an applicant- or licensee-initiated departure applicable to that applicant's or licensee's plants. Because these plant-specific departures result in a DCD that is unique for that plant, the applicant or licensee is required to maintain a plant-specific DCD. For purposes of brevity, this discussion refers to both generic changes and plant-specific departures as "change processes." The information provided by an applicant to address conceptual design information or COL information items are not considered to be departures provided the information remains consistent with the descriptions in the generic DCD.

The Commission cautions that when an exemption involves an underlying substantive requirement (applicable regulation), the applicant or licensee requesting the exemption must also show that an exemption from the underlying applicable requirement meets the criteria in 10 CFR 50.12.

All references in this section, with the exception of those that are clearly tied to a specific section of Title 10 of the CFR, refer to the DCR appendices to 10 CFR Part 52.

#### **C.IV.3.3.1 Tier 1 Information**

Generic changes to Tier 1 are accomplished by an NRC rulemaking that amends the generic DCD and are governed by the standards in 10 CFR 52.63(a)(1). The rulemaking must provide for notice and opportunity for public comment on the proposed change, as required by 10 CFR 52.63(a)(1). Departures from Tier 1 may occur in either of the following two ways:

- (1) The Commission may order a licensee to depart from Tier 1, as provided in the DCR appendices to 10 CFR Part 52.
- (2) An applicant or licensee may request an exemption from Tier 1.

If the Commission seeks to order a licensee to depart from Tier 1, the Commission must find both that the departure is necessary for adequate protection or for compliance and that special circumstances are present. The requirements of 10 CFR 52.63(b)(1) and 52.97(b), which provide an opportunity for a hearing, govern exemptions from Tier 1 requested by an applicant or licensee. In addition, the Commission will not grant requests for exemptions that may result in a significant decrease in the level of safety otherwise provided by the design.

#### **C.IV.3.3.2 Tier 2 Information**

This section addresses change processes for the three different categories of Tier 2 information, namely, Tier 2, Tier 2\*, and Tier 2\* with a time of expiration. The change process for Tier 2 has the same elements as the Tier 1 change process, although some of the standards for plant-specific orders and exemptions would be different.

The process for generic Tier 2 changes (including changes to Tier 2\* and Tier 2\* with a time of expiration) tracks the process for generic Tier 1 changes. Tier 2 changes are accomplished by NRC rulemaking amending the generic DCD and are governed by the standards in 10 CFR 52.63(a)(1). If a generic change is made to Tier 2\* information, the rulemaking also would determine the category and expiration, if necessary, of the new information, and the appropriate change process for that new information would apply.

Departures from Tier 2 may occur in any of the following five ways:

- (1) The Commission may order a plant-specific departure, as set forth in the DCR appendices to 10 CFR Part 52.
- (2) An applicant or licensee may request an exemption from a Tier 2 requirement, as set forth in paragraph VIII.B.4 in the DCR appendices to 10 CFR Part 52.
- (3) An applicant or licensee may make a departure without prior NRC approval under, paragraph VIII.B.5 in the DCR appendices to 10 CFR Part 52 (the “10 CFR 50.59-like” process). The NRC staff will assess such departures but need not provide formal approval as part of its review of the COL application.
- (4) The licensee may request NRC approval for proposed departures that do not meet the requirements in paragraph VIII.B.5, in the DCR appendices to 10 CFR Part 52 as provided in paragraph VIII.B.5.d. For COL applications, the NRC staff will review and document the related regulatory finding regarding these types of departures within the COL process.
- (5) The licensee may request NRC approval for a departure from Tier 2\* information under paragraph VIII.B.6.b in the DCR appendices to 10 CFR Part 52. For COL applications, the applicant may request NRC approval to depart from Tier 2\* information under paragraph VIII.B.6.a and the NRC staff will review and document the related regulatory finding regarding the request within the COL process.

Similar to Commission-ordered Tier 1 departures and generic Tier 2 changes, the agency cannot impose Commission-ordered Tier 2 departures except when necessary either to bring the certification into compliance with the applicable Commission regulations in effect at the time the design certification is approved or to ensure adequate protection of public health and safety or the common defense and security. However, the special circumstances for Commission-ordered Tier 2 departures do not have to outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order, as required by 10 CFR 52.63(a)(3). The Commission determined that it was not necessary to impose an additional limitation similar to that imposed on Tier 1 departures by 10 CFR 52.63(a)(3) and (b)(1). This type of additional limitation for standardization would unnecessarily restrict the flexibility of applicants and licensees with respect to Tier 2 information.

