NEI 96-07, Appendix C
Revision 0 – Corrected

Nuclear Energy Institute

# GUIDELINE FOR IMPLEMENTATION OF CHANGE PROCESSES FOR NEW NUCLEAR POWER PLANTS LICENSED UNDER 10 CFR PART 52

March 2014

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March 2014

# ACKNOWLEDGMENTS

This document, NEI 96-07, Appendix C, *Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52*, was developed by the NEI Combined License Task Force Change Process Team. We appreciate the time and effort of the individuals who contributed to the development of this guideline.

# NOTICE

# EXECUTIVE SUMMARY

NEI 96-07, Appendix C, *Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52*, provides generic guidance for the change processes to be used under a Part 52 combined license as specified in 10 CFR 52.98. The document reflects the discussions at Nuclear Regulatory Commission (NRC) public workshops during 2010-2013 concerning the development of the NRC's interim staff guidance on the preliminary amendment request process for changes during construction.

A main objective of this guideline is to provide all stakeholders a common framework and understanding of the Part 52 change processes.

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# GUIDELINE FOR IMPLEMENTATION OF CHANGE PROCESSES FOR NEW NUCLEAR POWER PLANTS LICENSED UNDER 10 CFR PART 52

## 1 INTRODUCTION

### 1.1 PURPOSE AND SCOPE

10 CFR 52.98 specifies the change processes to be used under a Part 52 combined license. Changes to or departures from information within the scope of a referenced certified design are subject to the applicable change and departure process in Section VIII of the applicable appendix to 10 CFR Part 52 which contains the design certification rule. Changes that are not within the scope of a referenced design certification rule are subject to the applicable change processes in 10 CFR Part 50 (e.g., 10 CFR 50.59). Some changes may affect information within the scope of the design certification rule as well as information outside the scope of the design certification rule; in those cases, the applicable provisions of both change processes apply.

The main body of NEI 96-07, Revision 1, was written to provide guidance for developing effective and consistent processes for implementing 10 CFR 50.59. This appendix was developed by starting with the NEI 96-07, Revision 1, guidance and providing additional guidance / clarification only as needed to ensure that licensee-initiated changes and departures are properly controlled, documented, and reported to the NRC in accordance with the Part 52 requirements.

This appendix also provides guidance for changes to early site permits (ESPs), per 10 CFR 52.39(e).

In general, this appendix has been written for holders of combined licenses (COLs). Additionally, this guidance is applicable to holders of operating licenses that reference a design certification. However, during construction, the change processes for site-specific information for a holder of a Part 50 construction permit and a holder of a COL are substantially different. This document is not intended to provide guidance for the change process for site-specific information in a preliminary safety analysis report for a Part 50 construction permit. Additionally, this document is not intended to provide guidance for seeking *generic changes* to the design certification through rulemaking. (This guidance document is focused on plant-specific changes and departures, and unless otherwise indicated, the term “change” as used in

this document refers to plant-specific changes outside the scope of the design control document (DCD) under 10 CFR 50.59.) Further, this document is not intended to provide guidance for a holder of a COL, construction permit, or operating license that references a manufacturing license.

## 1.2 Relationship of 10 CFR Part 52 Change Processes to Other Regulatory Requirements and Controls

Part 52 change processes interface with many other regulatory requirements and controls. To optimize the use of the change processes, the applicable rules and this guidance should be understood in the context of the proper relationship with these other regulatory processes. These relationships are generally the same as described in Section 1.2 of the main body of NEI 96-07, Revision 1, with differences noted in italics below:

### 1.2.1 Relationship to Other Processes That Control Licensing Basis Activities

In addition to 10 CFR 50.59 *and the design certification rule change processes*, there are several other complementary processes for controlling activities that affect other aspects of the licensing basis, including:

- Amendments to the *combined* license (including the technical specifications) are sought and obtained under 10 CFR 50.90.
- Where changes to the facility or procedures are controlled by more specific regulations, 10 CFR 50.59(c)(4) states that the more specific regulation applies.
- Changes *or departures* that require an exemption from a regulation are processed in accordance with 10 CFR 50.12 *and 52.7*.
- Guidance for controlling changes to licensee commitments is provided by NEI 99-04, "Guideline for Managing NRC Commitment Changes."
- *Changes to the fire protection program for Part 52 licensees are governed by 10 CFR 50.59 as discussed in Section 4.1 of this appendix, and licensee departures from the design of fire protection systems as described in the DCD are governed by Section VIII of a referenced design certification rule.*
- *Construction activities must result in SSCs that satisfy the requirements of ITAAC. After ITAAC are closed, construction*

*activities are subject to licensee programs that maintain the validity of ITAAC determinations as discussed in NEI 08-01, Section 8.1.*

- *During the operational phase,* maintenance activities, including associated temporary changes, are subject to the technical specifications and are assessed and managed in accordance with the Maintenance Rule, 10 CFR 50.65; screening and evaluation under 10 CFR 50.59 *and VIII.B.5* are not required.

Together with *10 CFR 52.98*, these processes form a framework of complementary regulatory controls over the licensing basis. To optimize the effectiveness of these controls and minimize duplication and undue burden, it is important to understand the scope of each process within the regulatory framework. This guideline discusses *new plant change processes per 10 CFR Part 52* in relation to other processes, including circumstances under which different processes (e.g., 10 CFR 50.59*/VIII.B.5* and 10 CFR 50.90) should be applied to different aspects of an activity.

### 1.2.2 Relationship to 10 CFR 50, Appendix B

10 CFR Part 50, Appendix B, assures that the facility design and construction meet applicable requirements, codes and standards in accordance with the safety classification of systems, structures and components (SSCs). Appendix B design control provisions ensure that all changes *and departures* continue to meet applicable design and quality requirements. Both Appendix B and *the Part 52 change processes* apply following receipt of a *combined* license.

### 1.2.3 Relationship to the UFSAR

*New plant change processes identified in 10 CFR 52.98 are* the processes that identify when a license amendment is required prior to implementing *departures from the plant-specific DCD, other* changes to the facility or procedures described in the FSAR (as updated, or UFSAR), or tests and experiments not described in the UFSAR. As such, it is important that the FSAR be properly maintained and updated in accordance with 10 CFR 50.71(e) *and Section X of the design certification rules*. Guidance for updating FSAR *information outside the scope of the plant-specific DCD* is provided by Regulatory Guide 1.181, which endorses NEI 98-03, Revision 1.

### 1.2.4 Relationship to 10 CFR 50.2 Design Bases

10 CFR 50.59 *and Section VIII.B.5.b of the design certification rules* control changes to *or departures from* both 10 CFR 50.2 design bases and supporting design information contained in the FSAR *and plant-specific DCD, respectively*. In support of implementation of 10 CFR 50.59 *and Section VIII.B.5.b*, Section 4.3.7 of *the main body of NEI 96-07, Revision 1*, defines the design basis limits for fission product barriers that are subject to control, and Section 4.3.8 *of the main body of NEI 96-07, Revision 1,* provides guidance on the scope of methods of evaluation used in establishing design bases or in the safety analyses. Additional guidance for identifying 10 CFR 50.2 design bases is provided in NEI 97-04, Appendix B.

As discussed in Section *3.4*, "design bases functions" (defined in NEI 97-04, Appendix B) are a subset of "design functions" for purposes of screening.

### 1.2.5 Relationship to Requirements on Safety/Security Interface

10 CFR 73.58 specifies requirements for safety/security interface. In addition to the change control requirements discussed in this appendix, the licensee shall assess and manage the potential for adverse effects on safety and security, including the site emergency plan, before implementing changes to plant configurations, facility conditions, or security. The scope of changes to be assessed and managed must include planned and emergent activities (such as, but not limited to, physical modifications, procedural changes, changes to operator actions or security assignments, maintenance activities, system reconfiguration, access modification or restrictions, and changes to the security plan and its implementation). Where potential conflicts are identified, the licensee shall communicate them to appropriate licensee personnel and take compensatory and/or mitigative actions to maintain safety and security under applicable Commission regulations, requirements, and license conditions.

## 1.3 10 CFR PART 52 CHANGE PROCESS OVERVIEW

After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR Part 52 change processes are applied to determine if a license amendment and/or exemption is required prior to implementation. This process involves the following basic steps as depicted in Figure 1:

- **Applicability and Screening:** Determine which change process applies and if an evaluation is required.

- **Evaluation:** Apply the applicable change process evaluation criteria to determine if prior NRC approval is required.

- **Documentation and reporting:** Document and report to the NRC changes and departures implemented under change processes in accordance with NRC requirements.

Later sections of this document discuss key definitions; provide guidance for determining applicability, screening, and performing change process evaluations; and present examples to illustrate the application of the process.

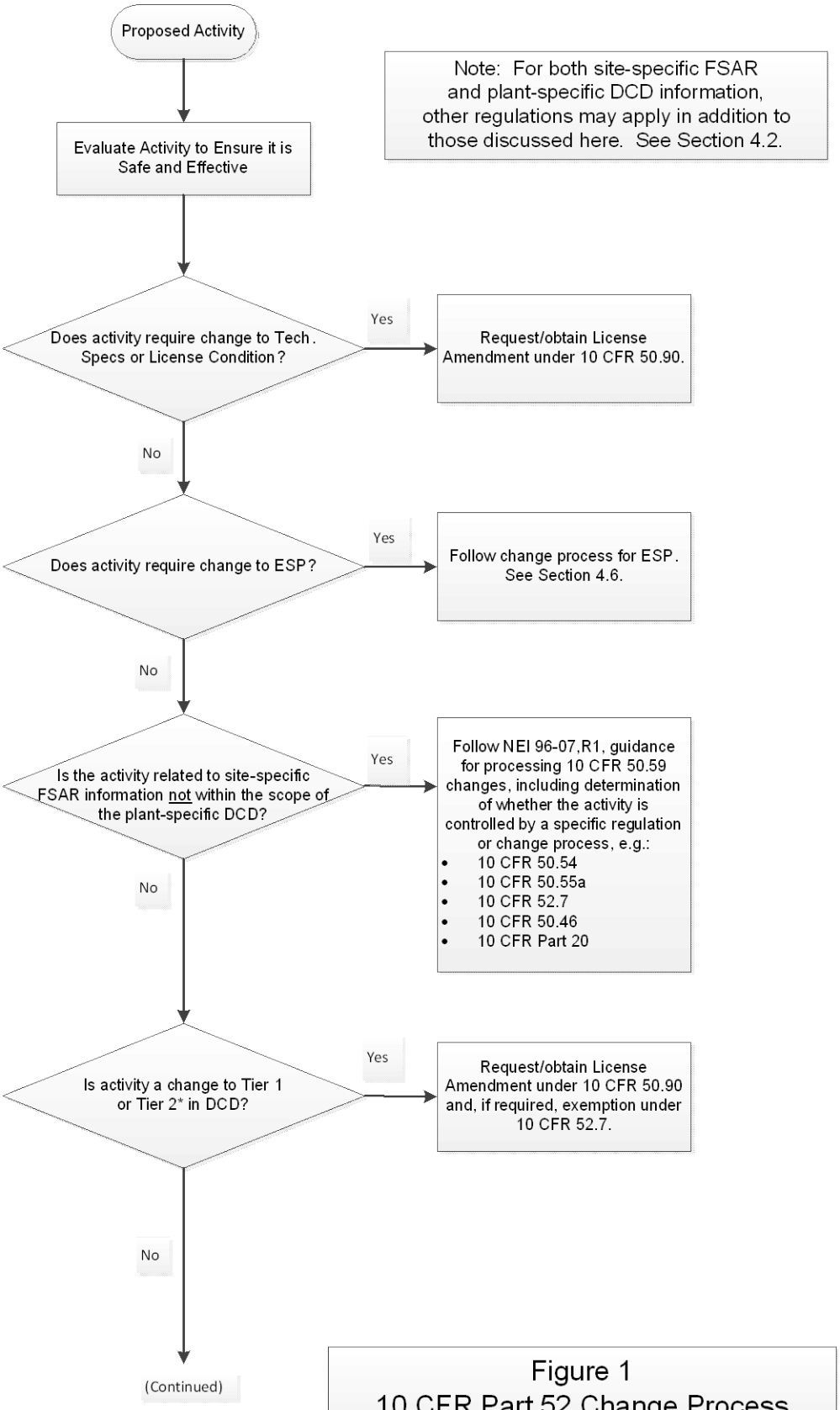


Figure 1
10 CFR Part 52 Change Process

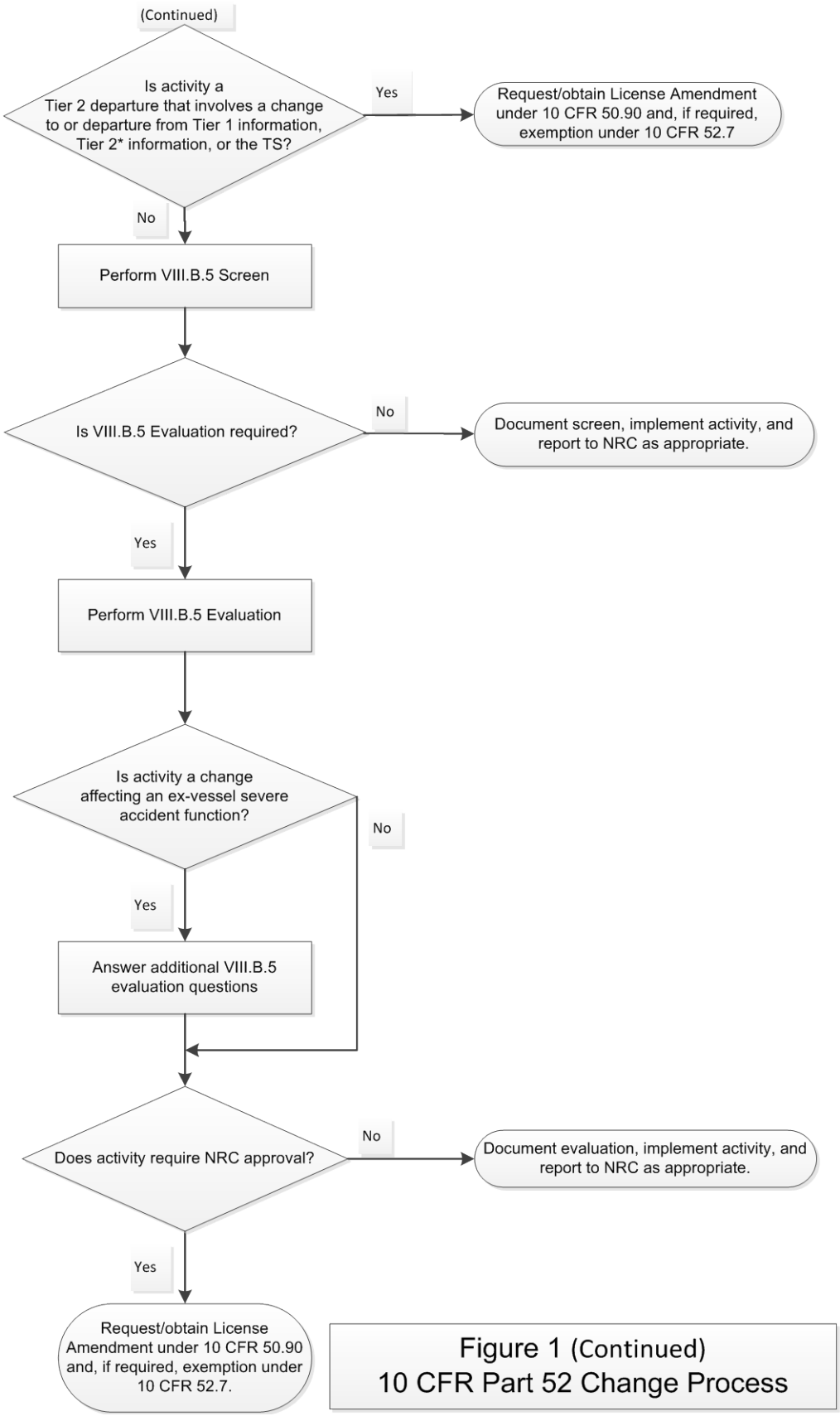


Figure 1 (Continued)
10 CFR Part 52 Change Process

## 1.4 SUMMARY OF THE 10 CFR PART 52 CHANGE PROCESSES

The following subsections provide an overview of Part 52 change processes for new plant applicants and licensees. Additional description of the change and departure process is provided in the Supplementary Information for each design certification rule (e.g., 10 CFR Part 52, Appendix D, for Westinghouse AP1000 (71 FR 4472-75)).

The change processes for licensees under Part 52 include the Section VIII change and departure process of the applicable design certification rule, 10 CFR 50.59, and other applicable Part 50 change processes, as identified in 10 CFR 52.98. Reference to 10 CFR 52.98 in this appendix is a reference to new plant/Part 52 change processes collectively.

### 1.4.1 Departures from Design Certification Information

The processes for changes to and departures from design certification information under 10 CFR Part 52 are specified in the Appendices to Part 52, which contain the design certification rules for each of the standard designs certified by the NRC. A typical design certification rule contains change processes in Section VIII. For the purposes of this document, the Part 52 change and departure processes will be referred to beginning with Section VIII, where it is understood that this is contained in the referenced rule governing the licensing basis of the plant under consideration.

Consistent with public comment resolution in the Standard Design Certification for the U.S. Advanced Boiling Water Reactor Design, the NRC has a reasonable expectation that vendors and utilities will cooperate with the NRC in assuring that the level of enhanced safety believed to be achieved with the certified designs will be reasonably maintained for their period of operations including renewal. This expectation that industry will cooperate with NRC in maintaining the safety level of the certified designs applies to design changes under Section VIII.B.5. (62 FR 25800; 25810; May 12, 1997)

Changes to or departures from certified design information may be performed by the NRC, an applicant for a combined license (COL), or a licensee who has already obtained a COL. The NRC may change design certification information though rulemaking. An applicant for a combined license (COL) or a licensee who has already obtained a COL may seek departures or exemptions from the design certification. The finality of a standard design certification, and considerations to modify, rescind, or impose new requirements through rulemaking, is addressed in 10 CFR 52.63 and will not be addressed further in this document.

