NEI 96-07, Appendix C
Draft Revision 0C

Nuclear Energy Institute

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

October 2011

NEI 96-07, Appendix C
Draft Revision 0C

Nuclear Energy Institute

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

October 2011

ACKNOWLEDGMENTS

This document, NEI 96-07, Appendix C, *Guideline for Implementation of Change Control Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52*, was developed by the NEI Combined License Task Force. 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 Control 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 2010-2011 concerning the development of the NRC's interim staff guidance on the preliminary inspection accessibility review 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.

TABLE OF CONTENTS

GUIDELINE FOR IMPLEMENTATION OF CHANGE CONTROL 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 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 applicant- and licensee-initiated changes are properly controlled, documented, and reported to the NRC in accordance with the Part 52 requirements.

To encompass all of the change processes that may be needed by a Part 52 COL applicant, this appendix also provides guidance for the activity screening and change process to be used for early site permits (ESPs), based on 10 CFR 52.39(e).

In general, this appendix has been written for applicants and holders of combined licenses (COLs). Additionally, this guidance is applicable to holders of operating licenses that reference a design certification. Furthermore, much of the information in this guidance is applicable to holders of construction permits 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 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

The Part 52 change control processes interface with many other regulatory requirements and controls. To optimize the use of the change control 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 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 changes to the design of fire protection systems as described in the DCD are governed by Section VIII.B.5 of a referenced design certification rule.*
- 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 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 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 FSARs is provided by Regulatory Guide 1.181, which endorses NEI 98-03, Revision 1. After the COL is issued, licensees may also apply this guidance to the plant-specific DCD information.

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 both 10 CFR 50.2 design bases and supporting design information contained in the FSAR. 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.

1.3 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 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 a license amendment must be obtained from the NRC.
- **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.

