

NUCLEAR REGULATORY COMMISSION

10 CFR PART 52

RIN 3150 - AF15

Standard Design Certification

for the System 80+ Design

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) is amending its regulations to certify the System 80+ design. The NRC is adding a new provision to its regulations that approves the System 80+ design by rulemaking. This action is necessary so that applicants for a combined license that intend to construct and operate the System 80+ design may do so by appropriately referencing this regulation. The applicant for certification of the System 80+ design was Combustion Engineering, Inc. (ABB-CE).

EFFECTIVE DATE: The effective date of this rule is [insert the date 30 days after the publication date]. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of [insert the date 30 days after the publication date].

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- I. Background

On March 30, 1989, Combustion Engineering, Inc. applied for certification of the System 80+ standard design with the NRC. The application was made in accordance with the procedures specified in 10 CFR Part 50, Appendix O, and the Policy Statement on Nuclear Power Plant Standardization, dated September 15, 1987.

On May 18, 1989 (54 FR 15372), the NRC added 10 CFR Part 52 to its regulations to provide for the issuance of early site permits, standard design certifications, and combined licenses for nuclear power reactors. Subpart B of 10 CFR Part 52 established the process for obtaining design certifications. A major purpose of this rule was to achieve early resolution of licensing issues and to enhance the safety and reliability of nuclear power plants.

On August 21, 1989, Combustion Engineering, Inc. requested that its application, originally submitted pursuant to 10 CFR Part 50, Appendix O, be considered as an application for design approval and subsequent design certification pursuant to Subpart B of 10 CFR Part 52. The application was docketed on May 1, 1991, and assigned Docket No. 52-002. Correspondence relating to the application prior to this date was also addressed to docket number STN 50-470 and Project No. 675. By letter dated May 26, 1992, Combustion Engineering, Inc. notified the NRC that it is a wholly owned subsidiary of Asea Brown Boveri, Inc., and the appropriate abbreviation for the company is ABB-CE. Therefore, ABB-CE will be used for Combustion Engineering, Inc. throughout the statements of consideration (SOC).

The NRC staff issued a final safety evaluation report (FSER) related to the certification of the System 80+ design in August 1994 (NUREG-1462). The FSER documents the results of the NRC staff's safety review of the System 80+ design against the requirements of 10 CFR Part 52, Subpart B, and delineates the scope of the technical details considered in evaluating the proposed design. A copy of the FSER may be obtained from the Superintendent of Documents, U. S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-9328 or the National Technical Information Service, Springfield, VA 22161. A final design approval for System 80+ was issued on July 26, 1994, and published in the Federal Register on August 2, 1994 (59 FR 39371).

The NRC staff originally proposed a conceptual design certification rule for evolutionary standard plant designs in SECY-92-287, "Form and Content for a Design Certification Rule." Subsequently, the NRC staff modified the draft rule language proposed in SECY-92-287 to incorporate Commission guidance and published a draft-proposed

design certification rule in the Federal Register on November 3, 1993 (58 FR 58665), as an Advanced Notice of Proposed Rulemaking (ANPR) for public comment. In accordance with the Administrative Procedure Act (APA), Part 52 provides the opportunity for the public to submit written comments on proposed design certification rules. However, Part 52 went beyond the requirements of the APA by providing the public with an opportunity to request a hearing before an Atomic Safety and Licensing Board in a design certification rulemaking. Therefore, on April 7, 1995 (60 FR 17924), the NRC published a proposed rule in the Federal Register which invited public comment and provided the public with the opportunity to request an informal hearing before an Atomic Safety and Licensing Board. The NRC staff conducted public meetings on the development of this design certification rule on November 23, 1993, May 11, 1995, and December 4, 1995, in order to enhance public participation. The period within which an informal hearing could be requested expired on August 7, 1995. The NRC did not receive any requests for an informal hearing during this period.

The Commission has considered the comments received and made appropriate modifications to this design certification rule, as discussed in Sections II and III. With these modifications, the Commission adopts as final this design certification rule, 10 CFR Part 52, Appendix B, for the System 80+ design.

II. Public Comment Summary and Resolution

The public comment period for the proposed design certification rule, the design control document, and the environmental assessment for the System 80+ design expired on August 7, 1995. The NRC received twenty letters containing public comments on the proposed rule. The most extensive comments were provided by the Nuclear Energy Institute (NEI), which provided comments on behalf of the industry. In general, NEI commended the NRC for its efforts to provide standard design certifications but expressed serious concerns about aspects of the proposed rule that would, in NEI's view, undermine the goals of design certification. These concerns are addressed in the following responses to the public comments. Fourteen utilities and three vendors also provided comments. All of these comment letters endorsed the NEI comments and some provided additional comments. The Department of Energy and the Ohio Citizens for Responsible Energy, Inc. (OCRE) also submitted comment letters. OCRE provided two sets of comments, the first addressed the

NRC's specific requests for comment and the second addressed OCRE's concerns about certain aspects of the U.S. ABWR design.

The NRC received other letters that were entered into the docket file and are part of the record of the rulemaking proceeding. An August 4, 1995 letter from NEI to the Chairman of the NRC, which submitted a copy of the Executive Summary of their public comment letter, and a May 11, 1995 letter, which provided suggestions on finality, secondary references, and other explanatory material. Also, the NRC received a second letter from the General Electric Company, which commented on the comments provided by OCRE, and a second letter from Combustion Engineering, Inc. (ABB-CE), which provided proposed Statements of Consideration (SOC) that conformed with its comments.

On February 6, 1996, the NRC staff issued SECY-96-028, "Two Issues for Design Certification Rules," which requested the Commission's approval of the staff's position on two major issues raised by NEI in its comments on the proposed design certification rules. The staff issued this paper because of fundamental disagreements with industry on the need for applicable regulations and the matters to be considered in verifying inspections, tests, analyses, and acceptance criteria (ITAAC). Both NEI and DOE commented on SECY-96-028 in letters dated March 5 and 13, 1996, respectively.

On March 8, 1996, the Commission conducted a public meeting in which industry representatives and NRC staff presented their views on SECY-96-028. During this meeting, NEI and the staff both indicated agreement on the ITAAC verification issue. Subsequently, in a staff requirements memorandum (SRM) dated March 21, 1996, the Commission requested the staff to meet again with industry to try to resolve the issue of applicable regulations. The staff met with representatives of ABB-CE, GE Nuclear Energy, and NEI in a public meeting on March 25, 1996 and proposed various means to reduce or otherwise resolve the need for new applicable regulations. The industry, represented by NEI, neither provided a proposal for resolution of applicable regulations (other than to eliminate them altogether) nor indicated any support for the staff's proposals. As a result, the staff has provided revised resolutions of applicable regulations and ITAAC determinations in the following discussion (sections II.A.3, II.A.4, and II.C.1) that supersede the proposals in SECY-96-028. In addition to the formally scheduled meetings noted above, there have also been numerous less formal interactions between NRC and industry representatives.

The following discussion is separated into three groups: (1) resolution of the principle issues raised by the commenters, (2) resolution of the NRC's specific requests for comment from the proposed rule, and (3) resolution of other issues raised by the commenters.

A. Principal Issues.

1. Issue Resolution (Issue Finality).

Comment Summary. The applicant and NEI criticized Section 6 of the proposed appendix, which describes the scope of issues that were proposed to be resolved by this design certification rulemaking. In brief, both commenters argued that:

- ! The scope of issues accorded finality is too narrow;
- ! Changes made in accordance with the change process are not accorded finality; and
- ! The rule does not provide finality in all subsequent proceedings.

These comments are found in NEI Comment, Attachment B, pp. 1-23 and ABB-CE Comment, B.1. The applicant and NEI provided specific language for a redrafted Section 6 which addresses their criticisms. With the exception of the industry position regarding the exclusion of Tier 2 departures from an opportunity for a hearing, the Commission generally agrees with the applicant and NEI.

Response: Scope of issues accorded finality.

The applicant and NEI took issue with the proposed rule's language limiting the scope of nuclear safety issues resolved to those issues "associated with" the information in the FSER or Design Control Document (DCD). Each argued that there were many other documents which included and/or addressed issues whose status should be regarded as "resolved in connection with" this design certification rulemaking. These additional documents include "secondary references" (i.e., DCD references to documents and information which are not contained in the DCD, including secondary references containing proprietary and safeguards information), docketed material, and the entire rulemaking record (refer to NEI Comments, Attachment B, pp. 6-9).

The Commission has reconsidered its position and decided that the ambit of issues resolved by this rulemaking should be the information that is reviewed and approved in the design certification rulemaking, which includes the rulemaking record for the standard design. This position reflects the Commission's SRM on SECY-90-377, dated February 15, 1991. Also, the Commission concludes that the set of issues resolved should be those that were addressed (or could have been addressed if they were considered significant) as part of the design certification rulemaking process. However, the Commission does not agree that all matters submitted on the docket for design certification should be accorded finality under 10 CFR 52.63(a)(4). Some of this information was neither reviewed nor approved and some was not directly related to the scope of issues resolved by this rulemaking. Therefore, the final rule provides finality for all nuclear safety issues associated with the information in the FSER and any supplements to it, the generic DCD including referenced information that is intended as requirements, and the rulemaking record.

