

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, 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.

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 Part 52 licensing process. The NRC refers to this application as one referencing a custom design with none of the siting issues resolved. Therefore, none of the unique Part 52 change processes apply to this type of COL application scenario.

When a COL is issued in this scenario, the change processes established in 10 CFR Parts 2, 50, and 52 apply to the entire final safety analysis report (FSAR). 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 52.63 Finality of standard design certifications
- 10 CFR 52.97 Issuance of combined licenses

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

Guidance for the change processes associated with an ESP will be included in the final guide after the NRC finalizes its revision of the 10 CFR Part 52 rule.

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). This restrictive change process was adopted to achieve a more stable licensing process for applicants and licensees who reference this 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.

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

DCD	Applicability		Rule	Change Standard
Tier 1	Generic	All	VIII.A.1 [§52.63(a)(1)]	adequate protection backfit or compliance exception
	Plant-specific	NRC	VIII.A.3 [§52.63(a)(3)]	adequate protection backfit or compliance exception, special circumstances, and standardization
		applicant/ licensee	VIII.A.4 [§52.63(b)(1)] [§52.97(b)]	§50.12(a), special circumstances, and standardization
Tier 2	Generic	All	VIII.B.1 [§52.63(a)(1)]	adequate protection backfit or compliance exception
	Plant-specific	NRC	VIII.B.3	adequate protection backfit or compliance exception, and special circumstances
		applicant/ licensee	VIII.B.4 [§50.12(a)]	no significant decrease in safety
		applicant/ licensee	VIII.B.5 [~ §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	§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	§2.309 and special circumstances
		licensee	VIII.C.6	generic TS have no further effect

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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 are applicable 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 applicant(s) or licensee(s), or an applicant- or licensee-initiated departure applicable only to that applicant's or licensee's plant(s), similar to a §50.59 departure or an exemption. 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 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 10 CFR section, 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 rulemaking that amends the generic DCD and are governed by the standards in 10 CFR 52.63(a)(1). This provision provides that the Commission may not modify, change, rescind, or impose new requirements by rulemaking, except when necessary either to bring the certification into compliance with the Commission's regulations that are applicable and 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.

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 two ways:

- (1) The Commission may *order* a licensee to depart from Tier 1, as provided in Appendix A to Part 52, §VIII.A.3 (71 FR 12913).
- (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 is required to find both that the departure is necessary for adequate protection or for compliance, and that special circumstances are present. Exemptions from Tier 1 requested by an applicant or licensee are governed by the requirements of 10 CFR 52.63(b)(1) and 52.97(b), which provide an opportunity for a hearing. 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 rulemaking amending the generic DCD and are governed by the standards in 10 CFR 52.63(a)(1). This provision provides that the Commission may not modify, change, rescind, or impose new requirements by rulemaking, except when necessary either to bring the certification into compliance with the Commission's regulations that are applicable and in effect at the time of approval of the design certification or to ensure adequate protection of public health and safety or the common defense and security. If a generic change is made to Tier 2* information, the category and expiration, if necessary, of the new information would also be determined in the rulemaking 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 Appendix A to Part 52, paragraph VIII.B.3 (71 FR 12913).
- (2) An applicant or licensee may request an exemption from a Tier 2 requirement as set forth in Appendix A to Part 52, paragraph VIII.B.4 (71 FR 12914).
- (3) A licensee may make a departure without prior NRC approval under Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914) [the “§50.59-like” process].
- (4) The licensee may request NRC approval for proposed departures that do not meet the requirements in Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914), as provided in paragraph VIII.B.5.d.
- (5) The licensee may request NRC approval for a departure from Tier 2* information under Appendix A to Part 52, paragraph VIII.B.6 (71 FR 12914).

Similar to Commission-ordered Tier 1 departures and generic Tier 2 changes, Commission-ordered Tier 2 departures cannot be imposed except when necessary either to bring the certification into compliance with the Commission’s regulations that are applicable and 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.