10 CFR 52.63 also identifies a process for changing a standard design certification by rulemaking, including amendments to the rule sought by the design certification sponsor. Guidance for changing a standard design certification by rulemaking is outside the scope of this document.

#### 1.4.1.1 Generic Technical Specifications and Other Operational Requirements

Changes requested by a COL applicant to generic Technical Specifications and other operational requirements fall under the requirements of Section VIII.C of the referenced design certification rule. After issuance of a license, the generic Technical Specifications have no further effect with respect to that licensee. Changes to the plant-specific Technical Specifications will be treated as license amendments under 10 CFR 50.90, and are addressed in Sections 1.4.2.2 and 4.3.4.

The Bases for the Technical Specifications are also a part of the defined term "generic technical specifications" in Section II of the referenced design certification rule, and thus, the generic Bases will also have no further effect with respect to that licensee. Changes to the plant-specific Bases for the Technical Specifications will be processed in accordance with the Bases Control Program as provided in the plant-specific Technical Specifications, and are also addressed in Section 4.3.4.

The NRC will approve plant-specific operational requirements as part of the COL proceeding. Therefore, after issuance of a COL, the operational requirements in the generic DCD are not applicable to that licensee, except to the extent that the FSAR incorporates by reference those operational requirements. Changes to operational requirements in an FSAR are governed by 10 CFR 50.59, whether or not the FSAR has incorporated by reference the operational requirements from the generic DCD. Additional discussion of changes to operational requirements is provided in Section 4.3.5 of this appendix.

#### 1.4.1.2 COL License Information Items (COL Action Items)

As provided in Section II.E of the design certification rules, a generic DCD includes COL License Information Items, which are also known as COL Action Items. Such items identify certain matters that must be addressed in the FSAR by an applicant who references a design certification. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items,

provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

Therefore, following issuance of the COL, a licensee does not need to apply any change control process with respect to the COL License Information Items in the generic DCD. Instead, the licensee must control changes to information that addresses the COL License Information Items per 10 CFR 50.59 or other more specific applicable change process for information in the FSAR outside the scope of the plant-specific DCD, or Section VIII.B.5 for information in the plant-specific DCD.

#### 1.4.1.3 Conceptual Design Information

In accordance with 10 CFR 52.47(a)(24), a generic DCD must contain conceptual design information for those portions of the plant for which the design certification application does not seek certification. Conceptual design information is only that information within the generic DCD that is within brackets. Although such information is located within Tier 2 of the generic DCD, it is not legally part of Tier 2 as provided in Section II.E of the design certification rules. The FSAR must provide design information for those areas that are addressed by conceptual design information in the generic DCD.

Therefore, a COL applicant or licensee does not need to apply any change control process to the conceptual design information in the generic DCD. Instead, the licensee must apply 10 CFR 50.59 or other applicable change processes to changes affecting the information in the FSAR.

#### 1.4.1.4 Changes to Departures or Exemptions from the Generic DCD

A COL applicant or licensee may take a departure or exemption from the generic DCD in accordance with Section VIII of the design certification rule. Such departures and exemptions become part of the plant-specific DCD.

Subsequently, the licensee may desire to take a departure from or exemption to provisions in the plant-specific DCD that were previously the subject of a departure or exemption. Such departures/exemptions shall be subject to the change control process that applied to the original departure or exemption. Thus, for example, a departure from a provision in Tier 1 of the plant-specific DCD that was the subject of a previous exemption shall be governed by the change control process applicable to Tier 1 of the generic DCD, and a

departure from a provision in Tier 2 of the plant-specific DCD that was the subject of a previous departure shall be governed by the change control process applicable to Tier 2 of the generic DCD. Note that for a departure from a provision in Tier 2* of the plant-specific DCD that was the subject of a previous departure, the appropriate change control process will depend on whether the information remains Tier 2* or becomes Tier 2 after the plant achieves full power for the first time. Additional discussion of departures from Tier 2* is provided in Sections 3.24 and 4.4.4 of this appendix.

### 1.4.2 Plant-Specific Facilities and Procedures Described in the UFSAR

#### 1.4.2.1 COL UFSAR Changes Subject to 10 CFR 50.59

Changes to facilities or procedures described in the COL UFSAR, and conduct of tests or experiments not described in the COL UFSAR, that are outside the scope of a referenced design certification rule are controlled under 10 CFR 50.59. Licensees should screen and evaluate, as appropriate, such changes using Sections 4.2 and 4.3 of the main body of NEI 96-07, Revision 1, except as updated to reflect new NRC requirements and/or regulatory guidance (e.g., dose limits identified in Section 4.4.2.2 of this appendix). Some changes may affect information within the scope of the design certification rule as well as information outside the scope of the design certification rule; in those cases, the applicable provisions of both change processes apply.

Rather than having two separate change processes (one applicable to site-specific UFSAR information and one applicable to the plant-specific DCD), licensees may elect to utilize an integrated change process. Licensees electing to utilize an integrated change process will apply the change and departure processes in Section VIII of the design certification rule to the entire UFSAR (rather than just the plant-specific DCD), recognizing the differences in the scope between the 50.59 evaluation and the Section VIII evaluation. The intent is that the results of such an integrated approach be equivalent to the results of implementing two separate change processes. 10 CFR 50.59 criteria governing changes to the site-specific information in the UFSAR are equivalent to the Tier 2 VIII.B.5.b criteria. As a result, application of the Section VIII.B.5.b change process to the site-specific information in the UFSAR is substantively equivalent to application of 10 CFR 50.59 to such information.

To facilitate UFSAR maintenance and change process implementation, licensees may wish to create an integrated UFSAR that includes information from a referenced design certification (and ESP, if any), as well as plant

specific UFSAR information. In general, the UFSARs for COL applications do not repeat the information from the generic DCD but instead incorporate such information by reference. Although such a format is desirable for the purposes of licensing, licensees may prefer an integrated UFSAR during construction and operation so that personnel do not need to consult multiple documents to understand the complete licensing basis in the UFSAR. Therefore, it is anticipated that licensees will prepare an integrated UFSAR for construction and operation. It is important to retain identification of Tier 1, Tier 2, and Tier 2* information in an integrated UFSAR to facilitate determination of the applicable change control process.

#### 1.4.2.2 Plant-Specific ITAAC and Technical Specifications in the COL

In accordance with 10 CFR 52.98(f), changes to plant-specific ITAAC and Technical Specifications require a license amendment. Additional discussion of changes to plant-specific ITAAC and Technical Specifications is provided in Sections 4.3.3 and 4.3.4 of this appendix.

### 1.4.3 Early Site Permits

After issuance of an ESP by the NRC for a proposed nuclear power plant site, changes to the ESP, including the Site Safety Analysis Report (SSAR), may not be made without prior NRC approval. Section 4.6 outlines the process for determining whether a proposed activity constitutes a change to the ESP or SSAR. Proposed activities that constitute a change to the ESP or SSAR are processed as license amendment requests (LARs) in accordance with 10 CFR 50.90 and 50.92. A change to an issued ESP requiring NRC approval may also be deferred by including a request for variance in the construction permit or combined license application. As described in 10 CFR 52.39(d), a COL applicant may request a variance from one or more site characteristics, design parameters, or terms and conditions of the ESP, or from the SSAR being referenced in the construction permit or combined license application.

Upon issuance of a construction permit or combined license by the NRC, a referenced ESP is subsumed, to the extent referenced, into the construction permit or combined license, as prescribed in 10 CFR 52.26(d). Changes at this point become changes to the construction permit or combined license. For example, after issuance of the COL, changes to the information in the SSAR, as incorporated in the FSAR, are evaluated pursuant to the change control processes in 10 CFR 50.59 or 10 CFR 52.98, as applicable, rather than 10 CFR 52.39.

### 1.5 CONTENT OF THIS GUIDANCE DOCUMENT

The content of this guidance document, NEI 96-07, Appendix C, relies on the applicable guidance in the main body of NEI 96-07, Revision 1, and only adds or clarifies guidance as necessary. In particular, Section VIII of the applicable design certification rule appendix establishes criteria for determining whether NRC approval is needed to depart from specific information within the scope of the certified design. In order to perform 10 CFR 50.59 / VIII.B.5 screenings and evaluations of proposed changes/departures, it is necessary to understand the design and licensing bases of the plant and the applicable regulatory requirements. Individuals performing 10 CFR 50.59 and VIII.B.5 screenings and evaluations should also understand the rules and concepts discussed in both this guidance document and the original guidance document, NEI 96-07, Revision 1.

Section 2 provides a reference to the discussion in the main body of NEI 96-07, Revision 1, of the relationship between the design criteria established in 10 CFR Part 50, Appendix A and the applicable change process requirements as background for applying the 10 CFR 50.59 and Section VIII rules.

Section 3 presents new and modified definitions and discussion of key terms used in 10 CFR 50.59, 10 CFR Part 52, and this guideline.

Section 4 discusses the application of Part 52 change process definitions and criteria to the process of changing the plant or procedures and the conduct of tests or experiments. This section includes guidance on applicability requirements, the screening process for determining when an evaluation must be performed, the applicable evaluation criteria for determining if prior NRC approval is required, and also addresses changes to early site permits. Examples are provided to reinforce the guidance. Guidance is also provided on addressing degraded and nonconforming conditions and on dispositioning 10 CFR 50.59 / VIII.B.5 evaluations.

Section 5 provides guidance on documenting 10 CFR 50.59 / VIII.B.5 evaluations and reporting to NRC.

## 2 DEFENSE IN DEPTH DESIGN PHILOSOPHY

The discussion in Section 2.0 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

# 3 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

| | | |
|---|---|---|
| 3.1 | 10 CFR 50.59/Section VIII.B.5 Evaluation | Modified for Part 52, see below. |
| 3.2 | Accident Previously Evaluated in the FSAR (as updated) | Modified for Part 52, see below. |
| 3.3 | All Matters Described in the Plant-Specific DCD (VIII.B.5.a) | New |
| 3.4 | Change/Departure | Modified for Part 52, see below. |
| 3.5 | Current Licensing Basis | New |
| 3.6 | Departure from a Method of Evaluation Described in the FSAR (as updated) | See main body of NEI 96-07, Revision 1. |
| 3.7 | Design Bases (Design Basis) | See main body of NEI 96-07, Revision 1. |
| 3.8 | Ex-Vessel Severe Accident | New |
| 3.9 | Facility as Described in the FSAR (as updated) | See main body of NEI 96-07, Revision 1. |
| 3.10 | Final Safety Analysis Report (as updated) | Modified for Part 52, see below. |
| 3.11 | Generic Design Control Document (DCD) | New |
| 3.12 | Input Parameters | See main body of NEI 96-07, Revision 1. |
| 3.13 | Malfunction of an SSC Important to Safety | See main body of NEI 96-07, Revision 1. |
| 3.14 | Methods of Evaluation | Modified for Part 52, see below. |
| 3.15 | Operational Requirements | New |

| | | |
|---|---|---|
| 3.16 | Plant-Specific DCD | New |
| 3.17 | Procedures as Described in the FSAR (as updated) | See main body of NEI 96-07, Revision 1. |
| 3.18 | Safety Analyses | See main body of NEI 96-07, Revision 1. |
| 3.19 | Screening | Modified for Part 52, see below. |
| 3.20 | Site Safety Analysis Report (SSAR) for Early Site Permits | New |
| 3.21 | Tests or Experiments Not Described in the FSAR (as updated) | See main body of NEI 96-07, Revision 1. |
| 3.22 | Tier 1 Information | New |
| 3.23 | Tier 2 Information | New |
| 3.24 | Tier 2* Information | New |

## 3.1 10 CFR 50.59/SECTION VIII.B.5 EVALUATION

**Definition:**

The definition of 10 CFR 50.59 Evaluation in Section 3.1 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for evaluations under 10 CFR 50.59 or Section VIII.B.5 of the design certification rule(s).

**Discussion**

The discussion in Section 3.1 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

Unique aspects of the VIII.B.5 screening and evaluation criteria are described in Section 4.4.2 of this appendix.

For Tier 2 design certification information, Section VIII.B.5.b contains criteria that are similar to 10 CFR 50.59. Thus, the Section VIII.B.5.b process also includes screening, evaluation, documentation, and reporting as discussed in Sections 4 and 5 of this appendix.

## 3.2 ACCIDENT PREVIOUSLY EVALUATED IN THE FSAR (AS UPDATED)

**Definition:**

The definition in Section 3.2 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

**Discussion:**

The discussion in Section 3.2 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s) with one clarification and one addition.

Changes to the fire protection program for Part 52 licensees are governed by 10 CFR 50.59 as discussed in Section 4.1 of this appendix; however, licensee departures from the design of fire protection systems as described in the DCD are governed by Section VIII of a referenced design certification rule.

The term "accident" is distinguished from the term "severe accident." Severe accidents are beyond design basis accidents in which substantial damage is done to the reactor core, whether or not there are serious offsite consequences, as defined in the "Commission Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138). Departures from information related to ex-vessel severe accidents as defined in Section 3.8 of this appendix are subject to different change control processes than departures from information related to design basis accidents. Section 4.4.2.3 in this appendix discusses the change control processes applicable to ex-vessel severe accident information.

## 3.3 ALL MATTERS DESCRIBED IN THE PLANT-SPECIFIC DCD

**Definition:**

The evaluation of a departure must consider more than just the descriptive information contained in the text of the design control document (DCD). Thus, "all matters described in the plant-specific DCD" includes:

(i) The structures, systems, and components (SSC) that are described in the plant-specific DCD,

(ii) The design and performance requirements for such SSCs described in the plant-specific DCD, and

(iii) The evaluations or methods of evaluation included in the plant-specific DCD for such SSCs which demonstrate that their intended function(s) will be accomplished.

Additionally, as discussed in the statement of considerations for the design certification rules, "all matters described in the plant-specific DCD" includes the information in the references in the DCD (so-called "secondary references"), to the extent that such information is intended to constitute a requirement based upon the context of the DCD.

**Discussion:**

Section VIII.B.5.a of a design certification rule specifies that an applicant or licensee who references the appendix to Part 52 that contains the rule may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to, or departure from Tier 1 information, Tier 2* information, or the Technical Specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of Section VIII. When evaluating the proposed departure, Section VIII.B.5.a requires that an applicant or licensee consider all matters described in the plant-specific DCD.

## 3.4 CHANGE/DEPARTURE (PLANT-SPECIFIC)

Under Part 52, licensees may 1) make plant-specific *changes* outside the scope of the plant-specific DCD under 10 CFR 50.59, 2) make plant-specific *departures* from the DCD under Section VIII of the design certification rule, or 3) seek *generic changes* to the design certification through rulemaking. This guidance document is focused on plant-specific changes and departures, and unless otherwise indicated, the term "change" as used in this document refers to plant-specific changes outside the scope of the DCD under 10 CFR 50.59. The definitions for plant-specific *change* and *departure* are discussed below.

**Definition:**

The definition of "change" in Section 3.3 of the main body of NEI 96-07, Revision 1, has been modified for Part 52 licensees as indicated in italics below to apply specifically to plant-specific changes under 10 CFR 50.59 outside the scope of the DCD, and a definition of "departure" has been added.

Change means a *plant-specific* modification or addition to, or removal from, the facility or procedures *outside the scope of the plant-specific DCD* that affects: (1) a design function; (2) a method of performing or controlling the function; or (3) an evaluation that demonstrates that intended functions will be accomplished.

*Departure is a plant-specific deviation from design information in a referenced standard design certification rule [72 FR 49371], i.e., a modification or addition to, or removal from, design information contained in a plant-specific DCD.*

**Discussion:**

The discussion in Section 3.3 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 and is supplemented as follows for departures under Section VIII of the design certification rule(s):

While affecting different parts of the UFSAR, the nature of a plant-specific design change outside the scope of the DCD is no different from a plant-specific departure from the DCD. Thus, licensees may screen and evaluate departures in the same manner as plant-specific changes, except that departure reviews must consider effects on ex-vessel severe accident functions as well as effects on design functions. Accordingly, plant-specific departures should be reviewed based on the effects of the departure on (1) a design function *or ex-vessel severe accident function*; (2) a method of performing or controlling the function; or (3) an evaluation that demonstrates that intended functions will be accomplished. Ex-vessel severe accident features are defined in Section 3.8 of this appendix.

Note that design documents and procedures are developed by the licensee in accordance with 10 CFR 50, Appendix B, and applicable processes to ensure consistency with the Current Licensing Basis/Design Basis. Initial issuance of these documents during construction does not constitute a change or departure and does not require review under 10 CFR 52.98 change processes.

## 3.5 CURRENT LICENSING BASIS

**Definition:**

(10 CFR 54.3) Current Licensing Basis (CLB) is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions

to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

**Discussion:**

For a Part 52 combined license holder, the current licensing basis will also include the 10 CFR 50.2 design-basis information documented in the most recent updated final safety analysis report (UFSAR) as required by 10 CFR 50.71, including any documents specifically incorporated by reference.

For a COL applicant, if the COL application references a certified design, the referenced generic DCD, including any reference documents (to the extent that such information is intended to constitute a requirement based upon the context of the DCD) will also include design basis information. Finally, if the COL application references an early site permit Site Safety Analysis Report (SSAR), the referenced SSAR, including any documents specifically incorporated by reference, will also include design basis information.

## 3.6 DEPARTURE FROM A METHOD OF EVALUATION DESCRIBED IN THE FSAR (AS UPDATED)

**Definition:**

The definition in Section 3.4 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

**Discussion:**

The discussion in Section 3.4 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

Note that Section II.G of the design certification rule(s) includes a definition for "departure from a method of evaluation…" which is identical to that in 10 CFR 50.59(a)(2) when "FSAR (as updated)" is replaced with "plant-specific

DCD." Because the plant-specific DCD is a part of the UFSAR, the definitions thus become identical.

## 3.7 DESIGN BASES (DESIGN BASIS)

**Definition:**

The definition in Section 3.5 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

**Discussion**

The discussion in Section 3.5 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

## 3.8 EX-VESSEL SEVERE ACCIDENT

**Definition:**

Section VIII.B.5.c of the design certification rule states as follows:

A proposed departure from Tier 2 affecting resolution of an ex-vessel severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

> (1) There is a substantial increase in the probability of an ex-vessel severe accident such that a particular ex-vessel severe accident previously reviewed and determined to be not credible could become credible; or
>
> (2) There is a substantial increase in the consequences to the public of a particular ex-vessel severe accident previously reviewed.

