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Nuclear Energy Institute

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

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ACKNOWLEDGMENTS

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FOREWORD

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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), unless they also involve changes to or departures from information within the scope of a referenced design certification rule.

The main body of NEI 96-07 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 guidance and modifying wording only as needed to ensure that applicant- and licensee-initiated changes are properly controlled, documented, and reported 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), and a description of the approach to be used to establish a site-specific change process for limited work authorizations (LWAs).

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 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 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 SUMMARY OF THE 10 CFR PART 52 CHANGES 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 for the applicable design certification rule, 10 CFR 50.59, and other applicable Part 50 change processes, as identified in Section 52.98. Reference to Section 52.98 in this appendix is a reference to new plant/Part 52 change processes collectively.

1.2.1 Departures from Design Certification Information

The processes for changes to and departures from design certification information under 10 CFR Part 52 by applicants and licensees are specified in the appendices to Part 52, which contain the design certification rules for each of the standard designs certified by the NRC. 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. This is discussed further in Section 4.1 of this appendix.

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 holder. Guidance for this process is outside the scope of this document.

1.2.1.1 Tier 1 Information

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 Section VIII.A.4 of the referenced design certification rule. Exemptions are discussed in more detail in Section 4.1.1 of this appendix.

1.2.1.2 Tier 2 Information

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 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 4.1.2 of this document.

1.2.1.3 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 FSAR. Section VIII.B.6 of the Part 52 Appendices 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 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 4.1.3 of this appendix.

1.2.1.4 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 1.2.2.3 and 4.2.3.

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 4.2.4 of this appendix.

1.2.1.5 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 apply 10 CFR 50.59 to the information in the FSAR that addresses the COL License Information Items.

1.2.1.6 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. 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 that pertains to those areas that are addressed by conceptual design information in the generic DCD.

1.2.1.7 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.

1.2.2 Plant-Specific Facilities and Procedures Described in the FSAR

1.2.2.1 COL FSAR Changes Subject to 10 CFR 50.59

Change to facilities or procedures described in the COL FSAR that are outside the scope of a referenced design certification rule are controlled under 10 CFR 50.59. Applicants and licensees should screen and evaluate such changes using Sections 4.1 and 4.2 of this appendix. These sections reflect 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 4.2.1.2). 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 FSAR 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 FSAR (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. Since the site-specific information in the FSAR will not include Tier 1 or Tier 2* information and is not expected to include any ex-vessel severe accident information, only the Tier 2 VIII.B.5.b criteria of Section VIII would apply; these are the same as the 50.59 criteria described in Section 4.2.1 of this appendix. As a result, application of the Section VIII change control process to the site-specific information in the FSAR is substantively equivalent to application of 10 CFR 50.59 to such information.

[Having an integrated change control process for the entire FSAR containing information within the scope of the design certification rule as well as information outside the scope of the design certification rule will facilitate developing and maintaining an integrated FSAR. In general, the FSARs 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, it is not desirable during construction and operation because personnel need to consult two documents to understand the complete licensing basis in the FSAR. Therefore, it is anticipated that licensees will prepare an integrated FSAR for construction and operation. Establishing an integrated change control process for an integrated FSAR would eliminate the need to keep track of the source of the information in the integrated FSAR since licensees would apply the same change control process regardless of whether the information originated in the plant-specific DCD or the COLA FSAR.]

1.2.2.2 Plant-Specific ITAAC in the COL

Changes to ITAAC are addressed in 10 CFR 52.99(d). Two cases are considered: an ITAAC derived from a referenced design certification, and an ITAAC not derived from a referenced design certification. Per 52.99(d)(1), a change to an ITAAC derived from a referenced design certification requires the licensee to request an exemption from the design certification ITAAC. The request for an exemption must also be accompanied by a request for a license amendment under 52.98(f). Per 52.99(d)(2), a change to an ITAAC that is not derived from a referenced design certification only requires a request for a license amendment under 52.98(f). The license amendment

requirement in both cases is derived from the fact that all ITAAC will be issued as part of the combined license in an appendix to the license.

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 ITAAC do not constitute regulatory requirements either for licensees or for renewal of the license. There may be specific ITAAC for which the Commission has granted a hearing under 52.103(a) and has determined in accordance with 52.103(c) that operation may be allowed during an interim period beyond the 52.103(g) finding if the hearing is not concluded, but all ITAAC expire upon final Commission action in the proceeding.

1.2.2.3 Plant-Specific Technical Specifications in the COL

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 the plant-specific TS, therefore, are treated as license amendments under 10 CFR 50.90, as described in Section VIII.C.6 of the design certification rules.

1.2.3 Other Change Processes

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 FSAR 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.

10 CFR 50.59(c)(4) specifically excludes from the scope of 10 CFR 50.59 changes to the facility or procedures that are controlled by other more specific requirements and criteria established by regulation. For example, 10 CFR

50.54 specifies criteria and reporting requirements for changing quality assurance, physical security and emergency plans that have been previously accepted by the NRC. These requirements typically indicate that changes can be made to the plan if it does not reduce a commitment or decrease the effectiveness of the plan. Additional regulatory change control process requirements are identified in Section 4.1.1 of NEI 96-07, which may take precedence over 50.59 for control of specific changes. A summary of these other regulatory change control processes, as applicable to 10 CFR Part 52 applicants and licensees, is provided below.

1.2.3.1 Security Plan

10 CFR 50.54 specifies criteria and reporting requirements for changing physical 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 the Security Plan is provided in NRC Generic Letter 95-08. The licensee may make changes to the security and safeguards contingency plans 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.

1.2.3.2 Quality Assurance Program

10 CFR 50.54 specifies criteria and reporting requirements for changing quality assurance plans approved by the NRC. Changes to these plans or descriptions are controlled by separate processes established in 10 CFR 50.54(a). The licensee may make changes to the quality assurance program description previously approved in the COL without prior NRC approval only if the change does not reduce the commitments in the program description as accepted by the NRC. Changes that require NRC approval are processed as COL amendment requests in accordance with 10 CFR 50.90 and 50.92.

1.2.3.3 Emergency Plan

10 CFR 50.54 specifies criteria and reporting requirements for changing emergency plans approved by the NRC. Changes to these plans or descriptions are controlled by separate processes established in 10 CFR 50.54(q). The licensee may make changes to these plans previously approved in the COL without NRC approval only if the changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of 10 CFR 50.47(b) and the requirements of 10 CFR 50 Appendix E. Changes that require NRC approval are processed as COL amendment requests in accordance with 10 CFR 50.90 and 50.92.

1.2.3.4 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.

1.2.3.5 Fire Protection Plan

As provided in Generic Letter 86-10, operating licenses for nuclear power plants licensed under Part 50 typically contain the following standard license condition:

> The licensee may make changes to the approved fire protection program without prior approval of the Commission only if those changes would not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire.

The standard form and content for a COL issued under Part 52 does not contain such a condition. Therefore, unlike plants licensed under Part 50, departures by a COL applicant or holder to the fire protection program as described in a plant-specific DCD are governed by Section VIII of a referenced design certification rule, and changes to the fire protection program as described in a FSAR are governed by 10 CFR 50.59.

1.2.3.6 Aircraft Impact Assessment

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

- For combined licenses referencing a certified design that has addressed the requirements of 10 CFR 50.150, the change process in Section VIII.B.5.d of the applicable Design Certification Rule applies. Section

4.1.2.2.3 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 4.1.2.2.3 is generally applicable, but the regulatory structure is different.

1.2.3.7 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 FSAR and as such is not subject to the 10 CFR 50.59 change process. There is no regulatory change process specific to the Loss of Large Area Assessment. Changes must conform to the applicable plant-specific license condition and 10 CFR 50.54(hh)(2).

1.2.3.8 Probabilistic Risk Assessment

In general, plants licensed under Part 50 do not have a description of a PRA as part of the FSAR 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, FSARs 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 in Section 4.3.1 of this appendix, the PRA information in the FSAR 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.

1.2.4 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 4.4 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 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.

1.2.5 Limited Work Authorizations

Future LWAs are anticipated to include a change process. An LWA holder may make a change to the LWA using the screening/change process that is included in the issued LWA. Those changes that require NRC approval are processed as license amendment requests in accordance with 10 CFR 50.90 and 50.92. The LWA change process is outlined in Section 4.5.

1.3 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 described below:

1.3.1 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 (e.g., quality assurance, security and emergency preparedness program changes controlled under 10 CFR 50.54(a), (p) and (q), respectively; Off-site Dose Calculation Manual changes controlled by technical specifications), 10 CFR 50.59(d) and 10 CFR 52.98(c)(2) state 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*.

- 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 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 10 CFR Part 52 in relation to other processes, including circumstances under which

different processes (e.g., 10 CFR 50.59 and 10 CFR 50.90) should be applied to different aspects of an activity.

1.3.2 Relationship to the FSAR

New plant change processes identified in Section 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 or tests and experiments not described in the FSAR. 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.

1.3.4 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 those sections, Section 4.1.2.2.1.7 of this appendix defines the design basis limits for fission product barriers that are subject to control, and Section 4.1.2.2.1.8 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 3.3, “design bases functions” (defined in NEI 97-04, Appendix B) are a subset of “design functions” for purposes of screening.

1.4 CONTENT OF THIS GUIDANCE DOCUMENT

The NRC has established requirements for nuclear plant systems, structures and components to provide reasonable assurance of adequate protection of the public health and safety. Many of these requirements and descriptions of how they are met, are documented in the FSAR. 10 CFR 50.59 allows a licensee to make changes in the facility or procedures as described in the FSAR, and to conduct tests or experiments not described in the FSAR, unless the changes require a change in the technical specifications or otherwise require prior NRC approval. 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 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 design certification rule screenings and evaluations should also understand the rules and concepts discussed in this guidance document.

Section 2 discusses 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 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 also addresses the change processes to be used for early site permits and limited work authorizations, and includes guidance on the applicability requirements for the rules, the screening process for determining when an evaluation must be performed and the applicable evaluation criteria for determining if prior NRC approval is required. Examples are provided to reinforce the guidance. Guidance is also provided on addressing degraded and nonconforming conditions and on dispositioning required evaluations.

Section 5 provides guidance on documenting the required evaluations and reporting to NRC.

2.0 DEFENSE IN DEPTH DESIGN PHILOSOPHY

One objective of Title 10 of the Code of Federal Regulations is to establish requirements directed toward protecting the health and safety of the public from the uncontrolled release of radioactivity. At the design stage, protection of public health and safety is ensured through the design of physical barriers to guard against the uncontrolled release of radioactivity. Other sources of radioactivity including radioactive waste systems are included. The defense-in-depth philosophy includes reliable design provisions to safely terminate accidents and provisions to mitigate the consequences of accidents. The three physical barriers that provide defense-in-depth are:

- Fuel Clad
- Reactor Coolant System Boundary
- Containment Boundary

These barriers perform a health and safety protection function. They are designed to reliably fulfill their operational function by meeting all criteria and standards applicable to mechanical components, pressure components and civil structures. These barriers are protected extensively by inherent safety features and through the implementation of engineered safety features. The public health and safety protection functions are analytically demonstrated and documented in the Early Site Permit SSAR, the Design Control Document, and ultimately in a plant-specific FSAR, as periodically updated (collectively referred to as "UFSAR" for purposes of this section). Analyses summarized in the UFSAR demonstrate that under the assumed accident conditions, the consequences of accidents challenging the integrity of the barriers will not exceed limits based on the criteria established in GDC 19 or the guidelines established in 10 CFR 50.34. Thus, the UFSAR analyses provide the final verification of the nuclear safety design phase by documenting plant performance in terms of public protection from uncontrolled releases of radiation. Certain of the change processes described herein address this aspect of design by requiring prior NRC approval of proposed activities that, although safe, require a technical specification change or meet specific threshold criteria for NRC review.

This protection philosophy pervades the UFSAR accident analyses and Title 10 of the CFR. To understand and apply certain of the change processes described herein, it is necessary to understand this perspective of maintaining the integrity of the physical barriers designed to contain radioactivity. This is because:

- UFSAR accidents and malfunctions are analyzed in terms of their effect on the physical barriers. There is a relationship between barrier integrity and dose.
- The principal "consequences" that the physical barriers are designed to preclude are due to the uncontrolled release of radioactivity. Thus, for the purposes of 10 CFR 50.59 and the related Section VIII change evaluation criteria described herein, the term "consequences" means dose.

For many licensees, ANSI standards define categories of accidents or malfunctions. For each category, a probability (frequency) and a corresponding acceptable consequence is given in terms of barrier loss and radioactivity release. Consequences resulting from accidents and malfunctions are analyzed and documented in the UFSAR and are evaluated against dose acceptance limits that vary depending on the event frequency.

The design effort and the operational controls necessary to ensure the required performance of the physical barriers during anticipated operational occurrences and postulated accidents are extensive. Because 10 CFR 50.59 and the related Section VIII change evaluation criteria described herein provide a mechanism for determining if NRC approval is needed for activities affecting plant design and operation, it is helpful to review briefly the requirements and the objectives imposed by the CFR on plant construction and operation. The review will define more clearly the extent of applicability of 10 CFR 50.59 or the related Section VIII change evaluation criteria described herein.

Appendix A to 10 CFR Part 50 provides General Design Criteria for most nuclear power plants (for pre-Appendix A, plants the criteria are in the UFSAR). Section II of Appendix A includes criteria for protection by multiple fission product barriers. The criteria establish requirements for inherent protection, instrumentation and control, reactor coolant pressure boundary and reactor coolant system design, containment design, control rooms, electric power systems, and related inspection and testing. All of these requirements concentrate on protecting fission product barriers either through inherent or mitigative means.

Section III of Appendix A establishes extensive requirements on reactor protection and reactivity control systems, the objectives again being the protection of fission product barriers. With similar intent, Sections IV, V and VI provide extensive design, inspection, testing and operational requirements for the quality of the reactor coolant pressure boundary, and fluid systems in general, reactor containment, and fuel and radioactivity control. These requirements ensure inherent and engineered protection of the fission

product barriers. Introductory statements of Appendix A address the need for consideration of a single failure criterion and redundancy, diversity and separation of mitigation and protection systems. Section I of Appendix A imposes requirements on the quality of implemented protection and the conditions under which these systems must function without loss of capability to perform their safety functions. These conditions include natural phenomena, fire, operational and accident generated environmental conditions.