The NRC may permit an applicant or licensee to request an exemption from Tier 2 information. To do so, the applicant or licensee must demonstrate that the exemption complies with one of the special circumstances in 10 CFR 50.12(a). In addition, the Commission will not grant requests for exemptions that may result in a significant decrease in the level of safety otherwise provided by the design. However, the special circumstances for the exemption do not have to outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. If an applicant for a license requests the exemption, the exemption is subject to litigation in the same manner as other issues in the license hearing, consistent with 10 CFR 52.63(b)(1). If a licensee requests the exemption, the exemption is subject to litigation in the same manner as a license amendment.

An applicant or licensee may depart from Tier 2 information, without prior NRC approval, if the proposed departure does not involve a change to, or departure from, Tier 1 or Tier 2\* information or technical specifications (TSs) or does not require a license amendment under the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5.b or paragraph VIII.B.5.c. The TSs referred to in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5.a, are those in Section 16.1 of the generic DCD, including bases, for departures made prior to issuance of the COL. After issuance of the COL, the plant-specific TSs are controlling under the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5. The bases control procedures for the plant-specific TS (analogous to the bases control provision in the

Improved Standard Technical Specifications) will control the bases for the plant-specific TSs. The requirement for a license amendment in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5.b, will be similar to the definition in 10 CFR 50.59 and will apply to all Tier 2 information except for the information that resolves the severe accident issues.

The Commission believes that the resolution of severe accident issues should be preserved and maintained in the same fashion as all other safety issues that were resolved during the design certification review (refer to the staff requirements memorandum associated with SECY-90-377, “Requirements for Design Certification under 10 CFR Part 50”). However, because of the increased uncertainty in severe accident issue resolutions, the Commission has adopted separate criteria in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5.c, for determining whether a departure from information that resolves severe accident issues would require a license amendment. For purposes of applying the special criteria in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5.c, severe accident resolutions are limited to design features when the intended function of the design feature is relied upon to resolve postulated accidents when the reactor core has melted and exited the reactor vessel and the containment is being challenged.

These design features are identified with other issues in Section 1.9.5 and Appendix 19B of the DCD and are described in other sections of the DCD. Therefore, the location of design information in the DCD is not important to the application of this special procedure for severe accident issues. However, the special procedure in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5.c, does not apply to design features that resolve so-called “beyond-design-basis accidents” or other low-probability events. The important aspect of this special procedure is that it is limited to severe accident design features, as defined above. Some design features may have intended functions to meet design-basis requirements and to resolve severe accidents. If these design features are reviewed under the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5, the appropriate criteria from either paragraph VIII.B.5.b or paragraph VIII.B.5.c are selected depending upon the function being changed.

The agency requires an applicant or licensee who plans to depart from Tier 2 information to prepare an evaluation that provides the bases for the determination that the proposed change does not require a license amendment or involve a change to Tier 1 or Tier 2\* information or a change to the TSs, as previously explained. To achieve the Commission’s goals for design certification, the evaluation would need to consider all of the matters that were resolved in the DCD, such as generic issue resolutions that are relevant to the proposed departure. The benefits of the early resolution of safety issues would be lost if departures from the DCD violated these resolutions without appropriate review.

The evaluation of the relevant matters needs to consider the proposed departure over the full range of power operation from startup to shutdown, as it relates to anticipated operational occurrences, transients, design-basis accidents, and severe accidents. The evaluation must also include a review of all relevant secondary references from the DCD because the secondary references contain Tier 2 information, which is intended to be treated as a requirement. The evaluation should consider the design specific information provided in the AP1000 DCD Tables 14.3-1 through 14.3-8 and 19.59-18 to ensure that the proposed change does not impact Tier 1 information. These tables contain cross-references from the safety analyses and probabilistic risk assessment in Tier 2 to the important parameters included in Tier 1.