As used in this section, ex-vessel severe accident refers to a postulated accident when the reactor core has melted and exited the reactor vessel and the containment is challenged. An ex-vessel severe accident design feature is a feature that has an intended function to resolve ex-vessel severe accidents. (72 FR 49394)

**Discussion:**

Typically, ex-vessel design features are identified in Chapter 19 of Tier 2 of the DCD. For example, such design features are identified in Tier 2 Appendix 19B of the AP1000 DCD and Tier 2 Section 19E of the ABWR DCD. (71 FR 4474; 62 FR 25806) For the ABWR such features include but are not limited to:

- AC Independent Water Addition System
- Passive Lower Drywell Flooder for the ABWR
- Containment Overpressure System
- Vacuum Breakers

However, the severe accident design features identified in Tier 2 Chapter 19 may also be described in other sections of the DCD. For example, the Lower Drywell Flooder for the ABWR is discussed in Section 19E and Section 9.5.12 of Tier 2 of the ABWR DCD. Thus, the location of the ex-vessel severe accident design information in the DCD is not important and all ex-vessel severe accident design information in the DCD is subject to the application of this special departure process in Section VIII.B.5.c of the design certification rule. (72 FR 49394)

The special departure process in Section VIII.B.5.c of the design certification rule is not intended for design features that are discussed in Chapter 19 for other reasons, such as resolution of generic safety issues. (62 FR 25806) This special departure process also is not applicable to PRA information in Chapter 19 of Tier 2 of the DCD and FSAR, which has a separate change process as discussed in Section 4.4.3 of this appendix. Furthermore, this special departure process does not apply to design features that resolve other beyond design basis accidents or other low probability events. (62 FR 25824) In that regard, for example, Table 19E.2-29 in Tier 2 of the ABWR DCD distinguishes between equipment that is needed for in-vessel severe accidents and ex-vessel severe accidents.

## 3.9 FACILITY AS DESCRIBED IN THE FSAR (AS UPDATED)

**Definition:**

The definition in Section 3.6 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59.

**Discussion:**

The discussion in Section 3.6 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59. As discussed in Section 3.23, the corresponding focus of Section VIII of the design certification rule(s) is changes or departures from the information presented in the plant-specific DCD. Although Facility is not defined in Part 52, the plant-specific DCD includes information that meets the definition of Facility, e.g., design and performance requirements for described SSCs. As such, the existing guidance on Facility may be applied to Section VIII reviews.

## 3.10 FINAL SAFETY ANALYSIS REPORT (AS UPDATED)

**Definition:**

The definition in Section 3.7 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s) with a few modifications in italics below.

Final Safety Analysis Report (as updated) means the Final Safety Analysis Report (*including the plant-specific Design Control Document (DCD)*) submitted in accordance with 10 CFR *52.79*, as amended and supplemented, and as updated per the requirements of *Section X.A of the applicable Part 52 design certification appendix, 10 CFR 52.3 and* 10 CFR 50.71(e).

**Discussion:**

The discussion in Section 3.7 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s) with a few modifications in italics below.

As used throughout this guidance document, UFSAR is synonymous with "FSAR (as updated)." The scope of the UFSAR includes its text, tables, diagrams, etc., as well as supplemental information explicitly incorporated by reference. References that are merely listed in the UFSAR and documents that are not explicitly incorporated by reference are not considered part of the UFSAR and therefore are not subject to control under 10 CFR 50.59. *However, as discussed in Section 3.3 of this appendix, the plant-specific DCD includes secondary references. To the extent that information in the secondary references is intended to constitute a requirement based upon the context of the plant-specific DCD, such information is part of the UFSAR and must be considered in evaluation of changes and departures.*

Per 10 CFR 50.59(c)(4), licensees are not required to apply 10 CFR 50.59 to UFSAR information that is subject to other specific change control regulations. For example, licensee quality assurance programs, security plans and emergency plans are controlled by 10 CFR 50.54(a), (p) and (q), respectively, *and departures from the plant-specific DCD are controlled by Section VIII of the applicable Part 52 certification appendix.*

## 3.11 GENERIC DESIGN CONTROL DOCUMENT

**Definition:**

Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into each design certification rule.

## 3.12 INPUT PARAMETERS

**Definition:**

The definition in Section 3.8 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

**Discussion:**

The discussion in Section 3.8 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

## 3.13 MALFUNCTION OF AN SSC IMPORTANT TO SAFETY

**Definition:**

The definition in Section 3.9 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

**Discussion:**

The discussion in Section 3.9 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

## 3.14 METHODS OF EVALUATION

**Definition:**

The definition in Section 3.10 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s).

**Discussion:**

The discussion in Section 3.10 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s) with the clarification that, with respect to the consequences of accidents, the dose limits for members of the public for Part 52 licensees are found in 10 CFR 52.47(a)(2) and 52.79(a)(1) rather than 10 CFR 100 for Part 50 licensees.

Methods of evaluation included in the plant-specific DCD to demonstrate that intended SSC design functions will be accomplished are considered part of the "Tier 2 information."

## 3.15 OPERATIONAL REQUIREMENTS

**Definition:**

"Operational requirements" includes the material in the generic DCD of an operational nature, such as programmatic or procedural descriptions including the technical specifications, the bases for the technical specifications, inservice testing program information, and inservice inspection program information. "Operational requirements" does not include programmatic information that pertains to design and construction, such as the design reliability assurance program, QA program for design, and pre-operational test programs.

**Discussion:**

The purpose of design certification is to review and approve design information. There is no provision in Subpart B of 10 CFR Part 52 for review and approval of purely operational matters. Thus the technical specifications in Chapter 16 of the DCD, bases for the technical specifications, and "other operational requirements" in the DCD, are treated as a special category of information, and changes to this information are addressed by Section VIII.C of the applicable design certification appendix. Such matters do not have finality in a COL proceeding pursuant to Section VI of the design certification rules.

The NRC considers that while the information in the DCD that is related to operational requirements was necessary to support the NRC's safety review of the standard designs, the review of this information was not sufficient to conclude that the operational requirements are fully resolved and ready to be assigned finality under 10 CFR 52.63.

The key to using the change and departure processes in Section VIII of the design certification rules is to determine if the proposed change or departure requires a change to a design feature described in the generic DCD. If a design change is required, then the appropriate change/departure process in Section VIII.A or VIII.B of the design certification rules applies. However, if a proposed change to the technical specifications or other operational requirements does not require a change to or departure from a design feature in the generic DCD, then Section VIII.C applies.

The special change process in Section VIII.C of the design certification rules only applies to departures from the generic technical specifications and other operational requirements by a COL applicant. After issuance of the COL, changes to the plant-specific technical specifications are governed by 10 CFR 50.90 and changes to operational requirements in the FSAR (including those incorporated by reference from the generic DCD) are governed by 10 CFR 50.59.

## 3.16 PLANT-SPECIFIC DESIGN CONTROL DOCUMENT (DCD)

**Definition:**

A plant-specific DCD is the document maintained by an applicant or licensee that consists of the information in the generic DCD as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of the applicable design certification rule appendix. The plant-specific DCD is a subset of the UFSAR.

## 3.17 PROCEDURES AS DESCRIBED IN THE FSAR (AS UPDATED)

**Definition:**

The definition in Section 3.11 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59.

**Discussion**

The discussion in Section 3.11 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59. Although

Procedures are not defined in Part 52, the plant-specific DCD includes information that meets the definition of Procedures, e.g., methods by which a design function is accomplished. As such the existing guidance on Procedures may be applied to Section VIII reviews. See also Section 3.23.

Construction and pre-operational procedures are not "procedures" as defined in Section 3.11 of the main body of NEI 96-07, Revision 1, and thus are not subject to control under the 10 CFR 52.98 change processes.

## 3.18 SAFETY ANALYSES

**Definition:**

The definition in Section 3.12 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s) with the clarification that the guidelines for potential offsite exposures for Part 52 licensees are found in 10 CFR 52.47(a)(2) and 52.79(a)(1). In addition, safety analyses are required to be presented in the UFSAR per 10 CFR 52.79(a) for Part 52 licensees rather than 10 CFR 50.34(b) for Part 50 licensees.

**Discussion:**

The discussion in Section 3.12 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s) with one clarification.

Changes to the fire protection program for Part 52 licensees are governed by 10 CFR 50.59 as discussed in Section 4.1 of this appendix; however, licensee departures from the design of fire protection systems as described in the DCD are governed by Section VIII.B.5 of a referenced design certification rule.

## 3.19 SCREENING

**Definition:**

Screening is the process for determining whether a proposed activity requires a 10 CFR 50.59 *or Section VIII.B.5* evaluation to be performed. *Screening may be considered a simplified evaluation for purposes of meeting the requirements of Section VIII.B.5.a.*

**Discussion:**

The discussion in Section 3.13 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59.

For plant-specific FSAR changes outside the scope of the DCD, further discussion and guidance on screening are provided in Section 4.2 of the main body of NEI 96-07, Revision 1.

Except for terminology differences, the eight evaluation criteria in 10 CFR 50.59(c) are substantially the same as those in Section VIII.B.5.b. As such, screening of departures from the DCD may be performed in the same manner as screening of plant-specific changes outside the scope of the DCD except that departure reviews must consider the effects on ex-vessel severe accident functions as well as effects on design functions. Guidance on screening for departures is provided in Section 4.4.2.1 of this appendix. Screening as described in Section 4.4.2.1 may be considered a simplified evaluation for purposes of meeting the requirements of Section VIII.B.5.a.

## 3.20 SITE SAFETY ANALYSIS REPORT (SSAR) FOR EARLY SITE PERMITS

**Definition:**

Site Safety Analysis Report contains the technical information required by 10 CFR 52.17(a)(1) to be submitted by an applicant as a component of an ESP application. This analysis evaluates the site characteristics and site-related design parameters used as inputs in performing safety analyses of the site. Upon issuance of a construction permit or combined license by the NRC, the SSAR referenced in the application is subsumed in the FSAR, except as modified in accordance with 10 CFR 52.93.

## 3.21 TESTS OR EXPERIMENTS NOT DESCRIBED IN THE FSAR (AS UPDATED)

**Definition:**

The definition in Section 3.14 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59.

**Discussion:**

The discussion in Section 3.14 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59.

The plant-specific DCD includes reference bounds of the design bases and analyses and descriptions of SSCs. Although Part 52 does not define or include requirements on control of tests or experiments, licensees may use the guidance in NEI 96-07, Revision 1, to determine if a proposed test or experiment would place the plant outside its reference bounds or would be inconsistent with the analyses or descriptions in the plant-specific DCD.

### 3.22 TIER 1 INFORMATION

**Definition:**

Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by an appendix to 10 CFR Part 52 (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;

2. Design descriptions;

3. Inspections, tests, analyses, and acceptance criteria (ITAAC);

4. Significant site parameters; and

5. Significant interface requirements.

**Discussion:**

Changes to and departures from Tier 1 information are addressed in Section VIII.A of the design certification rule appendices. Generic changes to Tier 1 information are governed by 10 CFR 52.63(a)(1). Plant-specific departures proposed by an applicant or licensee require exemptions, which are governed by the requirements in Section VIII.A.4. Exemptions are discussed in more detail in Section 4.4.1 of this appendix.

### 3.23 TIER 2 INFORMATION

**Definition:**

Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by an appendix to 10 CFR Part 52 (Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section

VIII of the corresponding appendix to 10 CFR Part 52. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change and departure process in Section VIII of the corresponding appendix to 10 CFR Part 52. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of the corresponding appendix to 10 CFR Part 52 to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.47(a) and 52.47(c), with the exception of generic technical specifications and conceptual design information;

2. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and

3. Combined license (COL) action items (COL license information), which identify certain matters that must be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references the corresponding appendix to 10 CFR Part 52. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

4. [Additional items, if any, as listed in Section II.E of the applicable design certification rule appendix.]

**Discussion:**

Changes to and departures from Tier 2 information are addressed in Section VIII.B of the design certification rule appendices. In summary, generic changes to Tier 2 information are governed by 10 CFR 52.63(a)(1), similar to generic changes to Tier 1 information. Generic changes are applicable to all applicants and licensees who reference the applicable appendix, except those for which the change has been rendered technically irrelevant. Although a plant-specific order by the NRC or an exemption requested by an applicant or licensee are mechanisms by which Tier 2 information may be changed, Section VIII.B.5 is the major process used to evaluate a proposed departure from Tier 2 information and determine if prior NRC approval is or is not required. The criteria in VIII.B.5.b are essentially identical to the criteria in 10 CFR 50.59(c), with two specific differences:

1. Reference is to a "departure from Tier 2 information" rather than "change to the facility as described in the FSAR (as updated)."
2. Reference is to the "plant-specific DCD" rather than the "FSAR (as updated)."

The process for performing a departure evaluation in accordance with the requirements of Section VIII.B.5 is described in detail in Section 4.4.2 of this document.

### 3.24 TIER 2* INFORMATION

**Definition:**

Tier 2* means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the departure process in Section VIII.B.6 of the corresponding appendix to 10 CFR Part 52. This designation expires for some Tier 2* information under paragraph VIII.B.6.

Tier 2* information is identified with italicized text or brackets and an asterisk in the generic DCD, and is carried over into the plant-specific DCD if the applicant or licensee incorporates the DCD by reference into its FSAR.

**Discussion:**

Section VIII.B.6 of the design certification rule appendices addresses the requirements for departures from Tier 2* information. All departures from Tier 2* information require prior NRC approval, but some Tier 2* matters revert to Tier 2 status after the plant first achieves full power and are then subject to the departure provisions in VIII.B.5. The specific list of information varies for each certified design and reference to the applicable appendix is required of each applicant or licensee.

As stated in VIII.B.6.b, all requests for Tier 2* departures will be treated as a request for a license amendment under 10 CFR 50.90, thus no screen/evaluation process is applicable to this category of departures. However, VIII.B.6.d states that an exemption from the applicable design certification rule appendix is not required for Tier 2* departures processed under Section VIII.B.6. Additional guidance may be found in Section 4.4.4 of this appendix.

# 4 IMPLEMENTATION GUIDANCE

## 4.1 APPLICABILITY

As stated in 10 CFR 52.98, for COLs that do not reference a design certification or a reactor manufactured under 10 CFR Part 52 Subpart F, the licensee may make changes in the facility as described in the UFSAR under the applicable change processes in 10 CFR Part 50. For COLs that do reference a certified design or a manufacturing license, changes that are not within the scope of the referenced design certification rule or manufacturing license and do not impact compliance with information within the scope of the referenced design certification rule or manufacturing license are subject to the applicable change processes in 10 CFR Part 50.

Applicants and licensees should determine the applicable change control process(es) for each proposed plant change. In general, proposed changes will fall into one of the following categories:

- Changes to the UFSAR, including the plant-specific DCD, subject to other, more specific change control processes established by regulation. Section 4.2 provides guidance on three specific change processes recently established in NRC regulations.

- Changes to plant-specific facilities and procedures described in the UFSAR outside the scope of the referenced certified design and subject to 10 CFR 50.59. See Section 4.3.

- Changes within the scope of the referenced certified design (plant-specific DCD) and subject to the change control processes in Section VIII of the design certification rule. See Section 4.4.

- Changes to Early Site Permit Information. See Section 4.6.

Note that a particular proposed change may fall into more than one of these categories and thus may be subject to more than one change control process.

Existing Applicability Guidance in NEI 96-07, Revision 1

Applicability guidance on the following topics provided in Section 4.1 of the main body of NEI 96-07 is applicable to plants licensed under Part 52:

- changes to technical specifications

- precedence of other more specific change processes (for information outside the scope of the plant-specific DCD)
- maintenance activities
- UFSAR modifications (for information outside the scope of the plant-specific DCD)
- changes to procedures governing the conduct of operations

One difference in the NEI 96-07, Revision 1, applicability guidance for Part 50 licensees versus Part 52 licensees concerns changes to approved Fire Protection Programs. COLs do not contain the standard license condition that controls changes to approved Fire Protection Programs for plants licensed under Part 50. Departures by a COL applicant or holder from the design of fire protection systems as described in the DCD are governed by Section VIII of a referenced design certification rule, and licensee changes to the plant-specific fire protection program as described in the UFSAR are governed by 10 CFR 50.59.

### 4.1.1 Construction Change Applicability

During the construction of a nuclear plant (as defined in 10 CFR 50.10(a)(1) and (2)), numerous changes to the plant design may be identified. These construction changes may be identified during the design finalization process, constructability conflict resolution process, or design and construction verification processes. These construction changes are controlled under 10 CFR Part 50, Appendix B, Criterion III, Design Control, and other provisions of Appendix B, and are managed by field change or engineering change processes.

In contrast to construction under a 10 CFR Part 50 construction permit, Part 52 requires that the facility be constructed in accordance with the COL. Consequently, in addition to the requirements of 10 CFR Part 50, Appendix B, Part 52 licensees should review construction changes for impacts on the current licensing basis (CLB), request a license amendment from the NRC, as appropriate, and update the UFSAR as required. Construction changes (including corrective actions for nonconformances to design requirements that are dispositioned as repair or use-as-is) may fall into one of three categories, as discussed below.

<u>Construction change activities that do not affect the CLB</u>

This is expected to be the largest category because construction change activities typically affect detailed design information that does not impact the CLB or require an LAR. (Thus, these construction change activities are not changes/departures as defined in Section 3.4.) This

includes various emerging unanticipated conditions or conflicts that may require an engineering change, e.g. interferences (recognized but not yet installed), conflicts with field routing, accumulation of acceptable field tolerances, etc. Licensees should manage these construction changes in accordance with 10 CFR Part 50, Appendix B, and should document the basis for concluding that the construction change does not affect the CLB (and thus does not require an LAR). Construction may proceed/continue while this type of change is dispositioned and documented.

Construction changes/departures that affect the CLB

If the change/departure is determined to affect the CLB, the licensee should apply the 10 CFR 50.59, Section VIII.B.5, or other applicable change process in accordance with this appendix to determine if an LAR is required. If the change/departure does not require an LAR, the licensee should document the screening/evaluation results, may construct the change/departure (i.e., construction may proceed/continue), and should update the UFSAR or other affected CLB documents in accordance with applicable requirements and licensee procedures.