In adopting this final design certification rulemaking, the Commission also finds that the design certification does not require any additional or alternative design criteria, design features, structures, systems, components, testing, analyses, acceptance criteria, or additional justifications in support of these matters. Inherent in the concept of design certification by rulemaking is that all these issues which were addressed, or could have been addressed, in this rulemaking are resolved and therefore, may not be raised in a subsequent NRC proceeding. If this were not the case and one could always argue in a subsequent proceeding that an additional, alternative, or modified system, structure or component of a previously-certified design was needed, or additional justification was necessary, or a modification to the testing and acceptance criteria is necessary, there would be little regulatory certainty and stability associated with a design certification. The underlying benefits of certification of individual designs by rulemaking, e.g., early Commission consideration and resolution of design issues and early Commission consideration and agreement on the methods and criteria for demonstrating completion of detailed design and construction in compliance with the certified design, would be virtually negated. Thus, in accord with the views of the applicant and NEI, the Commission clarifies and makes explicit its previously implicit determination that the scope of issues resolved in connection with the design certification rulemaking includes the lack of need for alternative, additional or modified design criteria, design features,

structures, systems, components, or inspections, tests, analyses, acceptance criteria or justifications, and such matters may not be raised in subsequent NRC proceedings.

In the SOC for the proposed rule, the Commission proposed that issues associated with "requirements" in secondary references, not specifically approved for incorporation by reference by the Office of the Federal Register (OFR) because they contained proprietary information, would not be considered resolved in the design certification rulemaking within the meaning of 10 CFR 52.63(a)(4) (See 60 FR 17924, 17934). NEI took exception to this position, arguing that issues arising from secondary references should be included in the set of issues resolved (See NEI Comments, Attachment B, pp. 6-9). The Commission has determined that the set of issues resolved by this rulemaking embraces those issues arising from secondary references that are requirements for the certified design, including those containing proprietary information. This is consistent with the intent of 10 CFR Part 52 that issues related to the design certification should be considered and resolved in the design certification rulemaking. However, since OFR does not approve of "incorporation by reference" of proprietary information, even though it was available to potential commenters on this proposed design certification rule (see 60 FR 17924; April 7, 1995), the Commission has included in Section 6(d) of this appendix, a process for obtaining proprietary information at the time that notice of a hearing in connection with issuance of a combined license is published in the Federal Register. Such persons will have actual notice of the requirements contained in the proprietary information and, therefore, will be subject to the issue finality provisions of Section 6 of this appendix.

Changes made in accordance with the change process.

The proposed design certification rule included a change process similar to that provided in 10 CFR 50.59. Specifically, Section 8(b)(5) provided "that such changes open the possibility for challenge in a hearing" for Tier 2 changes in accordance with the Commission's guidance in its SRM on SECY-90-377, dated February 15, 1991. The NRC also believed that providing an opportunity for a hearing would serve to discourage changes that could erode the benefits of standardization. The applicant and NEI argued that Tier 2 departures under the "§ 50.59-like" process should not be subject to any opportunity for

hearing but may only be challenged *via* a 10 CFR 2.206 petition; and, therefore should be subject to the backfit restrictions of 10 CFR 52.63(a).

The Commission has reconsidered and changed its position on issue resolution in connection with Tier 2 departures under the "\$ 50.59-like" process. Section 50.59 was originally adopted by the Commission to afford a Part 50 operating license holder greater flexibility in changing the facility as described in the FSAR while still assuring that safety-significant changes of the facility would be subject to prior NRC review and approval [refer to 27 FR 5491, 5492 (first column); June 9, 1962]. The "unreviewed safety question" definition was intended by the Commission to exclude from prior regulatory consideration those licensee-initiated changes from the previously NRC-approved FSAR that could not be viewed as having safety significance sufficient to warrant prior NRC licensing review and approval. To put it another way, any change properly implemented pursuant to § 50.59 should continue to be regarded as within the envelope of the original safety finding by the NRC. Moreover, the departure process for Tier 2 information, as specified in Section 8(b), includes additional restrictions derived from 10 CFR 52.63(b)(2), *viz.*, the Tier 2 change must not involve a change to Tier 1 information. Thus, the departure process of Section 8(b)(5), *if properly implemented by an applicant or licensee*, must logically result in departures which are both "within the envelope" of the Commission's safety finding for the design certification rule and for which the Commission has no safety concern. Therefore, it follows that *properly implemented* departures from Tier 2 should continue to be accorded the same extent of issue resolution as that of the original Tier 2 information from which it was "derived." Section 8(b)(5) has been amended to reflect the Commission's determination on issue resolution for Tier 2 changes made in accordance with the departure process and Section 6 has been amended to provide backfit protection for changes made in accordance with the processes of Section 8 of this appendix.

However, the converse of this reasoning leads the Commission to reject the applicant's and NEI's contention that *no* part of the applicant's or licensee's implementation of the Section 8(b)(5) departure process should be open to challenge in a subsequent licensing proceeding, but instead should be raised as a petition for enforcement action under 10 CFR 2.206. Because §2.206 applies to holders of licenses and is considered a request for enforcement action (thereby presenting some potential difficulties when attempting to apply this in the context of a combined license applicant), it is unclear why an applicant

or licensee who departs from the design certification rule in noncompliance with the Section 8(b)(5) process should nonetheless reap the benefits of issue resolution stemming from the design certification rule. An incorrect departure from the requirements of this appendix essentially places the departure outside of the scope of the Commission's safety finding in the design certification rulemaking. It follows that properly-founded contentions alleging such incorrectly-implemented departures cannot be considered "resolved" by this rulemaking. The industry also appears to oppose an opportunity for a hearing on the basis that there is no "remedy" available to the Commission in a licensing proceeding that would not also constitute a violation of the Tier 2 [Section 8(b)] backfitting restrictions applicable to the Commission and that in a comparable situation with an operating plant the proper remedy is enforcement action. However, for purposes of issue finality the focus should be on the initial licensing proceeding where the result of an improper change evaluation would simply be that the change is not considered resolved and no enforcement action is needed. Neither the applicant nor NEI provided compelling reasons why contentions alleging that applicants or licensees have not properly implemented the Section 8(b)(5) departure process should be entirely precluded from consideration in an appropriate licensing proceeding where they are relevant to the subject of the proceeding.

Although the Commission disagrees with the applicant and NEI over the admissibility of contentions alleging incorrect implementation of the departure process, the Commission acknowledges that they have a valid concern regarding whether the scope of the contentions will incorrectly focus on the substance of correctly-performed departures and the possible lengthened time necessary to litigate such matters in a hearing (See, e.g., Transcript of December 4, 1995 Public Meeting, p. 47). Therefore, the Commission has included in Section 8(b)(5)(vi) an expedited review process, similar to that provided in 10 CFR 2.758, for considering the admissibility of such contentions. Persons who seek a hearing on whether an applicant has departed from Tier 2 information in noncompliance with the applicable requirements must submit a petition, together with information required by 10 CFR 2.714(b)(2), to the presiding officer. If the presiding officer concludes that a *prima facie* case has been presented, he or she shall certify the petition and the responses to the Commission for final determination as to admissibility.

Finality in all subsequent proceedings.

NEI proposed that Section 6 of the proposed rule be expanded to include a more detailed statement regarding the findings, issues resolved, and restrictions on the Commission's ability to "backfit" this appendix. The Commission agrees that the industry's proposal has some merit, and has revised Section 6 of this appendix, beginning with the general subjects embodied in NEI's proposed redraft of Section 6, but restructured the NEI proposal into three sections to reflect the scope of issues resolved, change process, and rulemaking findings, thereby conforming the language to reflect the conventions of the appendix (e.g., generic *changes* versus plant-specific *departures*), and making minor editorial changes for clarity and consistency. However, one area in which the Commission declines to adopt the industry's proposal is the inclusion of a statement in Section 6 which extends issue finality to *all* subsequent proceedings.

Section 52.63(a)(4) explicitly states that issues resolved in a design certification rulemaking have finality in combined license proceedings, proceedings under § 52.103, and operating license proceedings. There are other NRC proceedings not mentioned in § 52.63(a)(4), e.g., combined license amendment proceedings and enforcement proceedings, in which the design certification should logically be afforded issue resolution and, therefore, will be included in Section 6. However, NEI listed NRC proceedings such as design certification renewal proceedings, for which issue finality would not be appropriate. Moreover, it should be understood that to say that this design certification rule is accorded "issue finality" does not eliminate changes properly made under the change restrictions in Section 8. Therefore, the Commission declines to adopt in its entirety the industry proposal that issue finality should extend to all subsequent NRC proceedings.

2. Tier 2 Change Process.

Comment Summary. NEI provided many comments in its Attachment B on the following aspects of the Tier 2 change process:

- ! Scope of the Section 8(b)(5) change process;
- ! Post-design certification rulemaking changes to Tier 2 information;
- ! Restrictions on Tier 2* information;

- ! Technical Specifications; and
- ! Additional aspects of the change process.