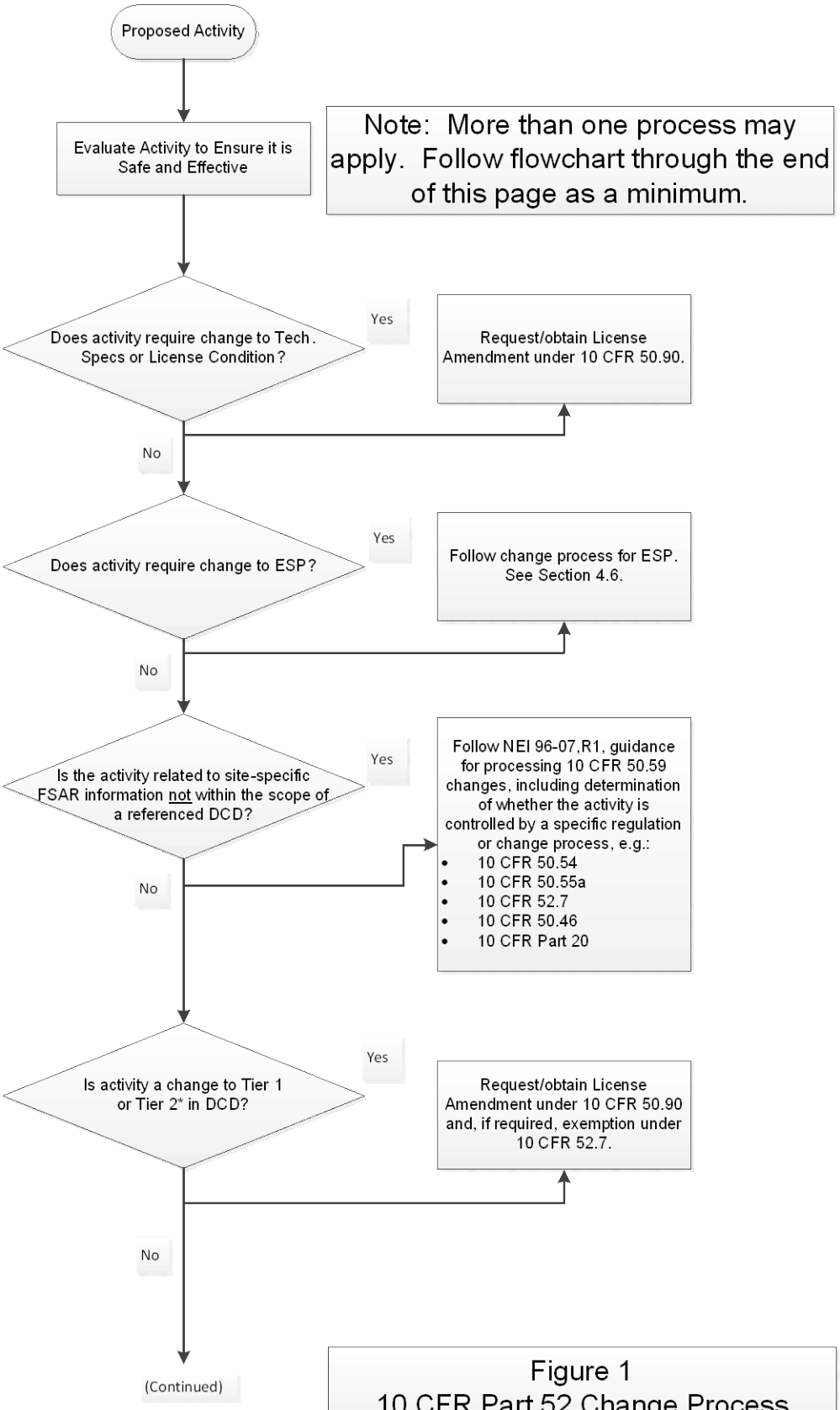

Figure 1
10 CFR Part 52 Change Process

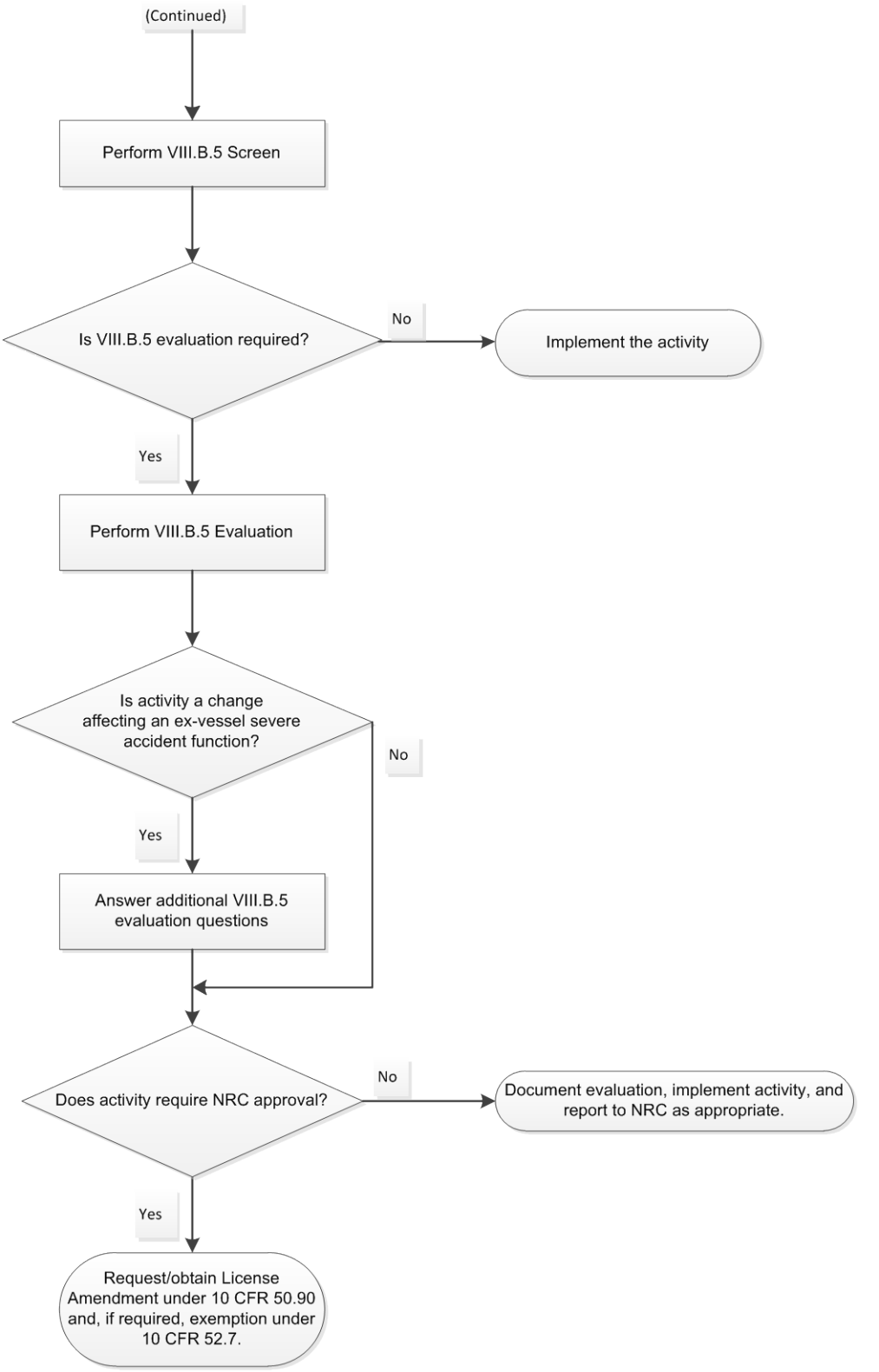

Figure 1 (Continued)
10 CFR Part 52 Change Process

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 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 new plant applicants and licensees under Part 52 include the Section VIII change 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 and departures to 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 Rule contains change control 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.

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, which includes amending the rule 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 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 to 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 make a change to provisions in the plant-specific DCD that were previously the subject of a departure or exemption. Such changes shall be subject to the change control process that applied to the original departure or exemption. Thus, for example, a change to 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 change to 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 change to 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 changes to 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 that are outside the scope of a referenced design certification rule are controlled under 10 CFR 50.59. Licensees should screen and evaluate 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 control process. Licensees electing to utilize an integrated change control process will apply the change control processes in Section VIII of the design certification rule to the entire UFSAR (rather than just the plant-specific DCD). The results of such an integrated approach should 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 of Section VIII. As a result, application of the Section VIII.B.5.b change control 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.