The implementation of this design philosophy requires extensive accident analyses to define the correct relationship among nominal operating conditions, limiting conditions for operations and limiting safety systems settings to prevent safety limits from being exceeded. The UFSAR presents the set of limiting analyses required by NRC. The limiting analyses are used to confirm the systems and equipment design, to identify critical setpoints and operator actions, and to support the establishment of technical specifications. Therefore, the results of the UFSAR accident analyses reflect performance of equipment under the conditions specified by NRC regulations or requirements. Changes to plant design and operation and conduct of new tests and experiments have the potential to affect the probability and consequences of accidents, to create new accidents and to impact the integrity of fission product barriers. Therefore, these activities are subject to 10 CFR 50.59 or the related Section VIII change evaluation criteria described herein.

3.0 DEFINITIONS AND APPLICABILITY OF TERMS

The following definitions and terms are discussed in this section:

3.1 Accident Previously Evaluated in the FSAR (as updated)

3.2 All Matters Described in the Plant-Specific DCD (VIII.B.5.a)

3.3 Change/Departure

3.4 Departure from a Method of Evaluation Described in the FSAR

3.5 Design Bases (Design Basis)

3.6 Evaluation

3.7 Ex-Vessel Severe Accident

3.8 Facility as Described in the FSAR (as updated)

3.9 Final Safety Analysis Report for Combined License

3.10 Generic Design Control Document (DCD)

3.11 Input Parameters

3.12 Licensing Basis for Combined License

3.13 Malfunction of an SSC Important to Safety

3.14 Methods of Evaluation

3.15 Operational Requirements

3.16 Plant-Specific DCD

3.17 Procedures as Described in the FSAR

3.18 Safety Analyses

3.19 Screening

3.20 Site Safety Analysis Report (SSAR) for Early Site Permits

3.21 Tests or Experiments Not Described in the FSAR (as updated)

3.1 ACCIDENT PREVIOUSLY EVALUATED IN THE FSAR (AS UPDATED)

Definition:

Accident previously evaluated in the FSAR (as updated) means a design basis accident or event described in the UFSAR including accidents, such as those typically analyzed in Chapters 6 and 15 of the UFSAR, and transients and events the facility is required to withstand such as floods, fires, earthquakes, other external hazards, anticipated transients without scram (ATWS) and station blackout (SBO).

Discussion:

The term "accidents" refers to the anticipated (or abnormal) operational transients and postulated design basis accidents that are analyzed to demonstrate that the facility can be operated without undue risk to the health and safety of the public. The term “accidents” encompasses other events for which the plant is required to cope and that are described in the UFSAR (e.g., turbine missiles, fire, earthquakes and flooding).

Accidents also include new transients or postulated events added to the licensing basis based on new NRC requirements and reflected in the UFSAR pursuant to 10 CFR 50.71(e)(e.g., ATWS and SBO).

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 3.5 of this appendix. Changes to information related to severe accidents are subject to different change control processes than changes to information related to design basis accidents. Section 4.1.2.2.3 in this appendix discusses the change control processes applicable to severe accident information.

3.2 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.

3.3 CHANGE/DEPARTURE

Definition:

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.

Discussion:

Additions to and removals from the facility or procedures can adversely impact the performance of SSCs and the bases for the acceptability of their design and operation. Thus the definition of change includes modifications of an existing provision (e.g., SSC design requirement, analysis method or parameter), additions or removals (physical removals, abandonment or nonreliance on a system to meet a requirement) to the facility or procedures.

The definitions of "change…," "facility…" (see Section 3.8), and "procedures…" (see Section 3.17) make clear that 10 CFR 50.59 applies to changes to underlying analytical bases for the facility design and operation as well as for changes to SSCs and procedures. Thus, 10 CFR 50.59 should be applied to a change being made to an evaluation for demonstrating adequacy of the facility even if no physical change to the facility is involved. Further discussion of the terms in this definition is provided as follows:

Design functions are UFSAR-described design bases functions and other SSC functions described in the UFSAR that support or impact design bases functions. Implicitly included within the meaning of design function are the conditions under which intended functions are required to be performed, such as equipment response times, process conditions, equipment qualification and single failure.

Design bases functions are functions performed by systems, structures and components (SSCs) that are (1) required by, or otherwise necessary to comply with, regulations, license conditions, orders or technical specifications, or (2) credited in licensee safety analyses to meet NRC requirements.[1]

UFSAR description of design functions may identify what SSCs are intended to do, when and how design functions are to be performed, and under what

[1] Definition of *design bases function* from revised Appendix B to NEI 97-04 (endorsed by Regulatory Guide 1.186).

conditions. Design functions may be performed by safety-related SSCs or nonsafety-related SSCs and include functions that, if not performed, would initiate a transient or accident that the plant is required to withstand.

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 3.7, 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 Fed. Reg. at 49,394).

As used above, "credited in the safety analyses" means that, if the SSC were not to perform its design bases function in the manner described, the assumed initial conditions, mitigative actions or other information in the analyses would no longer be within the range evaluated (i.e., the analysis results would be called into question). The phrase "support or impact design bases functions" refers both to those SSCs needed to support design bases functions (cooling, power, environmental control, etc.) and to SSCs whose operation or malfunction could adversely affect the performance of design bases functions (for instance, control systems and physical arrangements). Thus, both safety-related and nonsafety-related SSCs may perform design functions.

Method of performing or controlling a function means how a design function is accomplished as credited in the safety analyses, including specific operator actions, procedural step or sequence, or whether a specific function is to be initiated by manual versus automatic means. For example, substituting a manual actuation for automatic would constitute a change to the method of performing or controlling the function.

Evaluation that demonstrates that intended functions will be accomplished means the method(s) used to perform the evaluation (as discussed in Section 3.6). Example: a thermodynamic calculation that demonstrates the emergency core cooling system has sufficient heat removal capacity for responding to a postulated accident.

Temporary Changes

Temporary changes to the facility or procedures, such as jumpering terminals, lifting leads, placing temporary lead shielding on pipes and equipment, removal of barriers and use of temporary blocks, bypasses, scaffolding and supports, are made to facilitate a range of plant activities and are subject to 10 CFR 50.59 as follows:

- 10 CFR 50.59 should be applied to temporary changes proposed as compensatory actions to address degraded or nonconforming conditions as discussed in Section 4.4 of the main body of NEI 96-07.

- Other temporary changes to the facility or procedures that are not associated with maintenance are subject to 10 CFR 50.59 in the same manner as permanent changes, to determine if prior NRC approval is required. Screening and, as necessary, evaluation of such temporary changes may be considered as part of the screening/evaluation of the proposed permanent change.

Risk impacts of temporary changes associated with maintenance activities (i.e., temporary alterations) should be assessed and managed in accordance with 10 CFR 50.65(a)(4) and associated guidance, as discussed in Section 4.1.2 of the main body of NEI 96-07. Applying 10 CFR 50.59 to such activities is not required provided that temporary alterations are not in effect longer than 90 days at power, and affected SSCs are restored to their normal, as-designed condition at the conclusion of the maintenance activity.

3.4 DEPARTURE FROM A METHOD OF EVALUATION DESCRIBED IN THE FSAR

Definition:

Departure from a method of evaluation described in the FSAR (as updated) means (i) changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or (ii) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

Discussion:

The 10 CFR 50.59 definition of "departure …" provides licensees with flexibility to make changes in methods of evaluation that are "conservative" or that are not important with respect to demonstrating that SSCs can perform their intended design functions. See also the definition and discussion of "methods of evaluation" in Section 3.14. Guidance for evaluating changes in methods of evaluation under criterion 10 CFR 50.59(c)(2)(viii) is provided in Section 4.3.8 of the main body of NEI 96-07.

Conservative vs. Nonconservative Evaluation Results

Gaining margin by revising an element of a method of evaluation is considered to be a nonconservative change and thus a departure from a method of evaluation for purposes of 10 CFR 50.59. Such departures require

prior NRC approval of the revised method. In other words, analytical results obtained by changing any element of a method are "conservative" relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change in an element of a method of evaluation that changes the result of a containment peak pressure analysis from 45 psig to 48 psig (with design basis limit of 50 psig) would be considered a conservative change for purposes of 10 CFR 50.59(c)(2)(viii). This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making future physical or procedure changes without a license amendment.

If use of a modified method of evaluation resulted in a change in calculated containment peak pressure from 45 psig to 40 psig, this would be nonconservative. This is because the change would result in more margin being available (to the design basis limit of 50 psig) for a licensee to make more significant future changes to the physical plant or procedures.

"Essentially the Same"

Licensees may change one or more elements of a method of evaluation such that results move in the nonconservative direction without prior NRC approval, provided the results are "essentially the same" as the previous result. Results are "essentially the same" if they are within the margin of error for the type of analysis being performed. Variation in results due to routine analysis sensitivities or calculational differences (e.g., rounding errors and use of different computational platforms) would typically be within the analysis margin of error and thus considered "essentially the same."

"Approved by the NRC for the Intended Application"

Rather than make a minor change to an existing method of evaluation, a licensee may also adopt completely new methodology without prior NRC approval provided the new method is approved by the NRC for the intended application. A new method is "approved by the NRC for the intended application" if it is approved for the type of analysis being conducted and the licensee satisfies applicable terms and conditions for its use. Specific guidance for making this determination is provided in Section 4.3.8.2 of the main body of NEI 96-07.

3.5 DESIGN BASES (DESIGN BASIS)

Definition:

(10 CFR 50.2) Design bases means that information which identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be: (1) restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals; or (2) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

Discussion

Guidance and examples for identifying 10 CFR 50.2 design bases are provided in Appendix B of NEI 97-04, *Design Bases Program Guidelines*, Revision 1, February 2001.

3.6 EVALUATION

Definition:

An evaluation pursuant to 10 CFR 50.59 or Section VIII of the design certification rules is the documented evaluation against the criteria in 10 CFR 50.59(c)(2) or Section VIII.B.5. to determine if a proposed change, test or experiment requires prior NRC approval via license amendment under 10 CFR 50.90.

Discussion

The definitions of *Evaluation* and *Screening* are intended to clearly distinguish between the process and documentation of licensee screenings and the further evaluation that may be required of proposed activities against the criteria in 10 CFR 50.59(c)(2) and Section VIII.B.5. The 50.59 and Section VIII evaluation criteria are described in Sections 4.2.1.2 and 4.1.2.2, respectively, of this appendix.

The phrase “change made under 10 CFR 50.59” (or equivalent) refers to changes subject to 10 CFR 50.59 that either screened out of the 10 CFR 50.59 process or did not require prior NRC approval based on the results of a 10 CFR 50.59 evaluation. Similarly, the phrases “10 CFR 50.59 applies [to an activity]” or “[an activity] is subject to 10 CFR 50.59” mean that screening and, if necessary, evaluation are required for the activity. The “10 CFR 50.59

process" includes screening, evaluation, documentation and reporting to NRC of activities subject to the rule.

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

3.7 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 Fed. Reg. at 49,394).

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 Fed. Reg. at 25,806; 71 Fed. Reg. at 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 are 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 to the application of this special departure process in Section VIII.B.5.c of the design certification rule. (72 Fed. Reg. at 49,394).

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 Fed. Reg. at 25,806). 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 4.3.1 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 Fed. Reg. at 25,824). 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.

3.8 FACILITY AS DESCRIBED IN THE FSAR (AS UPDATED)

Definition:

Facility as described in the final safety analysis report (as updated) means:

- The structures, systems and components (SSC) that are described in the final safety analysis report (FSAR) (as updated),
- The design and performance requirements for such SSCs described in the FSAR (as updated), and
- The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs, which demonstrate that their intended function(s) will be accomplished.

Discussion:

The scope of information that is the focus is the information presented in the FSAR to satisfy the requirements of 10 CFR 50.34(b) or 52.79, as updated per the requirements of 10 CFR 50.71(e) and as supplemented pursuant to 10 CFR 54.21(d). The definition of "facility as described in the FSAR (as updated)" follows from the requirement of 10 CFR 50.34(b) or 52.79 that the FSAR (and by extension, the UFSAR) contains "a description and analysis of the SSCs of the facility, with emphasis upon performance requirements, the

bases, with technical justification therefore, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished."

Screening of facility changes is discussed in Section 4.2.1.1.

3.9 FINAL SAFETY ANALYSIS REPORT FOR COMBINED LICENSE

Definition:

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 certification appendix (if applicable), 10 CFR 52.3 and 10 CFR 50.71(e).

Discussion:

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 3.2 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 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, emergency plans and security 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.

Per 10 CFR 50.59(c)(3), the "FSAR (as updated)," for purposes of 10 CFR 50.59, also includes UFSAR update pages approved by the licensee for incorporation in the UFSAR since the last required update was submitted per Section VIII of the applicable Part 52 certification appendix or 10 CFR 50.71(e). The intent of this requirement is to allow ~~ensure that~~ decisions about proposed activities to be ~~are~~ made with the most complete and accurate information available. Pending UFSAR revisions may be relevant to a future

activity that involves that part of the UFSAR. Therefore, pending UFSAR revisions to reflect completed activities that have received final approval for incorporation in the next required update should be considered as part of the UFSAR for purposes of ~~10 CFR 50.59~~ screenings and evaluations of proposed changes, as appropriate. Appropriate configuration management mechanisms should be in place to identify and assess interactions between concurrent changes affecting the same SSCs or the same portion of the UFSAR.

Guidance on the required content of UFSAR updates is provided in Regulatory Guide 1.181 and NEI 98-03, Revision 1, *Guidelines for Updating FSARs*, June 1999.

3.10 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.

3.11 INPUT PARAMETERS

Definition:

Input parameters are those values derived directly from the physical characteristics of SSC or processes in the plant, including flow rates, temperatures, pressures, dimensions or measurements (e.g., volume, weight, size, etc.), and system response times.

Discussion:

The principal intent of this definition is to distinguish methods of evaluation from evaluation input parameters. Changes to methods of evaluation described in the UFSAR (see Section 3.14) are evaluated under criterion 10 CFR 50.59(c)(2)(viii) and Section VIII.B.5.b.8 of the design certification rules, whereas changes to input parameters described in the FSAR are considered changes to the facility that would be evaluated under the other seven criteria of 10 CFR 50.59(c)(2) and Section VIII.B.5.b. of the design certification rules, but not criterion 50.59(c)(2)(viii) and Section VIII.B.5.b.8.

If a methodology permits the licensee to establish the value of an input parameter on the basis of plant-specific considerations, then that value is an

input to the methodology, not part of the methodology. On the other hand, an input parameter is considered to be an element of the methodology if:

- The method of evaluation includes a methodology describing how to select the value of an input parameter to yield adequately conservative results. However, if a licensee opts to use a value more conservative than that required by the selection method, reduction in that conservatism should be evaluated as an input parameter change, not a change in methodology.