Response. The proposed design certification rule provided a change process for Tier 2 information that has the same elements as the Tier 1 change process in order to implement the two-tiered rule structure that was requested by industry. Specifically, the Tier 2 change process in Section 8(b) provides for generic changes, plant-specific changes, and exemptions similar to the provisions in 10 CFR 52.63, except that some of the standards for plant-specific orders and exemptions are different. Section 8(b) also has a provision similar to 10 CFR 50.59 that allows for departures from Tier 2 information by an applicant or licensee, without prior NRC approval, subject to certain restrictions, in accordance with the Commission's SRM on SECY-90-377, dated February 15, 1991.

Scope of the Section 8(b)(5) change process.

In its comments in Attachment B, pp. 67-82, NEI raised a concern regarding application of the § 50.59-like change process to severe accident information, and stated:

Instead of applying the § 50.59-like process to all of Chapter 19, we propose (1) that the process be applied only to those sections that identify features that contribute significantly to the mitigation or prevention of severe accidents (i.e., Section 19.8 for the ABWR and Section 19.15 for the System 80+), and (2) that changes in these sections should constitute unreviewed safety questions only if they would result in a substantial increase in the probability or consequences of a severe accident.

The Commission agrees that departures from Tier 2 information that describe the resolution of severe accident issues should use a criteria that is different from the criteria in 10 CFR 50.59 for determining if a departure constitutes an unreviewed safety question (USQ). Because of the increased uncertainty in severe accident issue resolutions, the NRC has included a "substantial increase" criteria in Section 8(b)(5)(iii) of this Appendix for Tier 2 information that is associated with the resolution of severe accident issues. The (§ 50.59-like) criteria in Section 8(b)(5)(ii), for determining if a departure constitutes a USQ, will apply to the remaining Tier 2

information. If the proposed departure from Tier 2 information involves the resolution of other safety issues in addition to the severe accident issues, then the USQ determination must use the criteria in Section 8(b)(5)(ii) of this appendix.

However, NEI has misidentified the sections of the DCD that describe the resolutions of the severe accident issues. Section 19.8 for the U.S. ABWR and Section 19.15 for the System 80+ design identify important features that were derived from various analyses of the design, such as seismic analyses, fire analyses, and the probabilistic risk assessment. This information was used in preparation of the Tier 1 information and, as stated in the proposed rule, it should be used to ensure that departures from Tier 2 information do not impact Tier 1 information. For these reasons, the Commission rejects the contention that the severe accident resolutions are contained in Chapter 19.15 of the generic DCD.

Post-design certification rulemaking changes to Tier 2 information.

In its comments in Attachment B, pp. 83-89, NEI requested that the NRC add a § 50.59-like provision to the change process that would allow design certification applicants to make generic changes to Tier 2 information prior to the first license application. These applicant-initiated, post-certification Tier 2 changes would be binding upon all referencing applicants and licensees (i.e., referencing applicants and licensees must comply with all such changes) and would continue to enjoy "issue preclusion" (i.e., issues with respect to the adequacy of the change could not be raised in a subsequent proceeding as a matter of right). However, the changes would not be subject to public notice and comment. Instead NEI proposed that the changes would be considered resolved and final (not subject to further NRC review) six months after submission, unless the NRC staff informs the design certification applicant that it disagrees with the determination that no unreviewed safety question exists.

The Commission declines to adopt the NEI proposal. The applicant-initiated Tier 2 changes proposed by NEI have the essential attributes of a "rule," and the process of NRC review and "approval" (negative consent) would appear to be "rulemaking," as these terms are defined in Section 551 of the APA. Section 553(b) of the APA requires public notice in the Federal Register and an opportunity for public comment for all rulemakings, except in certain situations delineated in Section 553(b)(A) and (B) which do not appear to be

applicable here. The NEI proposal appears to be in conflict with the rulemaking requirements of the APA. If the NEI proposal is based upon a desire to permit the applicant to disseminate worthwhile Tier 2 changes, there are three alternatives already afforded by Part 52 and this rule. The applicant (as any member of the public) may submit a petition for rulemaking pursuant to 10 CFR Part 2, Subpart H, to modify this design certification rule to incorporate the proposed changes to Tier 2. If the Commission grants the petition and adopts a final rule, the change is binding on all referencing applicants and licensees in accordance with Section 8(b)(2) of this rule. Also, the applicant could develop acceptable documentation to support a Tier 2 (including Tier 2*) departure in accordance with Section 8(b)(5) [or 8(b)(6)]. This documentation could be submitted for NRC staff review and approval, similar to the manner in which the NRC staff reviews topical reports². And finally, the applicant could provide its proposed changes to a COL applicant who could seek approval as part of its COL application review. The Commission regards these regulatory approaches to be preferable to the NEI proposal, which is fraught with the difficulties identified above. However, if NEI is requesting that the Commission change its preliminary determination, as set forth in its February 15, 1991 SRM on SECY 90-377, that generic Tier 2 rulemaking changes be subject to the same restrictive standard as generic Tier 1 changes, the Commission declines to do so. The Commission believes that maintaining a high standard for generic changes to both Tier 1 and Tier 2 will ensure that the benefits of standardization are appropriately achieved.

Restrictions on Tier 2* information.

²Topical reports, which are usually submitted by vendors such as GE, Westinghouse, and Combustion Engineering, request NRC staff review and approval of generic information and approaches for addressing one or more of the Commission's requirements. If the topical report is approved by the NRC staff, it issues a safety evaluation setting forth the bases for the staff's approval together with any limitations on referencing by individual applicants and licensees. Applicants and licensees may incorporate by reference topical reports in their applications, in order to facilitate timely review and approval of their applications or responses to requests for information. However, limitations in NRC resources may affect review schedules for these topical reports.

In its comments in Attachment B, pp. 119-123, NEI requested that the restriction on departures from all Tier 2* information expire at first full power and, in any event, the expiration of the restrictions should be consistent for both the U.S. ABWR and System 80+ designs. As stated in the proposed design certification rule, the restriction on changing Tier 2* information resulted from the development of the Tier 1 information in the generic DCD. During the development of the Tier 1 information, the applicant for design certification requested that the amount of information in Tier 1 be minimized to provide additional flexibility for an applicant or licensee who references this design certification. Also, many codes, standards, and design processes, which were not specified in Tier 1, that are acceptable for meeting ITAAC were specified in Tier 2. The result of these actions is that certain significant information only exists in Tier 2 and the NRC does not want this significant information to be changed without prior NRC approval. This Tier 2* information is identified in the generic DCD with italicized text and brackets and the change restriction has compensated for industry's desire to minimize the amount of information in Tier 1.

Although the Tier 2* designation was originally intended to last for the lifetime of the facility, like Tier 1 information, the NRC staff reevaluated the duration of the change restriction for Tier 2* information during the preparation of the proposed rule. The NRC staff determined that some of the Tier 2* information could expire when the plant first achieves full (100%) power, after the finding required by 10 CFR 52.103(g), while other Tier 2* information must remain in effect throughout the life of the plant that references this rule. The determining factors were the Tier 1 information that would govern these areas after first full power and the NRC staff's judgement on whether prior approval was required before implementation of the change due to the significance of the information.

As a result of NEI's comment, the NRC has again reevaluated the durations of the Tier 2* change restrictions. The NRC agrees with NEI that expiration of Tier 2* information for the two evolutionary designs should be consistent, unless there is a design-specific reason for a different treatment. One area of Tier 2* information that had different expiration dates was equipment seismic qualification methods. The NRC has determined that, due to its significance, changes to the qualification methodology must be approved before implementation. Therefore, the Tier 2* designation for this information will not expire for either design.

For reactor core acceptance criteria, the licensing criteria for fuel and control rods had not been developed sufficiently when ABB-CE's DCD was developed and, therefore, the Tier 2* designation was not applied to licensing acceptance criteria for the System 80+ but was applied to specific parameters of the initial core load. Consequently, many changes to ABB-CE fuel designs, including relatively minor changes and reload calculations, must be submitted to the NRC staff for review following the first fuel cycle.

Recent industry proposals for currently operating core fuel designs have indicated a desire to modify the fuel burnup limit design parameter. However, operational experience with fuel with extended fuel burnup has indicated that cores should not be allowed to operate beyond the burnup limits specified in the generic DCDs without NRC approval. This experience is summarized in a Commission memorandum from James M. Taylor, "Reactivity Transients and High Burnup Fuel," dated September 13, 1994, including Information Notice (IN) 94-64, "Reactivity Insertion Transient and Accident Limits for High Burnup Fuel," dated August 31, 1994. Experimental data on the performance of high burnup fuel under reactivity insertion conditions became available in mid-1993. The NRC issued IN 94-64 and IN 94-64, Supplement 1, on April 6, 1995, to inform industry of the data. The unexpectedly low energy deposition to initiation of fuel failure in the first test rod (at 62 GWd/MTU) led to a re-evaluation of the licensing basis assumptions in the NRC's standard review plan (SRP). The NRC performed a preliminary safety assessment and concluded that there was no immediate safety issue for currently operating cores because of the low to medium burnup status of the fuel (refer to Commission Memorandum from James M. Taylor, "Reactivity Transients and Fuel Damage Criteria for High Burnup Fuel," dated November 9, 1994, including an NRR safety assessment and the joint NRR/RES action plan). Therefore, the NRC has determined that additional actions by industry are not needed to justify current burnup limits for operating reactor fuel designs.