Activities on the proposed site that are not construction activities, as defined under 10 CFR 50.10(a)(2), are not restricted by an ESP. Therefore, a COL applicant may make changes to the description of such activities in the SSAR without prior NRC approval, but must identify such changes as part of its FSAR. Additionally, the environmental impact of such activities or site-related changes will need to be evaluated as potential variances or "new and significant information" in the construction permit or combined license application referencing the ESP.

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. In other words, after issuance of the construction permit or 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 change 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, 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 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 the applicability requirements for the rules, 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 the change processes to be used for 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 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	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 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 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 with unique aspects of the VIII.B.5.b process described in Section 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 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 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, and licensee changes to the design of fire protection systems as described in the DCD are governed by Section VIII.B.5 of a referenced design certification rule.

The term "accident" is distinguished from the term "severe accident". Severe accidents are events beyond the plant's design basis as that term is defined in 10 CFR 50.2 and Section 3.7 of this appendix. Changes to information related to ex-vessel severe accidents as defined in Section 3.8 of this appendix are subject to different change control processes than changes to 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 DCD. Thus, "all matters described in the plant-specific DCD" means:

(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 departure involves certain conditions requiring an exemption and/or a license amendment. The second sentence of this section specifies that, when evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

3.4 CHANGE/DEPARTURE

Definition:

The definition 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 as well as departures from a generic DCD under Section VIII of the design certification rule(s) with the clarifications in italics below.

Change *or departure* means a modification or addition to, or removal from, the facility or procedures that affects: (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.

Departure specifically refers to a modification or addition to, or removal from, information contained in a referenced standard design certification rule and reflected in a plant-specific DCD. [Adapted from RG 1.206.]

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 or Section VIII of

the design certification rule(s) with one addition to the discussion of design functions:

> Ex-vessel severe accident functions are SSC functions or design features for the prevention or mitigation of ex-vessel severe accidents. As defined in Section 3.8, 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)

Note that design documents and procedures are developed by the licensee in accordance with 10 CFR Part 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 design-basis information defined in 10 CFR 50.2 as 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. If the COL application references a certified design, the referenced generic DCD, including any documents specifically incorporated by reference in 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 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 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." As described in Section 1.4.2.1, for licensees that choose to use an integrated UFSAR, the plant-specific DCD will be a part of the UFSAR and 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 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 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. (62 FR 25806; 71 FR 4474) 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 change 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 change 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 change 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 or Section VIII of the design certification rule(s).

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 or Section VIII of the design certification rule(s) with the clarification that the focus is the information presented in the FSAR to satisfy the requirements of 10 CFR 52.79 for Part 52 licensees rather than 10 CFR 50.34(b) for Part 50 licensees.

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 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.B 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 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 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 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 changes to material in a referenced generic 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 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 Section VIII of the design certification rule(s).

Note that the counterpart of 10 CFR 50.59(c)(2)(viii) in Section VIII of the design certification rule(s) is Section VIII.B.5.b(8) of the design certification rules. Likewise, the counterpart of 10 CFR 50.59(c)(2)(i-vii) in Section VIII of the design certification rule(s) is Section VIII.B.5.b(1-7).

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 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 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 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 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 rather than 10 CFR 100 for Part 50 licensees.

Note that the counterpart of 10 CFR 50.59(c)(2)(viii) in Section VIII of the design certification rule(s) is Section VIII.B.5.b(8) of the design certification rules.

Likewise, the counterpart of 10 CFR 50.59(c)(2)(vii) in Section VIII of the design certification rule(s) is Section VIII.B.5.b(7).

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, the inservice testing program information, and inservice inspection program information. Section 13.4 of an FSAR typically includes a list of operational programs required by regulations. "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 preoperational 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, addressed by Section VIII.C of the applicable design certification appendix. Such matters do not have finality 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 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 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 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 or Section VIII of the design certification rule(s).

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 or Section VIII of the design certification rule(s) with the clarification that the focus is the information presented in the FSAR to satisfy the requirements of 10 CFR 52.79 for Part 52 licensees rather than 10 CFR 50.34(b) for Part 50 licensees.

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 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. 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 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, and licensee changes to 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:

The definition 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 or Section VIII of the design certification rule(s).

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 or Section VIII of the design certification rule(s).

Further discussion and guidance on screening are provided in Section 4.2 of the main body of NEI 96-07, Revision 1, (for plant-specific FSAR changes) with any unique aspects of VIII.B.5 screening described in Section 4.4.2.1 of this appendix (for departures from design certification information).

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 or Section VIII of the design certification rule(s).

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 or Section VIII of the design certification rule(s).

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 10 CFR 52.63(b)(1) and 52.98(f). 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 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 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 change 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 four 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
- maintenance activities
- UFSAR modifications
- 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 a plant-specific 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.

4.2 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/VIII.B.5 for control of changes to the UFSAR, including the plant-specific DCD. (Note that this list is 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 (proposed) 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. The guidance in 4.4.2.4 of this appendix is generally applicable, but the regulatory structure is different.

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.

4.2.4 Safety/Security Interface

10 CFR 73.58 specifies requirements for safety/security interface. 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.

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.

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, except as updated 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 the licensee may operate the facility, 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 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. As specified in Section VIII.C.4 of the design certification rules, if a COL applicant makes changes to the operational requirements specified in the DCD, the applicant must request an exemption in accordance with 10 CFR 52.7.

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, whether or not the FSAR has incorporated by reference the operational requirements from the generic DCD.