Construction changes/departures that require an LAR

Like any LAR, licensees should ensure that LARs during construction contain sufficient information to support the necessary safety determination by the NRC staff. In particular, LARs during construction should provide the technical design information related to the specific change, e.g., type and location of an additional penetration, the Codes/Standards to be used to install it, and calculations that directly support the change. The design information provided should be consistent with that provided in the DCD/COL application; licensees should consider applicable SRP criteria and other NRC guidance when preparing LARs during construction.

Changes/departures that require a LAR during construction may affect other plant analyses/calculations such as seismic, containment pressure, containment leakage, pipe stress and safety analyses that do not directly support the change. While licensees may choose to update such plant analyses/calculations for certain significant changes, these analyses/calculations are more typically expected to be updated one time based on as-built design information. Licensees should include enough information in such LARs to show that all implications of the proposed activity have been considered. For example, licensees should summarize the basis, such as sensitivity analysis or documented

engineering judgment, for concluding that the affected plant analyses/calculations, though impacted by the proposed activity, do not need to be updated to support the proposed activity. The basis provided may be qualitative.

Licensees ensure individual construction changes are tracked via design configuration control processes to monitor the effect of cumulative impacts and to supplement CLB information when necessary.

Licensees should update plant analyses/calculations prior to the 52.103(g) finding to reconcile with as-built design information, including the aggregate impact of individual changes and departures implemented during the construction phase via all applicable change processes. Update of these plant analyses/calculations is typically driven by other NRC requirements, such as ITAAC closure, Technical Specifications, and update of the plant-specific PRA. If the results of the updated, as-built plant analyses/calculations differ from those in the CLB, those differences should be assessed as a change/departure in accordance with this appendix, and an LAR submitted if necessary.

Licensees should also review construction changes/departures for impact on ITAAC-related SSCs and assess the need to submit an ITAAC Post-Closure Notification in accordance with 10 CFR 52.99(c)(2) and NEI 08-01.

#### 4.1.1.1 Nonconforming Conditions during Construction

Over the course of construction, and throughout the life of the plant, licensees may identify nonconformances between approved design and construction specifications and as-found conditions. To assure quality, licensees maintain a low threshold for identifying nonconforming conditions that require assessment and disposition before work proceeds. The low threshold can result in a particularly high volume of nonconforming conditions being identified during construction. Most nonconformances do not affect the CLB or are dispostioned as rework (and, by definition, do not affect the CLB). Of those that somehow affect the CLB, some few may be determined to require an LAR.

Nonconforming conditions are placed in the CAP (or other tracking process for nonconformances) and dispositioned by licensees as requiring rework, repair or use-as-is. Licensees will establish and maintain processes for review of corrective actions for nonconformances that are dispositioned as repair or use-as-is to determine the impact, if any, on the CLB and whether an LAR is required. Licensee processes ensure configuration management during construction and transparency of pending licensing basis changes. If

and when the licensee determines that corrective actions for nonconformances require an LAR, the licensee should stop the work that requires prior NRC approval and submit the required LAR without delay. If the licensee wishes to proceed with work that is the subject of an LAR, it should first request and receive a Preliminary Amendment Request (PAR) Notification of No Objection from the NRC as discussed in Section 4.7.1.1.

A licensee may continue with construction activities to resolve the nonconforming condition by repair or use-as-is determination, based on an approved engineering solution and the determination that prior NRC approval is not required.

## 4.2 APPLICABILITY OF OTHER MORE SPECIFIC CHANGE PROCESSES

In addition to the change control requirements listed in Section 4.1.1 of the main body of NEI 96-07, Revision 1, the following more recently codified change control requirements also meet the intent of 10 CFR 50.59(c)(4) and may take precedence over 10 CFR 50.59 for control of changes outside the scope of the plant-specific DCD. There is no equivalent to 10 CFR 50.59(c)(4) for departures within the scope of the plant-specific DCD. Thus, more specific change processes may apply in addition to Section VIII.B.5 reviews. (Note that the specific change processes discussed below are not intended to be comprehensive.)

### 4.2.1 Cyber Security Plan

10 CFR 50.54 specifies criteria and reporting requirements for changing cyber security plans approved by the NRC. Changes to these plans or descriptions are controlled by separate processes established in 10 CFR 50.54(p). Specific guidance for evaluating changes to Security Plans is provided in NRC Generic Letter 95-08. Although GL 95-08 was issued prior to the Cyber Security Rule, 10 CFR 73.54(b)(3) requires the incorporation of the cyber security program as a component of the physical protection program, and 10 CFR 73.55 identifies the cyber security plan as one of four security plans. The licensee may make changes to the cyber security plan previously approved in the COL without prior NRC approval only if the changes do not decrease the safeguards effectiveness of the plan. Changes that require NRC approval are processed as COL amendment requests in accordance with 10 CFR 50.90 and 50.92.

### 4.2.2 Aircraft Impact Assessment

10 CFR 50.150 provides the requirements for the Aircraft Impact Assessment for a Combined License holder:

- For combined licenses referencing a certified design that has addressed the requirements of 10 CFR 50.150, the change process in Section VIII.B.5.d of the applicable design certification rule applies. Section 4.4.2.4 of this appendix provides further guidance for that change process.

- For combined licenses that do not reference a certified design addressing the Aircraft Impact Assessment requirements, the change process is described in 10 CFR 50.150(c)(4)(i). While the regulatory structure is different, the guidance in 4.4.2.4 of this appendix is generally applicable.

### 4.2.3 Assessment of Loss of Large Areas of the Plant due to Explosions or Fire

10 CFR 50.54(hh)(2) is a condition of every combined license issued under Part 52 and provides that, "Each licensee shall develop and implement guidance and strategies intended to maintain or restore core cooling, containment, and spent fuel pool cooling capabilities under the circumstances associated with loss of large areas of the plant due to explosions or fire…"

A description and plans for implementation of the guidance and strategies required by 10 CFR 50.54(hh)(2) are required to be submitted as part of a combined license application in accordance with 10 CFR 52.80(d).
The Loss of Large Area Assessment is not required to be part of the UFSAR and as such is not subject to the 10 CFR 50.59 change process. Changes must conform to the applicable plant-specific license condition and 10 CFR 50.54(hh)(2). A change that does not conform to the applicable plant-specific license condition and/or 10 CFR 50.54(hh)(2) requires a license amendment and/or exemption request per 10 CFR 50.90 and 50.12, respectively.

## 4.3 CHANGES TO PLANT-SPECIFIC FACILITIES OR PROCEDURES DESCRIBED IN THE UFSAR

Once a combined license is issued, changes to the facility or departures from information within the scope of the referenced design certification rule depend on whether or not the combined license does or does not reference a certified design, as set forth in 10 CFR 52.98. For the purposes of this

discussion, it is assumed that a combined license references a certified design, and therefore the requirements of 10 CFR 52.98(c) apply.

10 CFR 52.98(c)(1) states that changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule (i.e., the process and criteria discussed in Section 4.4). 10 CFR 52.98(c)(2) states that changes that are not within the scope of the referenced design certification rule are subject to the applicable change processes in 10 CFR Part 50. This includes not only 10 CFR 50.59, but also change processes identified in 10 CFR 50.54 such as changes to the quality assurance program description, security plans (including cyber security), emergency plans and aircraft threat mitigation plans, and other more specific change processes for other plans and programs prescribed in regulations.

10 CFR 52.98(c)(2) also addresses the need to consider both the Part 50 change processes and the change processes in the design certification rule if the change would affect both. For example, a change to a building entry/exit doorway (e.g., change in location, type of door used) could involve a departure to Tier 2 information under the design certification rule, plus the evaluation of a change to one or more plans and programs such as security requirements, emergency preparedness requirements, fire protection requirements, or loss of large area mitigation plans.

For changes to the facility or procedures described in the COL FSAR that are outside the scope of a referenced design certification rule, the 10 CFR 50.59 process guidance in the main body of NEI 96-07, Revision 1, should be used, either by itself or in combination with the applicable change processes of the design certification rule.

### 4.3.1 Screening of Changes to Plant-Specific Facilities or Procedures Described in the UFSAR

The 10 CFR 50.59 screening process and guidance contained in the main body of NEI 96-07, Revision 1, is applicable to changes to plant-specific facilities or procedures described in the UFSAR outside the scope of the plant-specific DCD.

### 4.3.2 Evaluation of Changes to Plant-Specific Facilities or Procedures Described in the UFSAR

The 10 CFR 50.59 evaluation process and guidance contained in the main body of NEI 96-07, Revision 1, is applicable to changes to plant-specific facilities or procedures described in the UFSAR outside the scope of the plant-specific DCD, except as identified in Section 4.4.2.2 of this appendix.

### 4.3.3 Changes to Plant-Specific ITAAC

10 CFR 52.98(f) requires a license amendment for any change to the terms and conditions of a COL, including a change from plant-specific ITAAC. In addition, 10 CFR 52.99(d)(2) provides that a licensee that has not demonstrated that a plant-specific ITAAC has been met may take corrective actions to successfully complete that ITAAC or request a license amendment under 52.98(f).

In accordance with 10 CFR 52.103(h), after the Commission has made the finding in 52.103(g) that all acceptance criteria in the combined license are met, the completed ITAAC attached to the license do not constitute regulatory requirements either for licensees or for renewal of the license. However, as stated in 10 CFR 52.103(h), subsequent changes to the facility or procedures described in the UFSAR must comply with the requirements in 10 CFR 52.98(f), e.g., departures from Tier 1 information require an exemption and a license amendment as discussed in Section 4.4.1 of this appendix.

### 4.3.4 Changes to Plant-Specific Technical Specifications

10 CFR 52.97(c) states, "A combined license shall contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate." 10 CFR 52.98(f) states, "Any modification to, addition to, or deletion from the terms and conditions of a combined license, including any modification to, addition to, or deletion from the inspections, tests, analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment." Technical Specification changes, therefore, require an amendment since they are part of the terms and conditions of the license under 52.97(c).

Changes to Technical Specifications (including the Bases for the Technical Specifications) for an applicant are different than those for a licensee. For an applicant, departures from the Technical Specifications (including the Bases) would be in relation to the generic Technical Specifications contained in the

design certification rule. Section VIII.C.4 states that an applicant who references a design certification rule appendix may request an exemption from the generic Technical Specifications, and the Commission may grant such a request if it will comply with the requirements of 10 CFR 52.7.

Although the plant-specific Technical Specifications (TS) and the Bases are derived from the generic TS, at license issuance the generic TS (including the TS Bases) have no further effect on the plant-specific TS, and changes to the plant-specific TS are treated as license amendments under 10 CFR 50.90 as described in VIII.C.6, and changes to the TS Bases are addressed using the Bases Control Program as provided in the plant-specific Technical Specifications.

### 4.3.5 Changes to Operational Requirements

In accordance with Section VI.C of the design certification rules, operational requirements in the generic DCD do not have finality. Section VIII.C of the design certification rules discusses the processes for changes to and departures from operational requirements. As specified in Section VIII.C.4 of the design certification rules, if a COL applicant departs from the operational requirements specified in the DCD, the applicant must request an exemption in accordance with 10 CFR 52.7. However, the Section VIII.C processes only apply to specific operational requirements that were completely reviewed and approved in the design certification rulemaking (72 FR at 49365). For example, the Section VIII.C processes do not apply to the NRC's acceptance of portions of the inservice testing (IST) and inservice inspection (ISI) operational programs in the review of a design certification application because these portions of the operational programs were not completely reviewed and approved.

The Tier 2 portion of a generic DCD includes information considered as "other operational requirements" which are addressed for COL applicants in Section VIII.C of the design certification rules. The NRC will approve plant-specific operational requirements as part of the COL proceeding. Therefore, after issuance of a COL, the operational requirements in the generic DCD are not applicable to that licensee, except to the extent that the FSAR incorporates by reference those operational requirements. Changes to operational requirements in an FSAR are governed by 10 CFR 50.59 or 10 CFR 50.55a, whether or not the FSAR has incorporated by reference the operational requirements from the generic DCD.

Examples:

- The DCD Tier 2 states that IST will be performed in accordance with a specific edition and addenda of the ASME OM Code. The UFSAR incorporates by reference this particular provision from the DCD. The NRC regulations in 10 CFR 50.55a(f)(4)(i) require that the ISTs that are conducted by a COL holder during the initial 120-month interval to verify the operational readiness of pumps and valves, whose function is required for safety, must comply with the requirements in the latest edition and addenda of the Code incorporated by reference in 10 CFR 50.55a(b) (or the optional ASME Code cases listed in Regulatory Guide (RG) 1.192 that is incorporated by reference in 10 CFR 50.55a(b)), on the date 12 months before the date scheduled for initial fuel loading, subject to the limitations and modifications listed in 10 CFR 50.55a(b). RG 1.192, "Operation and Maintenance of Code Case Acceptability, ASME OM Code," is incorporated by reference in 10 CFR 50.55a identifying the most current set of NRC-approved ASME OM Code Cases with any applicable conditions. The 10 CFR 50.55a(f)(4)(i) required change from a specific edition and addenda of the ASME OM Code stated in DCD Tier 2 to the latest edition and addenda of the Code incorporated by reference in 10 CFR 50.55a(b) need not be evaluated in accordance with 10 CFR 50.59.

- If a COL holder desires to use a subsequently issued edition and addenda to the ASME OM Code that is incorporated by reference in 10 CFR 50.55a, the COL holder may submit a letter to the NRC requesting approval to use that later edition or addenda to the OM Code pursuant to 10 CFR 50.55a(f)(4)(iv). The change need not be evaluated in accordance with 10 CFR 50.59. Additional information on the use of later editions and addenda of the ASME Code for preservice and inservice testing programs (as well as ISI programs) is discussed in Revision 1 to RIS 2012-08, "Developing Inservice Testing and Inservice Inspection Programs under 10 CFR Part 52."

- If a COL holder desires to use a subsequently issued ASME code case for IST that has been endorsed by the NRC in RG 1.192, which has been incorporated by reference in 10 CFR 50.55a, a COL holder may do so without submitting an alternative request provided all conditions in RG 1.192 are implemented. The change need not be evaluated in accordance with 10 CFR 50.59.

- For the reactor vessel materials surveillance capsule operational program, the DCD describes the location of the surveillance capsules within the vessel as well as the associated lead factors and indicates that these are accordance with the requirements of 10 CFR Part 50, Appendix H. A

change in the location of a surveillance capsule must be evaluated in accordance with 10 CFR 50.59.

## 4.4 DEPARTURES FROM THE PLANT-SPECIFIC DCD

### 4.4.1 Departures from Tier 1 Information

Section VIII.A of the referenced design certification rule addresses changes to and departures from Tier 1 information. In summary, generic changes to Tier 1 information are governed by 10 CFR 52.63(a)(1). Generic changes are applicable to all applicants and licensees referencing that certified design, except those for which the change has been rendered technically irrelevant by action taken under Sections VIII.A.3 or VIII.A.4.

Section VIII.A.3 addresses departures from Tier 1 information that are required by the Commission through plant-specific orders which are governed by the requirements in 10 CFR 52.63(a)(4). These requirements are 1) to secure compliance with the Commission's regulations applicable and in effect at the time of certification issuance, or to ensure adequate protection of the public health and safety or the common defense and security, and 2) to ensure that special circumstances as defined in 10 CFR 52.7 are present.

Section VIII.A.4 addresses exemptions from Tier 1 information, which are governed by the requirements in 10 CFR 52.63(b)(1) and 10 CFR 52.98(f). A COL applicant or licensee may depart from the information in Tier 1 only by requesting an exemption. Plant-specific exemptions from Tier 1 information are governed by the standards in Section VIII.A.4 in the applicable design certification rule. In summary, the COL applicant or licensee must show the following:

- The departure is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security.

- Special circumstances are present, which consists of one or more of the following:

  (i) Application of Tier 1 in the particular circumstances conflicts with other rules or requirements of the Commission; or

  (ii) Application of Tier 1 in the particular circumstances would not serve its underlying purpose or is not necessary to achieve the underlying purpose; or

(iii) Compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the design certification rule was adopted, or that are significantly in excess of those incurred by others similarly situated; or

(iv) The exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption; or

(v) The exemption would provide only temporary relief from Tier 1 and the applicant has made good faith efforts to comply with Tier 1; or

(vi) There is present any other material circumstance not considered when the design certification rule was adopted for which it would be in the public interest to grant an exemption.

- The special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption.

- The design change will not result in a significant decrease in the level of safety.

The requirements in the first two bullets are derived from the requirements pertaining to exemptions in 10 CFR 50.12(a).

The exemption request is subject to litigation in the same manner as other issues material to the COL proceeding. After the COL is issued, exemption requests must be accompanied by a license amendment request in accordance with 10 CFR 50.90 and 50.92. It is expected that the NRC will review and disposition the license amendment and exemption requests concurrently.

Tier 1 includes design descriptions as well as ITAAC. As provided in 10 CFR 52.103(h) and Section IX.B.3 of the design certification rules, the ITAAC do not constitute requirements after the NRC has made the 52.103(g) finding. Therefore, after the 52.103(g) finding, a licensee does not need to evaluate whether changes constitute a departure from the ITAAC.

Tier 1 includes simplified diagrams of systems and structures whose interpretations are based upon the provisions in Tier 1 of the design certification rule (DCR). These diagrams are intended to represent functional arrangements of the systems and structures. Therefore, a COL holder may make changes from the configuration as depicted on the Tier 1 diagrams, provided that the functions of the systems and structures are not

affected, but only in accordance with the provisions in Tier 1 of the DCR that specify the interpretations of the simplified diagrams. In such cases, the Tier 1 diagram would not, itself, be changed – any departure from Tier 1 requires NRC approval. Rather, the as-built configuration could differ from the Tier 1 diagram as provided in the Tier 1 provisions describing the interpretation of simplified diagrams. Examples:

- A system diagram may show a run of pipe a temperature meter followed by a flow meter, without any intervening components. In the as-built plant, the flow meter can precede the temperature meter without the need for the Tier 1 departure, because the change in configuration does not affect the function of either meter.