However, the NRC is working with industry and fuel vendors to assess fuel performance for high burnup fuel and reevaluate current SRP licensing acceptance criteria. Because the fuel failure threshold may decline with increasing burnup, the NRC is assessing licensing-basis design acceptance criteria as a function of burnup or a performance-based design criteria. Therefore, the NRC has determined that it needs to carefully consider any proposed changes to the fuel burnup parameter in the generic DCDs for these fuel designs until further experience is gained with extended fuel burnup characteristics.

Requests for extension of these burnup limits will be evaluated based on supporting experimental data and analyses, as appropriate, for current and advanced fuel designs. Therefore, the NRC has determined that the Tier 2* designation for the fuel burnup parameters should not expire for the lifetime of a referencing facility.

Technical Specifications.

In its comments in Attachment B, pp. 124-129, NEI requested that the NRC establish a single set of integrated technical specifications governing the operation of each plant that references this design certification and that the technical specifications be controlled by a single change process. The NRC included the technical specifications for the standard designs in the generic DCD in order to maximize the standardization of the technical specifications for plants that reference this design certification. As a result, a plant that references this design certification would have two sets of technical specifications associated with its license: (1) technical specifications from Chapter 16 of Tier 2 of the generic DCD and applicable to the standardized portion of the plant, and (2) those technical specifications applicable to the site-specific portion for the plant. While each portion of the technical specifications would be subject to a different change process, the substantive aspects of the change processes would be essentially the same.

Although a potential loss in standardization may result, the Commission has decided not to require COL applicants to conform with the technical specifications in Chapter 16 of the generic DCD. These technical specifications will not be part of Tier 2 and will be treated like conceptual design information. Applicants who reference this appendix will be able to develop new technical specifications for their plant as part of their COL application and the NRC will consider future operating experience when it reviews the new technical specifications. However, the NRC expects that COL applicants will develop their new technical specifications based on the technical specifications in Chapter 16 that were prepared for this standard design. The change process for the new technical specifications will be similar to the current process in § 50.90 and § 50.92, provided that the changes do not affect the information in the DCD. A consequence of this decision is that there will not be any issue resolution for the technical specifications developed during this design certification review.

Additional aspects of the change process.

In its comments in Attachment B, pp. 109-118, NEI raised some additional concerns with the Tier 2 change process. The first concern was with the process for determining if a departure from Tier 2 information constituted an unreviewed safety question. Specifically, NEI identified the following statement in section III.H of the proposed rule. ". . . if the change involves an issue that the NRC staff has not previously approved, then NRC approval is required." A clarification of this statement was provided in the May 11, 1995 public meeting on design certification (pp. 12-14 of meeting transcript), when the NRC staff stated that the NRC was not creating a new criterion for determining unreviewed safety questions but was explaining existing criteria. A further discussion of this statement took place between the staff and counsel to GE Nuclear Energy at the December 4, 1995 public meeting on design certification (pp. 53-56 of meeting transcript), in which counsel for GE Nuclear Energy agreed that a departure which creates an issue that was not previously reviewed by the NRC would be evaluated against the existing criteria for determining whether there was an unreviewed safety question. With this clarification at the public meeting, the Commission does not believe there is a need for a change to the language of this appendix.

NEI also requested that Section 8(b) of this appendix be revised to state that exemptions are not required for changes to the technical specifications or Tier 2* information that do not involve an unreviewed safety question. The Commission has determined that this is consistent with the Commission's intent that permitted departures from Tier 2* under Section 8(b) of this appendix should not also require an exemption, unless otherwise required by, or implied by extension from 10 CFR Part 52, Subpart B and, accordingly, has revised Section 8(b) of this appendix. As discussed above, the technical specifications in Chapter 16 of the generic DCD are not requirements of this appendix and, therefore, the issue of exemptions to these technical specifications is moot. NEI also raised a concern with the requirement for quarterly reporting of design changes during the construction period. This issue is discussed in section III.J.

Finally, NEI raised a concern with the status of 10 CFR 52.63(b)(2) in the two-tiered rule structure that has been implemented in this appendix and claimed that 10 CFR 52.63(b) clearly embodies a two-tier structure. NEI's claim is not correct. The Commission adopted a two-tiered design certification rule structure (Commission SRM on SECY-90-377,

dated February 15, 1991) and created a change process for Tier 2 information that has the same elements as the Tier 1 change process. In addition, the Tier 2 change process includes a provision that is similar to 10 CFR 50.59, namely Section 8(b)(5). Therefore, as stated in section II (Topic 6) of the proposed rule, there is no need for 10 CFR 52.63(b)(2) in the two-tiered change process that has been implemented for this Appendix.

3. Need for Applicable Regulations.

Comment Summary. NEI and the other industry commenters criticized Section 5(c) of the proposed design certification rule, which designated additional applicable regulations for the purposes of 10 CFR 52.48, 52.54, 52.59, and 52.63 (refer to NEI Comment, Attachment B, pp. 24-56).

Response. In its first group of comments, NEI stated that there is no requirement in 10 CFR Part 52 that compels the Commission to adopt these new applicable regulations, that the new applicable regulations are not necessary for adequate protection or to improve the safety of the standard designs, and that the applicable regulations are inconsistent with the Commission's SRM, dated September 14, 1993. Although the Commission was not compelled to adopt new applicable regulations, it has been developing them in accordance with the goals of 10 CFR Part 52 and to achieve the purposes of 10 CFR 52.48, 52.54, 52.59, and 52.63 (refer to SECY-96-028, dated February 6, 1996). The Commission chose design-specific rulemaking rather than generic rulemaking for the new technical and severe accident issues. The Commission adopted this approach early in the design certification review process because it was concerned that generic rulemakings would cause significant delay in the design certification reviews and it was thought that the new requirements would be design-specific. In its SRM on SECY-91-262, dated January 28, 1992, the Commission approved the NRC staff's recommendation to proceed with design-specific rulemakings through individual design certifications to resolve these technical and severe accident issues for the U.S. ABWR and System 80+ designs and continued to support this approach, as stated in its SRM on SECY-93-226, dated September 14, 1993. However, the Commission delayed its decision on the need for generic rulemaking for advanced LWRs. It is this later guidance that NEI appears to have misunderstood.

In its second group of comments, NEI stated that the applicable regulations are unnecessary because the NRC staff has applied these technical positions in reviewing and approving the standard designs. In addition, each of these positions has corresponding

staff-approved provisions in the respective design control documents (DCD) and these provisions already serve the purpose of applicable regulations for all of the situations identified by the NRC staff. NEI's statement that information in the DCD will constitute an applicable regulation confuses the difference between design descriptions approved by rulemaking and the regulations (safety standards) that are used as the basis to approve the design. During a meeting on April 25, 1994, and in a letter from Mr. Dennis Crutchfield (NRC) to Mr. William Rasin (NEI), dated July 25, 1994, the NRC staff stated that design information cannot function as a surrogate for the new (design-specific) applicable regulations because this information describes only one method for meeting the regulation and would not provide a basis for evaluating proposed changes to the previously approved design descriptions. The NRC needs the applicable regulations to evaluate proposed changes (§ 52.63) and requests for renewals (§ 52.59). Also, the technical positions that form the basis for the new applicable regulations were used during the reviews because the design-specific rulemaking for the new applicable regulations has been established in parallel with the design certification rulemaking, in accordance with Commission guidance.

In its third group of comments, NEI is concerned that "broadly stated" applicable regulations could be used in the future by the NRC staff to impose backfits on applicants and licensees that could not otherwise be justified on the basis of adequate protection of public health and safety. However, NEI acknowledged in its comments that the NRC staff did not intend to reinterpret the applicable regulations to impose compliance backfits and because implementation of the applicable regulations was approved in the DCD, the NRC staff could not impose a backfit on the approved implementation without meeting the standards in the change process. In response to NEI's comments, the final design certification rules state that the standard designs meet the applicable regulations and by approving the design information that describes how these regulations were met, the potential for differing interpretations of the new applicable regulations has been minimized. Despite these assurances, the Commission has decided to include a special provision in Section 8(c) of this appendix for compliance backfits to the additional applicable regulations identified in Section 5(c) of this appendix.

Finally, in response to the comment that portions of some of the additional applicable regulations are requirements on an applicant or licensee who references this appendix, the Commission has removed those requirements from the new applicable regulations in Section

5(c) of this appendix and moved them to Section 4 of this appendix. Section 4 sets forth additional requirements applicable to applicants and licensees who reference this appendix.

4. Analysis of New Applicable Regulations.

In response to question 4 in the proposed design certification rules, NEI provided additional comments on the specific wording of each new applicable regulation. The following discussion responds to NEI's comments in the order that the new applicable regulations are listed in Section 5(c) of this appendix. Statements, in the following discussion, that indicate Commission approval of staff positions in SECY papers constitute "tentative" approval subject to the Commission's final decision in this design certification rulemaking.

Intersystem LOCA

Section 5(c)(1) imposes a requirement on the designer to reduce the possibility of a loss of coolant accident (LOCA) outside containment by designing as much of the systems and subsystems connected to the reactor coolant system (RCS) as possible to an ultimate rupture strength at least equal to the normal RCS operating pressure.