Examples:

- The DCD states that in-service testing (IST) will be performed in accordance with a specific edition and addendum of the ASME Code. The COL applicant desires to use a subsequently issued code case for IST that has been endorsed by the NRC. Such a change constitutes a departure from an operational requirement in the DCD. As a result, the COL applicant must request an exemption from the DCD to use the code case.

- The DCD states that IST will be performed in accordance with a specific edition and addendum of the ASME Code. The UFSAR incorporates by reference this particular provision from the DCD. After issuance of the COL, the COL holder desires to use a subsequently issued code case for IST that has been endorsed by the NRC. Such a change constitutes a change to an operational requirement in the UFSAR and 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 ensure 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) 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. Additional guidance related to required LARs for Tier 1 departures is provided in Section 4.7.3 of this appendix.

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. These diagrams are intended to represent functional arrangements of the systems and structures. Therefore, a COL applicant or holder may make changes from the configuration as depicted on the Tier 1 diagrams, provided that the functions of the systems and structures is not affected. 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. 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 safety function.

- A Tier 1 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.

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. 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 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 in the facility as described in the FSAR (as updated).

In the following sections and subsections the screening process, which is similar to that discussed in Section 4.2 of the main body of NEI 96-07, Revision 1, is described along with the evaluation process for a proposed departure with respect to the VIII.B.5.b and VIII.B.5.c criteria.

4.4.2.1 Screening of Departures from Tier 2 Information

The discussion in Section 4.2 of the main body of NEI 96-07, Revision 1, also applies to departures from Tier 2 information, i.e., VIII.B.5 screening for departures from the plant-specific DCD is analogous to 10 CFR 50.59 screening for changes to UFSAR information outside the scope of the plant-specific DCD.

Note that the counterpart of 10 CFR 50.59(c)(2)(i-viii) in Section VIII of the design certification rule(s) is Section VIII.B.5.b(1-8) of the design certification rules.

Screening of departures from the plant-specific DCD for impact on ex-vessel severe accident functions is addressed in Section 4.4.2.3 of this appendix.

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.

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."

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 Section VIII of the design certification rule(s), i.e., VIII.B.5 is analogous to 10 CFR 50.59 for departures that do not affect ex-vessel severe accident criteria with one exception as discussed below. Departures that affect ex-vessel severe accident design features are discussed in Section 4.4.2.3.

Note that the counterpart of 10 CFR 50.59(c)(2)(i-viii) in Section VIII of the design certification rule(s) is Section VIII.B.5.b(1-8) of the design certification rules.

Does the Proposed Departure Result in More Than a Minimal Increase in the Consequences of an Accident?

The discussion in Section 4.3.3 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for evaluation of changes under Section VIII.B.5.b.iii of the design certification rule(s), with the one difference. 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 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

[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.

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]

These examples will be revised for TEDE.

Example 1

The calculated fuel handling accident (FHA) dose is 50 rem to the thyroid at the exclusion area boundary. As a result of a proposed change, the calculated FHA dose would increase to 70 rem. Ten percent of the difference between the calculated value and the regulatory limit is 25 rem [10% of (300 rem- 50 rem)]. The SRP acceptance guideline is 75 rem. Because the calculated increase is less than 25 rem 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 25 rem thyroid at the exclusion area boundary. As a result of a proposed change, the calculated dose consequence would increase to 29 rem thyroid. The increase is not more than minimal because the new calculated dose does not exceed the applicable SRP guideline of 30 rem thyroid, nor does the incremental change in consequences (4 rem) exceed 10 percent of the difference between the previous calculated value and the regulatory limit of 300 rem thyroid. Ten percent of the difference between the regulatory limit (300 rem) and the calculated value (25 rem) is 27.5 rem (10% of 275). Since 4 rem is less than 27.5, this change does not cause more than a minimal increase in consequences.

Example 3

The calculated dose consequence of a fuel handling accident is 25 rem to the thyroid at the exclusion area boundary. Because of a proposed change, the calculated dose consequence would increase to 65 rem. The SRP guideline for this accident is 75 rem and is still met. The incremental increase in dose consequence (40 rem), however, exceeds 10 percent of the difference to the regulatory limit or 27.5 rem [10% of (300 rem - 25 rem)]. Therefore, the change results in more than a minimal increase in consequences and thus requires prior NRC approval.

[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 4

The calculated dose to the control room operators following a loss of coolant accident is 4 rem whole body. A change is proposed to the control room ventilation system such that the calculated dose would increase to 4.5 rem. The regulations dictate that the control room doses are to be controlled to less than 5 rem by General Design Criterion 19. Although the new calculated dose is less than the regulatory limits, the incremental increase in dose (0.5 rem) exceeds the value of 10 percent of the difference between the previously 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 to the thyroid of 77 rem. The SRP guideline for this event is 75 rem. A proposed change would result in an increase in the calculated dose from 77 to 77.1 rem. In this case, the proposed change would not cause more than a minimal increase in consequences because the new calculated value, even though greater than the SRP value, is within the guideline limit of 0.1 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

[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 Section 4.4.3.2.

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.