An applicant or licensee may be permitted 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 the exemption is requested by an applicant for a license, 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 the exemption is requested by a licensee, the exemption is subject to litigation in the same manner as a license amendment.

For plant-specific Tier 2 information, the change process in the existing DCRs would be commensurate with the change process in the former 10 CFR 50.59. The proposed rule would revise Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914) to conform the terminology in the §50.59-like change process to that used in the revised §50.59. This amendment would delete references to unreviewed safety questions and safety evaluation, and would conform to the evaluation criteria concerning when prior NRC approval is needed. Also, a definition would be added (Appendix A to Part 52, paragraph II.G (71 FR 12912)) for “departure from a method of evaluation” to support the evaluation criterion in Appendix A to Part 52, paragraph VIII.B.5.b(8) (71 FR 12914).

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 (TS), or does not require a license amendment under Appendix A to Part 52, paragraph VIII.B.5.b or paragraph VIII.B.5.c (71 FR 12914). The TS referred to in Appendix A to Part 52, paragraph VIII.B.5.a (71 FR 12914) 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 TS are controlling under Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914). The bases for the plant-specific TS will be controlled by the bases control procedures for the plant-specific TS (analogous to the bases control provision in the Improved Standard Technical Specifications). The requirement for a license amendment in Appendix A to Part 52, paragraph VIII.B.5.b (71 FR 12914) will be similar to the definition in the new 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 (SRM) associated with SECY-90-377]. However, because of the increased uncertainty in severe accident issue resolutions, the Commission has adopted separate criteria in Appendix A to Part 52, paragraph VIII.B.5.c (71 FR 12914) 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 Appendix A to Part 52, paragraph VIII.B.5.c (71 FR 12914), 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 Appendix A to Part 52, paragraph VIII.B.5.c (71 FR 12914) 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 Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914), the appropriate criteria from either Appendix A to Part 52, paragraph VIII.B.5.b or paragraph VIII.B.5.c (71 FR 12914) are selected depending upon the function being changed.

An applicant or licensee who plans to depart from Tier 2 information, is required 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 TS, as previously explained. In order 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 were made that 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 Tier 2 information, which is intended to be treated as a requirement, is contained in the secondary references. The evaluation should consider Tables 14.3-1 through 14.3-8 and 19.59-18 of the generic DCD 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 that were included in Tier 1. Although many issues and analyses could have been cross-referenced, the listings in these tables were developed only for key analyses for the AP1000 advanced passive reactor design.

A party to an adjudicatory proceeding (e.g., for issuance of a COL) who believes that an applicant or licensee has not complied with Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914) when departing from Tier 2 information is permitted to petition to admit such a contention into the proceeding under Appendix A to Part 52, paragraph VIII.B.5.f (71 FR 12914). The Commission included this provision because an incorrect departure from the requirements of Appendix A to 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 Appendix A to Part 52, paragraph VIII.B.5.f (71 FR 12914), the petition must comply with the requirements of 10 CFR 2.309, and must show that the departure does not comply with Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914). 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, petitions alleging nonconformance with Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914) requirements applicable to Tier 2 departures will be treated as petitions for enforcement action under 10 CFR 2.206.

Appendix A to Part 52, paragraph VIII.B.6 (71 FR 12914) provides 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 (ABWR) design certification (Appendix A to 10 CFR Part 52) and the Asea Brown Boveri-Combustion Engineering (ABB-CE) System 80+ reactor design certification (Appendix B to 10 CFR Part 52). During this development process, these applicants requested that the amount of information in Tier 1 be minimized to allow additional flexibility for an applicant or licensee who references these appendices. Also, Tier 2 specified many codes, standards, and design processes, which were not specified in Tier 1 but are acceptable for meeting inspections, tests, analyses, and acceptance criteria ITAAC. The result of these actions is that certain significant information only exists in Tier 2, and the Commission does not want this significant information to be changed without prior NRC approval. This Tier 2* information is identified in the generic DCD 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 the first full-power was achieved were whether the Tier 1 information would govern these areas after first full-power 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 Appendix A to Part 52, paragraph VIII.B.6.c (71 FR 12914) ceases to retain its Tier 2* designation after full-power operation is first achieved following the Commission's 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 Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914). By contrast, the Tier 2* information identified in Appendix A to Part 52, paragraph VIII.B.6.b (71 FR 12914) retains its Tier 2* designation throughout the duration of the license, including any period of license renewal.