The requirements for resolving GSI 105, "Interfacing System LOCA at LWRs," were established in SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements," dated January 12, 1990, and the Staff Requirements Memorandum (SRM) dated June 26, 1990. The Commission position regarding ISLOCA protection is that future ALWR designs should reduce the possibility of a LOCA outside containment by designing, to the extent practicable, all systems and subsystems connected to the RCS to a pressure that would ensure reasonable protection against burst failure should the low-pressure system be subjected to full RCS pressure.

The Commission has determined that using a design pressure equal to 40 percent of the normal operating RCS pressure resolves this issue for the design because that value will provide sufficient design margin such that (1) the likelihood of rupture of the pressure boundary is low, (2) the likelihood of intolerable leakage of flange joints or valve bonnets is reasonably low, and (3) an acceptably small number of piping components might undergo gross yielding. The Commission also notes that the degree of isolation or number

of barriers (e.g., three isolation valves) is not sufficient justification for using low-pressure components that are practical to design to a higher pressure. For example, piping runs should always be designed to meet the higher pressure, as should all associated flanges, connectors, and packings, including valve stem seals, pump seals, heat exchanger tubes, valve bonnets, and RCS drain and vent lines. The design should attempt to reduce the level of pressure challenge to all systems and subsystems connected to the RCS should an ISLOCA occur. The Commission does recognize, however, that all systems must eventually interface with atmospheric pressure and that it would be difficult or prohibitively expensive to design certain large tanks and heat exchangers to a higher pressure.

ABB-CE provided acceptable justification for each interfacing system and component not designed to the higher pressure by demonstrating that it is not practicable to reduce the pressure challenge any further. ABB-CE also demonstrated a compensating isolation capability for each such interface. In NUREG-1462, "Final Safety Evaluation Report [FSER] Related to the Certification of the System 80+ Design," the NRC concluded that the System 80+ design meets the criteria of SECY-90-016 regarding ISLOCA prevention and mitigation. Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(1) of this appendix.

Comment Summary. NEI raised the following objections to the proposed wording:

! The phrases "the effects . . . shall be minimized" and "to the extent practical" are vague and subject to numerous interpretations. The state-of-the-art may change over time, and what is infeasible today may be practical in the future. If so, NRC's proposed language could be used to require a backfit to the standard design even though such a backfit would not be needed for adequate protection. This result would be destabilizing and contrary to the intent of design certification.

! Additionally, the phrase "the effects . . . shall be minimized" is inconsistent with "to the extent practical." It also deviates from the staff position in SECY-90-16 that the Commission approved in a Staff Requirements Memorandum (SRM) dated June 26, 1990, which does not require the effects of intersystem LOCAs to "be minimized."

! Finally, "withstand" has no standard definition, and could be subject to future reinterpretation.

Response. In response to the comments from NEI, the Commission has removed the phrases "the effects...shall be minimized," and "withstand" and has reworded the regulation to make it clearer and consistent with SECY-90-016. Finally, the term "to the extent practical" was modified to reflect that the Commission intends to define practicality as the capabilities and means available at the time of design certification.

Inservice Testing of Pumps and Valves

Section 5(c)(2) imposes a requirement on the designer to allow for proper testing of pumps and valves. This requirement is necessary to ensure that adequate testing to verify operability can be conducted. For check valves in particular, the important issue is the ability to adequately monitor or assess the condition of the valve.

In the FSER, the staff states that a licensee will periodically test the performance and measure performance parameters of safety-related pumps and valves in accordance with ASME Code Section XI, as required by 10 CFR 50.55a(f). Periodic measurements of various parameters will be compared to baseline measurements to detect long-term degradation of the pump or valve performance. The tests, measurements, and comparisons will ensure the operational readiness of these pumps and valves. However, as discussed in SECY-90-016, the staff determined that ASME Code Section XI requirements do not assure the necessary level of component operability that is desired for evolutionary LWR designs. Accordingly, in SECY-90-016, as supplemented by the staff's April 27, 1990, response to comments by the ACRS, the staff recommended criteria to the Commission to be used to supplement Section XI of the ASME Code. In its SRM of June 26, 1990, on SECY-90-016, the Commission approved the staff's recommendations. Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(2) of this appendix.

Comment Summary. NEI raised the following objections to the proposed wording:

! With respect to paragraph (i), it is not always possible to test check valves at maximum design flow. Some check valves can only be tested at full system flow. Thus, paragraph (i) is not possible to implement fully.

! Paragraph (ii) relates to the inservice testing program, not to the design. Inservice testing programs are the responsibility of the applicant/licensee, and are not appropriate as an "applicable regulation" for the standard design. If the NRC believes

that the requirements in this paragraph should be imposed on applicants and licensees, it should initiate rulemaking to amend Part 50 to do so.

! Additionally, the term "advanced non-intrusive techniques" is vague and its application will change as the state-of-the-art changes. Therefore, this provision is particularly susceptible to changing interpretations and potential backfits over time. This result would be destabilizing and contrary to the intent of design certification.

Response. The staff agrees with NEI's first comment. Paragraph (i) of the rule was rewritten to allow for less than maximum design flow. The staff believes that it is acceptable to exercise check valves with sufficient flow to fully-open the valve, provided the valve's full-open position can be positively confirmed, or with the maximum required accident flowrate.

With regard to NEI's second comment regarding the appropriateness of addressing applicant/licensee issues in the design certification rulemaking, the Commission has reconsidered its position and moved these issues to Section 4 of this appendix which sets forth requirements for applicants and licensees referencing this design certification rule. While it would be possible to amend 10 CFR 50.55a to reflect these IST requirements, the Commission believes it is better to consolidate the design certification-specific technical requirements which are applicable to plants referencing this design certification rule in the design certification rule itself.

Digital Instrumentation and Control Systems

Section 5(c)(3) imposes a requirement on the designer to consider the unique concerns related to the use of digital instrumentation and control (I&C) systems. The I&C systems of this design are microprocessor-based systems that share processing functions (software) and process equipment (hardware). Therefore, a hardware design error, a software design error, or a software programming error may cause redundant equipment to fail. The Commission is concerned that the use of digital computer technology could result in safety-significant common-mode failures (CMFs). CMFs could both defeat the redundancy achieved by the hardware architectural structure and result in the loss of more than one echelon of defense-in-depth provided by the I&C system. The two principal factors for defense against CMFs are quality and diversity. The Commission position on defense-in-

depth and diversity for ALWRs, as discussed in the dated July 21, 1993, SRM in response to SECY-93-087, is as follows:

(1) The vendor or applicant shall assess the defense-in-depth and diversity of the proposed instrumentation and control system to demonstrate that vulnerabilities to CMFs have been adequately addressed.

(2) In performing the assessment, the vendor or applicant shall analyze each postulated event that is in the accident analysis section of the SAR using best-estimate methods. The vendor or applicant shall demonstrate adequate diversity within the design for each of these events.

(3) If a postulated CMF could disable a safety function, then a diverse means, with a documented basis that the diverse means is unlikely to be subject to the same CMF, shall be required to perform either the same function or a different function. The diverse or different function may be performed by a non-safety system if the system is of sufficient quality to perform the necessary function under the associated event conditions.

(4) A set of displays and controls located in the main control room (MCR) shall be provided for system-level actuation and control of critical safety functions. The displays and controls shall be independent and diverse from the safety computer system identified in items 1 and 3.

Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(3) of this appendix.

Comment Summary. NEI commented that the terms "adequate defense" and "critical safety functions" are vague and subject to numerous interpretations.

Response. The Commission does not agree with NEI's comment. The terms are widely used in industry standards and the Commission has clearly found the design acceptable as it is.

Alternate Offsite Power Source to Non-Safety Equipment

Section 5(c)(4) imposes a requirement on the designer to include a second offsite power source and to ensure that it has sufficient capacity and capability to provide power to non-safety equipment sufficient to provide the operator with the capability to bring the plant to a safe shutdown, following a loss of the normal power supply and plant trip. The second offsite power source will significantly reduce the number of plant trips that

involve a loss of power to the non-safety loads and require that the plant be shut down under natural circulation. Such an additional source of power would improve plant safety, because these events continue to be identified as more severe than the turbine-trip-only event in standard plant safety analysis reports.

The requirement for alternate sources of power for non-safety-related loads arose from an NRC policy issue. In SECY-91-078, the staff recommended that the Commission approve the staff's position that an evolutionary plant design should include an alternate power source to the non-safety-related loads, unless it can be demonstrated that the design margins are so great that transients resulting from a loss of non-safety power event are no more severe than those associated with the turbine-trip-only event in current existing plant designs. In its August 15, 1991 SRM, the Commission approved the staff's position. The staff, in its safety evaluation report (SER) for the EPRI Evolutionary Utility Requirements Document (URD) clarified the intent of this position by stating that: "...an alternate power source be provided to a sufficient string of non-safety loads so that forced circulation could be maintained, and the operator would have available to him the complement of non-safety equipment that would most facilitate his ability to bring the plant to a stable shutdown condition, following a loss of the normal power supply and plant trip." The staff believes that this issue provides defense-in-depth. Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(4) of this appendix.

Comment Summary. NEI commented that the terms "most facilitate" and "necessary complement of non-safety equipment" are vague and subject to numerous interpretations.