Severe accident mitigation features are design specific and are discussed primarily in the 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 change 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 change 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 change 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 change 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 change 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 Required to Address 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. It 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 document; 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 52.47(a)(28) requires some specific 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 management of the safety/security interface (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; a change to the proposed design feature modifications could be another possible outcome. 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 plant-specific DCD, and (3) plant-specific information that constitutes a departure from the generic DCD.

An applicant or licensee who changes 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). Submittal of this updated information is governed by the reporting 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). Such additions or changes are not specifically governed by either change control requirements in the applicable design certification rule or 10 CFR 50.150 since supplemental information is not defined as a departure. However, the regulatory intent is that the same criteria should apply. 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). Submittal of this updated information would be governed by the reporting requirements in 10 CFR 50.59 for UFSAR changes.

As noted in Section 1.4.1.4, an applicant or licensee who changes information in the plant-specific DCD which was previously added and evaluated as a departure should treat any subsequent changes as a departure. Submittal of this updated information is governed by the reporting 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 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). 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. 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 which 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 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. Changes to 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.

As discussed in more detail below, the PRA information in the UFSAR is not subject to the change processes in Section VIII of the design certification rule or 10 CFR 50.59.

The plant-specific PRA itself is subject to maintenance and upgrade requirements specified in 10 CFR 50.71(h). Guidance on PRA maintenance and upgrade is outside the scope of this appendix.

As discussed by the NRC in meetings with the industry on July 19 and August 8-9, 2007, changes to the description and results of the PRA as provided in Chapter 19 of Tier 2 of the DCD are not subject to the change control processes contained in Section VIII of the design certification rule. Similarly, changes to the description and results of the PRA as provided in Chapter 19 of

the UFSAR that do not involve changes to other Tier 2 information are not subject to the change control process contained in 10 CFR 50.59. Instead, 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."

Detailed 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"
- Interim Staff Guidance DC/COL-ISG-03, "Probabilistic Risk Assessment Information to Support Design Certification and Combined License Applications"
- Slide presentations at NRC meeting on August 8, 2007 (ADAMS # ML072840296), "Refined Guidance on PRA Information to Support Design Certification and Combined License Applications"

It is beyond the scope of this appendix, to provide detailed guidance for PRA changes for a COL application that references a design certification. Suffice it to state, a COL applicant does not need to update the PRA information in the DCD to account for relatively minor changes. Instead, COL applicants should provide the following information as described in ISG-03:

> If there are any design changes or departures from the certified design, the staff expects COL applicants to submit the PRA numerical changes when the cumulative risk impact of the changes resulting from the COL departure is more than a 10% change (either positive or negative) in the total core-damage frequency or total LRF from the DC PRA. Additionally, all changes in key assumptions per RG 1.200 and all changes in risk insights as defined in RG 1.206 including differences between the updated risk insights and the certified design risk insights

> should also be submitted to the NRC in accordance with the guidance in Section C.III of RG 1.206. All changes or departures from the design that result in a revision of PRA-based qualitative results should also be reported to the NRC.

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 indicated by the structure of 10 CFR 50.71(h), the first upgrade to the PRA is due prior to fuel load. The requirements for maintenance and periodic upgrades of the PRA apply after the initial upgrade prior to fuel load. During construction, a licensee is not required to maintain the PRA provided in the COL application, due to the large number of changes to the PRA that are

expected during construction as the detailed design is finalized and equipment is procured.

As stated in the SOC, the NRC intends that PRA maintenance and upgrades be consistent with the guidance for those processes in American Society of Mechanical Engineers (ASME) "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications" (ASME–RA–Sb–2005). In particular, the SOC state:

- 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 issued 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 screen some changes in the design and procedures to 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), including a description of the 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, to the extent that changes in the PRA information are attributable to changes in design or procedures, the changes may affect other sections within the DCD or FSAR, and the applicable change process should be followed for such changes (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 DCD typically includes information regarding risk-significant systems, structures, and components (SSC). Any change to such information would require an exemption from Tier 1 and would therefore be subject to NRC review and approval. Similarly, changes to Tier 2 of the plant-specific DCD that result in significant 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 changes in 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:
    - may defer any changes to the PRA information in Chapter 19 pending the PRA upgrade required by 10 CFR 50.71(h)(1); and

- must review the modifications in accordance with the change processes described in Sections 4.1 and 4.4.2 and update the FSAR (except for the PRA information) at the next regulatory scheduled interval.

2) Use of NRC-Endorsed Consensus Standard - - The DCD for a plant uses a seismic margins analysis rather than a seismic PRA. After issuance of the COL but more than one year prior to fuel load, the NRC endorses a consensus standard for a seismic 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), must 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 regularly scheduled interval to replace the discussion of the seismic margins analysis with a description of the seismic PRA and the results of the seismic 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 repeats 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 regularly 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 regularly 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 change criteria in Section VIII.B.5.b of the design certification rule applies to departures "other than one affecting resolution of a severe accident issue" and the change criteria in Section VIII.B.5.c of the design certification rule applies 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 process (e.g., Tier 1, Tier 2, or Tier 2*), as discussed below. Guidance for evaluating changes that affect ex-vessel severe accidents under Section VIII.B.5.c is provided in Section 4.4.2.3.