- The development or approval of a methodology was predicated on the degree of conservatism in a particular input parameter or set of input parameters. In other words, if certain elements of a methodology or model were accepted on the basis of the conservatism of a selected input value, then that input value is considered an element of the methodology.

Guidance and examples for screening changes to and departures from methods of evaluation are provided in Section 4.2.1.3 of the main body of NEI 96-07 and Section 4.1.2.1.3 of this appendix, respectively.

Guidance and examples for evaluating changes to and departures from methods of evaluation are provided in Section 4.3.8 of the main body of NEI 96-07 and Section 4.1.2.2.1.8 of this appendix, respectively.

3.12 LICENSING BASIS FOR COMBINED LICENSE

Definition:

Licensing Basis means 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 current licensing basis 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 updated final safety analysis report (UFSAR) 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:

The current licensing basis included in the applicable 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 (except as modified by exemptions); any applicable orders; and your license (including license conditions and the technical specifications included and attached thereto) are obvious licensing basis.

For a Part 52 combined license holder, this 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 referenced a certified design in its application, the referenced generic Design Control Document, including any documents specifically incorporated by reference, will also include design basis information. Finally, if the COL application referenced an early site permit Site Safety Analysis Report (SSAR) in its application, the referenced SSAR, including any documents specifically incorporated by reference, will also include design basis information.

Finally, licensing basis is also included in 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.

3.13 MALFUNCTION OF AN SSC IMPORTANT TO SAFETY

Definition:

Malfunction of SSCs important to safety means the failure of SSCs to perform their intended design functions described in the UFSAR (whether or not classified as safety-related in accordance with 10 CFR 50, Appendix B).

Discussion:

Guidance and examples for applying this definition are provided in Section 4.3 of the main body of NEI 96-07 and Section 4.1.2.2 of this appendix.

3.14 METHODS OF EVALUATION

Definition:

Methods of evaluation means the calculational framework used for evaluating behavior or response of the facility or an SSC.

Discussion:

Examples of methods of evaluation are presented below. Changes to such methods of evaluation require evaluation under 10 CFR 50.59(c)(2)(viii) and Section VIII.B.5.b.8 of the design certification rules only for evaluations used either in UFSAR safety analyses or in establishing the design bases, and only if the methods are described, outlined or summarized in the UFSAR. Methodology changes that are subject to 10 CFR 50.59 and Section VIII.B.5.b of the design certification rules include changes to elements of existing methods described in the UFSAR and to changes that involve replacement of existing methods of evaluation with alternative methodologies.

Elements of Methodology	Example
■ Data correlations	■ DNBR correlations
■ Means of data reduction	■ ASME III and Appendix G methods for evaluating reactor vessel embrittlement specimens
■ Physical constants or coefficients	■ Heat transfer coefficients
■ Mathematical models	■ Decay heat models
■ Specific limitations of a computer program	■ No voiding in PWR hot legs for non-LOCA analyses
■ Specified factors to account for uncertainty in measurements or data	■ 120% of 1971 decay heat model
■ Statistical treatment of results	■ Vendor-specific thermal design procedure
■ Dose conversion factors and assumed source term(s)	■ ICRP factors

Methods of evaluation described in the UFSAR subject to criterion 10 CFR 50.59(c)(2)(viii) and Section VIII.B.5.b.8 of the design certification rules are:

- Methods of evaluation used in analyses that demonstrate that design basis limits of fission product barriers are met (i.e., for the parameters subject to criterion 10 CFR 50.59(c)(2)(vii) and Section

VIII.B.5.b.7 of the design certification rules)

- Methods of evaluation used in UFSAR safety analyses, including containment, ECCS and accident analyses typically presented in UFSAR Chapters 6 and 15, to demonstrate that consequences of accidents do not exceed 10 CFR 50.34 or 10 CFR 50, Appendix A, dose limits

- Methods of evaluation used in supporting UFSAR analyses that demonstrate intended design functions will be accomplished under design basis conditions that the plant is required to withstand, including natural phenomena, environmental conditions, dynamic effects, station blackout and ATWS.

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.

3.17 PROCEDURES AS DESCRIBED IN THE FSAR

Definition:

Procedures as described in the final safety analysis report (as updated) means those procedures that contain information described in the FSAR (as updated) such as how structures, systems, and components are operated and controlled (including assumed operator actions and response times).

Discussion

The scope of information that is the focus is the information presented in the original FSAR to satisfy the requirements of 10 CFR 50.34(b) or 52.79, as updated per the requirements of 10 CFR 50.71(e) and as supplemented pursuant to 10 CFR 54.21(d).

For purposes of 10 CFR 50.59 and Section VIII.B.5.b of the design certification rules, "procedures" are not limited to plant procedures specifically identified in the UFSAR (e.g., operating and emergency procedures). Procedures include UFSAR descriptions of how actions related

to system operation are to be performed and controls over the performance of design functions. This includes UFSAR descriptions of operator action sequencing or response times, certain descriptions (text or figure) of SSC operation and operating modes, operational and radiological controls, and similar information. If changes to these activities or controls are made, such changes are considered changes to procedures described in the UFSAR, and the changes are subject to 10 CFR 50.59 or Section VIII.B.5 of the design certification rules.

Even if described in the UFSAR, procedures that do not contain information on how SSCs are operated or controlled do not meet the definition of "procedures as described in the UFSAR" and are not subject to 10 CFR 50.59 or Section VIII.B.5.b of the design certification rules. Sections 4.1.2 and 4.1.4 of the main body of NEI 96-07 identify examples of procedures that are not subject to 10 CFR 50.59 or Section VIII.B.5.b of the design certification rules.

Screening of procedure changes is discussed in Section 4.2.1.2 of this appendix.

3.18 SAFETY ANALYSES

Definition:

Safety analyses are analyses performed pursuant to NRC requirements to demonstrate the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guidelines in 10 CFR 50.34(a)(1). Safety analyses are required to be presented in the UFSAR per 10 CFR 50.34(b) and 52.79(a) and are required to be updated per 10 CFR 50.71(e) and include, but are not limited to, the accident analyses typically presented in Chapter 15 of the UFSAR.

Discussion:

Safety analyses are those analyses or evaluations that demonstrate that acceptance criteria for the facility's capability to withstand or respond to postulated events are met. Containment, ECCS and accident analyses typically presented in Chapters 6 and 15 of the UFSAR clearly fall within the meaning of "safety analyses" as defined above. Also within the meaning of this definition are:

- Supporting UFSAR analyses that demonstrate that SSC design functions will be accomplished as credited in the accident analyses

- UFSAR analyses of events that the facility is required to withstand such as turbine missiles, fires, floods, earthquakes, station blackout and ATWS.

3.19 SCREENING

Definition:

Screening is the process for determining whether a proposed activity requires an evaluation to be performed.

Discussion:

Screening is that part of the process that determines whether an evaluation is required prior to implementing a proposed activity.

The definitions of "change," "facility as described…," "procedures as described…" and "test or experiment not described…" constitute criteria for the screening process. Activities that do not meet these criteria are said to "screen out" from further review, i.e., may be implemented without an evaluation.

Engineering and technical information concerning a proposed activity may be used along with other information as the basis for determining if the activity screens out or requires an evaluation.

Further discussion and guidance on screening are provided in Section 4.2 of the main body of NEI 96-07 (for plant-specific FSAR changes) and Section 4.1.2.1 of this appendix (for departures from design certification information).

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

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:

Tests or experiments not described in the final safety analysis report (as updated) means any activity where any structure, system, or component is utilized or controlled in a manner which is either:

- Outside the reference bounds of the design bases as described in the UFSAR, or

- Inconsistent with the analyses or descriptions in the UFSAR.

Discussion:

10 CFR 50.59 and Section VIII.B.5.b of the design certification rules is applied to tests or experiments not described in the UFSAR. The intent of the definition is to ensure that tests or experiments that put the facility in a situation that has not previously been evaluated (e.g., unanalyzed system alignments) or that could affect the capability of SSCs to perform their intended design functions (e.g., high flow rates, high temperatures) are evaluated before they are conducted to determine if prior NRC approval is required.

Maintenance-related testing is assessed and managed under 10 CFR 50.65(a)(4), as discussed in Section 4.1.2 of the main body of NEI 96-07. Screening of tests and experiments unrelated to maintenance is discussed in Section 4.2.2 of the main body of NEI 96-07. Examples of tests unrelated to maintenance and thus subject to 10 CFR 50.59 and Section VIII.B.5.b of the design certification rules include: (1) most core physics testing; (2) room heat-up testing to validate a design/analysis input; and (3) testing to help determine which of two redesign alternatives to pursue.

4 IMPLEMENTATION GUIDANCE

4.1 DEPARTURES FROM DESIGN CERTIFICATION INFORMATION

The processes for changes and departures to design certification information under 10 CFR Part 52 are described in the Appendices to Part 52, which contain the Design Certification Rule 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.

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.

4.1.1 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.

Tier 1 includes design descriptions as well as ITAAC. As provided in 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), 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 proceed 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, following 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 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 form 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.

4.1.2 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 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 that requires definition, 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 3.2 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 Appendix A to this document, 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.

4.1.2.1 Screening of Departures from Tier 2 Information

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

Engineering, design and other technical information concerning the departure and affected SSCs should be used to assess whether the departure is a test or experiment not described in the plant-specific DCD or a modification, addition or removal (i.e., change) that affects:

- A design function of an SSC
- A method of performing or controlling the design function, or
- An evaluation for demonstrating that intended design functions will be accomplished.

Sections 4.1.2.1.1 and 4.1.2.1.2 provide guidance and examples for determining whether a departure is: (1) a change to the facility or procedures as described in the plant-specific DCD; or (2) a test or experiment not described in the plant-specific DCD. If a departure is determined to be neither, then it screens out and may be implemented without further evaluation under VIII.B.5. Activities that are screened out from further evaluation under VIII.B.5 should be documented as discussed in Section 4.6 of this appendix.

Each element of a proposed departure must be screened except in instances where linking elements of a departure is appropriate, in which case the linked elements can be considered together. A test for linking elements of proposed changes is interdependence.

It is appropriate for discrete elements to be considered together if: (1) they are interdependent as in the case where a modification to a system or component necessitates additional changes to other systems or procedures; or (2) they are performed collectively to address a design or operational issue. For example, a pump upgrade modification may also necessitate a change to a support system, such as cooling water.

If concurrent changes are being made that are not linked, each must be screened separately and independently of each other.

Activities that screen out may nonetheless require plant-specific DCD information to be updated. Licensees should provide updated plant-specific DCD information to the NRC in accordance with Sections X.B.3.b and X.B.3.c of the applicable design certification rule.

4.1.2.1.1 Is the Proposed Departure a Change to the Facility or Procedures as Described in the Plant-Specific DCD?

To determine whether or not a proposed departure affects a design function, method of performing or controlling a design function or an evaluation that demonstrates that design functions will be accomplished, a thorough understanding of the proposed departure is essential. A given departure may have both direct and indirect effects that the screening review must consider. The following questions illustrate a range of effects that may stem from a proposed departure:

- Does the departure decrease the reliability of an SSC design function, including either functions whose failure would initiate a transient/ accident or functions that are relied upon for mitigation?

- Does the departure reduce existing redundancy, diversity or defense-in-depth?
- Does the departure add or delete an automatic or manual design function of the SSC?
- Does the departure convert a feature that was automatic to manual or vice versa?
- Does the departure introduce an unwanted or previously unreviewed system or materials interaction?
- Does the departure adversely affect the ability or response time to perform required actions, e.g., alter equipment access or add steps necessary for performing tasks?
- Does the departure degrade the seismic or environmental qualification of the SSC?
- Does the departure adversely affect other units at a multiple unit site?
- Does the departure affect a method of evaluation used in establishing the design bases or in the safety analyses?
- For activities affecting SSCs, procedures, or methods of evaluation that are not described in the plant-specific DCD, does the change have an indirect effect on electrical distribution, structural integrity, environmental conditions or other plant-specific DCD-described design functions?

Per the definition of "change/departure" discussed in Section 3.3, the VIII.B.5 change process is applicable to additions as well as to changes to and removals from the facility or procedures. Additions should be screened for their effects on the existing facility and procedures as described in the plant-specific DCD and, if required, a Section VIII.B.5 evaluation should be performed. NEI 98-03 provides guidance for determining whether additions to the facility and procedures should be reflected in the plant-specific DCD per 10 CFR 50.71(e).

Consistent with historical practice, changes affecting SSCs or functions not described in the plant-specific DCD must be screened for their effects (so-called "indirect effects") on plant-specific DCD-described design functions. A Section VIII.B.5 departure evaluation is required when such changes adversely affect a plant-specific DCD-described design function, as described below.

Screening for Adverse Effects

A Section VIII.B.5 departure evaluation is required for changes that adversely affect design functions, methods used to perform or control design functions, or methods of evaluations that demonstrate that intended design functions will be accomplished (i.e., "adverse changes"). In general, hanges that have none of these effects, or have positive effects, may be screened out because only adverse changes have the potential to increase the likelihood of malfunctions, increase consequences, create new accidents or otherwise meet the Section VIII.B.5 departure evaluation criteria. However, as discussed in Section 4.1.2.1.2 of this appendix, any change that alters a design basis limit for a fission product barrier—positively or negatively—must be screened in.

Per the definition of "design function," SSCs may have preventive, as well as mitigative, design functions. Adverse changes to either must be screened in. Thus a change that decreases the reliability of a function whose failure could initiate an accident would be considered to adversely affect a design function and would screen in. In this regard, changes that would relax the manner in which Code requirements are met for certain SSCs should be screened for adverse effects on design function. Similarly, changes that would introduce a new type of accident or malfunction would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and Section VIII.B.5. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

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

The screening process is not concerned with the magnitude of adverse effects that are identified. Any change that adversely affects a plant-specific DCD-described design function, method of performing or controlling design functions, or evaluation that demonstrates that intended design functions will be accomplished is screened in. The magnitude of the adverse effect (e.g., is the minimal increase standard met?) is the focus of the Section VIII.B.5 departure evaluation process.

Screening determinations are made based on the engineering/technical information supporting the change. The screening focus on design functions, etc., ensures the essential distinction between Section VIII.B.5 screenings and departure evaluations, which focus on whether changes meet any of the criteria in VIII.B.5.b and VIII.B.5.c. Technical/engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse effect on plant-specific DCD-described design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended

design functions will be accomplished may be used as basis for screening out the change. If the effect of a change is such that existing safety analyses would no longer be bounding and therefore plant-specific DCD safety analyses must be re-run to demonstrate that all required safety functions and design requirements are met, the change is considered to be adverse and must be screened in. The revised safety analyses may be used in support of the required VIII.B.5 departure evaluation of such changes.