Response. The Commission has decided to modify the words to more specifically define the non-safety equipment required.

Offsite Power Source to Safety Divisions

Section 5(c)(5) imposes a requirement on the designer to ensure that faults from non-safety loads will not effect safety buses. Powering safety buses directly from an offsite power source is an NRC policy issue. The issue was raised by the staff because feeding safety buses from the offsite power sources through non-safety buses is not the most reliable configuration. In this configuration, the safety loads are subjected to transients caused by the non-Class 1E loads and add additional failure points between the offsite power sources and safety loads. To overcome these shortcomings, the staff

recommended energizing the safety buses directly from the offsite power source's transformers.

In its August 15, 1991, SRM, on SECY-91-078, the Commission approved the position that an evolutionary plant design should include at least one offsite circuit to each redundant safety division supplied directly from one of the offsite power sources with no intervening non-safety buses in such a manner that the offsite source can power the safety buses upon a failure of any non-safety bus. Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(5) of this appendix.

Comment Summary. NEI commented that although the staff found the designs acceptable, it is possible that in the future members of the NRC staff could determine that the designs do not satisfy the literal language of the NRC's proposed applicable regulation.

Response The Commission has decided to modify the words to clarify design requirements for the offsite circuit to more clearly reflect the original intent.

Post-Fire Safe Shutdown

Section 5(c)(6) imposes a requirement on the designer to ensure that, among other things, the plant can be shutdown safely after a fire that renders all equipment in any one fire area inoperable.

As background information, the NRC established fire protection requirements for nuclear power plants in GDC 3, 10 CFR 50.48, and Appendix R to 10 CFR Part 50. The Commission considered Sections III.G, III.J, and III.O, and Appendix R to be of particular importance. In July 1981, NRC revised BTP APCS 9.5-1 (SRP Section 9.5.1) to include these provisions from Appendix R.

The Commission has also issued supplemental guidance on fire protection in documents such as Generic Letter (GL) 81-12 (45 FR 76602, November 19, 1981), dated February 20, 1981, and GL 86-10, dated April 24, 1986. GL 81-12 presents information on safe-shutdown methodology and GL 86-10 presents technical information on conformance with National Fire Protection Association codes and standards.

The Commission has concluded that fire protection issues raised through operating experience and through the External Events Program must be resolved for evolutionary ALWRs. To minimize fire as a significant contributor to the likelihood of severe accidents for advanced plants, the Commission concluded that current NRC guidance must be

enhanced. The enhanced guidelines are discussed in SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements," dated January 12, 1990 and in SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light Water Reactor (ALWR) Designs".

The Commission expects any new reactor design to propose fire protection systems based on the best technology available, not on the methods allowed for plants already operating or in the advanced stages of design and construction. Specifically, the Commission expects that the new designs will have improved separation of fire areas and that physical separation within an area will not generally be relied on. Therefore, the Commission evaluated the fire protection system of the standard designs against the new criteria of SRP Section 9.5.1 (BTP CMEB 9.5-1 Rev. 2), which meets the requirements of GDC 3.

Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(6) of this appendix.

Comment Summary NEI raised the following objections to the proposed wording:

! The reference in paragraph (i) to 10 CFR 50.48 is unnecessary. Section 50.48 is already applicable to plants that reference the ABWR or System 80+ through Section 52.83. Therefore, this reference is redundant and confusing.

! The reference to structures, systems and components "important to safety" in paragraphs (i) and (ii) is inappropriate and incorrect. Part 50, Appendix R, Section III.G.1.a, applies to structures, systems, and components "important to safe shutdown." Furthermore, this applicable regulation does not reflect the language in SECY-90-016, as approved by the Commission in the SRM dated June 26, 1990, which refers to "safe shutdown", not "important to safety" or "safety-related".

! The proposed "applicable regulation" contained in the ABWR FSER, p. 9-57, and in the System 80+ FSER, p. 9-57, recognized that because of "unique design layout", areas other than the containment and control room might be accepted on an individual basis. This provision was deleted in the proposed rule. As discussed on pages 9-59 to 9-61 of the ABWR FSER, the ABWR has certain exceptions to the general provision on separation (e.g., in the main steam tunnel), and the NRC has found this to be acceptable. Without the allowance for "unique design layout," the currently-approved ABWR design might be found to be inconsistent with the "applicable regulation" on fire protection.

! System 80+ does not have 3-hour fire barrier separation between redundant shutdown equipment inside the annulus, as discussed on pg. 9-61 of the FSER. The staff concluded that the design is acceptable, however, because sufficient separation between redundant equipment exists in the annulus. Although protection is provided by separation in the annulus, deletion of the allowance for ". . . unique design layout. . ." for areas other than the containment and control room could allow the adequacy of the separation provisions in the annulus to be challenged.

! Furthermore, because the allowance for "unique design layout" was in SECY-90-016, as approved by the Commission in the SRM dated June 26, 1990, the "applicable regulation" is inconsistent with the Commission's previous directions.

! The term "to the extent practical" is vague and subject to numerous interpretations. Additionally, as the state-of-the-art evolves, what is "practical" will evolve, resulting in the potential for destabilizing backfits to the standard design.

Response The Commission has decided to modify the wording. Paragraph (i) of the regulation has been deleted in response to the first comment. The references to SSCs that are "important to safety" have been changed to "important to safe shutdown" in response to the second comment. The exception for the containment annulus was added to address the third and fifth comments. Finally, the term "to the extent practical" was modified to reflect that the Commission intends to define practicality as the capabilities and means available at the time of design certification.

Analysis of External Events

Section 5(c)(7) imposes a requirement on the designer to include both internal and external events in the design-specific probabilistic risk assessment. In its July 21, 1993 SRM on SECY-93-087, the Commission approved several positions related to this topic including: (1) the requirement that the analyses submitted in accordance with 10 CFR 52.47 include an assessment of internal events; (2) the use of 1.67 times the design basis safe shutdown earthquake for a margin-type assessment of seismic events; and (3) the requirement that the ALWR vendors should perform bounding analyses of site-specific external events likely to be a challenge to the plant. In Generic Letter 88-20, "Individual Plant Examinations for Severe Accident Vulnerabilities - 10 CFR 50.54(f)" and its supplements, the NRC staff stated that construction permit holders and power reactor

Licensees should consider the safety implications of both internal and external events. Such consideration should involve performing separate individual plant examinations (IPes) and individual plant examinations for external events. PRAs and IPes that have evaluated both internal and external events generally estimate the risks from external events to be the same order of magnitude as internal events. Therefore, the Commission concluded that the design-specific PRAs required in 10 CFR 52.47 should include an assessment of both internal and external events.

Lessons from past risk-based studies indicate that fire, internal floods, and seismic events can be important potential contributors to core damage. However, the estimates of the core damage frequencies for fire and seismic events continue to include considerable uncertainty. Consequently, the Commission concluded that fire and seismic events can be evaluated using simplified (bounding) probabilistic methods and margin methods similar to those developed for existing plants, supported by insights from internal event PRAs, including ALWR design-specific PRAs.

The Commission determined that the plant designer can best determine the seismic capability of the plant through a combined approach that takes advantage of the strengths of both PRA and margins methods. This approach (based on an internal events PRA, its existing event and fault trees, and its random failures and human errors) allows for a comprehensive and integrated treatment of the plant's response to an earthquake. This approach should yield meaningful measures of a proposed design's seismic capability.

The major difference between a seismic PRA and the proposed PRA-based margins approach is that the latter does not combine fragility curves with hazard curves. Rather, the PRA-based margins approach measures the robustness of the plant to withstand earthquakes of a given ground acceleration level. This method eliminates the need to deal with uncertainty in the seismic hazard curve for the site and identifies potential design-specific seismic vulnerabilities. Understanding these vulnerabilities may be useful in developing the reliability assurance programs, identifying operator training requirements, and focus on accident management capabilities.

The Commission believes that it is important to fully understand potentially significant seismic vulnerabilities and other seismic insights. The Commission concluded that this information would be captured by a PRA-based seismic margins analysis that considers sequence-level high confidence in low probability of failure (HCLPF) values and

fragilities for all sequences leading to core damage or containment failures up to approximately one and two-thirds of the SSE.

Based on the FSER, the Commission concludes that the design-specific PRA submitted by ABB-CE satisfies Section 5(c)(7) of this appendix.

Comment Summary. There were no technical comments on this applicable regulation.

Alternate AC Power Source

Section 5(c)(8) imposes a requirement on the designer to include an on-site alternate AC power source in the design to deal with station blackout conditions. As background information, the staff developed a policy issue in SECY-90-016, dated January 12, 1990, that was approved by the Commission on June 26, 1990, which requires that the evolutionary ALWRs meet the requirements of the station blackout (SBO) rule by including an alternate AC power source (e.g., CTG) of diverse design capable of powering at least one complete set of normal shutdown loads and to back up the EDGs. The Commission's policy is that a coping analysis or a less capable alternate AC source would not be acceptable because the CTG provides the operator with power to more equipment to cope with the event, and does not require complicated operator actions to shed loads. Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(8) of this appendix.

Comment Summary. NEI commented that the NRC staff's language does not reflect the specifics of each of the standard designs. Moreover NEI stated that, as written, the "applicable regulation" appears to conflict with the regulation that already governs use of an alternate AC power source, § 50.63.