- A Tier 1 figure depicts a stairwell in the southeast corner of a hallway and the note on the figure indicates that the stairwell is NOT part of the Tier 1 information. In the as-built plant, the stairwell can be located in the northeast corner of the same hallway without the need for a Tier 1 departure, because the change in location does not affect any Tier 1 safety function. The change in location would be reviewed as a Tier 2 departure, including review for any other potentially affected programs/plans (e.g., physical security), to determine if prior NRC approval is required.

- A Tier 1 figure depicts a temperature meter, followed by a junction of two pipe runs, followed by a flow meter. The licensee decides to switch the location of the temperature and flow meters. Such a change would involve a departure from Tier 1, because the change in configuration could affect the readings of the flow meter (and possibly the temperature meter).

Similarly, the Tier 1 descriptions and diagrams are intended to describe the design of systems and structures, rather than their operation. Therefore, a COL applicant or holder may make changes in the operation as discussed or depicted in Tier 1 without taking a departure from Tier 1. Examples:

- A Tier 1 figure shows a valve to be in the opened position. The licensee decides to close the valve to facilitate maintenance. Such a change in valve position does not constitute a departure from Tier 1.

- A Tier 1 design description states that a certain valve closes automatically. The licensee decides to change the function to a manual action. Such a change would constitute a departure from Tier 1, because the design of the component is affected.

The design descriptions and figures in Tier 1 are not intended to represent a complete depiction of a system or structure. Instead, they are only intended

to depict those components with safety significance. As a result, a COL applicant or holder may add components not discussed in Tier 1 or delete components not discussed in Tier 1, unless such addition or deletion would adversely affect the safety functions discussed or depicted in Tier 1. Examples:

- The licensee decides to add a valve not shown in a Tier 1 diagram. The sole purpose of the valve is to facilitate maintenance, and it does not affect any of the functions discussed in Tier 1. The addition of such a valve would not constitute a departure from Tier 1.

- The licensee decides to delete a valve shown on a Tier 2 diagram but not shown in a Tier 1 diagram. Such a change would not constitute a departure from Tier 1 (but would constitute a departure from Tier 2).

- A Tier 1 diagram shows that a system has two trains. During construction, a licensee decides to add a third train to provide more operational flexibility. The addition of such a train would constitute a departure from Tier 1, since it fundamentally affects the manner in which the system functions as shown on the Tier 1 diagram, and would have been discussed in Tier 1 if it had been initially proposed by the design certification applicant.

NRC staff reviewer guidance on the scope of Tier 1 is available in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 14.3.

### 4.4.2 Departures from Tier 2 Information

Section VIII.B of the referenced design certification rule addresses changes to and departures from Tier 2 information. In summary, generic changes to Tier 2 information are governed by 10 CFR 52.63(a)(1), similar to generic changes to Tier 1 information. Generic changes are applicable to all applicants and licensees who reference the applicable appendix, except those for which the change has been rendered technically irrelevant by action taken under VIII.B.3, VIII.B.4, VIII.B.5 or VIII.B.6.

Section VIII.B.3 addresses new requirements on Tier 2 information that are imposed by the Commission through plant-specific orders. This can occur only under circumstances where:

1. a modification is necessary to ensure compliance with the Commission's regulations applicable and in effect at the time the appendix containing the Rule was approved, or to ensure adequate

protection of the public health and safety or the common defense and security, and
2. special circumstances as defined in 10 CFR 50.12(a) are present.

Section VIII.B.4 identifies that an applicant or licensee may request an exemption from Tier 2 information, and the Commission may grant the request if it is determined that the exemption will comply with the requirements of 50.12(a). Note that the granting of an exemption from Tier 2 carries the requirement that the exemption be subject to litigation in the same manner as other issues material to the license hearing for an applicant, or be subject to an opportunity for a hearing in the same manner as a license amendment for a licensee. It is expected that the request for an exemption from Tier 2 information would be rare, especially for an applicant.

Section VIII.B.5 describes the process used to evaluate a proposed departure from Tier 2 information and determine if prior NRC approval is or is not required. Tier 2 departures that involve a change to or departure from Tier 1 information, Tier 2* information or the Technical Specifications require a license amendment under Section VIII.B.5.a. As noted in Section 4.4.1, Tier 1 departures also require an exemption from the design certification rule. The criteria in VIII.B.5.b are essentially identical to the criteria in 10 CFR 50.59(c), with two specific differences:

1. Reference is to a "departure from Tier 2 information" rather than "change to the facility as described in the FSAR (as updated)."
2. Reference is to the "plant-specific DCD" rather than the "FSAR (as updated)."

In addition to the differences identified above, Section VIII.B.5.a contains a second sentence, which reads as follows: "When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD (emphasis added)."

The definition of "all matters described in the plant-specific DCD" in Section 3.3 of this appendix encompasses the information that meets the definitions of "facility" and "procedures" as described in the UFSAR. This ensures that the evaluation process for a proposed departure from Tier 2 information is consistent in terms of scope and level of detail with the evaluation process for a change to the facility as described in the FSAR (as updated).

Similar to the discussion in Section 4.2 of the main body of NEI 96-07, Revision 1, the following sections and subsections describe the screening and evaluation process for proposed departures with respect to the VIII.B.5.b and VIII.B.5.c criteria. The criteria in Section VIII.B.5.b(1-8) of the design

certification rules correspond with those in 10 CFR 50.59(c)(2)(i-viii). The criteria in VIII.B.5.c are specific to ex-vessel severe accident design features.

Finally, Section VIII.B.5 includes VIII.B.5.d which requires consideration of the effect of a changed feature or capability on the original aircraft impact assessment required by 10 CFR 50.150(a). Guidance is provided in Section 4.4.2.4.

Section VIII.B.6 requires a license amendment for Tier 2* departures from the plant-specific design certification information. Additional guidance related to Tier 2* departures is provided in Section 4.4.4 of this appendix.

### 4.4.2.1 Screening of Departures from Tier 2 Information

Section VIII.B.5.a of a design certification rule specifies that an applicant or licensee who references the appendix to Part 52 that contains the rule may depart from Tier 2 information without prior NRC approval, unless the departure involves a change to, or departure from Tier 1 information, Tier 2* information, or the Technical Specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of Section VIII.

Any deviation from Tier 2 information in the plant-specific DCD is a departure that requires an evaluation under Section VIII.B.5.a to determine if prior NRC approval is required. As identified in Section 3.19 of this appendix, screening in accordance with this guidance may be considered a simplified evaluation for purposes of Section VIII.B.5.a. As such, the 10 CFR 50.59 screening guidance in Section 4.2 of the main body of NEI 96-07, Revision 1, may be used, with modification to account for the differences noted in Section 4.4.2, to perform simplified evaluations under Section VIII.B.5.a to determine that prior NRC approval is not required.

Screening of departures from the plant-specific DCD must include consideration of impacts on ex-vessel severe accident functions as discussed in Section 4.4.2.3 of this appendix.

Departures that cannot be determined based on screening/simplified evaluation to not require prior NRC approval (i.e., departures that fail to screen out) must be evaluated under the criteria in Section VIII.B.5.b and/or VIII.B.5.c, as appropriate.

Section VIII.B.5.b evaluations, including screens, are subject to the record-keeping and reporting requirements in Section X of the DCRs. Further guidance on documentation and reporting is provided in Section 5.

Just as activities that screen out of the 10 CFR 50.59 process may nonetheless require UFSAR information to be updated, activities that screen out of the VIII.B.5 process may nonetheless require plant-specific DCD information to be updated. Licensees should provide updated plant-specific DCD information to the NRC in accordance with Sections X.B.3.b and X.B.3.c of the applicable design certification rule.

#### 4.4.2.2 Evaluation of Departures from Tier 2 Information That Do Not Affect Ex-Vessel Severe Accident Criteria

The discussion in Section 4.3 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s), i.e., VIII.B.5.b is analogous to 10 CFR 50.59 for departures that do not affect ex-vessel severe accident criteria with one difference as discussed below. Departures that affect ex-vessel severe accident design features are discussed in Section 4.4.2.3.

COL holders may find value in using the PRA information in assessing the risk impact of plant changes and performing 10 CFR 50.59 or Section VIII.B.5 evaluations. For example, PRA information may be used to quantitatively address increase in the frequency of occurrence of an accident previously evaluated or the likelihood of a malfunction of a structure, system, or component important to safety.

The one difference in the evaluation guidance for Tier 2 departures concerns the evaluation criterion in Section VIII.B.5.b(3): Does the proposed departure "result in more than a minimal increase in the consequences of an accident…"

With respect to the consequences of accidents, the dose limits for members of the public for Part 52 licensees are found in 10 CFR 52.47 (in terms of total effective dose equivalent) rather than 10 CFR 100 (in terms of thyroid and whole body dose) for Part 50 licensees.[1] Differences from the guidance in Section 4.3.3 of the main body of NEI 96-07, Revision 1, are noted in italics below.

> General Design Criterion 19 of Appendix A to 10 CFR 50 requires radiation protection to permit access to and occupancy of the control room under accident conditions without personnel receiving radiation

[1] Each DCD contains the applicable radiation protection requirements for that DCD as approved in the associated design certification rule, e.g. the ABWR DCD requirements are based on 10 CFR 100.

exposure in excess of *5 rem TEDE as defined in 10 CFR 50.2* for the duration of the accident. *10 CFR 52.47* establishes requirements for the exclusion area and low population zones around the reactor so that an individual located at any point on its boundary immediately following onset of the postulated fission product release would not receive a radiation dose in excess of *25 rem total effective dose equivalent (TEDE).* In the Standard Review Plan (SRP), NUREG-0800, the NRC established lower acceptance criteria for certain events that are considered to have greater likelihood than the limiting accidents. For example, for a *Small Line Break Accident*, the SRP acceptance guideline is that the dose be less than or equal to a small fraction (i.e., 10 percent) of the *10 CFR 52.47* dose value or *2.5 rem TEDE.*

Therefore, for a given accident, calculated or bounding dose values for that accident would be identified in the UFSAR/*plant-specific DCD.* These dose values should be within the GDC 19 or *10 CFR 52.47* limits, as applicable, as modified by SRP guidelines (e.g., small fraction of *10 CFR 52.47*), as applicable. An increase in consequences from a proposed activity is defined to be no more than minimal if: (1) the increase is less than or equal to 10 percent of the difference between the current calculated dose value and the regulatory guideline value (*10 CFR 52.47* or GDC 19, as applicable); and (2) the increased dose does not exceed the current SRP guideline value for the particular design basis event. The current calculated dose values are those documented in the most up-to-date analyses of record. This approach establishes the current SRP guideline values as a basis for minimal increases for all facilities, not just those that were specifically licensed against those guidelines.[2]

An increase in consequences is no more than minimal and no LAR is required if:

$$\left\{\left[\left[\text{regulatory guideline value}\right] - \left[\text{current calculated value}\right]\right] * 0.1\right\} + \left[\text{current calculated value}\right] \geq \left[\text{proposed value}\right] \leq \left[\text{SRP guideline value}\right]$$

The following examples illustrate the use of the total effective dose (TEDE) concept and the current SRP accident dose criteria.

[2] *Similar to Part 52 licensees,* for licensees who adopt the alternative source term, evaluations against this criterion should be in terms of total effective dose equivalent and the limits established by 10 CFR 50.67 (effective January 24, 2000).

Example 1

The calculated fuel handling accident (FHA) dose is 3.0 rem TEDE at the exclusion area boundary. As a result of a proposed change, the calculated FHA dose would increase to 4.0 rem TEDE. Ten percent of the difference between the current calculated value and the regulatory limit is 2.2 rem TEDE [10% of (25 rem - 3 rem)]. The SRP acceptance guideline is 6.3 rem TEDE. Because the calculated increase is less than 2.2 rem TEDE and the total is less than the SRP guideline, the increase is not more than minimal.

Example 2

The calculated dose consequence for a particular steam generator tube rupture accident is 2.6 rem TEDE at the exclusion area boundary. As a result of a proposed change, the calculated dose consequence would increase to 4.0 rem TEDE. The increase is not more than minimal because the new calculated dose does not exceed the applicable SRP guideline of 25 rem TEDE, nor does the incremental change in consequences (1.4 rem) exceed 10 percent of the difference between the current calculated value and the regulatory limit of 25 rem TEDE. Ten percent of the difference between the regulatory limit (25 rem) and the current calculated value (2.6 rem) is 2.2 rem (10% of 22.4). Since 1.4 rem is less than 2.2 rem this change does not cause more than a minimal increase in consequences.

Example 3

The calculated dose consequence of a fuel handling accident is 2.5 rem TEDE at the exclusion area boundary. Because of a proposed change, the calculated dose consequence would increase to 5.0 rem TEDE. The SRP guideline for this accident is 6.3 rem TEDE and is still met. The incremental increase in dose consequence (2.5 rem), however, exceeds 10 percent of the difference to the regulatory limit or 2.3 rem [10% of (25 rem – 2.5 rem)]. Therefore, the change results in more than a minimal increase in consequences and thus requires prior NRC approval.

Example 4

The calculated dose to the control room operators following a loss of coolant accident is 4 rem TEDE. A change is proposed to the control room ventilation system such that the calculated dose would increase to 4.2 rem TEDE. The exposure acceptance criteria specified in GDC 19 is met if the total calculated radiological consequences for the control room doses are controlled to less than 5 rem TEDE. Although the new calculated dose is less than the regulatory limits, the incremental increase in dose (0.2 rem) exceeds the value of 10 percent of the difference between the current calculated value and

the regulatory value or 0.1 rem [10% of (5 rem - 4 rem)]. This change would require prior NRC review because the increase in consequences exceeds the minimal standard.

Example 5

The existing safety analysis for a fuel handling accident predicts an off-site dose of 4 rem TEDE. The SRP guideline for this event is 6.3 rem TEDE. A proposed change would result in an increase in the calculated dose to 5.8 rem TEDE. In this case, the proposed change would not cause more than a minimal increase in consequences because the new calculated value does not exceed the SRP guideline value (6.3 rem TEDE) or 10 percent of the difference between the current calculated value and the regulatory value or 2.1 rem [10% of (25 rem - 4 rem)].

#### 4.4.2.3 Evaluation of Tier 2 Departures that Affect Ex-Vessel Severe Accident Design Features

Per 10 CFR 52.47(a)(23), design certification applications must include descriptions and analyses of design features for preventing and mitigating severe accidents. In particular, design certification information should address challenges to containment integrity caused by:

- core-concrete interaction,
- steam explosions,
- high pressure core melt ejection,
- hydrogen combustion, and
- containment bypass[3]

Each design certification rule appendix contains criteria in Section VIII.B.5.c for determining whether a license amendment is required to depart from Tier 2 information that affects resolution of ex-vessel severe accident (EVSA) design features. In the Statements of Consideration for Part 52 (72 FR 49394), the NRC explained that the Section VIII.B.5.c criteria should be used for severe accident design features where 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.

[3] Design features that prevent or mitigate containment bypass events are important from an overall severe accident safety perspective. However, these features are not in and of themselves EVSA features and as such may not fall under Section VIII.B.5.c criteria. Proposed changes to containment bypass features need to be evaluated to other criteria in either Section VIII.B.5.a or Section VIII.B.5.b.

Severe accident mitigation features are design specific and are discussed primarily in Chapter 19 of the DCD. However, EVSA features may be described elsewhere in the DCD, and the location of the EVSA design information in the DCD is not important to application of the Section VIII.B.5.c criteria (i.e., the information does not need to be located in Chapter 19 of the DCD).

Examples of EVSA design features used in various new plant designs include but are not limited to:

- Reactor cavity flooding to promote in-vessel cooling and retention of core debris
- Reactor vessel depressurization to promote in-vessel cooling and retention of core debris
- Reactor vessel depressurization to prevent high pressure melt ejection
- Reactor cavity flooding to provide ex-vessel cooling of core debris
- Reactor cavity design to enhance core debris spreading and coolability
- Containment overpressure protection
- Containment combustible gas control
- Containment sprays and heat removal

The following performance characteristics could impact the ability of such features to prevent or mitigate an EVSA:

- Capacity (e.g., flow rate, battery life)
- Type
- Number
- Configuration
- Power source
- Active or passive nature
- Need for operator action
- Ability to function in harsh environment

Applicability of Section VIII.B.5.c Criteria

The Section VIII.B.5.c criteria are applicable to proposed departures affecting design features described in a referenced standard design certification that are relied upon to resolve postulated accidents when the reactor core has melted and exited the reactor (ex-vessel severe accidents) and the containment is challenged. If a proposed departure does not affect or involve an EVSA design feature or function, the Section VIII.B.5.c criteria do not need to be considered.

Screening

Once it has been determined that a proposed departure is within the scope of the referenced design certification rule and the Section VIII.B.5.c criteria are applicable, screening is performed to determine if the departure should be evaluated against the criteria in Section VIII.B.5.c.

Section VIII.B.5.c evaluations are required for departures that adversely affect EVSA functions, including methods used to perform or control EVSA functions.

EVSA design features may have preventive as well as mitigative functions. For example, design features that ensure in-vessel retention of core debris are considered EVSA design features because they prevent a severe accident from becoming an EVSA.

Some design features may have multiple functions (i.e., they may be used to perform EVSA functions as well as design functions as defined in Section 3.4). If a design feature has both EVSA functions and design functions, the Section VIII.B.5.c criteria are used to evaluate departures related to the EVSA functions, and the Section VIII.B.5.b criteria are used to evaluate departures related to design functions.

Departures are "screened in" (i.e., require a Section VIII.B.5.c evaluation) if they adversely affect EVSA functions or how EVSA functions are performed or controlled (including changes to equipment, procedures, assumed operator actions, and response times). For purposes of Section VIII.B.5.c screening, departures that remove or fundamentally alter the existing means of performing or controlling EVSA functions should be conservatively treated as adverse and screened in. Such departures include but are not limited to replacement of automatic action by manual action (or vice versa), changes to the human-machine interface, and changing a valve from "locked closed" to "administratively closed." Departures that are determined to have a positive

or no effect on EVSA functions and how those functions are performed or controlled may be "screened out" (i.e., do not require a Section VIII.B.5.c evaluation).

If a departure has both positive and adverse effects on EVSA functions, the departure should be screened in. The Section VIII.B.5.c evaluation should focus on the adverse effects.