Changes that entail update of safety analyses to reflect improved performance, capacity, timing, etc., resulting from a change (beneficial effects on design functions) are not considered adverse and need not be screened in, even though the change calls for safety analyses to be updated. For example, a change that improves the closure time of main control room isolation dampers reduces the calculated dose to operators, and plant-specific DCD dose consequence analyses are to be updated as a result. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of the dampers (post-accident isolation of the main control room) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used in support of the VIII.B.5 departure evaluation to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between VIII.B.5 screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the ECCS analyses is for the diesel to start within 12 seconds. This change would screen out because it is apparent that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's start time to 13 seconds would screen in because the change adversely affects the design function (to start in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of VIII.B.5 screening reviews. Thus a VIII.B.5 departure evaluation would be required. The revised safety analyses would be used in support of the VIII.B.5 departure

evaluation to determine whether any of the evaluation criteria are met such that prior NRC approval is required for the change.

Additional specific guidance for identifying adverse effects due to a procedure or methodology change is provided in subsections 4.1.2.1.2 and 4.1.2.1.3, respectively.

4.1.2.1.2 Screening of Changes to the Facility as Described in the Plant-Specific DCD

Screening to determine that a VIII.B.5 departure evaluation is required is straightforward when a change adversely affects an SSC design function, method of performing or controlling a design function, or evaluation that demonstrates intended design functions will be accomplished as described in the plant-specific DCD.

However, a facility also contains many SSCs not described in the plant-specific DCD. These can be components, subcomponents of larger components or even entire systems. Changes affecting SSCs that are not explicitly described in the plant-specific DCD can have the potential to adversely affect SSC design functions that are described and thus may require a VIII.B.5 departure evaluation. In such cases, the approach for determining whether a change involves a change to the facility as described in the plant-specific DCD is to consider the larger, plant-specific DCD-described SSC of which the SSC being modified is a part. If for the larger SSC, the change adversely affects a plant-specific DCD-described design function, method of performing or controlling the design function, or an evaluation demonstrating that intended design functions will be accomplished, then a VIII.B.5 departure evaluation is required.

Another important consideration is that a change to nonsafety-related SSCs not described in the plant-specific DCD can indirectly affect the capability of SSCs to perform their plant-specific DCD-described design function(s). For example, increasing the heat load on a non safety-related heat exchanger could compromise the cooling system's ability to cool safety-related equipment.

Seismic qualification, missile protection, flooding protection, fire protection, environmental qualification, high energy line break and masonry block walls are some of the areas where changes to nonsafety-related SSCs, whether or not described in the plant-specific DCD, can affect the plant-specific DCD-described design function of SSCs through indirect or secondary effects.

Equivalent replacement is a type of change to the facility that does not alter the design functions of SSCs. Licensee equivalence assessments (e.g.,

consideration of performance/operating characteristics and other factors) may thus form the basis for screening determinations that no plant-specific DCD departure evaluation is required.

As discussed in Section 4.1.2.1.1 of this appendix, only proposed changes to SSCs that would, based on supporting engineering and technical information, have adverse effects on design functions require evaluation under Section VIII.B.5.b. Changes that have positive or no effect on design functions may generally be screened out. In addition, any change to a design bases limit for a fission product barrier must be considered adverse and screened in. This is because VIII.B.5.b(7) requires prior NRC approval any time a proposed change would "exceed *or alter*" a design bases limit for a fission product barrier.

The following examples illustrate the Section VIII.B.5.b screening process as applied to proposed facility changes:

Example 1

A licensee proposes to replace a relay in the overspeed trip circuit of an emergency diesel generator with a nonequivalent relay. The relay is not described in the plant-specific DCD, but the design functions of the overspeed trip circuit and the emergency diesel generator (EDG) are. Based on engineering/technical information supporting the change, the licensee determines if replacing the relay would adversely affect the design function of either the overspeed trip circuit or EDG. If the licensee concludes that the change would not adversely affect the design function of the circuit or EDG as described in the plant-specific DCD, then this determination would form the basis for screening out the change, and no VIII.B.5 departure evaluation would be required.

Example 2

A licensee proposes a nonequivalent change to the operator on one of the safety injection accumulator isolation valves. The plant-specific DCD describes that these isolation valves are open with their circuit breakers open during normal operation. These are motor operated, safety-related valves required for pressure boundary integrity. They are required to remain open so that flow to the reactor coolant system (RCS) will occur during a loss of coolant accident (LOCA) as RCS pressure drops below ~600 psi. They are remotely closed during a normal shutdown to avoid inadvertent injection. Technical/engineering work supporting this change ensures that the replacement operator is capable of performing the functions of the existing operator and will not adversely affect the connected Class 1E bus or diesel. This change would screen out because: (1) the valve operator does not

perform, support or impact the design function described in the plant-specific DCD (to ensure pressure boundary integrity and remain open when required) that supports safety injection performance credited in the safety analyses; and (2) the change does not adversely affect other SSC design functions (e.g., of the Class 1E bus).

If the proposed change was to configure the valve as a normally closed valve that automatically opens on loss of reactor coolant system pressure, a Section VIII.B.5 departure evaluation would be required because the change would adversely affect the reliability of the safety injection function as credited in the safety analyses.

Example 3

A licensee proposes to replace a globe valve with a ball valve in a vent/drain application to reduce the propensity of this valve to leak. The design function of this valve as described in the plant-specific DCD is to maintain the integrity of the system boundary when closed. The vent/drain function of the valve does not relate to design functions credited in the safety analyses, and the licensee has determined that a ball valve is adequate to support the vent/drain function and is superior to the globe valve in terms of its isolation function. Thus, while the proposed change affects the design of the existing vent/drain valve, it does not affect the design function (pressure boundary integrity) that supports system performance credited in the safety analyses, and evaluation/reporting under Section VIII.B.5 is not required. The screening determination should be documented, and the plant-specific DCD should be updated per Sections X.B.3.b and X.B.3.c of the applicable design certification rule to reflect the change.

Example 4

The bolts for retaining a rupture disk are being replaced with bolts of a different material and fewer threads, but equivalent load capacity and strength, such that the rupture disk will still relieve at the same pressure as before the change. Because the replacement bolts are equivalent to the original bolts, the design function of the rupture disk (to relieve at a specified pressure) is unaffected, and this departure may be screened out as an equivalent change.

4.1.2.1.3 Screening of Changes to Procedures as Described in the Plant-Specific DCD

Changes are "screened in" (i.e., require a Section VIII.B.5 departure evaluation) if they adversely affect how SSC design functions are performed or controlled (including changes to procedures described in the plant-specific DCD, assumed operator actions and response times). Proposed changes that are determined to have positive or no effect on how SSC design functions are performed or controlled may be screened out.

For purposes of VIII.B.5 screening, changes that fundamentally alter (replace) the existing means of performing or controlling design functions should be conservatively treated as adverse and screened in. Such changes include replacement of automatic action by manual action (or vice versa), changes to the human-machine interface, changing a valve from "locked closed" to "administratively closed" and similar changes.

The following examples illustrate the VIII.B.5 screening process as applied to proposed changes affecting how SSC design functions are performed or controlled:

~~Example 1~~

Deleted pending development of guidance on screening for impact on ex-vessel severe accident functions/features. ~~If the plant-specific DCD description of the reactor start-up procedure contains eight fundamental sequences, the licensee's decision to eliminate one of the sequences would screen in. On the other hand, if the licensee consolidated the eight fundamental sequences and did not affect the method of controlling or performing reactor start up, the change would screen out.~~

Example 1~~2~~

The plant-specific DCD states that a particular flow path is isolated by a locked closed valve when not in use. A procedure change would remove the lock from this valve such that it becomes a normally closed valve. In this case, the design function is to remain closed, and the method of performing the design function has fundamentally changed from locked closed to administratively closed. Thus this change would screen in and require a Section VIII.B.5 departure evaluation to be performed.

Example 2~~3~~

Operations proposes to revise its procedures to change from 8-hour shifts to 12-hour shifts. This change results in mid-shift rounds being conducted every 6 hours as opposed to every 4 hours. The plant-specific DCD describes high

energy line breaks including mitigation criteria. Operator action to detect and terminate the line break is described in the plant-specific DCD, which specifically states that 4 hours is assumed for the pipe break to go undetected before it would be identified during operator mid-shift rounds. The change from 4 to 6 hour rounds is a change to a procedure as described in the plant-specific DCD that adversely affects the timing of operator actions credited in the safety analyses for limiting the effects of high energy line breaks. Therefore, this change screens in, and a Section VIII.B.5 evaluation is required.

4.1.2.1.4 Screening Changes to Plant-Specific DCD Methods of Evaluation

As discussed in Section 3.14 of this appendix, 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." Thus use of new or revised methods of evaluation (as defined in Section 3.14) is considered to be a change that is controlled by Section VIII.B.5 and needs to be considered as part of this screening step. Adverse changes to elements of a method of evaluation included in the plant-specific DCD, or use of an alternative method, must be evaluated under VIII.B.5.b(8) to determine if prior NRC approval is required (see Section 4.1.2.2.1.8 of this appendix). Changes to methods of evaluation (only) do not require evaluation against the first seven criteria.

Changes to methods of evaluation not included in the plant-specific DCD or to methodologies included in the plant-specific DCD that are not used in the safety analyses or to establish design bases may be screened out.

Methods of evaluation that may be identified in references listed at the end of plant-specific DCD sections or chapters are not subject to control under Section VIII.B.5 unless the plant-specific DCD states they were used for specific analyses within the scope of VIII.B.5.b(8).

Changes to methods of evaluation included in the plant-specific DCD are considered adverse and require evaluation under VIII.B.5 if the changes are outside the constraints and limitations associated with use of the method (e.g., identified in a topical report and/or SER). If the changes are within constraints and limitations associated with use of the method, the change is not considered adverse and may be screened out.

Proposed use of an alternative method is considered an adverse change that must be evaluated under VIII.B.5.b(8).

The following examples illustrate the screening of changes to methods of evaluation:

Example 1

The plant-specific DCD identifies the name of the computer code used for performing containment performance analyses, with no further discussion of the methods employed within the code for performing those analyses. Changes to the computer code may be screened out provided that the changes are within the constraints and limitations identified in the associated topical report and SER. A change that goes beyond restrictions on the use of the method would be considered adverse and evaluated under VIII.B.5.b(8) to determine if prior NRC approval is required.

Example 2

The plant-specific DCD describes the methods used for atmospheric heat transfer and containment pressure response calculations contained within the CONTEMPT computer code. The code is also used for developing long-term temperature profiles (post-recirculation phase of LOCA) for environmental qualification through modeling of the residual heat removal system. Neither this application of the code nor the analysis method is discussed in the plant-specific DCD. A revision to CONTEMPT to incorporate more dynamic modeling of the residual heat removal system transfer of heat to the ultimate heat sink would screen out because this application of the code is not described in the plant-specific DCD as being used in the safety analyses or to establish design bases. Changes to CONTEMPT that affect the atmospheric heat transfer or containment pressure predictions may not screen out (because the plant-specific DCD describes this application in the safety analyses), and may require a VIII.B.5 departure evaluation.

Example 3

The steamline break mass and energy release calculations were originally performed at a power level of 105% of the nominal power (plus uncertainties) in order to allow margin for a future power up-rate. The utility later decided that it would not pursue the power up-rate and wished to use the margin to address other equipment qualification issues. The steamline break mass and energy release calculations were reanalyzed, using the same methodology, at 100% power (plus uncertainties). This change would screen out as a methodology change because the proposed departure involved a change to an input parameter (% power) and not a methodology change. This change should be screened per Section 4.1.2.1.1 to determine if it constitutes a departure from Tier 2 information in the plant-specific DCD that requires evaluation under VIII.B.5.b(1-7).

Example 4

The LOCA mass and energy release calculations were originally performed at a power level of 105% of the nominal power, plus uncertainties. Some of the assumptions in the analysis were identified as nonconservative, but the NRC concluded in the associated SER that the overall analysis was conservative because of the use of the higher initial power. The utility later decided that it would not pursue the power up-rate and wished to use the margin to address other equipment qualification issues. The LOCA break mass and energy release calculations were reanalyzed, using the same methodology, at 100% power (plus uncertainties). This change would not screen out because the proposed departure involved a change to an input parameter that was integral to the NRC approval of the methodology.

Example 5

Due to fuel management changes, core physics parameters change for a particular reload cycle. The topical report and associated SER that describe how the core physics parameters are to be calculated explicitly allow use of either 2-D or 3-D modeling for the analysis. A change to add or remove discretionary conservatism via use of 3-D methods instead of 2-D methods or vice-versa would screen out because the change is within the terms and conditions of the SER.

4.1.2.1.5 Is the Proposed Departure a Test or Experiment Not Described in the Plant-Specific DCD?

As discussed in Section 3.21, tests or experiments not described in the plant-specific DCD are activities where an SSC is utilized or controlled in a manner that is outside the reference bounds of the design for that SSC or inconsistent with analyses or description in the plant-specific DCD.

As discussed in Section 4.1.2 of the main body of NEI 96-07, testing associated with maintenance is assessed and managed under 10 CFR 50.65(a)(4) and is not subject to Section VIII.B.5.

Tests and experiments that are described in the plant-specific DCD may be screened out at this step. Tests and experiments that are not described in the plant-specific DCD may be screened out provided the test or experiment is bounded by tests and experiments that are described. Similarly, tests and experiments not described in the plant-specific DCD may be screened out provided that affected SSCs will be appropriately isolated from the facility.

Examples of tests that would “screen in” at this step (assuming they were not associated with maintenance or described in the plant-specific DCD) would be:

1. For BWRs, hydrogen injection into the reactor coolant system to minimize stress corrosion cracking

2. For BWRs, zinc injection into the reactor coolant system to reduce activation

3. For PWRs, ECCS flow tests that affect the ability to remove decay heat

4. Operation with fuel demonstration assemblies.

Examples of tests that would "screen out" would be:

1. Steam generator moisture carryover tests (provided such testing is described in the plant-specific DCD)

2. Balance-of-plant heat balance test

3. Information gathering that is nonintrusive to the operation or design function of the associated SSC.

4.1.2.1.6 Screening Documentation

Section VIII.B.5 record-keeping requirements apply to Section VIII.B.5 departure evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with plant procedures of screenings that conclude a proposed departure may be screened out (i.e., that a Section VIII.B.5 departure evaluation was not required). The basis for the conclusion should be documented to a degree commensurate with the safety significance of the change. For changes, the documentation should include the basis for determining that there would be no adverse effect on design functions, etc. Typically, the screening documentation is retained as part of the change package. This documentation does not constitute the record of changes required by Section VIII.B.5, and thus is not subject to Section VIII.B.5 documentation and reporting requirements. Screening records need not be retained for activities for which a Section VIII.B.5 departure evaluation was performed or for activities that were never implemented.