Response. The Commission did not necessarily intend that the language for each regulation be different for each design. The staff clearly stated the requirement that the designs were evaluated against. This requirement is meant to be more restrictive than 50.63 in that an alternate AC source that is fully capable of powering at least one complete set of equipment necessary to achieve and maintain safe-shutdown is the required approach.

Core Debris Cooling

Section 5(c)(9) imposes requirements on the designer to include features to enhance core debris cooling in the design. As background information, core debris coolability and quenchability have been the subject of extensive research over the past decade; however, much uncertainty still exists relative to this phenomenon which will most likely not be resolved in the near future. Because of this uncertainty, the Commission decided that the question is not whether coolability or quenchability has been achieved or can be achieved; but rather, what is the impact on the containment design if they are not achieved.

Corium-concrete interaction (CCI) is a severe-accident phenomenon that involves the melting and decomposition of concrete in contact with molten core debris. This phenomenon may occur following accident sequences which result in molten core debris breaching the reactor vessel and spreading onto the floor of the reactor cavity. The thickness of the layer of core debris within the reactor cavity depends upon the amount of core debris, its spreadability, and the area of the reactor cavity floor. Once on the reactor cavity floor, the molten core debris may react with the concrete and any available water producing non-condensable gases, water vapor, and heat from exothermic reactions.

CCI can challenge the containment by various mechanisms including: pressurization from non-condensable gas and steam generated, destruction of structural support members, and melt-through of the containment liner. Non-condensable gases, primarily carbon dioxide, carbon monoxide, and hydrogen, are released from the concrete as it decomposes and are formed from reactions between water and metals within the molten core debris. The core debris and concrete are heated from the combined effects of decay heat and exothermic chemical reactions.

In its July 21, 1993, SRM on SECY-93-087, the Commission approved the position that both the evolutionary and passive LWR designs meet the following criteria: (1) provide reactor cavity floor space to enhance debris spreading; (2) provide a means to flood the reactor cavity to assist in the cooling process; (3) protect the containment liner and other structural members with concrete if necessary; and (4) ensure that the best-estimate environmental conditions (pressure and temperature) resulting from core-concrete interactions do not exceed ASME Code Service Level C limits for steel containments or factored load category for concrete containments, for approximately 24 hours. In

addition, ensure that the containment capability has margin to accommodate uncertainties in the environmental conditions from CCIs.

Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(9) of this appendix.

Comment Summary. NEI raised the following objections to the proposed wording:

! The terms "reduce the potential for," "enhance," "assist in the cooling process," and "most significant" are vague and subject to numerous interpretations.

! The term "structural members" lacks specificity.

! The term "best-estimate" is open-ended, and could lead to needless recalculations of "estimates" as the state-of-the-art evolves.

Response The Commission has decided to modify the wording. The specific severe accident sequences have been identified instead of using the term "most significant." The size of the reactor cavity floor space and the actual structural members of concern have also been identified. To address the comment on the term "best estimate," the section of the DCD that defines the environmental conditions is now cited.

High Pressure Core Melt Ejection

Section 5(c)(10) imposes a requirement on the designer to include a means to depressurize the reactor coolant system and cavity design features to mitigate the effects of a high pressure core melt ejection accident. As background information, in its June 26, 1990, SRM on SECY-90-016, the Commission approved the position that evolutionary LWR designs should have a depressurization system and cavity design features to contain ejected core debris. In addition, the Commission stated that the cavity design, as a mitigating feature, should not unduly interfere with such operations as refueling, maintenance, or surveillance.

In its July 21, 1993, SRM on SECY-93-087, the Commission modified its position slightly and approved the general criteria that the evolutionary LWR designs should have a reliable depressurization system and cavity design features to decrease the amount of ejected core debris that reaches the upper containment.

On the basis of engineering judgment, the Commission believes that examples of cavity design features that will decrease the amount of ejected core debris reaching the upper

containment are ledges or walls that would deflect core debris and a tortuous path from the reactor cavity to the upper containment.

Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(10) of this appendix.

Comment Summary. NEI commented that the terms "reliable means" and "reduce the amount" are vague and subject to numerous interpretations. NEI also stated that what is considered "reliable" may change as the state-of-the-art changes, leading to the potential for destabilizing backfits to the standard designs.

Response. The Commission has decided to modify the wording to allow for a safety-related depressurization system for this application. The Commission did not remove the phrase "reduce the amount" because it believes that it is the most appropriate wording based on the engineering judgement involved in the review.

Equipment Survivability

Section 5(c)(11) imposes a requirement on the designer to perform analyses to demonstrate that certain equipment and instrumentation can function under severe accident environmental conditions. As background information, in its SRM of July 21, 1983, on SECY-93-087, the Commission approved the position that for the review of the credible severe-accident scenarios for ALWRs, the Commission will evaluate the design certification applicant's identification of the equipment needed to perform mitigative functions as well as the conditions under which the mitigative systems must operate.

Beyond design basis events can generally be categorized into in-vessel and ex-vessel severe accidents. The environmental conditions resulting from these events are generally more limiting than those from design bases events. The Commission established a criterion to provide a reasonable level of confidence that the necessary equipment will function in the severe accident environment for the time span for which it is needed. This criterion is commonly referred to as "equipment survivability" and is fundamentally different from equipment qualification.

The applicable criteria for mechanical and electrical equipment and instrumentation required for recovery from in-vessel severe accidents are provided in 10 CFR 50.34(f).

! Part 50.34(f)(2)(ix)(c) states that equipment necessary for achieving and maintaining safe shutdown of the plant and maintaining containment integrity will perform

its safety function during and after being exposed to the environmental conditions attendant with the release of hydrogen generated by the equivalent of a 100 percent fuel-clad metal-water reaction including the environmental conditions created by activation of the hydrogen control system.

! Part 50.34(f)(3)(v) states that systems necessary to ensure containment integrity shall be demonstrated to perform their function under conditions associated with an accident that releases hydrogen generated from 100 percent fuel-clad metal-water reaction.

! Part 50.34(f)(2)(xvii) requires instrumentation to measure containment pressure, containment water level, containment hydrogen concentration, containment radiation intensity, and noble gas effluents at all potential accident release points.

! Part 50.34(f)(2)(xix) requires instrumentation adequate for monitoring plant conditions following an accident that includes core damage.

The applicable criteria for mechanical and electrical equipment required to mitigate the consequences of ex-vessel severe accidents are discussed in the Equipment Survivability section of SECY-90-016. In its SRM of June 26, 1990, relating to SECY-90-016, the Commission approved the position that features provided only for severe-accident protection, prevention and mitigation (i.e. not required for design basis accidents) need not be subject to the 10 CFR 50.49 environmental qualification requirements; 10 CFR Part 50, Appendix B quality assurance requirements; and 10 CFR Part 50, Appendix A redundancy/diversity requirements. The reason for this judgment is that the Commission believes that severe core damage accidents should not be treated as design basis accidents (DBAs).

However, mitigation features must be designed to provide reasonable assurance that they will operate in the severe-accident environment for which they are intended and over the time span for which they are needed. In cases where safety-related equipment (equipment provided for DBAs) is relied upon to cope with severe accident situations, there should be reasonable assurance that this equipment will survive accident conditions for the period that is needed to perform its intended function.

Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(11) of this appendix.

Comment Summary. NEI raised the following objections to the proposed wording:

! The term "needed" is inappropriate because severe accident features are not "needed" to satisfy NRC regulations or assure the adequate protection of public health and safety.

! Further, the term "best available" and "best-estimate" are open-ended, and could lead to needless re-evaluations and the potential for backfits as the state-of-the-art evolves. Such a result is very likely to occur, because research regarding the effects of severe accidents is still in its infancy, and knowledge of severe accident phenomena is rapidly increasing. Additionally, requirements for use of the "best-available" method and "best-estimates" deviate from the provision in SECY-90-16 that was approved by the Commission in the SRM dated June 26, 1990, which only required "reasonable assurance" of equipment survivability.

Response. The Commission has decided to modify the words in response to these comments. The analytical techniques available at the time of the design certification were deemed to be acceptable and the specific environmental conditions were referenced.

Containment Performance

Section 5(c)(12) imposes a requirement on the designer to include features intended to limit the conditional containment failure probability. As background information, the Commission's approach for ensuring containment survivability from severe accident challenges consists of requiring inclusion of accident prevention and consequence mitigation features and the containment performance goal (CPG). The CPG ensures that the containment would perform its function in the face of most severe-accident challenges and that the design (including its mitigation features) would be adequate if called upon to mitigate a severe accident.

Two alternative CPGs were identified in SECY-90-016: a conditional containment failure probability (CCFP) of 0.1 or a deterministic CPG that offers comparable protection. In its June 26, 1990, SRM, the Commission approved the use of the 0.1 CCFP as a basis for establishing regulatory guidance for evolutionary ALWRs. In assessing the probability of containment failure, two definitions of containment failure were considered. These include a CCFP based on structural integrity and on a dose definition. The Commission also directed that the use of a 0.1 CCFP should not be imposed as a requirement, and that the use of the CCFP should not discourage accident prevention.