Evaluation

For proposed departures that screen in, Section VIII.B.5.c requires prior NRC approval if:

1. There is a substantial increase in the probability of an EVSA such that a particular EVSA previously reviewed and determined to be not credible could become credible; or
2. There is a substantial increase in the consequences to the public of a particular EVSA previously reviewed.

For the first criterion, a license amendment is required for proposed departures that could result in a new, credible EVSA. To evaluate whether a proposed departure results in a new, credible EVSA, licensees should use criteria consistent with those used in the referenced DCD. It should be noted that the DCDs for the various new reactor designs may have used different terms for what constitutes not credible, including *practically eliminated*, *not physically feasible*, and *not relevant*. The full context of the relevant DCD discussion should be considered in the determination of what EVSAs had been previously reviewed and deemed not credible.

For the second criterion, a licensee may show that the departure will not result in a substantial increase in consequence to the public by demonstrating that the affected EVSA functions will still be successfully accomplished. Note that this review may be qualitative rather than the quantitative approach required for consequence evaluations under Section VIII.B.5.b(3) of the design certification rule(s) or criterion iii of 10 CFR 50.59(c)(2). A license amendment is required for departures that remove, defeat or significantly degrade the performance of an EVSA design feature such that one or more functions of EVSA design features as described in the FSAR would not be accomplished. A change that would adversely impact an EVSA feature such that the containment performance goals in SECY-93-087 and SECY-90-016 would no longer be met could constitute a substantial increase in consequences to the public.

For plants licensed or certified on the basis that there are no credible EVSAs (e.g., the design ensures in-vessel retention), criteria VIII.B.5.c(2) is not applicable. In this case, applicants and licensees may address the second EVSA criterion by stating that no credible EVSAs exist for the design, therefore no evaluation of consequences resulting from previously reviewed EVSAs is required. For changes to design features for combustible gas control, the applicants and licensees would still need to evaluate the proposed change against the requirements of 10 CFR 50.44(c) even if there were no credible EVSAs.

Examples

The following examples illustrate the implementation of these criteria.

1. The licensee proposes to increase the starting time for the emergency diesel generators (EDGs). In the referenced DCD, the EDGs do not perform EVSA functions (i.e., they are not relied upon to prevent or mitigate an EVSA). Therefore, the change to the EDG starting time may be screened out and does not require evaluation under Section VIII.B.5.c of the design certification rule.

2. The licensee of an AP1000 plant proposes to reduce the capacity of the In-containment Refueling Water Storage Tank (IRWST) by 2%. Per Appendix 19B of Tier 2 of the AP1000 DCD, the IRWST has an EVSA function of flooding the reactor cavity to submerge the outer surface of the reactor vessel to the reactor coolant loop nozzles. Therefore, this departure cannot be screened out and must be evaluated under Section VIII.B.5.c of the design certification rule. The licensee performs a review of the existing analysis and determines that this small change in IRWST capacity would have a negligible effect on cooling the outer surface of the reactor vessel because the remaining capacity would be sufficient to submerge the outer surface of the reactor vessel to the reactor coolant loop nozzles. Therefore, the licensee concludes that the departure does not require a license amendment under VIII.B.5.c. (Note that a Tier 1 or technical specification change would still require a license amendment.)

3. During construction, the licensee identifies a nonconformance in that the thickness of a portion of the reactor cavity floor concrete is 0.1 foot less than the minimum thickness specified in Tier 2 of the referenced DCD. The reactor cavity floor is an EVSA design feature; therefore, Section VIII.B.5.c of the design certification rule must be considered to determine whether NRC approval is needed to accept this nonconformance. Based on a comparison with the existing analysis, the licensee determines that

the reduction in thickness would have a negligible impact on the functional performance of the reactor cavity floor in the presence of core debris. Therefore, the licensee concludes that this nonconformance can be accepted as-is without a license amendment.

4. The licensee considers reducing the capacity of the containment venting system by 50%. The containment venting system is an EVSA design feature described at a high level in Tier 1 and in detail with specified pressure and flow rate in Tier 2 of the DCD; therefore, this departure cannot be screened out and must be evaluated under Section VIII.B.5.c of the design certification rule. The licensee performs a calculation and determines that a 50% reduction would significantly degrade the containment venting system function such that the containment may not be able to survive the pressures associated with the containment performance goals identified in SECY-93-087 and SECY-90-016, as approved by the associated Staff Requirements Memoranda, and described in NUREG-0800. As a result, the licensee concludes that there would be a substantial increase in the consequences of an EVSA previously evaluated, and this departure would require a license amendment.

5. A licensee proposes a departure to change the normal position of isolation MOVs on the lines connecting the IRWST to the spreading area for ex-vessel core debris quench. Tier 2 specifies that these flooding lines are isolated by a fuse valve (designed to open when the corium reaches the spreading area) and an MOV that is normally in the closed position. Changing the MOVs from a normally closed to a normally open position would be beneficial for an EVSA in that it would guarantee a passive flooding function upon opening of the fuse valve (i.e., flooding would not be impacted by mechanical or electrical failure of the MOV). On the other hand, changing the normal position of the MOV could increase the possibility of losing IRWST water inventory needed for emergency core cooling (due to a single failure if the fuse valve fails to remain closed). If the licensee determines that this departure would have no adverse effects on the EVSA flooding/core debris quenching function, then it would not need to be evaluated to the criteria in Section VIII.B.5.c. However, since the departure could have an adverse effect on a design basis function (ECCS), this departure may need to be evaluated to other criteria in Section VIII of the referenced design certification rule.

#### 4.4.2.4 Departures from Tier 2 Information Concerning Aircraft Impact

10 CFR 50.150 provides the requirements for the Aircraft Impact Assessment for standard design certifications issued after July 13, 2009. For combined licenses referencing certified designs that have addressed the requirements of 10 CFR 50.150, Section 50.150(c)(4)(ii) states that the change control process for FSAR aircraft impact information is provided in the applicable design certification rule.

Section VIII.B.5.d states:

> If an applicant or licensee proposes to depart from the information required by 10 CFR 52.47(a)(28) to be included in the FSAR for the standard design certification, then the applicant or licensee shall consider the effect of the changed feature or capability on the original assessment required by 10 CFR 50.150(a). The applicant or licensee must also document how the modified design features and functional capabilities continue to meet the assessment requirements in 10 CFR 50.150(a)(1) in accordance with Section X of this appendix.

There are two types of information concerning Aircraft Impact Assessment to consider.

First, the Aircraft Impact Assessment required by 10 CFR 50.150(a) is anticipated to include safeguards information. The assessment is not part of the UFSAR or the generic DCD and is not required to be submitted to the NRC; however, it is subject to NRC inspection. The design certification rule presumes that the combined license applicant or holder has direct access to the original Aircraft Impact Assessment from the design certification applicant or sponsor if it has contracted with the design certification applicant to provide the proprietary and safeguards information to support its license application or license. Regulations do not specifically require the combined license holder to maintain or update the assessment; however, this could be a practical way of maintaining compliance with the intent of 10 CFR 50.150. The design certification applicant is required to maintain safeguards information referenced in the generic DCD.

Second, 10 CFR 52.79(a)(47) requires certain aircraft impact information, as identified in 10 CFR 50.150(b), to be in the UFSAR. This summary information is typically in Chapter 19 of the UFSAR and is expected to be non-safeguards information. One purpose of the UFSAR information is to assist in assessment and management of the safety/security interface (required by 10 CFR 73.58) associated with the Aircraft Impact Assessment. It is the intent of 10 CFR 50.150 that any change to the design features or functional capabilities which could potentially affect the Aircraft Impact

Assessment, would be initially identified through a review of the UFSAR summary information.

If a licensee identifies changes to the design features or functional capabilities in the aircraft impact summary description (non-safeguards information) in the UFSAR, a subsequent review of the Aircraft Impact Assessment by a safeguards-authorized individual would be triggered. The review of the Aircraft Impact Assessment would determine if modified design features or functional capabilities continue to meet the assessment requirements. The Aircraft Impact Assessment could be changed if necessary per Section VIII.B.5.d. If the requirements in 10 CFR 50.150(a)(1) cannot be met, either the proposed change will need to be abandoned/altered or an exemption must be requested per 10 CFR 50.12. No further regulatory action would be required for the Assessment change as long as compliance with 10 CFR 50.150(a) was maintained. However, licensees should ensure that the UFSAR describes how the modified design features or functional capabilities continue to meet the assessment requirements in 10 CFR 50.150(a)(1).

From a licensing perspective, the UFSAR Aircraft Impact information potentially includes several categories of information: (1) Tier 2 information incorporated by reference from the generic DCD, (2) plant-specific supplemental information added to the UFSAR, and (3) plant-specific information that constitutes a departure from the generic DCD.

An applicant or licensee who departs from Tier 2 information is required to consider the effect of the changed design feature or functional capability on the original Aircraft Impact Assessment required by 10 CFR 50.150(a). The applicant or licensee is also required to describe in the plant-specific DCD how the modified design features and functional capabilities continue to meet the assessment requirements in 10 CFR 50.150(a)(1). Reporting of this updated information is governed by the requirements in Section X.B for departures.

An applicant or licensee who adds or changes supplemental information in the UFSAR should consider the effect of the changed design feature or functional capability on the original Aircraft Impact Assessment required by 10 CFR 50.150(a). If there is an effect, the applicant or licensee should describe in the plant-specific DCD how the design features and functional capabilities continue to meet the assessment requirements in 10 CFR 50.150(a)(1). Reporting of this updated information would be governed by the requirements in 10 CFR 50.59 for UFSAR changes.

If a change to supplemental Aircraft Impact Assessment information in the UFSAR affects the design or functional capabilities of SSCs as described in

Tier 2, the change should be treated as a departure in accordance with Section VIII.

As noted in Section 1.4.1.4, an applicant or licensee who changes information in the plant-specific DCD that was previously added and evaluated as a departure should treat any subsequent changes as a departure. Reporting of this updated information is governed by the requirements in Section X.B for departures.

Example Screening Question:

> Does the proposed change affect the design features or functional capabilities that are identified in or referenced by the summary description of the Aircraft Impact Assessment in FSAR Chapter 19 (10 CFR 50.150(a)(1))?
>
> If Yes, the original Aircraft Impact Assessment shall be reviewed to determine the effect of the proposed change on the original aircraft impact assessment required by 10 CFR 50.150(a). If there is an effect, the plant-specific DCD shall be changed to describe how the modified design features and functional capabilities continue to meet the aircraft impact assessment requirements in 10 CFR 50.150(a)(1). Note: Even if the review concludes there is no effect on the Aircraft Impact Assessment, the summary description wording and/or figures may need revision to reflect the proposed change. This question should be answered "yes" if existing features/capabilities are affected or if new features/capabilities are being added that should trigger a review of the original Aircraft Impact Assessment.
>
> If No, no further action is necessary.

### 4.4.3 CHANGES TO CHAPTER 19

There are four types of information in Chapter 19 of Tier 2 of the DCD and the FSAR:

- *Design basis information* – For some plants, Chapter 19 contains design basis information; e.g., Section 19.B for the ABWR provides information on unresolved safety issues and generic safety issues. Changes to such information are governed by the change processes discussed in Section VIII.B.5.b of the design certification rule and 10 CFR 50.59, as applicable, as discussed in Section 4.4.2.

- *PRA information* - Chapter 19 contains PRA information, as reflected in the format for Section 19.1 provided in Regulatory Guide 1.206. Changes to or departures from such information are discussed in Section 4.4.3.1.

- *Information related to ex-vessel severe accidents* - Chapter 19 contains ex-vessel severe accident information, as reflected in the format for Section 19.2 provided in Regulatory Guide 1.206. Departures from such information are governed by the change processes discussed in Section VIII.B.5.c of the design certification rule, as discussed in Section 4.4.2.3.

- *Other information related to severe accidents* - Chapter 19 contains other information related to severe accidents and beyond-design-basis-events, as reflected in the format for Section 19.2 provided in Regulatory Guide 1.206. Changes to such information are discussed in Section 4.4.3.2.

### 4.4.3.1 Changes to Probabilistic Risk Assessment (PRA) Information

In general, plants licensed under Part 50 do not have a description of a PRA as part of the UFSAR or the licensing basis in general. Therefore, plants licensed under Part 50 do not have PRAs that are subject to a change process (except to the limited extent that some licensees have sought risk-informed regulatory relief).

In contrast, UFSARs for plants licensed under 10 CFR Part 52 must contain a description of the PRA and its results (typically in Chapter 19). A COL applicant that references a design certification must use the PRA information in Chapter 19 of the DCD, which must be updated by the COL applicant to account for site-specific design information and any design changes or departures.

Tier 2 is defined in Section 3.23 to include, among other things, the PRA summary information required by 10 CFR 52.47(a). A description of the design-specific PRA and its results is Tier 2 information contained in Chapter 19 of the UFSAR as required by 52.47(a)(27) and 52.79(d)(1). A change to either the description of the PRA or its results is a departure from Tier 2 information, requiring a Section VIII.B.5 review to determine if prior NRC approval is required; however, such departures will screen out of further review because they will not meet the eight criteria of Section VIII.B.5.b or the two criteria of Section VIII.B.5.c. Thus, as a general matter, the VIII.B.5 review conclusion for departures from either the description of the PRA or its results will be that no prior NRC approval is required.

Similarly, as a general matter, the 10 CFR 50.59 review conclusion for changes to the description and results of the PRA as provided in Chapter 19 of the UFSAR will be that no prior NRC approval is required.

*Generic PRA Description or Results Departure Evaluation*

Evaluation Questions

1. Does the proposed activity result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the UFSAR?
2. Does the proposed activity result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the UFSAR?
3. Does the proposed activity result in more than a minimal increase in the consequences of an accident previously evaluated in the UFSAR?
4. Does the proposed activity result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the UFSAR?
5. Does the proposed activity create the possibility for an accident of a different type than any previously evaluated in the UFSAR?
6. Does the proposed activity create the possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the UFSAR?
7. Does the proposed activity result in a design basis limit for a fission product barrier as described in the UFSAR being exceeded or altered?
8. Does the proposed activity result in a departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analyses?
9. Is there a substantial increase in the probability of an ex-vessel severe accident such that a particular ex-vessel severe accident previously reviewed and determined to be not credible could become credible?
10. Is there a substantial increase in the consequences to the public of a particular ex-vessel severe accident previously reviewed?

For changes to the PRA description or results, all responses are, “No.”

Justification

A probabilistic risk assessment (PRA) is an analysis to determine the relative risk (probability) of an undesirable outcome, specifically, core damage frequency and large early release frequency. While the PRA uses the design attributes of SSCs, the PRA does not affect SSCs. As a result, a change to the PRA description or PRA results does not affect an SSC, SSC design function, or method of performing or controlling a design function. While the PRA uses the design attributes of SSCs, the PRA is not used to establish the design bases of an SSC nor is it used in the safety analyses. Further, since no SSC is affected, no SSC used to mitigate severe accidents is affected. Thus, all responses are, "No," and based on the negative response to the 10 evaluation questions above, a change to the PRA description or PRA results in Chapter 19 of the UFSAR does not require a license amendment.

Consequently, licensees may use or refer to a generic evaluation similar to that above as justification for determining that changes to the PRA description or results do not require prior NRC approval without providing a specific departure screening or departure evaluation for each change.

The plant-specific PRA itself is subject to maintenance and upgrade requirements specified in 10 CFR 50.71(h). The PRA required by 50.71(h) must be developed by the scheduled date of initial fuel load. Changes in accordance with 10 CFR 50.71(h) are not considered departures as these activities are specifically directed by rule. Therefore, the development of the PRA under 10 CFR 50.71(h)(1) and the maintenance and upgrade of this PRA throughout the life of the plant are not subject to the Section VIII departure process. While guidance on PRA maintenance and upgrade is outside the scope of this appendix, changes to the PRA information are governed by the processes discussed below:

*Changes to the PRA Information in Chapter 19 of Tier 2 of the DCD by a COL Applicant*

Changes by a COL applicant that pertain to the PRA information in Chapter 19 of Tier 2 of the DCD are governed by 10 CFR 52.79(d)(1). That section states that "the plant-specific PRA information must use the PRA information for the design certification and must be updated to account for site-specific design information and any design changes or departures."

Guidance for implementing 10 CFR 52.79(d)(1) is contained in the following documents:

- Section C.I.19, "Probabilistic Risk Assessment and Severe Accident Evaluation," of Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants"

- SRP 19.0, "Probabilistic Risk Assessment Information and Severe Accident Evaluation for New Reactors"

It is beyond the scope of this appendix to provide detailed guidance for PRA changes for a COL application that references a design certification. SRP 19.0 provides NRC staff reviewer guidance on the content of the PRA summary information in the FSAR.

After issuance of a COL, 10 CFR 52.79(d)(1) no longer applies to the PRA information. Instead, the PRA information is controlled as discussed below.

*Changes to the PRA Information in Chapter 19 of the FSAR by a COL Holder*

After issuance of a COL, the PRA information in Chapter 19 of the FSAR is controlled by 10 CFR 50.71(h), which states:

> (h)(1) No later than the scheduled date for initial loading of fuel, each holder of a combined license under subpart C of 10 CFR part 52 shall develop a level 1 and a level 2 probabilistic risk assessment (PRA). The PRA must cover those initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel.
>
> (2) Each holder of a combined license shall maintain and upgrade the PRA required by paragraph (h)(1) of this section. The upgraded PRA must cover initiating events and modes of operation contained in NRC-endorsed consensus standards on PRA in effect one year prior to each required upgrade. The PRA must be upgraded every four years until the permanent cessation of operations under 52.110(a) of this chapter.
>
> (3) Each holder of a combined license shall, no later than the date on which the licensee submits an application for a renewed license, upgrade the PRA required by paragraph (h)(1) of this section to cover all modes and all initiating events.

As discussed in the Statement of Considerations (SOC) for 10 CFR 50.71(h), the PRAs and upgrades are not required to be submitted to the NRC, but instead should be maintained by the licensee for NRC inspection. (72 FR 49362) The need for any such submittal or review would be determined by

any risk-informed application for which the licensee might wish to use this PRA, such as in support of licensing actions. (72 FR 49405)

As required by 10 CFR 50.71(h), a PRA that covers those initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel must be developed by initial fuel load. The requirements for maintenance and periodic upgrades of the PRA apply after initial fuel load. During construction, a licensee is not required to maintain or upgrade the PRA provided in the COL application, but it is recommended that licensees maintain the PRA as necessary to support other programs (e.g., reliability assurance program). Licensees may also find it beneficial to update the plant-specific PRA to reflect significant design changes during construction. However, if there are changes to the PRA summary or results presented in Chapter 19 of the UFSAR, the licensee is required to update the FSAR, as appropriate, in accordance with 10 CFR 50.71(e).