Therefore, when performing screening of changes 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 (report evaluations NOT screens) and 10 CFR 50.71(e), such changes 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 changes to severe accident information in Chapter 19 not involving ex-vessel events or aircraft impact are not directly subject to any special change criteria, much of that information is indirectly subject to change controls. 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 change 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 change 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 change to severe accident information in Chapter 19 that does not involve an ex-vessel severe accident, provided that 1) the change is included as part of the periodic FSAR updates to the NRC; and 2) checks are performed to determine whether the change affects other parts of the licensing basis that are subject to change controls, such as Tier 1.

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 but not ex-vessel severe accidents. Additionally, the ADS pressure relief valves also act as safety relief valves (SRVs). In order to make this change, the licensee:

- Does not need to assess the change against the criteria in Section VIII.B.5.c of the design certification rule, because the ADS is not used to mitigate ex-vessel severe accidents;

- May screen out the change in Chapter 19 related to the ADS;

- Needs to assess the change 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 change in 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 which have a design basis function; and

- Needs to assess the change 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 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*. Instead, only those portions of Regulatory Guide 1.92 that discuss combinations of modes that have natural frequencies less than that at which the spectral acceleration approximately returns to 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*. Instead, 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. To determine whether a proposed activity is considered a "change" to the ESP or SSAR, the activity is screened based on the criteria in Section 4.6.1.

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 Screening of Proposed ESP Changes

Screen proposed ESP activities/changes using the screening questions below to determine whether an ESP amendment request and prior NRC approval is needed before the proposed activity/change can be implemented.

1. Is the proposed ESP activity a preconstruction (i.e., not construction) activity, as defined by 10 CFR 50.10(a)(2)?

   - If the answer is "Yes," then the proposed activity can be implemented without prior NRC approval. Note: If the activity represents a change from any of the information contained in the SSAR, the COL applicant must identify the changes in the FSAR.

   - If the answer is "No," continue on to screening question No. 2.

2. Does the proposed ESP activity constitute a "change" to the ESP or SSAR? A change to the ESP or SSAR is defined as an activity that differs from the information contained in the ESP or SSAR that is material to the bases for the NRC's issuance of the ESP. When determining whether a change is material to the bases for the NRC's issuance of the ESP, licensees should consider the information contained in the SSAR, corresponding discussion in the NRC's Safety Evaluation Report, and whether the proposed activity represents a deviation from one or more of the site characteristics, design parameters, or ESP terms or conditions.

   - If the answer is "Yes," then an amendment request must be submitted and prior NRC approval is required before the proposed activity can be implemented.

   - If the answer is "No," then the proposed activity can be implemented without prior NRC approval.

4.6.2 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. Thus, after issuance of the COL, the change process in 10 CFR 52.39 no longer applies, and instead changes are controlled by 10 CFR 50.59. 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.

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. Changes during construction may not be implemented until after required LARs/exemptions are approved by the NRC.

Because SSCs are not considered in service during construction, and technical specifications are not in effect until after the 10 CFR 52.103(g) ITAAC finding, additional criteria are needed for determining when a change is "implemented" during the construction phase. During construction, a change is considered "implemented" when an ITAAC closure letter for the affected SSC is submitted under 10 CFR 52.99 (e.g., after the change is

installed and tested), or otherwise credited in the licensing basis of the plant (e.g., described in an update to the FSAR). This means that NRC approval of ITAAC-related LARs/exemption requests is required before closure letters for affected ITAAC are submitted and before changes are reflected in required annual updates to the FSAR.

Changes to technical specifications and certain other LARs might not involve ITAAC. LARs that do not involve ITAAC would need to be approved before associated technical specifications (if any) become applicable.

LARs required for changes to operational programs not subject to ITAAC or technical specifications must be approved before the affected program element is required to be implemented. Implementation requirements for required operational programs are specified in NRC regulations and/or the FSAR.

Some SSCs are required to be placed in service prior to the 10 CFR 52.103(g) finding to comply with requirements other than Technical Specifications such as; security, fire protection, radiation protection and emergency planning requirements. NRC approval of LARs/exemption requests associated with such SSCs is required prior to when the SSC is needed to perform its intended function to comply with the applicable requirement.

Licensees should discuss planned changes with the NRC staff prior to submittal of LARs/exemption requests. The purposes of pre-LAR submittal interactions are to:

- Ensure the NRC is informed and can plan for submittal of LARs and changes to fabrication/construction activities or schedules
- Facilitate preparation of LARs that are complete in terms of administrative requirements and technical basis
- Identify potential challenges to timely NRC approval of LARs
- Determine if the licensee needs to request a Preliminary Acceptability Review (PAR)

Frequent and early communication between the licensee and NRC staff can help avoid unnecessary delays in NRC's processing of license-related requests.

When an LAR is accompanied by an exemption request, the LAR and exemption request are reviewed and dispositioned by the NRC in simultaneously. Licensee LARs should identify impacts of the change on installation and testing schedules for affected SSCs and the date by which an NRC decision is needed to support ITAAC closure or other actions.

Many LARs for changes during construction are expected to stem from changes to the standard designs for first-of-kind units. Approved LARs applicable to follow-on units of the same design may be referenced 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 in corresponding LARs during construction for subsequent units, and those licensees may use the Preliminary Acceptability Review process described in the following section as needed.

4.7.1.1 Preliminary Acceptability Review for Inspectability for "At Risk" Construction

To maintain schedule, licensees may need to proceed with installation and testing of changes pending a final NRC decision on a required LAR/exemption request. Before proceeding with installation and testing of a change during construction that requires NRC approval of an LAR, Part 52 licensees should notify the NRC and request a Preliminary Acceptability Review (PAR).