4.1.2.2 Evaluation of Departures from Tier 2 Information

Once it has been determined that a given departure requires a VIII.B.5 evaluation, the written evaluation must address the applicable criteria of VIII.B.5.b. These eight criteria are used to evaluate the effects of proposed

activities on accidents and malfunctions previously evaluated in the plant-specific DCD and their potential to cause accidents or malfunctions whose effects are not bounded by previous analyses.

Criteria B.5.b(1-7) are applicable to activities other than changes in methods of evaluation. Criterion B.5.b(8) is applicable to changes in methods of evaluation. Each departure must be evaluated against each applicable criterion. If any of the criteria are met, the licensee must apply for and obtain a license amendment per 10 CFR 50.90 before implementing the departure. The evaluation against each criterion should be appropriately documented as discussed in Section 5.0. Subsections 4.1.2.2.1.1 through 4.1.2.2.1.8 provide guidance and examples for evaluating proposed activities against the eight criteria.

Each element of a proposed departure must undergo a Section VIII.B.5 departure evaluation, except in instances where linking elements of a departure is appropriate, in which case the linked elements can be evaluated together. A test for linking elements of proposed changes is interdependence.

It is appropriate for discrete elements to be evaluated together if: (1) they are interdependent as in the case where a modification to a system or component necessitates additional changes to other systems or procedures; or (2) they are performed collectively to address a design or operational issue. For example, a pump upgrade modification may also necessitate a change to a support system, such as cooling water.

If concurrent changes are being made that are not linked, each must be evaluated separately and independently of each other.

The effects of a proposed departure being evaluated under Section VIII.B.5 should be assessed against each of the evaluation criteria separately. For example, an increase in frequency/likelihood of occurrence cannot be compensated for by additional mitigation of consequences. Evaluations should consider the effects of the proposed departure on operator actions.

4.1.2.2.1 Evaluation of Departures that do not Affect Ex-Vessel Severe Accident Criteria

4.1.2.2.1.1 Does the Proposed Departure Result in More Than a Minimal Increase in the Frequency of Occurrence of an Accident?

In answering this question, the first step is to identify the accidents that have been evaluated in the plant-specific DCD that are affected by the proposed departure. Then a determination should be made as to whether the

frequency of these accidents occurring would be more than minimally increased.

For most licensees, accidents and transients have been divided into categories based upon a qualitative assessment of frequency. For example, ANSI standards define the following categories for plant conditions for most PWRs as follows:

- Normal Operations - Expected frequently or regularly in the course of power operation, refueling, maintenance or maneuvering

- Incidents of Moderate Frequency - Any one incident expected per plant during a calendar year

- Infrequent Incidents - Any one incident expected per plant during plant lifetime

- Limiting Faults - Not expected to occur but could release significant amounts of radioactive material thus requiring protection by design.

ANSI standards for BWRs have slightly different but equivalent definitions.

During initial plant licensing, accidents were typically assessed in relative frequencies, as described above. Minimal increases in frequency resulting from subsequent licensee activities do not significantly change the licensing basis of the facility and do not impact the conclusions reached about acceptability of the facility design.

Since accident and transient frequencies were considered in a broad sense as described above, a change from one frequency category to a more frequent category is clearly an example of a change that results in more than a minimal increase in the frequency of occurrence of an accident.

Changes within a frequency category could also result in more than a minimal increase in the frequency of occurrence of an accident. Normally, the determination of a frequency increase is based upon a qualitative assessment using engineering evaluations consistent with the plant-specific DCD analysis assumptions. However, a plant-specific accident frequency calculation or PRA may be used to evaluate a proposed departure in a quantitative sense. It should be emphasized that PRAs are just one of the

tools for evaluating the effect of proposed activities, and their use is not required to perform VIII.B.5 departure evaluations.

Reasonable engineering practices, engineering judgment and PRA techniques, as appropriate, should be used in determining whether the frequency of occurrence of an accident would more than minimally increase as a result of implementing a proposed departure. A large body of knowledge has been developed in the area of accident frequency and risk significant sequences through plant-specific and generic studies. This knowledge, where applicable, should be used in determining what constitutes more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD. The effect of a proposed departure on the frequency of an accident must be discernable and attributable to the proposed departure in order to exceed the more than minimal increase standard.

Although this criterion allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as contained in regulatory guides and nationally recognized industry consensus standards, e.g., the ASME B&PV Code and IEEE standards). Further, departures from the design, fabrication, construction, testing and performance standards as outlined in the General Design Criteria (Appendix A to Part 50) are not compatible with a "no more than minimal increase" standard.

Because frequencies of occurrence of natural phenomena were established as part of initial licensing and are not expected to change, changes in design requirements for earthquakes, tornadoes and other natural phenomena should be treated as potentially affecting the likelihood of a malfunction rather than the frequency of occurrence of an accident.

The following are examples where there is not more than a minimal increase in the frequency of occurrence of an accident:

Example 1

The proposed departure has a negligible effect on the frequency of occurrence of an accident. A negligible effect on the frequency of occurrence of an accident exists when the change in frequency is so small or the uncertainties in determining whether a change in frequency has occurred are such that it cannot be reasonably concluded that the frequency has actually changed (i.e., there is no clear trend toward increasing the frequency).

Example 2

The proposed departure meets applicable NRC requirements as well as the design, material and construction standards applicable to the SSC being modified. If the proposed departure would not meet applicable requirements and standards, the change is considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required.

Example 3

The change in frequency of occurrence of an accident is calculated to support the evaluation of the proposed departure, and one of the following criteria are met:

- The increase in the pre-change accident or transient frequency does not exceed 10 percent or
- The resultant frequency of occurrence remains below 1E-6 per year or applicable plant-specific threshold.

If the proposed departure would not meet either of the above criteria, the change is considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required.

4.1.2.2.1.2 Does the Proposed Departure Result in More Than a Minimal Increase in the Likelihood of Occurrence of a Malfunction of an SSC Important to Safety?

The term "malfunction of an SSC important to safety" refers to the failure of a structure, system, or component (SSC) to perform its intended design function, regardless of whether the SSC is classified as safety-related in accordance with 10 CFR 50, Appendix B. The cause and mode of a malfunction should be considered in determining whether there is a change in the likelihood of a malfunction. The effect or result of a malfunction should be considered in determining whether a malfunction with a different result is involved per Section 4.1.2.2.1.6.

In determining whether there is more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC to perform its design function as described in the plant-specific DCD, the first step is to determine what SSCs are affected by the proposed departure. Next, the effects of the proposed departure on the affected SSCs should be determined. This evaluation should include both direct and indirect effects.

Direct effects are those where the proposed departure affects the SSCs (e.g., a motor change on a pump). Indirect effects are those where the proposed departure affects one SSC and this SSC affects the capability of another SSC to perform its design function as described in the plant-specific DCD. Indirect effects also include the effects of proposed activities on the design functions of SSCs credited in the safety analyses. The safety analysis assumes certain design functions of SSCs in demonstrating the adequacy of design. Thus, certain design functions, while not specifically identified in the safety analysis, are credited in an indirect sense.

After determining the effect of the proposed departure on the SSCs important to safety, a determination is made of whether the likelihood of a malfunction of those SSCs has increased more than minimally. The effect of a proposed departure on the likelihood of malfunction must be discernable and attributable to the proposed departure in order to exceed the more than minimal increase standard. Qualitative engineering judgment and/or an industry precedent is typically used to determine if there is more than a minimal increase in the likelihood of occurrence of a malfunction. An appropriate calculation can be used to demonstrate the change in likelihood in a quantitative sense, if available and practical. A proposed departure is considered to have a negligible effect on the likelihood of a malfunction when a change in likelihood is so small or the uncertainties in determining whether a change in likelihood has occurred are such that it cannot be reasonably concluded that the likelihood has actually changed (i.e., there is no clear trend toward increasing the likelihood). A proposed departure that has a negligible effect satisfies the minimal increase standard.

Evaluations of a proposed departure for its effect on likelihood of a malfunction would be performed at the level of detail that is described in the plant-specific DCD. The determination of whether the likelihood of malfunction is more than minimally increased is made at a level consistent with existing failure modes and effects analyses described in the plant-specific DCD. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed departure. For instance, if failures were previously postulated on a train level because the trains were independent, and a proposed departure introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade), the departure should be evaluated to determine whether the likelihood of malfunction has been increased.

Changes in design requirements for earthquakes, tornadoes and other natural phenomena should be treated as potentially affecting the likelihood of malfunction.

Although this criterion allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as contained in regulatory guides and nationally recognized industry consensus standards, e.g., the ASME B&PV Code and IEEE standards). Further, departures from the design, fabrication, construction, testing and performance standards as outlined in the General Design Criteria (Appendix A to Part 50) are not compatible with a "no more than minimal increase" standard.

Examples 1-4, below, illustrate cases where there would not be more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety:

Example 1

The change involves installing additional equipment or devices (e.g., cabling, manual valves, protective features) provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met. For example, adding protective devices to breakers or installing an additional drain line (with appropriate isolation capability) would not cause more than a minimal increase in the likelihood of malfunction.

Example 2

The change involves substitution of one type of component for another of similar function, provided all applicable design and functional requirements (including applicable codes, standards, etc.) continue to be met and any new failure modes are bounded by the existing analysis.

Example 3

The change satisfies applicable design bases requirements (e.g., seismic and wind loadings, separation criteria, environmental qualification, etc.).

Example 4

The change involves a new or modified operator action that supports a design function credited in safety analyses provided all of the following conditions are met:

- The action (including required completion time) is reflected in plant procedures and operator training programs

- The licensee has demonstrated that the action can be completed in the time required considering the aggregate affects, such as workload or environmental conditions, expected to exist when the action is required
- The evaluation of the change considers the ability to recover from credible errors in performance of manual actions and the expected time required to make such a recovery
- The evaluation considers the effect of the change on plant systems.

Examples 5-8 are cases that would require prior NRC approval because they would result in more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety:

Example 5

The change would cause design stresses to exceed their code allowables or other applicable stress or deformation limit (if any), including vendor-specified stress limits for pump casings that ensure pump functionality.

Example 6

The change would reduce system/equipment redundancy, diversity, separation or independence.

Example 7

The change would (permanently) substitute manual action for automatic action for performing plant-specific DCD -described design functions. (Guidance for temporary substitution of manual action for automatic action to compensate for a degraded/nonconforming condition is provided in NRC Generic Letter 91-18, Revision 1.)

Example 8

The change in likelihood of occurrence of a malfunction is calculated in support of the evaluation and increases by more than a factor of two. Note: The factor of two should be applied at the component level. Certain changes that satisfy the factor of two limit on increasing likelihood of occurrence of malfunction may meet one of the other criteria for requiring prior NRC approval (e.g., exceed the minimal increase standard for accident/transient frequency under criterion VIII.B.5.b(1)). For example, a change that increases the likelihood of malfunction of an emergency diesel generator by a

factor of two may cause more than a 10% increase in the frequency of station blackout.

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

The plant-specific DCD, based on logic similar to ANSI standards, provides an acceptance criterion and frequency relationship for "conditions for design." When determining which activities represent "more than a minimal increase in consequences" pursuant to Section VIII.B.5, it must be recognized that “consequences” means dose. Therefore, an increase in consequences must involve an increase in radiological doses to the public or to control room operators. Changes in barrier performance or other outcomes of the proposed departure that do not result in increased radiological dose to the public or to control room operators are addressed under Section 4.1.2.2.1.7, concerning integrity of fission product barriers, or the other criteria of Section VIII.B.5.b.

NRC regulates compliance with the provisions of 10 CFR 50 to ensure adequate protection of the public health and safety. Proposed departures affecting on-site dose consequences that may require prior NRC approval are those that impede required actions inside or outside the control room to mitigate the consequences of reactor accidents. For changes affecting the dose to operators performing required actions outside the control room, an increase is considered more than minimal if the resultant “mission dose” exceeds applicable GDC 19 criteria. The guidance in the remainder of this section applies to evaluation of effects of changes on main control room and off-site doses.

The consequences covered include dose resulting from any accident evaluated in the plant-specific DCD. The accidents include those typically covered in plant-specific DCD Chapters 6 and 15 and other events for which the plant is designed to cope and are described in the plant-specific DCD (e.g., turbine missiles and flooding). The consequences referred to in VIII.B.5 do not apply to occupational exposures resulting from routine operations, maintenance, testing, etc. Occupational doses are controlled and maintained As Low As Reasonably Achievable (ALARA) through formal licensee programs.

10 CFR Part 20 establishes requirements for protection against radiation during normal operations, including dose criteria relative to radioactive waste handling and effluents. VIII.B.5 accident dose consequence criteria and evaluation guidance are not applicable to proposed activities governed by 10 CFR Part 20 requirements.

The dose consequences referred to in VIII.B.5 are those calculated by licensees—not the results of independent, confirmatory dose analyses by the NRC that may be documented in safety evaluation reports.

The evaluation should determine the dose that would likely result from accidents associated with the proposed departure. If a proposed departure would result in more than a minimal increase in dose from the existing calculated dose for any accident, then the departure would require prior NRC approval. Where a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed (i.e., there is no clear trend toward increasing the consequences), the change need not be considered an increase in consequences.

Note: The following highlighted paragraphs been updated to be consistent with the current regulations for new plants.

10 CFR 50.34(a)(1) establishes requirements for the ability of plant design features to mitigate the off-site radiological consequences of an accident. First, an individual located on the exclusion area boundary may not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE) for any 2 hour period following onset of the postulated fission product release. Second, an individual located on the outer boundary of the low population zone, who is exposed to the radiation cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 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 2.5 rem TEDE at the exclusion area boundary and the low population zone outer boundary.

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.

Therefore, for a given accident, calculated or bounding dose values for that accident would be identified in the plant-specific DCD. These dose values should be within the GDC 19 or 10 CFR 50.34 limits, as applicable, as modified by SRP guidelines, as applicable. An increase in consequences from a proposed departure 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 50.34 or GDC 19, as applicable); and (2) the increased dose does not exceed

the current SRP guideline value for the particular design basis event. The current calculated dose values are those documented in the most up-to-date analyses of record. This approach establishes the current SRP guideline values as a basis for minimal increases for all facilities, not just those that were specifically licensed against those guidelines.