The NRC permits a party to an adjudicatory proceeding (e.g., for issuance of a COL) who believes that an applicant or licensee has not complied with the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5, when departing from Tier 2 information to petition to admit such a contention into the proceeding under paragraph VIII.B.5.f. The Commission included this provision because an incorrect departure from the requirements of the DCR appendices to 10 CFR Part 52 essentially places the

departure outside the scope of the Commission's safety finding in the design certification rulemaking. Therefore, it follows that properly founded contentions alleging such incorrectly implemented departures cannot be considered resolved by this rulemaking. As set forth in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5.f, the petition must comply with the requirements of 10 CFR 2.309 and must show that the departure does not comply with paragraph VIII.B.5. Any other party may file a response to the petition. If, on the basis of the petition and any responses, the presiding officer in the proceeding determines that the required showing has been made, the matter shall be certified to the Commission for its final determination. In the absence of a proceeding, the agency will treat petitions alleging nonconformance with requirements applicable to Tier 2 departures under the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5, as petitions for enforcement action under 10 CFR 2.206, "Requests for Action under this Subpart."

The DCR appendices to 10 CFR Part 52, paragraph VIII.B.6, provide a process for departing from Tier 2\* information. The creation of, and restrictions on, changing Tier 2\* information resulted from the development of Tier 1 information for the advanced boiling-water reactor design certification (Appendix A to 10 CFR Part 52) and the Asea Brown Boveri-Combustion Engineering System 80+ reactor design certification (Appendix B, "Design Certification Rule for the System 80+ Design," to 10 CFR Part 52). During this development process, these applicants requested that the agency minimize the amount of information in Tier 1 to allow additional flexibility for an applicant or licensee who references these appendices. Tier 2 also specified many codes, standards, and design processes that Tier 1 does not specify but that are acceptable for meeting inspections, tests, analyses, and acceptance criteria. As a result, certain significant information only exists in Tier 2, and the Commission does not want this significant information to be changed without prior NRC approval. The generic DCD identifies this Tier 2\* information with italicized text and brackets (see Table 1-1 of the AP1000 DCD introduction).

Although the Tier 2\* designation was originally intended to last for the lifetime of the facility, like Tier 1 information, the NRC determined that some Tier 2\* information could expire when the plant first achieves full (100-percent) power, after the finding required by 10 CFR 52.103(g), while other Tier 2\* information must remain in effect throughout the life of the facility. The factors determining whether Tier 2\* information could expire after achievement of the first full-power operation were whether the Tier 1 information would govern these areas after first full-power operation and the NRC's determination that prior approval was required before implementation of the change because of the significance of the information. Therefore, certain Tier 2\* information listed in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.6.c, ceases to retain its Tier 2\* designation after full-power operation is first achieved following the Commission finding under 10 CFR 52.103(g). Thereafter, that information is deemed to be Tier 2 information that is subject to the departure requirements in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.5. By contrast, the Tier 2\* information identified in the DCR appendices to 10 CFR Part 52, paragraph VIII.B.6.b, retains its Tier 2\* designation throughout the duration of the license, including any period of license renewal.

Appendices C and D to 10 CFR Part 52, paragraph VIII.B.6.c, designates certain preoperational tests to be performed only for the first or the first three plants that reference the applicable appendix. Section 14.2.5 of the DCD provide Westinghouse's basis for performing these "first-plant-only" and "first-three-plants-only" preoperational tests. The NRC found that Westinghouse had an acceptable basis for performing these tests, as well as an acceptable justification for only performing the tests on the first plant or first three plants. The NRC based its decision on the need to verify that plant-specific manufacturing and/or construction variations do not adversely impact the predicted performance of certain passive safety systems, while recognizing that these special tests will result in significant thermal transients being applied to critical plant components. The NRC believes that the range of manufacturing

or construction variations that could adversely affect the relevant passive safety systems would be adequately disclosed after performing the designated tests on the first plant or first three plants, as applicable. The COL action item in Section 14.4.6 of the DCD states that subsequent plants shall either perform these preoperational tests or justify that the results of the first-plant-only or first-three-plants-only tests are applicable to the subsequent plant. The Tier 2\* designation for these tests will expire after the first plant or first three plants complete these tests, as indicated in the applicable appendices to 10 CFR Part 52, paragraph VIII.B.6.c.

If a generic rulemaking changes Tier 2\* information, the rulemaking also would determine the designation of the new information (Tier 1, 2\*, or 2), and the appropriate process for future changes would apply. If a plant-specific departure is made from Tier 2\* information, the new designation would apply only to that plant. If an applicant who references this design certification makes a departure from Tier 2\* information, the new information is subject to litigation in the same manner as other plant-specific issues in the licensing hearing. If a licensee makes a departure from Tier 2\* information, the agency will treat it as a license amendment under 10 CFR 50.90, "Application for Amendment of License or Construction Permit," and will determine the finality in accordance with the DCR appendices to 10 CFR Part 52, paragraph VI.B.5. Any requests for departures from Tier 2\* information that affect Tier 1 must also comply with the requirements in the DCR appendices to 10 CFR Part 52, paragraph VIII.A.