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

License Conditions on Changes during Construction

> (i) The licensee may request use of a preliminary acceptability review (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.

These license conditions will expire upon the NRC's 10 CFR 52.103(g) finding.

The primary purpose of the PAR is to 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 request, the NRC may issue the licensee a PAR Notification 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 request to support a timely response. Following licensee receipt of the NRC's PAR Notification 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 letters 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 Notification 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 request should contain the following information:

1. 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)

2. 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.

3. Evaluation of the impact of the change on installation and testing schedules for affected SSCs. PAR requests should identify the following types of inspectability 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

4. 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.

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.

6. Preliminary assessment of whether or not the proposed change involves no significant hazards consideration based on the criteria of 10 CFR 50.92(c). The complete technical bases for the no significant hazards consideration determination should be provided in the LAR.

   If the licensee's preliminary assessment indicates that the proposed change does not meet the criteria for a no significant hazards consideration determination, the NRC may decline to issue a PAR Notification allowing construction at risk.

7. Preliminary assessment of whether or not the proposed change qualifies for exclusion from environmental review under 10 CFR 51.22. The complete technical bases for the licensee's determination regarding environmental exclusion should be provided in the LAR.

   In the event the licensee's preliminary assessment is that the proposed change does not qualify for categorical exclusion from environmental review, the NRC's response to such a PAR request may limit the licensee's work under a PAR, pending completion of the environmental review, to that which does not involve environmental impact, or work that does not result in irreversible environmental impact. In order to respond to such PAR requests, the licensee should provide additional information regarding the extent of work that may be performed without irreversible environmental impact. Most proposed changes

during construction are expected to qualify for categorical exclusion such that changes that do not qualify are expected to be rare.

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 COL-ISG-025.

The PAR process to address inspectability issues is 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 request 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 request 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 request. The PAR request 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.

PAR requests should be submitted in writing in accordance with 10 CFR 52.3. Less formal (e.g., verbal) communications may precede and/or supplement 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 request 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.