~~For some licensees the current calculated dose consequences may already be in excess of the SRP guidelines for some events. In such cases, *minimal increase* is defined as less than or equal to 0.1 rem.~~

In determining if there is more than a minimal increase in consequences, the first step is to determine which accidents evaluated in the plant-specific DCD may have their radiological consequences affected as a direct result of the proposed departure. Examples of questions that assist in this determination are:

- Will the proposed departure change, prevent or degrade the effectiveness of actions described or assumed in an accident discussed in the plant-specific DCD?

- Will the proposed departure alter assumptions previously made in evaluating the radiological consequences of an accident described in the plant-specific DCD?

- Will the proposed departure play a direct role in mitigating the radiological consequences of an accident described in the plant-specific DCD?

The next step is to determine if the proposed departure does, in fact, increase the radiological consequences of any of the accidents evaluated in the plant-specific DCD. If it is determined that the proposed departure does have an effect on the radiological consequences of any accident analysis described in the plant-specific DCD, then either:

1. Demonstrate and document that the radiological consequences of the accident described in the plant-specific DCD are bounding for the proposed departure (e.g., by showing that the results of the plant-specific DCD analysis bound those that would be associated with the proposed departure), or

2. Revise and document the analysis taking into account the proposed departure and determine if more than a minimal increase has occurred as described above.

The following examples illustrate the implementation of this criterion. In each example it is assumed that the calculated consequences do not include a change in the methodology for calculating the consequences. Changes in methodology would need to be separately considered under 10 CFR VIII.B.5.b(8) as discussed in Section 4.1.2.2.1.8.

Note: The following highlighted examples need to be updated to be consistent with the current requirements in 10 CFR 50.34 and GDC 19.

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.

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.

4.1.2.2.1.4 Does the Proposed Departure Result in More Than a Minimal Increase in the Consequences of a Malfunction?

In determining if there is more than a minimal increase in consequences, the first step is to determine which malfunctions evaluated in the plant-specific DCD have their radiological consequences affected as a result of the proposed departure. The next step is to determine if the proposed departure does, in fact, increase the radiological consequences and, if so, are they more than minimally increased. The guidance for determining whether a proposed departure results in more than a minimal increase in the consequences of a malfunction is the same as that for accidents. Refer to Section 4.1.2.2.1.3.

4.1.2.2.1.5 Does the Proposed Departure Create a Possibility for an Accident of a Different Type?

The set of accidents that a facility must postulate for purposes of plant-specific DCD safety analyses, including LOCA, other pipe ruptures, rod ejection, etc., are often referred to as “design basis accidents.” The terms accidents and transients are often used in regulatory documents (e.g., in Chapter 15 of the Standard Review Plan), where transients are viewed as the

more likely, low consequence events and accidents as less likely but more serious. In the context of probabilistic risk assessment, transients are typically viewed as initiating events, and accidents as the sequences that result from various combinations of plant and safety system response. This criterion deals with creating the possibility for accidents of similar frequency and significance to those already included in the licensing basis for the facility. Thus, accidents that would require multiple independent failures or other circumstances in order to occur would not meet this criterion.

Certain accidents are not discussed in the plant-specific DCD because their effects are bounded by other related events that are analyzed. For example, a postulated pipe break in a small line may not be specifically evaluated in the plant-specific DCD because it has been determined to be less limiting than a pipe break in a larger line in the same area. Therefore, if a proposed design change would introduce a small high energy line break into this area, postulated breaks in the smaller line need not be considered an accident of a different type.

The possible accidents of a different type are limited to those that are as likely to happen as those previously evaluated in the plant-specific DCD. The accident must be credible in the sense of occurring within the range of assumptions previously considered in the licensing basis (e.g., random single failure, loss of off-site power, etc.). A new initiator of an accident previously evaluated in the plant-specific DCD is not a different type of accident. However, a change or activity that increases the frequency of an accident previously thought to be incredible to the point where it becomes as likely as the accidents in the plant-specific DCD could create the possibility of an accident of a different type. For example, there are a number of scenarios, such as multiple steam generator tube ruptures, that have been determined to have such low probability that they may not have been considered to be part of the design basis. If a change or departure is proposed that causes such a scenario to become credible, the change or departure could create the possibility of an accident of a different type.

In evaluating whether the proposed change or departure creates the possibility of an accident of a different type, the first step is to determine the types of accidents that have been evaluated in the plant-specific DCD. Accidents of a different type are credible accidents that the proposed departure could create that are not bounded by accidents evaluated in the plant-specific DCD.

4.1.2.2.1.6 Does the Proposed Departure Create a Possibility for a Malfunction of an SSC Important to Safety with a Different Result?

Malfunctions of SSCs are generally postulated as potential single failures to evaluate plant performance with the focus being on the result of the malfunction rather than the cause or type of malfunction. A malfunction that involves an initiator or failure whose effects are not bounded by those explicitly described in the plant-specific DCD is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result if the result or effect is the same as, or is bounded by, that previously evaluated in the plant-specific DCD. The following examples illustrate this point:

- If a pump is replaced with a new design, there may be a new failure mechanism introduced that would cause a failure of the pump to run. But if this effect (failure of the pump to run) was previously evaluated and bounded, then a malfunction with a different result has not been created.

- If a feedwater control system is being upgraded from an analog to a digital system, new components may be added that could fail in ways other than the components in the original design. Provided the end result of the component or subsystem failure is the same as, or is bounded by, the results of malfunctions currently described in the UFSAR (i.e., failure to maximum demand, failure to minimum demand, failure as-is, etc.), then this upgrade would not create a malfunction with a different result.

  An example of a change that would create the possibility for a malfunction with a different result is a substantial modification or upgrade to control station alarms, controls, or displays that are associated with SSCs important to safety that creates a new or common cause failure that is not bounded by previous analyses or evaluations.

  Certain malfunctions are not explicitly described in the plant-specific DCD because their effects are bounded by other malfunctions that are described. For example, failure of a lube oil pump to supply oil to a component may not be explicitly described because a failure of the supplied component to operate was described.

  The possible malfunctions with a different result are limited to those that are as likely to happen as those described in the plant-specific DCD. For example, a seismic induced failure of a component that has been designed to the appropriate seismic criteria will not cause a malfunction with a different result. However, a proposed change or departure that increases the likelihood of a malfunction previously thought to be incredible to the point where it becomes as likely as the malfunctions assumed in the

plant-specific DCD could create a possible malfunction with a different result.

In evaluating a proposed departure against this criterion, the types and results of failure modes of SSCs that have previously been evaluated in the plant-specific DCD and that are affected by the proposed departure should be identified. This evaluation should be performed consistent with any failure modes and effects analysis (FMEA) described in the plant-specific DCD, recognizing that certain proposed activities may require a new FMEA to be performed. Attention must be given to whether the malfunction was evaluated in the accident analyses at the component level or the overall system level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and resulting event initiators or mitigation impacts, it also needs to consider the nature of the proposed departure. For instance, if failures were previously postulated on a train level because the trains were independent, a proposed departure that introduces a cross-tie or credible common mode failure (e.g., as a result of an analog to digital upgrade) should be evaluated further to see whether new outcomes have been introduced.

Once the malfunctions previously evaluated in the plant-specific DCD and the results of these malfunctions have been determined, then the types and results of failure modes that the proposed departure could create are identified. Comparing the two lists can provide the answer to the criterion question. An example that might create a malfunction with a different result could be the addition of a normally open vent line in the discharge of an emergency core cooling system pump. The different result of a malfunction could be potential voiding in the system causing it not to operate properly.

4.1.2.2.1.7 Does the Proposed Departure Result in a Design Basis Limit for a Fission Product Barrier Being Exceeded or Altered?

VIII.B.5.b(7) departure evaluation criterion focuses on the fission product barriers (fuel cladding, reactor coolant system boundary and containment) and on the critical design information that supports their continued integrity. Guidance for applying this criterion is structured around a two-step approach:

1. Identification of affected design basis limits for a fission product barrier

2. Determination of when those limits are exceeded or altered.

Identification of affected design basis limits for a fission product barrier

The first step is to identify the fission product barrier design basis limits, if any, that are affected by a proposed departure. Design basis limits for a fission product barrier are the controlling numerical values established during the licensing review as presented in the plant-specific DCD for any parameter(s) used to determine the integrity of the fission product barrier. These limits have three key attributes:

- **The parameter is fundamental to the barrier's integrity.** Design basis limits for fission product barriers establish the reference bounds for design of the barriers, as defined in 10 CFR 50.2. They are the limiting values for parameters that directly determine the performance of a fission product barrier. That is, design bases limits are fundamental to barrier integrity and may be thought of as the point at which confidence in the barrier begins to decrease.

  For purposes of this evaluation, design bases parameters that are used to directly determine fission product barrier integrity should be distinguished from subordinate parameters that can indirectly affect fission product barrier performance. Indirect effects of changes to subordinate parameters are evaluated in terms of their effect on the more fundamental design bases parameters/limits that ensure fission product barrier integrity. For example, auxiliary feedwater design flow is a subordinate parameter for purposes of this evaluation, not a design bases parameter/limit. The acceptability of a reduction in AFW design flow would be determined based on its effect on design bases limits for the RCS (e.g., RCS pressure).

- **The limit is expressed numerically.** Design basis limits are numerical values used in the overall design process, not descriptions of functional requirements. Design basis limits are typically the numerical event acceptance criteria used in the accident analysis methodology. The facility's design and operation associated with these parameters as described in the plant-specific DCD will be at or below (more conservative than) the design basis limit.

- **The limit is identified in the plant-specific DCD.** As required by 10 CFR 50.34(b), design basis limits are presented in the plant-specific DCD. They may be located in a vendor topical report that is incorporated by reference in the plant-specific DCD.

Any design basis limit for a fission product barrier that is controlled by another, more specific regulation or technical specification would not require evaluation under criterion VIII.B.5.b.(7). The effect of the proposed departure on those parameters would be evaluated in accordance with the more specific

regulation. Effects (either direct or indirect) on design basis parameters covered by another regulation or technical specification need not be considered as part of evaluations under VIII.B.5.b(7).

Examples of typical fission product barrier design basis limits are identified in the following table:

Barrier	Design Bases Parameter	Typical Design Basis Limit
Fuel Cladding	DNBR/MCPR	Value corresponding to the 95/95 DNB criterion for a given DNB correlation
	Fuel temperature	Centerline fuel melting temperature
	Linear heat rate	Peak linear heat rate (typ. in kW/ft) established to ensure clad integrity
	Fuel enthalpy	Cal/gm associated with dispersion
	Clad strain	Internal pressure associated with clad liftoff
	Fuel burnup	Limit (typ. in MWd/ton) established to ensure clad integrity
	Clad temperature *	2200 degrees F
	Clad oxidation *	17% local and 1% overall
RCS Boundary	Pressure	Designated limit in safety analysis for specific accident
	Stresses *	ASME Code compliance for normal, upset, faulted, etc., as appropriate for accident
	Heat-up/Cool-down*	Applicable ASME Code stress limits
Containment	Pressure	Containment design pressure

* These parameters are commonly controlled by 10 CFR 50.55a, 10 CFR 50.46 and/or a specific technical specification and therefore would not be subject to VIII.B.5.

The list above may vary slightly for a given facility and/or fuel vendor and may include other parameters for specific accidents. For example,

- PWR licensees may use 100% pressurizer level as a limiting parameter to ensure RCS integrity for some accident sequences.

- A peak containment temperature may be established in the plant-specific DCD as an independent limit for ensuring the integrity of the containment.

If a given facility has these or other parameters incorporated into the plant-specific DCD as a design basis limit for a fission product barrier, then changes affecting it should be evaluated under this criterion.

Two of the ways that a licensee can evaluate proposed departures against this criterion are as follows. The licensee may identify all design bases parameters for fission product barriers and include them explicitly in the procedure for performing VIII.B.5 evaluations. Alternatively, the effects of a proposed departure could be evaluated first to determine if the change affects design bases parameters for fission product barriers. The results of these two approaches are equivalent provided the guidance for "exceeded or altered" described below is followed. In all cases, the direct and indirect effects of proposed departures must be included in the evaluation.

Exceeded or altered

A specific proposed departure requires a license amendment if the design basis limit for a fission product barrier is "exceeded or altered." The term "exceeded" means that as a result of the proposed departure, the facility's predicted response would be less conservative than the numerical design basis limit identified above. The term "altered" means the design basis limit itself is changed.

The effect of the proposed departure includes both direct and indirect effects. Extending the maximum fuel burn-up limits until the fuel rod internal gas pressure exceeds the design basis limit is a direct effect that would require a license amendment. As discussed earlier, indirect effects provide for another parameter or effect to cascade from the proposed departure to the design basis limit. For example, reducing the design flow of auxiliary feedwater pumps following a loss of main feedwater could reduce the heat transferred from the RCS to the steam generators. That effect could increase the RCS temperature, which would raise RCS pressure and pressurizer level. The VIII.B.5.b(7) evaluation of this change would focus on whether the design

basis limit associated with RCS pressure for that accident sequence would be exceeded.

Altering a design basis limit for a fission product barrier is not a routine departure, but it can occur. An example of this would be changing the DNBR value from the value corresponding to the 95/95 criterion for a given DNB correlation, perhaps as a result of a new fuel design being implemented. (A new correlation or a new value for the "95/95 DNB criterion" with the same fuel type would be evaluated under criterion b(8) of the rule.) Another example is redesigning portions of the RCS boundary to no longer comply with the code of construction. These are infrequent departures affecting key elements of the defense-in-depth philosophy. As such, no distinction has been made between a conservative and nonconservative change in these limits. In contrast with these examples, altering AFW design flow, or other subordinate parameter/limit, is not subject to the "may not be altered" criterion because AFW design flow is not a design bases limit for fission product barrier integrity.

Evaluations performed under this criterion may incorporate a number of refinements to simplify the review. For example, if an engineering evaluation demonstrates that no parameters are affected that have design basis limits for fission product barriers associated with them, no further VIII.B.5.b(7) evaluation is required. Similarly, most parameters that require evaluation under this criterion have calculations or analyses supporting the facility's design. If an engineering evaluation demonstrates that the analysis presented in the plant-specific DCD remains bounding, then no further VIII.B.5.b(7) evaluation is required. When using these techniques, both indirect and direct effects must be considered to ensure that important interactions are not overlooked.