Certain preoperational tests in Appendix A to Part 52, paragraph VIII.B.6.c (71 FR 12914) are designated to be performed only for the first, or first three, plant(s) that reference(s) this appendix. Westinghouse's basis for performing these "first-plant-only" and "first-three-plants-only" preoperational tests is provided in Section 14.2.5 of the DCD. The NRC found 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's decision was based 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-plant-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(s) these tests, as indicated in Appendix A to Part 52, paragraph VIII.B.6.c (71 FR 12914).

If Tier 2* information is changed in a generic rulemaking, the designation of the new information (Tier 1, 2*, or 2) would also be determined in the rulemaking 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, it will be treated as a license amendment under 10 CFR 50.90 and the finality will be determined in accordance with Appendix A to Part 52, paragraph VI.B.5 (71 FR 12913). Any requests for departures from Tier 2* information that affects Tier 1 must also comply with the requirements in Appendix A to Part 52, paragraph VIII.A (71 FR 12913).

C.IV.3.3.3 Operational Requirements

The change process for TS 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 TS and other operational requirements, the Commission decided to designate a special category of information, consisting of the TS and other operational requirements, with its own change process in proposed Appendix A to Part 52, paragraph VIII.C (71 FR 12914). The key to using the change processes proposed 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 appropriate change process in Appendix A to Part 52, paragraph VIII.A or paragraph VIII.B (71 FR 12913) applies. However, if a proposed change to the TS or other operational requirements does not require a change to a design feature in the generic DCD, Appendix A to Part 52, paragraph VIII.C (71 FR 12914) applies. The language in Appendix A to Part 52, paragraph VIII.C (71 FR 12914) also distinguishes between generic (Section 16.1 of DCD) and plant-specific TS to account for the different treatment and finality accorded TS before and after a license is issued.

The process for making generic changes to the generic TS 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 generic TS and other operational requirements were completely reviewed and approved in the design certification rulemaking is based upon the extent to which an NRC safety conclusion in the final safety evaluation report (FSER) is being modified or changed. If it cannot be determined that the TS or operational requirements were comprehensively reviewed and finalized in the design certification rulemaking, there is no backfit restriction under 10 CFR 50.109 because no prior position was taken on this safety matter. Generic changes made under proposed Appendix A to Part 52, paragraph VIII.C.1 (71 FR 12914) are applicable to all applicants or licensees (refer to Appendix A to Part 52, paragraph VIII.C.2 (71 FR 12914)), unless the change is irrelevant because of a plant-specific departure.

Some generic TS 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 referencing the AP1000 DCR must replace the values in brackets with final plant-specific values. The values in brackets are neither binding nor part of the design certification rule. Therefore, the replacement of bracketed values with final plant-specific values does not require an exemption from the generic TS or investment protection short-term availability controls.

Plant-specific departures may occur by either a Commission order or an applicant's exemption request. The basis for determining whether the TS or operational requirements were completely reviewed and approved for these processes is the same as for Appendix A to Part 52, paragraph VIII.C.1 (71 FR 12914) (above). If the TS or operational requirements were comprehensively reviewed and finalized 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 TS 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 TS 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 TS. 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.

Finally, the generic TS will have no further effect on the plant-specific TS after the issuance of a license that references Appendix A to Part 52. The bases for the generic TS will be controlled by the change process in Appendix A to Part 52, paragraph VIII.C (71 FR 12914). After a license is issued, the bases will be controlled by the bases change provision set forth in the administrative controls section of the plant-specific TS.