#### **C.IV.3.3.3 Operational Requirements**

The change process for TSs and other operational requirements has elements similar to the Tier 1 and Tier 2 change processes, but with significantly different change standards. Because of the different finality status for TSs and other operational requirements, the Commission decided to designate a special category of information, consisting of the TSs and other operational requirements, with its own change process in the DCR appendices to 10 CFR Part 52, paragraph VIII.C. The key to using the change processes in Section VIII is to determine whether the proposed change or departure requires a change to a design feature described in the generic DCD. If a design change is required, the change process in paragraph VIII.A or paragraph VIII.B applies. However, if a proposed change to the TSs or other operational requirements does not require a change to a design feature in the generic DCD, paragraph VIII.C applies. The language in paragraph VIII.C of the DCR appendices also distinguishes between generic (Section 16.1 of DCD) and plant-specific TSs to account for the different treatment and finality accorded TSs before and after a license is issued.

The process for making generic changes to the generic TSs in Section 16.1 of the DCD or other operational requirements in the generic DCD is accomplished by rulemaking and governed by the backfit standards in 10 CFR 50.109. The determination of whether the agency completely reviewed and approved the generic TSs and other operational requirements in the design certification rulemaking is based upon the extent to which an NRC safety conclusion in the final safety evaluation report is being modified or changed. If it cannot be determined that the NRC comprehensively reviewed and finalized the TSs or operational requirements in the design certification rulemaking, there is no backfit restriction under 10 CFR 50.109 because the agency did not take a prior position on this safety matter. Generic changes made under paragraph VIII.C.1 apply to all applicants or licensees (refer to paragraph VIII.C.2), unless the change is irrelevant because of a plant-specific departure.

Some generic TSs and investment protection short-term availability controls contain values in brackets [ ]. These brackets are placeholders indicating that the NRC's review is not complete and represent a requirement that COL applicants replace the values in brackets with final plant-specific values. The values in brackets are neither binding nor part of the DCR. Therefore, the replacement of bracketed values with final plant-specific values does not require an exemption from the generic TSs or investment protection short-term availability controls. The generic DCDs may also include COL information items to provide values for bracketed information in TS and values or procedures to determine values for bracketed information within short-term availability controls. See Section C.III.4 of this guide for additional discussions on COL information items.

Plant-specific departures may occur by either a Commission order or an applicant's exemption request. The basis for determining whether the NRC completely reviewed and approved the TSs or operational requirements for these processes is the same as paragraph VIII.C.1 (described above). If the agency comprehensively reviewed and finalized the TSs or operational requirements in the design certification rulemaking, the Commission must demonstrate that special circumstances are present before ordering a plant-specific departure. If not, there is no restriction on plant-specific changes to the TSs or operational requirements, prior to the issuance of a license, provided that a design change is not required. Although the NRC staff reviewed the generic TSs to facilitate the design certification review, the Commission intends to consider the lessons learned from subsequent operating experience during its licensing review of the plant-specific TSs. The process for the NRC to require plant-specific departures from generic TS is provided in paragraph VIII.C.5.3 of the appendices to 10 CFR Part 52. The process for petitioning to intervene on a TS or operational requirement is similar to that for other issues in a licensing hearing, except that the petitioner must also demonstrate why special circumstances exist.

Moreover, the generic TSs will have no further effect on the plant-specific TSs after the issuance of a license that references the applicable DCR appendix to 10 CFR Part 52. The change process in paragraph VIII.C, controls the bases for the generic TSs. After a license is issued, the bases change provision set forth in the administrative controls section of the plant-specific TSs will control the bases. Changes to other operational programs will be controlled in accordance with conditions within the COL and 10 CFR 52.98, "Finality of combined licenses; information requests," such that (1) changes to or departures from information within the scope of the referenced DCR are subject to the applicable change processes in that rule; and (2) changes that are not within the scope of the referenced DCR are subject to the applicable change processes in 10 CFR part 50, unless they also involve changes to or noncompliance with information within the scope of the referenced DCR, which would make applicable provisions in 10 CFR part 52 and the DCR.