As discussed in the SOC, the NRC intends that PRA maintenance and upgrades be consistent with the guidance for those processes in consensus standards, such as American Society of Mechanical Engineers (ASME) "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications" (ASME–RA–Sb–2005) or other PRA standards endorsed by RG 1.200. In particular:

- The maintenance of the PRA models should reflect plant changes, such as modifications, procedure changes or plant performance. No specific frequency is defined in the rule for such maintenance; the NRC expects licensees to follow the ASME (or other consensus body) guidance on this aspect. (72 FR 49405)

- The PRA upgrade should incorporate new methodologies and significant changes in scope or capability. If no new PRA standards are endorsed by NRC in RG 1.200 during a four-year upgrade cycle, licensees would not be required to upgrade their PRAs; however, the requirement to maintain the PRA would still be in effect. It should also be noted that there may be situations where a PRA upgrade is needed more frequently than the four year cycle, as for instance to support a new risk-informed application. (72 FR 49405)

It is beyond the scope of this appendix to provide guidance for the maintenance and upgrading of the PRA.

Although the PRA (as maintained) and the PRA upgrades do not need to be submitted to the NRC, the PRA information in Chapter 19 needs to be

controlled like other FSAR information in accordance with 10 CFR 50.71(e). Thus, for example, the periodic updates to the FSAR should account for the following types of changes related to maintenance of the PRA:

- Changes in the design and procedures as described in the PRA information.
- Changes in frequencies and probabilities discussed in Chapter 19 to account for changes in the design and procedures, to the extent that the licensee is required to calculate revised frequencies and probabilities per ASME–RA–Sb–2005 or similar NRC-endorsed consensus PRA standards. In that regard, licensees are allowed to perform sensitivity analyses for some changes in the design and procedures in order to defer revision of the PRA to a later time.
- Changes in the PRA results discussed in Chapter 19, including the risk insights.

In addition, the periodic updates to Chapter 19 of the FSAR should account for the following types of changes related to the PRA updates:

- Changes to the PRA models and methodologies as described in Chapter 19.
- A description of any new PRA models and methodologies needed to comply with 10 CFR 50.71(h), and their results.

A licensee is not required to seek NRC approval for changes to the PRA information in Chapter 19. As a result, a licensee does not need to perform screening or prepare an evaluation per 10 CFR 50.59 or Section VIII.B.5 of the design certification rules for changes in the PRA information in Chapter 19. However, any changes to the PRA information in Chapter 19 should be reported to the NRC in accordance with 10 CFR 50.71(e).

To the extent that changes in the PRA information are attributable to changes in design or procedures, described elsewhere within the FSAR, the applicable change process should be followed for such changes/departures (including, as necessary, requesting NRC approval for the change). As a general matter, it is expected that any change that significantly impacts the results of the PRA (e.g., a significant design change) would be subject to the other change control processes discussed in Section 4.4.2 above. For example, Tier 1 of the plant-specific DCD typically includes information regarding risk-significant systems, structures, and components (SSC). Any departure from such information would require an exemption from Tier 1 and would therefore be subject to NRC review and approval. Similarly, departures from Tier 2 of the plant-specific DCD that result in substantial increases in the probability or consequences of design basis accidents or ex-vessel severe accidents would

require NRC approval per Section VIII.B.5 of the design certification rules. Consequently, while NRC approval is not directly required for changes to the PRA information in Chapter 19, NRC approval would likely be required for departures from other portions of the plant-specific DCD that have a significant impact on the results of the PRA.

*Examples*

1) Changes during Construction – Early during construction, the licensee decides to make a number of plant modifications to enable it eventually to request a power uprate. The modifications affect a number of chapters of the FSAR, including the PRA information in Chapter 19. The licensee:
   - must review the modifications in accordance with the change processes described in Sections 4.1 and 4.4.2 and update the FSAR, including any changes to the PRA information in Chapter 19, as necessary, at the next required update; and
   - may defer any changes to the PRA pending development of the PRA required by 10 CFR 50.71(h)(1).

2) Use of NRC-Endorsed Consensus Standard – The plant-specific DCD uses a low power and shutdown conditions (LPSD) analysis rather than a LPSD PRA. After issuance of the COL but more than one year prior to fuel load, the NRC endorses a consensus standard for a LPSD PRA. The licensee:
   - must upgrade its PRA to use the NRC-endorsed consensus standard within the time frames provided in 10 CFR 50.71(h), and should make the PRA available for inspection or review by the NRC staff upon request, but does not need to seek NRC approval for the upgrade; and
   - following the PRA upgrade, must update its FSAR at the next required update to replace the discussion of the LPSD analysis with a description of the LPSD PRA and the results of the LPSD PRA, including an identification of any risk insights.

3) Modifications during Operation – FSAR Section 9.5 states the fire water system has redundant 100% pumps, and the PRA information in FSAR Chapter 19 reflects that information. The licensee desires to change the fire water system to provide three 50% pumps. The licensee must:
   - perform a 10 CFR 50.59 review of the modification to FSAR Section 9.5. Assuming that the review concludes

that the modification does not need NRC approval, the licensee can implement the modification and update FSAR Section 9.5 at the next regulatory scheduled interval to reflect the modification; and

- perform a PRA screening of the modification. Assuming that the licensee determines that the modification can be screened out due to its low impact on the results of the PRA, the licensee can defer a revision of the PRA. However, the licensee must update FSAR Chapter 19 at the next regulatory scheduled interval to reflect the modification.

#### 4.4.3.2 Changes to Other Severe Accident Information

Chapter 19 includes information related to prevention and mitigation of severe accidents that do not necessarily progress to an ex-vessel severe accident. Part 52 does not specify a change process for such information. That is, the criteria in Section VIII.B.5.b of the design certification rule apply to departures "other than one affecting resolution of a severe accident issue" and the criteria in Section VIII.B.5.c of the design certification rule apply to departures "affecting resolution of an ex-vessel severe accident design feature." Therefore, a COL applicant or holder may make changes in the severe accident information in Chapter 19, unless that information pertains to ex-vessel severe accidents or is also subject to another applicable change/departure process (e.g., Tier 1, Tier 2, or Tier 2*), as discussed below. Guidance for evaluating departures that affect ex-vessel severe accidents under Section VIII.B.5.c is provided in Section 4.4.2.3.

When performing screening of departures to severe accident information under Section VIII.B.5 of the design certification rules, changes in Chapter 19 that do not affect ex-vessel severe accident design features may be screened out. However, in accordance with Section X.B and 10 CFR 50.71(e), such departures must be periodically reported to the NRC and must be reflected in periodic updates of the plant-specific PRA in accordance with 10 CFR 50.71(h), as appropriate.

Aircraft impact is considered a beyond design basis event and, thus, summary information required by Sections 52.47(a)(28) and 52.79(a)(47) is typically provided in Chapter 19. Control of changes affecting aircraft impact information is discussed in Section 4.4.2.4.

Although departures from severe accident information in Chapter 19 not involving ex-vessel events or aircraft impact are not directly subject to any special change criteria, change control mechanisms may apply. Specifically:

- Design features that are important contributors to the prevention or mitigation of severe accidents are identified in DCD Tier 1. As discussed in Section 4.4.1, departures from Tier 1 require NRC approval.

- Many design features address ex-vessel severe accidents as well as severe accidents in general. As discussed above, departures from Chapter 19 that involve ex-vessel severe accidents are subject to the criteria in Section VIII.B.5.c of the design certification rule.

- Many design features address severe accidents as well as design basis accidents. As discussed above, departures that involve design basis accidents are subject to the criteria in Section VIII.B.5.b of the design certification rule. Furthermore, to the extent that such features are addressed in a plant's Technical Specifications, those features cannot be deleted without NRC approval.

- Many design features that prevent or mitigate severe accidents are addressed in the PRA. As discussed above, changes to the PRA information in Chapter 19 of the FSAR are controlled by 10 CFR 50.71(e) and (h).

In summary, a COL applicant or holder may make a departure from severe accident information in Chapter 19 that does not involve an ex-vessel severe accident, provided that 1) the departure is included as part of the periodic FSAR updates to the NRC; and 2) other applicable change processes are applied, if any.

Example

An ABWR plant makes a change to the Automatic Depressurization System (ADS), to decrease the capacity of the ADS pressure relief valves. As stated in Table 19E.2-29 in Tier 2 of the ABWR DCD, the ADS pressure relief valves help mitigate in-vessel severe accidents. Additionally, the ADS pressure relief valves also act as safety relief valves (SRVs). Per Section 19K.4 of the ABWR DCD, "The ADS depressurizes the RPV so that the low pressure systems can inject water. Even if no water injection is available, the depressurization via one safety/relief valve (SRV) eliminates the potential for direct containment heating in the event of RPV failure." In order to make this change, the licensee:

- Needs to assess the departure against Criterion 1 in Section VIII.B.5.c of the design certification rule, because the ADS is used to eliminate

(i.e., make not credible) a particular ex-vessel severe accident (direct containment heating (DCH));

- Needs to assess the departure against the provisions in DCD Tier 1 Section 2.1.2, which discusses the capacities of the SRVs and ADS pressure relief valve;

- Needs to assess the departure for the ADS pressure relief valves against the criteria in Section VIII.B.5.b of the design certification rule because the valves are also SRVs that have a design basis function; and

- Needs to assess the departure against the Technical Specifications for the ADS.

### 4.4.4 Departures from Tier 2* Information

Tier 2* information is identified with italicized text or brackets and an asterisk in the generic DCD, and is carried over into the plant-specific DCD if the applicant or licensee incorporates the DCD by reference into its UFSAR. Section VIII.B.6 of Part 52 design certification rules addresses the requirements for departures from Tier 2* information. All departures from Tier 2* information require prior NRC approval, but some Tier 2* matters revert to Tier 2 status after the plant first achieves full power and are then subject to the departure provisions in Section VIII.B.5.

As stated in Section VIII.B.6.b, all requests for departures will be treated as a request for a license amendment under 10 CFR 50.90, thus no screen/evaluation process is applicable to this category of departures. However, Section VIII.B.6.d states that an exemption from the applicable design certification rule is not required for any departures processed under this section.

Examples of Tier 2* information that continues to be applicable throughout plant life are:

a) Fuel burn-up limit.
b) Fuel licensing acceptance criteria.
c) Fire areas.
d) Small-break LOCA analysis methodology.

Examples of Tier 2* information that reverts to Tier 2 information after the plant first achieves full power are:

a) ASME Boiler & Pressure Vessel Code, Section III.

b) Equipment seismic qualification methods.
c) Nuclear design of fuel and reactivity control system, except burnup limit.
d) Definition of critical locations and thicknesses.
e) Polar crane parked orientation.

The specific list of information varies for each certified design and reference to the applicable design certification rule is required of each applicant or licensee.

In some cases, Tier 2* information references codes or standards or regulatory guidance. Such references do not necessarily render the entire code, standard, or guidance document part of Tier 2*. Instead, the context of the reference within Tier 2 should be evaluated to determine whether only part of the referenced document is intended, in context, to constitute a Tier 2* requirement. Examples:

- Tier 2* for the ABWR (Section 3.7.3.7.2) states that "*Modes that have natural frequencies less than that at which the spectral acceleration approximately returns to the ZPA are combined in accordance with Regulatory Guide 1.92.*" In this case, not all of Regulatory Guide 1.92 is Tier 2*. The only portions of Regulatory Guide 1.92 that are Tier 2* are those that discuss combinations of modes that have natural frequencies less than that at which the spectral acceleration approximately returns to the zero period acceleration (ZPA).

- Tier 2* for the AP1000 (Section 3.8.4.5.1) states that "*Supplemental requirements for ACI-349-01 are given in the position on Regulatory Guide 1.142 in Appendix 1A. The structural design meets the supplemental requirements identified in Regulatory Positions 2 through 8, 10 through 13, and 15.*" In this case, not all of Regulatory Guide 1.142 is Tier 2*. Only Regulatory Positions 2 through 8 and 10 through 13, and 15 of Regulatory Guide 1.142 are Tier 2*.

## 4.5 APPLYING 10 CFR 50.59/VIII.B.5 TO COMPENSATORY ACTIONS TO ADDRESS NONCONFORMING OR DEGRADED CONDITIONS

The guidance in Section 4.4 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees after the 52.103(g) finding for addressing nonconforming or degraded conditions.

## 4.6 CHANGES TO EARLY SITE PERMITS

As described in 10 CFR 52.39(e), the holder of an early site permit may not make changes to the ESP, including the Site Safety Analysis Report (SSAR), without prior Commission approval, with the exception of typographic and administrative corrections to the SSAR (see 72 FR 49360, Aug. 28, 2007).

If it is determined that a proposed activity requires prior NRC approval, then an ESP amendment request must be submitted in accordance with 10 CFR 50.90 and 10 CFR 50.92. An amendment to an ESP would apply to all COL applications that incorporate by reference the ESP.

Alternatively, a COL applicant referencing an ESP may include in the COL application a request for a variance in accordance with 10 CFR 52.39(d) and 10 CFR 52.93(b). 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. A variance is reviewed and approved by NRC as a part of the COLA. The ESP is not changed as a result of NRC approval of a variance to the ESP in a COLA licensing action.

### 4.6.1 Changes Related to an ESP after Issuance of a COL

After issuance of a COL, the ESP and SSAR no longer have any affect with respect to the plant that is the subject of the COL. Instead, as provided in 10 CFR 52.26(d), after issuance of the COL, the ESP is subsumed within the COL to the extent referenced in the COL. Therefore, after issuance of the COL, the governing documents are the COL and the FSAR. In other words, the information that was contained in the SSAR, except as modified in accordance with 10 CFR 52.93, becomes part of the FSAR upon issuance of the COL in the same manner as if the COL applicant had not referenced an ESP. After issuance of the COL, the change process in 10 CFR 52.39 no longer applies, and instead changes are controlled by 10 CFR 52.98. See 72 FR 49352, and 72 FR 49377 (Aug. 28, 2007).

It is possible that an ESP is sufficient to accommodate two units, but the COL applicant only seeks a license for a single unit. In such an event, the COL will subsume the ESP and SSAR as discussed above. However, the ESP will remain in effect for the other possible unit. As a result, changes to the ESP and SSAR continue to be governed by 10 CFR 52.39, as such changes pertain to the other unit.

## 4.7 DISPOSITION OF CHANGE PROCESS REVIEW

The guidance for Part 52 licensees on implementation of changes/departures that require a license amendment request is different during construction versus after the 10 CFR 52.103(g) finding that all ITAAC are met, as discussed in the following sections. However, in both cases the licensing basis is changed when (1) the licensee approves the licensing basis change/departure package per 10 CFR 50.59/Section VIII.B.5 or (2) the LAR/exemption is approved by the NRC.

### 4.7.1 Evaluations performed during construction (before the 10 CFR 52.103(g) finding)

Licensees must comply with applicable change processes in accordance with Section 52.98 (e.g., 10 CFR 50.59, 50.54, design certification, etc.), including the requirements governing submittal of LARs and exemption requests when necessary. Licensing basis changes that require prior NRC approval may not be constructed until after the required LARs/exemptions are approved by the NRC or a PAR No Objection Letter is received. NRC approval of ITAAC-related LARs/exemption requests is required before the ITAAC closure notifications for affected ITAAC are submitted.

LARs that do not involve construction would need to be approved before associated Technical Specifications (if any) become applicable or an associated ITAAC ICN is submitted. LARs required for changes to operational programs must be approved before the affected program element is required to be implemented. Implementation requirements for required operational programs are specified in NRC regulations, the FSAR and/or license conditions.

Licensees may discuss planned changes/departures with the NRC staff prior to submittal of Preliminary Amendment Requests (PARs)/LARs/exemption requests. The purposes of pre-LAR submittal interactions are to:

- Ensure the NRC is informed and can plan for submittal of PARs/LARs/exemption requests and changes to fabrication/construction activities or schedules
- Facilitate preparation of PARs/LARs/exemption requests that are complete in terms of administrative requirements and technical basis
- Identify potential challenges to timely NRC consideration of PARs/LARs/exemption requests
- Determine if the licensee wants to request a PAR

Frequent and early communication between the licensee and NRC staff can help avoid unnecessary delays in NRC's processing of licensing actions.

When an LAR is accompanied by an exemption request, the LAR and exemption request can be reviewed and dispositioned by the NRC simultaneously.

Many LARs for changes during construction are expected to stem from changes to and departures from the standard designs for first-of-kind units. Approved LARs applicable to follow-on units of the same design may be referenced as precedent in subsequent COL applications. To facilitate NRC review and approval, subsequent applicants should address the applicability of the prior LAR approval to their plant specific circumstances. If timing does not permit reference in subsequent COLAs, approved LARs may be referenced as precedent in corresponding LARs during construction for subsequent units, and those licensees may use the Preliminary Amendment Request process described in the following section as needed.

#### 4.7.1.1 Preliminary Amendment Request During Construction

To maintain schedules, licensees may elect to use the Preliminary Amendment Request (PAR) process described in DC/COL-ISG-025. If a licensee elects to use this process, the PAR and the LAR must be submitted, and a PAR Notice of No Objection must be approved by the NRC prior to proceeding with installation and/or testing of any change/departure during construction that requires NRC approval.

For licensees to be able to request a PAR for license amendment/exemption requests, the COL must contain license conditions similar to the following:

<u>License Conditions on Changes during Construction</u>

> (i) The licensee may request use of a preliminary amendment request (PAR) process, for license amendments, at any time before the finding in Section 2.D(3). To use the PAR process, the licensee shall submit a written request to the Office of New Reactors (NRO) in accordance with COL-ISG-025, "Changes during Construction under Part 52."
>
> (ii) Prior to NRO's issuance of a written PAR notification, the licensee shall submit the license amendment request (LAR). Thereafter, NRO will issue a written PAR notification, setting forth whether the licensee may proceed in accordance with the PAR, LAR, and COL-ISG-

025. If the licensee elects to proceed and the LAR is subsequently denied, the licensee shall return the facility to its current licensing basis.