Examples illustrating the two-step approach for evaluations under this criterion are provided below:

<u>Example 1</u>

It is proposed to delay the automatic start of the stand-by condensate booster pump to eliminate spurious automatic starts. The proposed change is of sufficient magnitude such that it "screens in" as affecting a design function as described in the plant-specific DCD.

Identification of design basis limits

The direct effects of a reduction in condensate flow would be reviewed to identify potentially affected design basis parameters. In addition, the

indirect effect on feedwater flow and feedwater pump NPSH of a possible transient reduction in condensate flow/pressure would be considered. Likewise, consideration of indirect effects would be extended to the reactor or steam generator (BWR or PWR, as applicable). The review concludes that no design basis limits are either directly or indirectly affected.

The change in the frequency of a reactor trip as a result of normal condensate system malfunctions would be evaluated under other VIII.B.5 criteria.

Exceeded or altered

Since no design basis limits were identified, this element of the evaluation is not applicable.

Example 2

The heat transfer capability of an RHR heat exchanger tube bundle has degraded, and it is proposed to accept the condition "as-is."

Identification of design basis limits

The effects of the reduced heat transfer capability would be reviewed. The direct effect would include the increased temperature of the suppression pool or containment sump [BWR or PWR, as applicable]. The indirect effects would include increasing the peak containment post-accident pressure and increased enthalpy of ECCS flow. The increased ECCS enthalpy would also affect peak clad temperature (PCT). Thus, the proposed departure affects two design basis limits: containment pressure and PCT. In this example, the design basis limits would most likely serve as the acceptance criteria for the two parameters in the LOCA analysis described in the plant-specific DCD. (Most licensees use containment design pressure and 2200 degrees F for those values.)

Exceeded or altered

Any increase in peak containment post-accident pressure would be compared to the design basis limit, in this case, containment design pressure. If the revised peak post-accident containment pressure exceeded the design basis limit, then a license amendment would be required.

On the other hand, PCT is governed by a more specific regulation, 10 CFR 50.46. Therefore, the evaluation under this criterion would not address the impact on this parameter. Rather, any changes or corrections to an acceptable evaluation model or application of such a model that affects the

PCT calculation would be evaluated per the requirements of 10 CFR 50.46(3)(ii).

In this example, the design basis limit for containment pressure is not being altered. Therefore, this element of the review is not applicable.

Example 3

Recently identified corrosion inside the primary containment has prompted a re-evaluation of the existing containment design pressure of 55 psig. This re-evaluation has concluded that a design pressure of 48 psig is the maximum supportable. As the final resolution to the degraded containment condition, the licensee proposes to reduce the containment design pressure as reflected in UFSAR safety analyses from 55 to 48 psig.

Identification of design basis limit

The affected parameter is post-accident peak containment pressure. This parameter directly affects the containment barrier. Its design basis limit from the UFSAR is the existing containment design pressure of 55 psig.

Exceeded or altered

The design basis limit itself has been "altered" and thus a license amendment is required. The issue of conservative vs. nonconservative is not germane to requiring a submittal. That is, prior NRC approval is required regardless of direction because this is a fundamental change in the facility's design.

4.1.2.2.1.8 Does the Proposed Departure Result in a Departure from a Method of Evaluation Described in the Plant-Specific DCD Used in Establishing the Design Bases or in the Safety Analyses?

The plant-specific DCD contains design and licensing basis information for a nuclear power facility, including description on how regulatory requirements for design are met and how the facility responds to various design basis accidents and events. Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and why the facility's response to accidents and events is acceptable. As such, in cases where the analytical methodology was considered to be an important part of the conclusion that the facility met the required design bases, these analytical methods were described in the plant-specific DCD and received varying levels of NRC review and approval during licensing.

Because VIII.B.5 provides a process for determining if prior NRC approval is required before changing Tier 2 information in the plant-specific DCD,

changes to the methodologies described in the plant-specific DCD also fall under the provisions of the VIII.B.5 process, specifically criterion b(8). In general, applicants and licensees can make changes to elements of a methodology without first obtaining a license amendment if the results are essentially the same as, or more conservative than, previous results. Similarly, applicants and licensees can also use different methods without first obtaining a license amendment if those methods have been approved by the NRC for the intended application.

If the proposed departure does not involve a change to a method of evaluation, then the VIII.B.5 evaluation should reflect that this criterion is not applicable. If the proposed departure involves only a change to a method of evaluation, then the VIII.B.5 evaluation should reflect that criteria VIII.B.5.b(1-7) are not applicable.

The first step in applying this criterion is to identify the methods of evaluation that are affected by the change. This is accomplished during application of the screening criteria in Section 4.1.2.1.

Next, the licensee must determine whether the change constitutes a departure from a method of evaluation that would require prior NRC approval. As discussed further below, for purposes of evaluations under this criterion, the following changes are considered a departure from a method of evaluation described in the plant-specific DCD:

- Changes to any element of analysis methodology that yield results that are nonconservative or not essentially the same as the results from the analyses of record

- Use of new or different methods of evaluation that are not approved by NRC for the intended application.

By way of contrast, the following changes are not considered departures from a method of evaluation described in the plant-specific DCD:

- Departures from methods of evaluation that are not described, outlined or summarized in the plant-specific DCD (such changes may have been screened out as discussed in Section 4.1.2.1)

- Use of a new NRC-approved methodology (e.g., new or upgraded computer code) to reduce uncertainty, provide more precise results or other reason, provided such use is (a) based on sound engineering practice, (b) appropriate for the intended application and (c) within the

limitations of the applicable SER. The basis for this determination should be documented in the applicant or licensee evaluation

- Use of a methodology revision that is documented as providing results that are essentially the same as, or more conservative than, either the previous revision of the same methodology or another methodology previously accepted by NRC through issuance of an SER.

Section 4.1.2.2.1.8.1 provides guidance for making changes to one or more elements of an existing method of evaluation used to establish the design bases or in the safety analyses. Section 4.1.2.2.1.8.2 provides guidance for adopting an entirely new method of evaluation to replace an existing one.

Examples illustrating the implementation of this criterion are provided in Section 4.1.2.2.1.8.3.

4.1.2.2.1.8.1 Guidance for Changing One or More Elements of a Method of Evaluation

The definition of "departure …" provides applicants or licensees with the flexibility to make changes under VIII.B.5 to methods of evaluation whose results are conservative or that are not important with respect to the demonstrations of performance that the analyses provide. Changes to elements of analysis methods that yield conservative results, or results that are essentially the same, would not be departures from approved methods.

Conservative vs. Nonconservative Results

Gaining margin by changing one or more elements of a method of evaluation is considered to be a nonconservative change and thus a departure from a method of evaluation for purposes of VIII.B.5. Such departures require prior NRC approval of the revised method. Analytical results obtained by changing any element of a method are conservative relative to the previous results, if they are closer to design bases limits or safety analyses limits (e.g., applicable acceptance guidelines). For example, a change from 45 psig to 48 psig in the result of a containment peak pressure analysis (with design basis limit of 50 psig) using a revised method of evaluation would be considered a conservative change when applying this criterion. In other words, the revised method is more conservative if it predicts more severe conditions given the same set of inputs. This is because results closer to limiting values are considered conservative in the sense that the new analysis result provides less margin to applicable limits for making potential physical or procedure changes without a license amendment.

In contrast, if the use of a modified method of evaluation resulted in a change in calculated containment peak pressure from 45 psig to 40 psig, this would be a nonconservative change. That is because the change would result in more margin being available (to the design basis limit of 50 psig) for the licensee to make more significant changes to the physical facility or procedures.

"Essentially the Same"

Applicants or licensees may change one or more elements of a method of evaluation such that results move in the nonconservative direction without prior NRC approval, provided the revised result is "essentially the same" as the previous result. Results are "essentially the same" if they are within the margin of error for the type of analysis being performed. Variation in results due to routine analysis sensitivities or calculational differences (e.g., rounding errors and use of different computational platforms) would typically be within the analysis margin of error and thus considered "essentially the same." For example, when a method is applied using a different computational platform (mainframe vs. workstation), results of cases run on the two platforms differed by less than 1%, which is the margin of error for this type of calculation. Thus the results are essentially the same and do not constitute a departure from a method that requires prior NRC approval.

The determination of whether a new analysis result would be considered "essentially the same" as the previous result can be made through benchmarking the revised method to the existing one, or may be apparent from the nature of the differences between the methods. When benchmarking a revised method to determine how it compares to the previous one, the analyses that are done must be for the same set of plant conditions to ensure that the results are comparable. Comparison of analysis methods should consider both the peak values and time behavior of results, and engineering judgment should be applied in determining whether two methods yield results that are essentially the same.

4.1.2.2.1.8.2 Guidance for Changing from One Method of Evaluation to Another

The definition of "departure…" provides applicants and licensees with the flexibility to make changes under Section VIII.B.5 of the design certification rules from one method of evaluation to another provided that the new method is approved by the NRC for the intended application. A new method is approved by the NRC for intended application if it is approved for the type of

analysis being conducted, and applicable terms, conditions and limitations for its use are satisfied.

NRC approval has typically followed one of two paths. Following the first path, most reactor or fuel vendors and several utilities have prepared and obtained NRC approval of topical reports that describe methodologies for the performance of a given type or class of analysis. Through a safety evaluation report (SER), NRC approved the use of the methodologies for a given class of power plants. In some cases, the NRC has accorded generic approval of analysis methodologies. Terms, conditions and limitations relating to the application of the methodologies are usually documented in the topical reports, the SER, and correspondence between the NRC and the methodology owner that is referenced in the SER or associated transmittal letter.

Following the second path involves obtaining approval of a specific analysis rather than a more generic methodology. In these cases, the NRC's approval has typically been part of a plant's licensing basis and limited to a given plant design and a given application. Again, a thorough understanding of the terms, conditions and limitations relating to the application of the methodology is essential. This information is usually documented in the original license application or license amendment request, the SER, and any correspondence between the NRC and the analysis owner that is referenced in the SER or associated transmittal letter.

It is incumbent upon the users of a new methodology—even one generically approved by the NRC—to ensure they have a thorough understanding of the methodology in question, the terms of its existing application and conditions/limitations on its use. A range of considerations is identified below that may be applicable to determining whether new methods are technically appropriate for the intended application. The licensee should address these and similar considerations, as applicable, and document in the VIII.B.5 evaluation the basis for determining that a method is appropriate and approved for the intended application. To obtain an adequate understanding of the method and basis for determining it is approved for use in the intended application, applicants or licensees should consult various sources, as appropriate. Relevant sources include SERs, topical reports, applicant or licensee correspondence with the NRC and applicant or licensee personnel familiar with the existing application of the method. If adequate information cannot be found on which to base the intended application of the methodology, the method should not be considered "approved by the NRC for the intended application."

The applicable terms and conditions for the use of a methodology are not limited to a specific analysis; the qualification of the organization applying the methodology is also a consideration. Through Generic Letter 83-11,

Supplement 1,[2] the NRC has established a method by which licensees can demonstrate they are generally qualified to perform safety analyses. Licensees thus qualified can apply methods that have been reviewed and approved by the NRC, or that have been otherwise accepted as part of another plant's licensing basis, without requiring prior NRC approval. Licensees that have not satisfied the guidelines of Generic Letter 83-11, Supplement 1, may, of course, continue to seek plant-specific approval to use new methods of evaluation.

When considering the application of a methodology, it is necessary to adopt the methodology *en toto* and apply it consistent with applicable terms, conditions and limitations. Mixing attributes of new and existing methodologies is considered a revision to a methodology and must be evaluated as such per the guidance in Section 4.1.2.2.1.8.1.

Considerations for Determining if New Methods May be Considered "Approved by the NRC for the Intended Application"

The following questions highlight important considerations for determining that a particular application of a different method is technically appropriate for the intended application, within the bounds of what has been found acceptable by NRC, and does not require prior NRC approval.

- Is the application of the methodology consistent with the facility's licensing basis (e.g., NUREG-0800 or other plant-specific commitments)? Will the methodology supersede a methodology addressed by other regulations such as 10 CFR 50.46, 10 CFR 50.55a or the plant technical specifications (Core Operating Limits Report or Pressure/Temperature Limits Report)? Is the methodology consistent with relevant industry standards?

  If application of the new methodology requires exemptions from regulations or plant-specific commitments, exceptions to relevant industry standards and guidelines, or is otherwise inconsistent with a facility's licensing basis, then prior NRC approval may be required. The applicable change process must be followed to make the plant's licensing basis consistent with the requirements of the new methodology.

[2] Generic Letter 83-11, Supplement 1, "Licensee Qualification for Performing Safety Analyses," June 24, 1999

- If a computer code is involved, has the code been installed in accordance with applicable software quality assurance requirements? Has the plant-specific model been adequately qualified through benchmark comparisons against test data, plant data or approved engineering analyses? Is the application consistent with the capabilities and limitations of the computer code? Has industry experience with the computer code been appropriately considered?

  The computer code installation and plant-specific model qualification are not directly transferable from one organization to another. The installation and qualification should be in accordance with the licensee's quality assurance program.

- Is the facility for which the methodology has been approved designed and operated in the same manner as the facility to which the methodology is to be applied? Is the relevant equipment the same? Does the equipment have the same pedigree (e.g., Class 1E, Seismic Category I, etc.)? Are the relevant failure modes and effects analyses the same? If the plant is designed and operated in a similar, but not identical, manner, the following types of considerations should be addressed to assess the applicability of the methodology:

  - How could those differences affect the methodology?
  - Are additional sensitivity studies required?
  - Should additional single failure scenarios be considered?
  - Are analyses of limiting scenarios, effects of equipment failures, etc., applicable for the specific plant design?
  - Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?

- Differences in the plant configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing basis of older vintage plants may not include an analysis of the feedwater line break event that is required in later vintage plants. Some plants may be required to postulate a loss of off-site power or a maximum break size for certain events; others may have obtained exemptions to these requirements from the NRC. Some plants may have pressurizer power-operated relief valves that are qualified for water relief; other

plants do not. Plant specific failure modes and effects analyses may reveal new potential single failure scenarios that can not be adequately assessed with the original methodology. The existence of these differences does not preclude application of a new methodology to a facility; however, differences must be identified, understood and the basis documented for concluding that the differences are not relevant to determining that the new application is technically appropriate.

4.1.2.2.1.8.3 Examples

The following examples illustrate the implementation of this criterion:

Example 1

The plant-specific DCD states that a damping value of 0.5 percent is used in the seismic analysis of safety-related piping. The licensee wishes to change this value to 2 percent to reanalyze the seismic loads for the piping. Using a higher damping value to represent the response of the piping to the acceleration from the postulated earthquake in the analysis would result in lower calculated stresses because the increased damping reduces the loads. Since this analysis was used in establishing the seismic design bases for the piping, and since this is a change to an element of the method that is not conservative and is not essentially the same, this change would require prior NRC approval under this criterion.