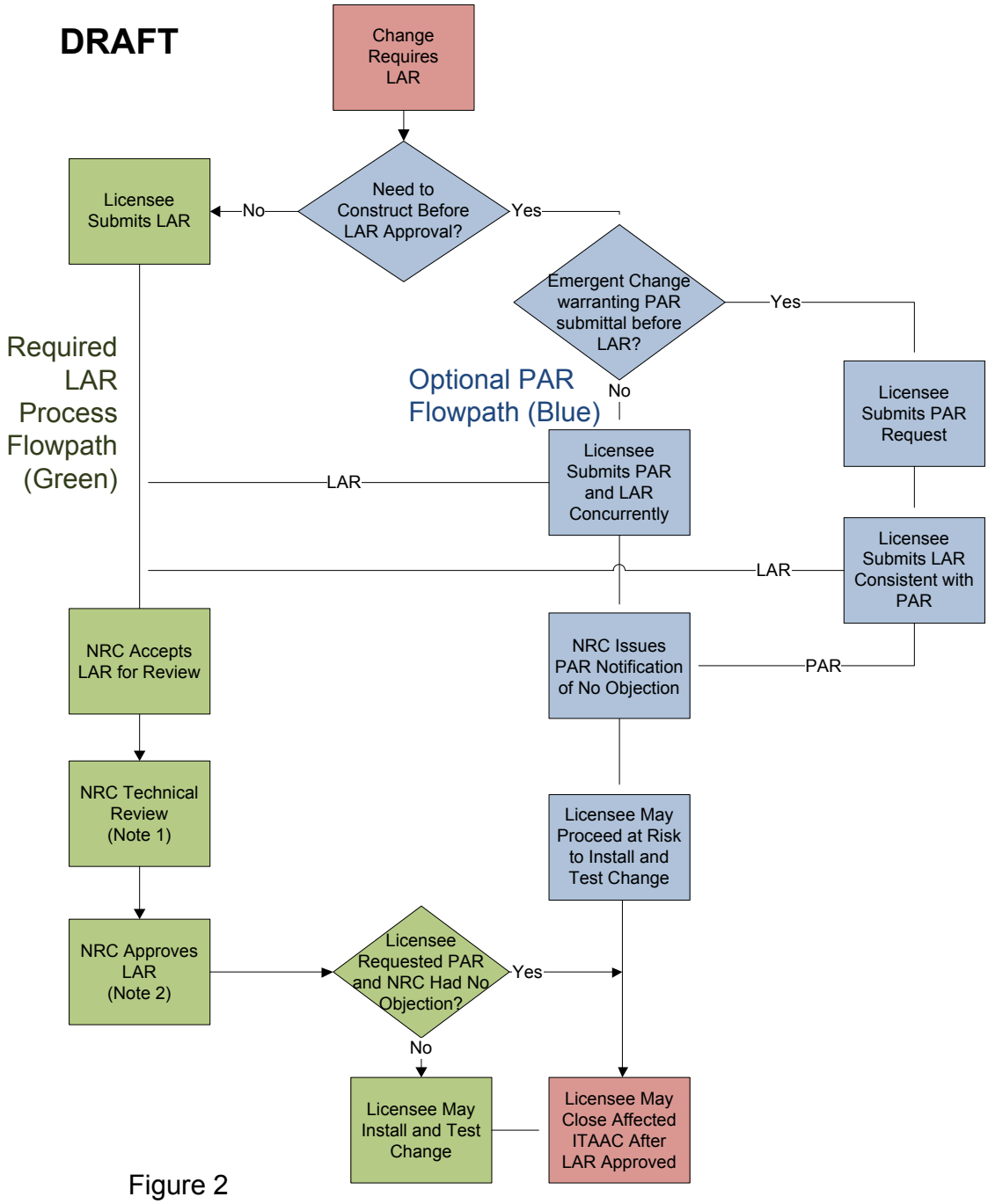

Figure 2
Changes during Construction License Amendment Request (LAR) Preliminary Acceptability Review (PAR) Option

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 Acceptability Review (PAR) Request Template

PAR Request Number	Station Name	Unit Number	PAR Request Date

1. NRC PAR Notification Requested Date (see Block 9 for basis) _

Enter the date by which the NRC is requested to issue the PAR notification. Block 9 should 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.

PAR Request Number	Station Name	Unit Number	PAR Request Date

6. 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.

7. Preliminary Assessment of Significant Hazards Consideration [10 CFR 50.92(c)]

Summarize the preliminary assessment of whether or not the proposed change involves a significant hazards consideration based on the criteria of 10 CFR 50.92(c). Note: the complete technical bases for the licensee's no significant hazards consideration determination should be provided in the LAR.

8. Preliminary Assessment of Categorical Exclusion from Environmental Review [10 CFR 51.22]

Summarize the preliminary assessment of whether or not the proposed change qualifies for an exclusion from environmental review under 10 CFR 51.22. Note: the complete technical bases for the licensee's determination regarding environmental review exclusion should be provided in the LAR.

For changes that do not qualify for categorical exclusion, provide additional information on the scope of proposed work that may be performed without irreversible environmental impact.

9. 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 should provide the basis for the date the NRC is requested to issue the PAR notification (Block 1) and should identify the following types of inspectability impacts

PAR Request Number	Station Name	Unit Number	PAR Request Date

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

10. 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.

11. 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.

12. Preparer Name (Print)	**13 Preparer Signature**	**14. Date**
15. Reviewer Name (Print)	**16. Reviewer Signature**	**17. Date**
18. Approver Name (Print)	**19. Approver Signature**	**20. 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 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 be accompanied by a request for an exemption from the referenced design certification, as discussed in Section 4.4.1.

4.7.3 LARs for Conforming Changes – Conforming LARs

It is expected that some LARs will describe proposed changes to the plant or procedures that require a license amendment solely because they involve a change to Tier 1 information or COL ITAAC and not because the change has a significant impact on safety as determined by applying the applicable change process criteria. Like changes to Technical Specifications under 10 CFR Parts 50 and 52, a license amendment is always required for changes to Tier 1/ITAAC information, regardless of their safety significance. LARs required solely because a change impacts Tier 1/ITAAC information that could otherwise be made under the Section VIII process are called conforming LARs because they are necessary to conform Tier 1/ITAAC information to the corresponding Tier 2 information in the FSAR that is being modified.

Licensees should review and document such changes in accordance with 10 CFR 50.59 or other more specific applicable change process criteria. The associated conforming LARs should focus on the impacts on Tier 1/ITAAC information (e.g., the addition of a component to the scope of an ITAAC, or a change to a dimension identified in Tier 1) and may state that the LAR is being requested in order to conform Tier 1/ITAAC to a change made in accordance with the applicable change process. See applicable sections of this appendix, for guidance on performing these evaluations.

Conforming LARs need not contain the detailed design information, evaluations or analyses that support the plant or procedure change, but should otherwise conform to the licensee's format and content guidance for LARs. Detailed design information, evaluations and analyses that support the change should be retained by the licensee in accordance with its plant change and document control processes. Conforming LARs should describe the plant change or modification and include a summary of the VIII.B.5

evaluation. The summary information should be sufficient to demonstrate that the proposed change may be considered a conforming LAR. The NRC staff is expected to review this summary information to verify that the LAR is a conforming LAR and may request additional information concerning the licensee's evaluation of the change in connection with this verification or its review of the conforming LAR.

If a change requires prior NRC approval for reasons other than an impact on Tier 1/IITAAC, (e.g., a proposed change in safety analysis methodology), the LAR needs to include the technical basis for the change, and the NRC must approve the proposed change, as well as the associated Tier 1/ITAAC impacts.

As discussed above, conforming LARs need not contain evaluations, analyses, or other technical bases for the proposed change. Thus by their nature, conforming LARs should require less time and resources for the licensee to prepare, and less time and resources for the NRC staff to review. To the extent that conforming LARs can be submitted and approved more quickly, the need for licensees to submit PAR requests in connection with conforming LARs during construction should be reduced. However, licensees may submit a PAR request in connection with a conforming LAR during construction in the same manner as for any other LAR, as discussed in Section 4.7.1.1.

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 changes to 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 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 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.

Additionally, the written evaluation should address the ex-vessel change process criteria in Section VIII.B.5.c 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. 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 updates to 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 the plant-specific DCD. Such modifications should be reported to NRC in accordance with NEI 98-03, Revision 1.