The primary purpose of the PAR is to maintain licensing basis configuration control and avoid unnecessary construction delays related to changes during construction arising after the issuance of the COL and before the 10 CFR 52.103(g) finding. This process will enable the NRC to assess and ensure the inspectability of SSCs affected by the proposed change and adjust its inspection activities as necessary. Based on the information provided in the licensee's PAR, the NRC may issue the licensee a PAR No Objection Letter stating that the NRC has no objection to the licensee proceeding at its own risk with installation and testing of the proposed plant change pending the outcome of the NRC's technical review of the license amendment/exemption request. The NRC may ask the licensee to supplement or clarify the PAR to support a timely response. Following licensee receipt of the NRC's PAR Notice of No Objection, the licensee may perform installation and testing activities, including inspections, tests or analyses specified in the ITAAC, and may document determinations that ITAAC acceptance criteria have been met. However, as discussed in Section 4.7.1, closure notifications for affected ITAAC may not be submitted until after NRC approval of the related LAR/exemption request. Activities associated with the proposed change should be performed in accordance with the licensee's approved design engineering processes. The PAR process is depicted in Figure 2.

An NRC PAR Notice of No Objection is not a pre-approval of the LAR/exemption request, nor does it imply any NRC approval of the proposed change. The PAR has no effect on the NRC's LAR process; the NRC will perform its normal LAR acceptance review and technical review, request additional information as needed, and make a decision on the LAR in accordance with NRC requirements and processes.

A licensee's PAR should contain the following information:

1. The date by which an NRC PAR Notification is needed to support licensee construction schedules and sequencing. The timeframe for NRC issuance of the PAR Notification will be based on consideration of the licensee's schedule expectations and expressed priorities, and could be as little as 1–2 days, with the goal of minimizing delays in licensee construction plans/schedules.

2. Summary description of the proposed change and a summary of the reason for concluding that an LAR (and exemption request, if any) is

required (i.e., summary result of the change process evaluation).

3. (Optional) Briefly identify applicable precedents, if any, discussed in the associated LAR to maximize staff efficiency, minimize requests for additional information, and promote consistency of licensing actions. Guidance for identifying applicable precedents is provided in NEI 06-02, *License Amendment Request Guidelines*, Revision 2.

4. (As needed) At the licensee's discretion an evaluation of the impact of the change on installation and testing schedules for affected SSCs could be included in the PAR. PARs may identify the following types of impacts resulting from the proposed change:
    - acceleration or delay in planned installation or test activities
    - inaccessibility of certain SSCs for NRC inspection following the change
    - new or modified activity with a limited time window for NRC inspection

5. Plans to identify new or modified ITAAC, or removal of any ITAAC; a summary of the reasons for the new, modified or removed ITAAC; and the estimated schedule for installation and testing activities associated with the change(s). The licensee should also identify specific activities for which direct inspection can take place only within a given time frame. For example, licensees should identify when proposed new tests, including one-time type tests, will be performed, and when changes will become inaccessible for inspection due to ongoing construction activities.

A template for submittal of PAR requests by licensees is provided at the end of this section. PAR requests should be submitted to the Office of New Reactors in accordance with DC/COL-ISG-025.

The PAR process also addresses inspectability issues unique to the construction phase and independent of the technical review of the proposed change to the licensing basis. As such, the licensee's PAR request should be provided and responded to by NRC separately from the LAR. To the extent possible, licensees should provide the PAR request at the time the LAR is submitted. Even when submitted concurrently with the LAR, the PAR results in a separate earlier response from the NRC and should be submitted separately. When submitted concurrently, the licensee PAR may reference, rather than duplicate, information contained in the LAR.

When necessary, the PAR request may be submitted before or after the LAR submittal depending on the circumstances. For example, the need for some

LARs may arise with little or no warning (e.g., to address an emergent construction issue or in response to the identification of a nonconforming condition that the licensee desires to accept as-is). If the licensee desires to proceed with installation and testing activities for such changes but does not have sufficient time to prepare an LAR, it may first submit a PAR request that contains the information outlined above. This will enable the NRC to begin its assessment of the inspection impacts in support of a timely NRC PAR Notification upon licensee submittal of the associated LAR. NRC will not issue the PAR Notification of No Objection until the licensee submits the associated LAR. NRC response to a licensee PAR is separate and independent of the status/schedule for the associated LAR acceptance and technical reviews.

For emergent situations when the PAR is submitted prior to the LAR, it is important to ensure that the LAR is consistent with a previously submitted PAR. Thus, before requesting a PAR, licensees should perform sufficient engineering evaluations to ensure there is a firm basis for preparation and submittal of an LAR that is consistent with the summary and preliminary information contained in the PAR.

A PAR may also be submitted *during* the NRC technical review of an LAR. At any time during the pendency of an LAR, licensees may notify the NRC of plans to proceed with installation and testing of changes prior to NRC approval of the LAR via submittal of a PAR. The PAR would include the necessary information concerning inspectability of the change and identify the date that installation and testing is scheduled to proceed. Based on that information, the NRC may issue a PAR Notification as discussed above. The need to install and test changes prior to LAR approval might be identified subsequent to LAR submittal due to changes in the licensee's construction sequence or schedule, or if approval of the LAR takes longer than expected.

PARs should be submitted in writing in accordance with 10 CFR 52.3. Less formal (e.g., verbal) communications may precede the required written submittal; this type of interaction may be especially important for communicating emergent situations.

Design, procurement, fabrication, installation and testing of a proposed change during construction that is performed prior to NRC approval of a required LAR (and exemption request, if applicable) are performed at-risk. Such work is considered "at-risk" because the NRC may ultimately decline to approve the change as proposed in the LAR. In that event, the licensee must restore the design to that approved by the NRC or adopt an alternative design that is acceptable to the NRC. Because of the nature of at-risk construction and the potentially high cost for rework and project delay due to

NRC denial of an LAR/exemption request, licensees should carefully consider the scope and complexity of changes that require an LAR when determining whether to submit a PAR to proceed with the change, and how much work to perform at-risk prior to obtaining NRC approval for the change. For example, licensees may choose not to proceed with changes that involve use of unapproved design codes or analysis methodologies due to the potential that NRC may not approve the proposed change, or because NRC review and approval may not be timely with respect to the project schedule.

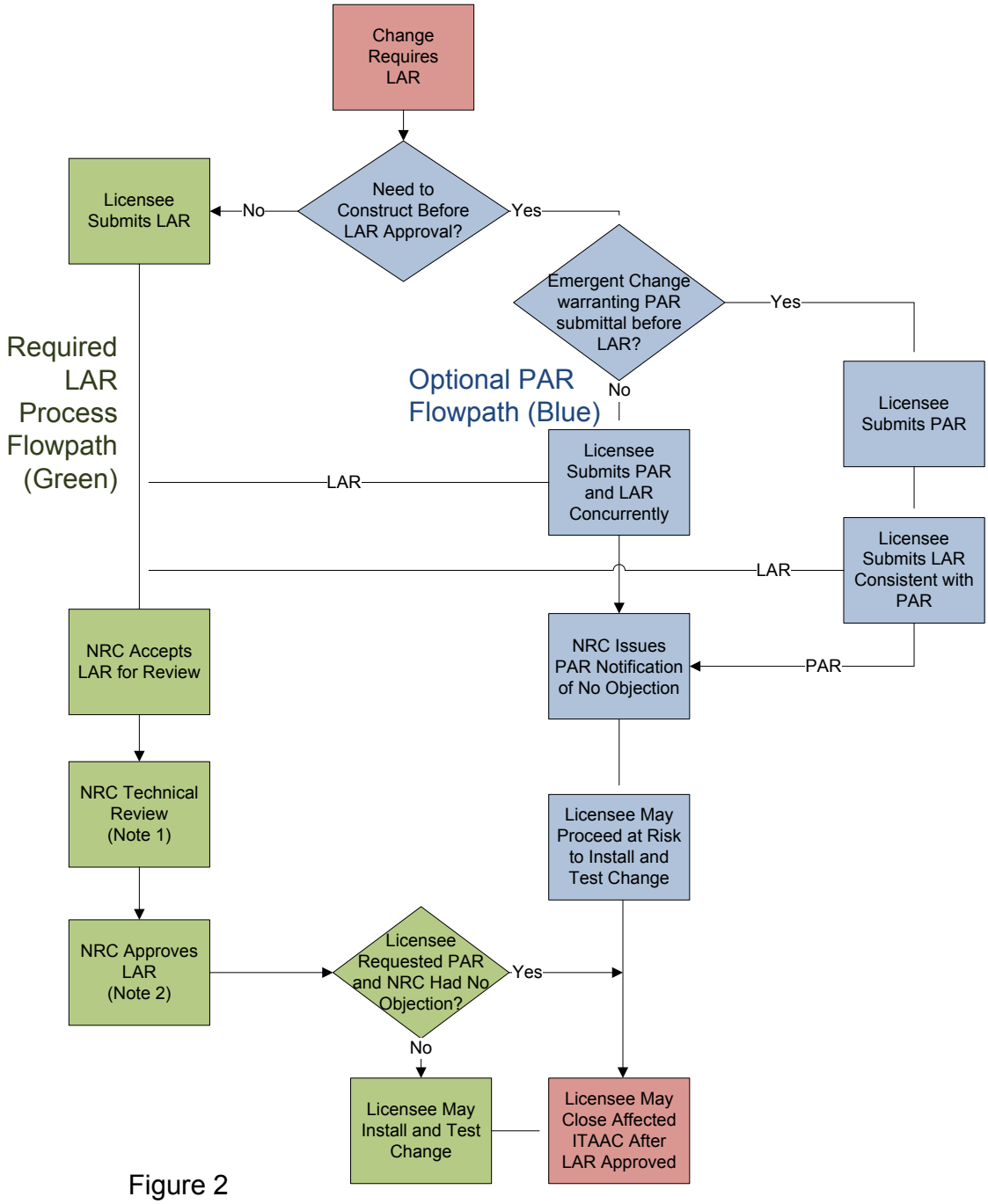


Figure 2
Changes during Construction License Amendment Request (LAR) Preliminary Amendment Request (PAR) Option

Note 1 – If NRC technical review takes longer than expected or if the construction schedule accelerates, the licensee may request a PAR after the LAR is submitted.

Note 2 – NRC may request additional information and may ultimately deny the LAR. In the event that an NRC PAR Notification was issued and at-risk work was performed, the licensee would need to restore SSCs to the approved design or an alternative configuration acceptable to the NRC.

**Preliminary Amendment Request (PAR) Template**

| PAR Number | Station Name | Unit Number | PAR Date |
|---|---|---|---|
| | | | |

**1. NRC PAR Notification Requested Date (see Block 7 for basis)** _____

Enter the date by which the NRC is requested to issue the PAR notification. Block 9 may provide the basis for the requested date.

**2. License Amendment Request References (as applicable)**

☐ **LAR submittal date and letter number** _____

☐ **Expected LAR submittal date** _____

If the associated LAR was previously submitted or is being submitted concurrent with the PAR, mark the top box and enter the LAR submittal letter number and date. If the LAR has not been submitted, mark the lower box and enter the expected LAR submittal date.

**3. Brief Description of Proposed Change**

Enter a summary description of the proposed change. Note: a complete description of the proposed change should be provided in the LAR.

**4. Reason for License Amendment Request**

Briefly summarize the reason for concluding that an LAR is required (i.e., a summary of the change process evaluation).

**5. Is Exemption Request Required?** ☐ **Yes** ☐ **No**

**If Yes, Briefly Describe Reason for Exemption**

Mark the Yes or No box to indicate whether or not an exemption request is required. If Yes, enter the reason for concluding that an exemption request is required. The exemption request, including complete technical bases, should be provided with the LAR.

**6. (Optional) Identify Applicable Precedents**

- Prior applicant experience with similar amendments or licensing actions.
- Experience with similar licensing actions at plants with a similar design and licensing basis.

Guidance for identifying LAR precedents is provided in NEI 06-02, *License Amendment Request Guidelines*", Revision 2.

| PAR Number | Station Name | Unit Number | PAR Date |
|---|---|---|---|
| | | | |

**7. (As needed) Impact of Change on Installation and Testing Schedules**

Summarize the results of the evaluation of the impact of the proposed change on the installation and testing schedules for affected SSCs. This block may provide the basis for the date the NRC is requested to issue the PAR notification (Block 1) and identify the following types of impacts resulting from the proposed change:

- acceleration or delay in planned installation or test activities
- inaccessibility of certain SSCs for NRC inspection following the change
- new or modified activity with a limited window for NRC inspection

**8. Impact of Change on ITAAC**

Summarize the results of the evaluation of the impact of the proposed change on ITAAC. The summary should describe plans for any new or modified ITAAC, or the removal of any ITAAC, along with the reason for such changes. An estimated schedule for the installation and testing activities associated with the proposed change(s) should be included. This block should also identify specific activities for which direct inspection can only take place within a given time frame. For example, licensees should identify when proposed new tests, including one-time type tests, will be performed, and when changes will become inaccessible for inspection due to ongoing construction activities.

**9. Additional Information**

This PAR section is optional and may be used to provide any additional information that may facilitate the NRC's review. Enter "None" if no additional information is provided.

| 10. Preparer Name (Print) | 11. Preparer Signature | 12. Date |
|---|---|---|
| | | |
| **13. Reviewer Name (Print)** | **14. Reviewer Signature** | **15. Date** |
| | | |
| **16. Approver Name (Print)** | **17. Approver Signature** | **18. Date** |
| | | |

### 4.7.2 Evaluations performed after the 10 CFR 52.103(g) ITAAC finding

Once the NRC makes the 10 CFR 52.103(g) finding that all ITAAC are met, plant Technical Specifications take effect and the guidance on disposition of departures and changes is the same for new plants as it is for any other operating plant. Therefore the discussion in Section 4.5 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s), i.e., VIII.B.5 is analogous to 10 CFR 50.59, with one addition: For a Tier 1 departure or change, the license amendment request must demonstrate that there is no significant decrease in the level of safety provided by the certified design and must be accompanied by a request for an exemption from the referenced design certification, as discussed in Section 4.4.1.

# 5 DOCUMENTATION AND REPORTING

## 5.1 UPDATES TO THE FINAL SAFETY ANALYSIS REPORT

10 CFR 50.71(e) requires an update of the FSAR be submitted annually during the period from the docketing of an application for a combined license under 10 CFR 52 Subpart C until the Commission makes the finding under 10 CFR 52.103(g).

Subsequent revisions must be filed annually or 6 months after each refueling outage provided the interval between successive updates does not exceed 24 months, in accordance with Section 50.71(e).

The updated FSAR shall be retained by the licensee until the Commission terminates their license.

## 5.2 RECORDS AND REPORTING FOR CHANGES SUBJECT TO 10 CFR 50.59

Changes that are not within the scope of the referenced design certification rule are subject to the applicable change processes in 10 CFR Part 50, unless they also involve departures from or noncompliance with information within the scope of the referenced design certification rule. In such dual-scope cases, the applicable provisions of 10 CFR 52.98 and the design certification rule apply. For changes subject to 10 CFR 50.59, the guidance in Section 5.0 of the main body of NEI 96-07, Revision 1, applies with the following additional guidance on report intervals.

Per 10 CFR 50.59(d)(2), for combined licenses, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a combined license to the date the Commission makes its findings under 10 CFR 52.103(g). Since 10 CFR 50.59(d)(2) only applies to licensees, the effective application of this requirement is only from issuance of the combined license until the 10 CFR 52.103(g) finding.

After the Commission makes the finding required by 10 CFR 52.103(g), the licensee shall submit, as specified in 10 CFR 52.3, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. The report must be submitted at intervals not to exceed 24 months. The report and updates to the site-specific portion of the final safety analysis report for the facility must be submitted, along with updates to the plant-specific DCD, at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e)(4), or at shorter intervals as specified in the license.

## 5.3 RECORDS AND REPORTING FOR CHANGES SUBJECT TO A DESIGN CERTIFICATION RULE

Changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule.

An applicant or licensee who references a design certification rule appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of the design certification rule appendix throughout the period of application and for the term of the license (including any period of renewal).

An applicant or licensee who references a design certification rule appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of the design certification rule appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

Documenting Change Process Evaluations

The guidance provided in Section 5.0 of the main body of NEI 96-07, Revision 1, for documenting a 10 CFR 50.59 evaluation of a proposed activity is similarly applicable for plant-specific departures under Section VIII of the design certification rule appendices including Tier 2 changes under Section VIII.B.5.b, ex-vessel severe accident changes under Section VIII.B.5.c and aircraft impact assessment changes under 10 CFR 50.150(c) and Section VIII.B.5.d, when applicable.

Reporting to NRC

Consistent with current practice and guidance in the main body of NEI 96-07, Revision 1 for 10 CFR 50.59 (d)(2), an applicant or licensee who references a design certification rule appendix shall submit a summary report of VIII.B.5 evaluations for activities implemented under VIII.B.5 to the NRC containing a brief description of any plant-specific departures from the DCD. Note that the summary report of VIII.B.5 evaluations should also include screens, i.e., simplified evaluations. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 52.3.

An applicant or licensee who references a design certification rule appendix shall submit updates to its DCD, which reflect the generic changes to and plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates must be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 52.3 and 50.71(e).

The above noted reports and updates must be submitted as follows:

a. On the date that an application for a license referencing a design certification rule appendix is submitted, the application must include the VIII.B.5 summary report and any generic changes to, or plant-specific departures from, the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes its findings required by 10 CFR 52.103(g), the VIII.B.5 summary report must be submitted semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by 10 CFR 52.103(g), the VIII.B.5 summary reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e)(4), respectively, (not to exceed 24 months) or at shorter intervals as specified in the license.

As discussed in Section 1.2.3 of this appendix, licensees may apply the UFSAR update guidance in NEI 98-03, Revision 1, to information outside the scope of the plant-specific DCD. Such modifications should be reported to NRC in accordance with 10 CFR 50.71(e)(3)(iii) prior to the Part 52.103(g) finding and 10 CFR 50.71(e)(4) thereafter.