On the other hand, had NRC approved an alternate method of seismic analysis that allowed 2 percent damping provided certain other assumptions were made, and the licensee used the complete set of assumptions to perform its analysis, then the 2 percent damping under these circumstances would not be a departure because this method of evaluation is considered "approved by the NRC for the intended application."

Example 2

A facility has a design basis containment pressure limit of 50 psig. The current worst-case design basis accident calculation results in a peak pressure of 45 psig within two minutes. The licensee revises the method of evaluation, and the recalculated result is 40 psig. This change would require prior NRC approval because the result of the recalculation is not conservative. If the licensee used a different method that was approved by the NRC and met all the terms and conditions of the method, a recalculated result of 40 psig would not require prior NRC approval.

Example 3

An applicant or licensee revises the seismic analysis described in the plant-specific DCD to include an inelastic analysis procedure. This revised method is used to demonstrate that cable trays have greater capacity than previously calculated. This change would require prior NRC approval as it would not produce results that are essentially the same.

Example 4

Applicant or Licensee X has received NRC approval for the use of a method of evaluation at Facility A for performing steamline break mass and energy release calculations for environmental qualification evaluations. The terms and conditions for the use of the method are detailed in the NRC SER. The SER also describes limitations associated with the method. Applicant or Licensee Y wants to apply the method at its Facility B. Applicant or Licensee Y has satisfied the guidelines of GL 83-11, Supplement 1. After reviewing the method, approved application, SER and related documentation, to verify that applicable terms, conditions and limitations are met and to ensure the method is applicable to their type of plant, Applicant or Licensee Y conducts a VIII.B.5 evaluation. Applicant or Licensee Y concludes that the change is not a departure from a method of evaluation because it has determined the method is appropriate for the intended application, the terms and conditions for its use as specified in the SER have been satisfied, and the method has been approved by the NRC.

Example 5

The NRC has approved the use of computer code and the associated analysis of a steamline break for use in the evaluation of component stresses. An applicant or licensee uses the same computer code and analysis methodology to replace its evaluation of the containment temperature response. This change would require prior NRC approval unless the methodology had been previously approved for evaluating containment temperature response.

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

To Be Developed

4.1.2.2.3 Evaluation of 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:

> A proposed departure from Tier 2 information required by 10 CFR 52.47(a)(28) to address aircraft impacts shall 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 shall describe in the plant-specific DCD how the modified design features and functional capabilities continue to meet the aircraft impact assessment requirements in 10 CFR 50.150(a)(1).

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 FSAR 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 holder 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 FSAR. This summary information is typically in Chapter 19 of the FSAR and is expected to be non-safeguards information. One purpose of the FSAR 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 FSAR 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 FSAR, 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 (see above discussion); modifications to the proposed design feature changes 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 FSAR 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 FSAR 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 FSAR 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 FSAR changes.

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/Evaluation 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). 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 fully implement 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.

4.1.3 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 FSAR. 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 burnup 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) Automatic depressurization system (ADS) and core make-up tank (CMT) verification tests (first three plants only).
f) 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 1.92 are Tier 2*.

4.2 CHANGES TO PLANT-SPECIFIC FACILITIES OR PROCEDURES DESCRIBED IN THE FSAR

Once a combined license is issued, changes to the facility or departures from information within the scope of the referenced design certification rule depends 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 52.98(c) applies.

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 4.1). 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 50.59, but also change processes identified in 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 change processes for other plans and programs prescribed in regulations (for example, 50.150 for aircraft impact assessment).

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.

4.2.1 Changes to Plant-Specific Facilities or Procedures Described in the FSAR

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 evaluation 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.

4.2.1.1 Screening of Changes to Plant-Specific Facilities or Procedures Described in the FSAR

The screening process and guidance contained in the main body of NEI 96-07 is applicable to 50.59 changes.

4.2.1.2 Evaluation of Changes to Plant-Specific Facilities or Procedures Described in the FSAR

The evaluation process and guidance contained in the main body of NEI 96-07 is applicable to 50.59 changes, except as updated as identified in Section 4.1.2.2.1.3.

4.2.2 Changes to Plant-Specific ITAAC

Changes to ITAAC are addressed in 10 CFR 52.99(d). Two cases are considered: (1) an ITAAC derived from a referenced standard design certification, and (2) an ITAAC not derived from a referenced design certification. Per 52.99(d)(1), a change to an ITAAC derived from a referenced standard design certification requires the licensee to request an exemption from the standard design ITAAC, as applicable. The request for an exemption must also be accompanied by a request for a license amendment under 52.98(f). Per 52.99(d)(2), a change to an ITAAC that is not derived from a referenced standard design certification only requires a request for a license amendment under 52.98(f). The license amendment requirement in both cases is derived from the fact that all ITAAC will be issued as part of the combined license in an appendix to the license.

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 ITAAC do not constitute regulatory requirements either for licensees or for renewal of the license. There may be specific ITAAC for which the Commission has granted a hearing under 52.103(a) and has determined in accordance with 52.103(c) that operation may be allowed during an interim period beyond the 52.103(g) finding if the hearing is not concluded, but all ITAAC expire upon final Commission action in the proceeding.

4.2.3 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 criteria in 10 CFR 50.59.

4.2.4 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 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 inservice 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 FSAR 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 FSAR and must be evaluated in accordance with 10 CFR 50.59.

4.3 CHANGES TO CHAPTER 19

To Be Developed

4.4 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 4.4.1.

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.

4.4.1 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.

4.4.2 Changes Related to an ESP after Issuance of a COL

After issuance of a COL, the ESP and SSAR no longer have any effect with respect to the plant that is the subject of the COL. Instead, as provided in 10 CFR 52.27(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 Fed. Reg. 49352, 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.

4.5 CHANGES UNDER LIMITED WORK AUTHORIZATIONS

The applicant for a Limited Work Authorization (LWA) will include in the application a process for making changes to the issued LWA. The LWA change process may be similar to the process described in 10 CFR 50.59, including screening/evaluation criteria, and will be incorporated into the LWA when it is issued by the NRC.

Using the LWA change process, proposed changes are screened and evaluated to determine whether the changes can be implemented without prior NRC review and approval. If it is determined that a proposed change requires prior NRC approval, then an LWA amendment request must be submitted in accordance with 10 CFR 50.90 and 10 CFR 50.92.

4.6 DISPOSITION OF DEPARTURES AND CHANGES

4.6.1 Evaluations performed after the Section 52.103(g) ITAAC finding

Once the NRC makes the Section 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. The following guidance is therefore adapted from NEI 96-07, Section 4.5:

There are two possible conclusions to an evaluation conducted under Section 52.98 and the applicable change control process:

(1) The proposed departure or change may be implemented without prior NRC approval.

(2) The proposed departure or change requires prior NRC approval.

Where a departure requires prior NRC approval, the departure or change must be approved by the NRC via license amendment in accordance with 10 CFR 50.90 prior to implementation. A departure or change is considered "implemented" when it provides its intended function, that is, when it is placed in service and declared operable. Thus, a licensee may design, plan, install and test a modification prior to receiving the license amendment to the extent that these preliminary activities do not themselves require prior NRC approval.

For example, a modification to a facility involved the replacement of a train of a safety system with one including diverse primary components (diesel-driven pump vice a motor-driven pump). The installation of the replacement train was largely in a new, separate structure. Ultimately the modification would require NRC approval because of impacts on the technical specifications as well as due to differences in reliability of the replacement pump in some situations. There was insufficient time to seek and gain NRC approval prior to construction. The licensee prepared a Section VIII.B.5 screening to support construction of the separate structure through preliminary testing. The limited interfaces with the existing facility were assessed and determined to not change the facility or procedures as described in the UFSAR. Upon receipt of the license amendment, the final tie-in, testing and operation were fully authorized. The Section VIII.B.5 change process should be applied to any aspects of the proposed departure or change

not adequately addressed in the license amendment request and/or associated safety evaluation report.

For proposed departures that are determined to require prior NRC approval, there are three possible options:

(1) Cancel the planned departure or change.

(2) Redesign the proposed departure or change so that it may proceed without prior NRC approval.

(3) Apply for and obtain a license amendment under 10 CFR 50.90 prior to implementing the departure or change. Technical and licensing evaluations performed for such departures/changes may be used as part of the basis for license amendment requests.

It is important to remember that determining that a proposed departure or change requires prior NRC approval does not determine whether it is safe. In fact, a proposed departure or change that requires prior NRC approval may significantly enhance overall plant safety at the expense of a small adverse impact in a specific area. It is the responsibility of the utility to assure that proposed activities are safe, and it is the role of the NRC to confirm the safety of those activities that are determined to require prior NRC review.

4.6.2 Evaluations performed before the Section 52.103(g) ITAAC finding

After the Section 52.103(g) ITAAC finding and throughout the operational phase of the plant, technical specifications are in effect and provide compliance points by which LARs must be approved before a departure or change may be implemented, as discussed above.

Prior to the Section 52.103(g) ITAAC finding, NRC processes applicable to new plant construction under a Part 52 COL provide compliance points analogous to technical specifications for operating plants. Compliance points during construction include: (1) ITAAC closure; and (2) initial applicability of plant technical specifications upon the Section 52.103(g) finding that the ITAAC acceptance criteria in the combined license are met.

Analogous to operating plant licensees, Part 52 new plant licensees may design, procure, fabricate, install and test SSC design elements that differ from those approved in the COL pending NRC approval of required LARs. Applying the concept of compliance points to changes during construction, NRC approval of LARs is required before ITAAC closure letters for affected ITAAC (if any) are submitted, or before associated technical specifications initially apply. The activities permitted prior to approval of ITAAC-related

LARs include licensee performance of inspections, tests or analyses specified in the ITAAC and determination that ITAAC acceptance criteria are met. By their nature, ITAAC-related LARs must be dispositioned prior to the Section 52.103(g) finding (prior to plant operation).

Changes to technical specifications and certain other LARs may not involve ITAAC such that the ITAAC closure compliance point does not apply. LARs that do not involve ITAAC would need to be dispositioned 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 implementation milestone for the affected program as indicated in the FSAR. Thus, required program implementation milestones constitute compliance points for program changes that require prior NRC approval via the LAR process.

Note that the additional compliance points during construction do not affect when departures or changes are considered "implemented." As discussed in Section 4.6.1, a departure or change is considered "implemented" when it provides its intended function, that is, when it is placed in service and declared operable. For most SSCs, this occurs when associated technical specifications initially apply. Certain SSCs are placed in service and provide their intended functions before technical specifications take effect upon the Section 52.103(g) finding). These may include SSCs associated with security, fire protection, radiation protection and emergency planning. Modifications associated with such SSCs are considered implemented when they are placed in service and provide their intended functions.

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 mixed-scope cases, the applicable provisions of Section 52.98 and the design certification rule apply. For changes subject to Section 50.59, the following applies.

10 CFR 50.59(d) requires the following documentation and recordkeeping:

The licensee shall maintain records of changes in the facility, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation that provides the bases for the determination that the change, test or experiment does not require a license amendment pursuant to paragraph (c)(2) of this section.

(a) The licensee shall submit, as specified in § 52.3, a report containing a brief description of any changes, tests and experiments, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months.

(b) The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR Part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years.

The documentation and reporting requirements of 10 CFR 50.59(d) apply to activities that require evaluation against the eight criteria of 10 CFR 50.59(c)(2) and are determined not to require prior NRC approval. That is, the phrase in 10 CFR 50.59(d)(1), "made pursuant to paragraph (c)," refers to those activities that were evaluated against the eight evaluation criteria (because, for example, they affect the facility as described in the UFSAR), but not to those activities or changes that were screened out. Similarly, documentation and reporting under 10 CFR 50.59 is not required for activities that are canceled or that that are determined to require prior NRC approval and are implemented via the license amendment request process.

Documenting 10 CFR 50.59 Evaluations

In performing a 10 CFR 50.59 evaluation of a proposed activity, the evaluator must address the eight criteria in 10 CFR 50.59(c)(2) to determine if prior NRC approval is required. Although the conclusion in each criterion may be

simply "yes," "no" or “not applicable,” there must be an accompanying explanation providing adequate basis for the conclusion. Consistent with the intent of 10 CFR 50.59, these explanations should be complete in the sense that another knowledgeable reviewer could draw the same conclusion. Restatement of the criteria in a negative sense or making simple statements of conclusion is not sufficient and should be avoided. It is recognized, however, that for certain very simple activities, a statement of the conclusion with identification of references consulted to support the conclusion would be adequate and the 10 CFR 50.59 evaluation could be very brief.

The importance of the documentation is emphasized by the fact that experience and engineering knowledge (other than models and experimental data) are often relied upon in determining whether evaluation criteria are met. Thus the basis for the engineering judgment and the logic used in the determination should be documented to the extent practicable and to a degree commensurate with the safety significance and complexity of the activity. This type of documentation is of particular importance in areas where no established consensus methods are available, such as for software reliability, or the use of commercial-grade hardware and software where full documentation of the design process is not available.

Since an important goal of the 10 CFR 50.59 evaluation is completeness, the items considered by the evaluator must be clearly stated.

Each 10 CFR 50.59 evaluation is unique. Although each applicable criterion must be addressed, the questions and considerations listed throughout this guidance document to assist evaluating the criteria are not requirements for all evaluations. Some evaluations may require that none of these questions be addressed while others will require additional considerations beyond those identified in this guidance.

When preparing 10 CFR 50.59 evaluations, licensees may combine responses to individual criteria or reference other portions of the evaluation.

As discussed in Section 4.2.3, licensees may elect to use screening criteria to limit the number of activities for which written 10 CFR 50.59 evaluations are performed. A documentation basis should be maintained for determinations that the changes meet the screening criteria, i.e., screen out. This documentation does not constitute the record of changes required by 10 CFR 50.59, and thus is not subject to the recordkeeping requirements of the rule.

Reporting to NRC

A summary of 10 CFR 50.59 evaluations for activities implemented under 10 CFR 50.59 must be provided to NRC. Activities that were screened out,

canceled or implemented via license amendment need not be included in this report.

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).

After the Commission makes the finding required by 10 CFR 52.103(g), the licensee shall submit, as specified in § 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 above 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.

Reporting to NRC

An applicant or licensee who references a design certification rule appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. 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 reports and updates required by paragraphs X.B.1 and X.B.2 of the design certification rule appendix 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 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 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 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, or at shorter intervals as specified in the license.