The FSER contains the staff's analysis of the design features that contribute to limiting the CCFP and their evaluation of the severe accident phenomena that are mitigated by these design features. Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(12) of this appendix.

Comment Summary. NEI commented that the terms "limit" and "more likely" are vague and subject to numerous interpretations.

Response. The Commission has decided to modify the wording. The new regulation defines the CCFP limit as 0.1 and identifies the DCD section which lists the severe accident sequences that are subject to this requirement.

Shutdown Risk

Section 5(c)(13) imposes a requirement on the designer to perform specific assessments of the design with regard to shutdown risk. As background information, various incidents occurring at nuclear power plants during low power and shutdown operation modes over the past several years have raised Commission concerns regarding plant vulnerability during these operating modes. The Commission conducted a comprehensive review of low-power and shutdown operations including hot shutdown, cold shutdown, and refueling at all nuclear plants and other shutdown-related issues identified by foreign regulatory organizations and the NRC. The findings of the review were published in NUREG-1449, "Shutdown and Low Power Operation at Commercial Nuclear Power Plants in the United States."

In SECY-90-016, the Commission identified reduced inventory operation as a significant safety issue. In SECY-93-190, "Regulatory Approach to Shutdown and Low-Power Operations," the Commission discussed the advantages and disadvantages of a proposed rulemaking to establish new regulatory requirements for shutdown and low-power operations in the following areas: outage planning and control, technical specifications, fire protection, and instrumentation.

Based on the above, the Commission required that the designer perform a systematic examination of shutdown risk, including evaluation of specific design features that minimize shutdown risk, quantification of the reliability of the decay heat removal systems, identification of any vulnerabilities introduced by new design features and consideration of fires and floods with the plant in modes other than full power.

The Commission reviewed the applicant's submittals and found that the PRA shutdown risk evaluation was acceptable. Further, the Commission concluded that the designer adequately addressed the shutdown risk concerns in NUREG-1449 and has demonstrated that the design will not introduce significant risk during shutdown operations. Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(13) of this appendix.

Comment Summary. NEI raised the following objections to the proposed wording:

! The terms "systematic," "minimize," "new design features," and "modes other than full power" are vague and subject to numerous interpretations.

! Paragraph (ii) relates to the COL applicant, not the standard design. It is not appropriate as an "applicable regulation" for the standard design. If the NRC believes that the requirements in this paragraph should be imposed on applicants and licensees, it should initiate a rulemaking to amend Part 50 to do so.

! In this regard, NRC has already initiated a rulemaking proceeding to amend Part 50 to include requirements related to shutdown conditions. (See 59 Fed. Reg. 52707 (October 19, 1994).) The NRC should not pre-empt or prejudge the results of that rulemaking by imposing an "applicable regulation" on shutdown conditions.

Response. The Commission has decided to modify the wording. In response to the first comment, the wording has been made more specific where possible. In response to the second and third comments regarding the appropriateness of addressing applicant/licensee issues in the design certification rulemaking, the Commission has reconsidered its position and moved these issues to Section 4 of this appendix which sets forth requirements for applicants and licensees referencing this design certification rule. While the Commission has initiated a rulemaking proceeding to amend Part 50 to include requirements related to shutdown conditions, the Commission believes it is better to consolidate the design certification-specific technical requirements which are applicable to plants referencing this design certification rule in the design certification rule itself.

Steam Generator Tube Ruptures

Section 5(c)(14) imposes a requirement on the designer to perform a systematic evaluation of plant response to a steam generator tube rupture (SGTR). As background information, during a steam generator tube rupture event, the potential exists for lifting of SG safety or relief valves and discharging primary system radioactive inventory outside the containment. Such a containment bypass is undesirable for either a design-basis event or a postulated severe accident. Consequently, the Commission believes that possible mitigation of this containment challenge should be considered.

In its June 26, 1990, SRM on SECY-90-016, the Commission required designers of ALWRs to reduce the potential for conditional containment failure through use of quantitative guidelines or alternative deterministic objectives. In addition, with respect to design-basis events, in the URD, EPRI states that PWR containments should be designed to produce a leak-tight barrier to prevent uncontrolled release of radioactivity in the event of a postulated accident. Containment bypass due to SG tube ruptures would potentially violate containment integrity and hamper meeting both the severe-accident (SECY-90-016) and EPRI containment performance goals.

In its July 21, 1993, SRM on SECY-93-087, the Commission decided that evolutionary PWR designers should consider potential design features that would reduce the amount of containment bypass leakage from such a scenario. The three design features presented were:

- ! incorporating a highly reliable (closed-loop) SG, shell-side, heat removal system that relies on natural circulation and stored water sources
- ! piping some SG relief valve discharge back into the primary containment
- ! increasing the SG shell-side pressure capacity with a corresponding increase in the safety valve setpoints

ABB-CE performed a study to evaluate certain automatic design features that can be used to enable the plant to mitigate SGTR consequences. Sections 3 and 4 of DCD Appendix 5F describe these analyses and provide an evaluation of the attendant benefits and limitations of each of these automatic design features. The realistic analyses were performed for a five-tube rupture case and a single-tube rupture case. ABB-CE assessed the three design alternatives identified in SECY-93-087 in a report dated September 23,

1993 and titled, "Design Alternatives for the System 80+ Nuclear Power Plant," and found these alternatives to be cost prohibitive.

As a result of these analyses, some features have been added to the System 80+ design to reduce the potential containment bypass leakage from the SGTR events. These features include: (1) a design modification to the component cooling water system (CCWS) to ensure continued cooling of the instrument air compressors after a safety injection actuation signal (SIAS), (2) addition of two nitrogen-16 (N-16) radiation monitors (one per SG) in the steamlines, (3) implementation of technical specifications and ITAACs related to N-16 monitors, and (4) emergency operations guidelines (EOGs) improvements. The Commission has determined that this issue has been properly addressed with these enhancements. In arriving at this conclusion, the Commission considered whether the System 80+ design provides sufficient time, diagnostic information, mitigation capability, and proper EOGs for operator coping actions following an SGTR event to mitigate the consequence. Based on the FSER, the Commission concludes that the design satisfies Section 5(c)(14) of this appendix.

Comment Summary. NEI commented that the phrases "best-estimate, systematic evaluation" and "mitigate the amount of" are vague and subject to various interpretations. In addition, what constitutes a best-estimate evaluation is likely to change as evaluation methods evolve. It is also noted that this applicable regulation as stated in the FSER requires evaluation of potential design improvements "which are significant and practical and do not impact excessively on the plant." That phrase does not appear in the applicable regulation as stated in the proposed rules, thereby making the scope of the existing evaluation more vulnerable to challenge. For these reasons, this applicable regulation is destabilizing and contrary to the intent of design certification.

Response. The Commission has decided to modify the words to address NEI's comments and make it consistent with the statements in the FSER.

B. Responses to specific requests for comment.

Only two commenters addressed the specific requests for comments that were set forth in section IV of the proposed rule. These commenters were NEI and the Ohio Citizens for Responsible Energy, Inc. (OCRE). The following discussion provides a summary of the comments and the Commission's response to each of the specific requests.

1. Should the requirements of 10 CFR 52.63(c) be added to a new 10 CFR 52.79(e)?

Comment Summary. OCRE agreed that the requirements of 10 CFR 52.63(c) should be added to a new 10 CFR 52.79(e) and NEI had no objection, as long as the substantive requirements in § 52.63(c) were not changed.

Response. Because there is no objection to adding the requirements of 10 CFR 52.63(c) to Subpart C of Part 52, as 10 CFR 52.79(e), the Commission will consider this amendment as part of a future review of Part 52. This future review will also consider lessons learned from this rulemaking and will determine if 10 CFR 52.63(c) should be deleted from Subpart B of Part 52.

2. Are there other words or phrases that should be defined in Section 2 of the proposed rule?

Comment Summary. Neither NEI nor OCRE suggested other words or phrases that need to be added to the definition section. However, NEI recommended expanded definitions for specific terms in Section 2 of the proposed rule.

Response. The Commission has revised Section 2 of this appendix as a result of comments from NEI and DOE. A discussion of these changes is provided in section II.C.2 and II.C.3.

3. What change process should apply to design-related information developed by a combined license (COL) applicant or holder that references this design certification rule?

Comment Summary. OCRE recommended the change process in Section 8(b)(5)(i) of the proposed rule and stated that it is essential that any design-related COL information including the plant-specific PRA (and changes thereto) developed by the COL applicant or holder not have issue preclusion and be subject to litigation in any COL hearing. NEI recommended that the COL information be controlled by 10 CFR 50.54 and 50.59 but recognized that the COL applicant or holder must also consider impacts on Tier 1 and Tier 2 information.

Response. The Commission will develop a change process for the plant-specific information submitted in a COL application that references this design certification as part of a future review of Part 52. The Commission expects that the change process for the plant-specific portion of the COL application will be similar to Section 8(b)(5). This approach is generally consistent with the recommendations of OCRE and NEI.

The Commission agrees with OCRE that the plant-specific portion of the COL application will not have issue preclusion in the COL proceeding. A discussion of the information that will have issue preclusion is provided in section II.A.1.

4. Are each of the applicable regulations set forth in Section 5(c) of the proposed rule justified?

Comment Summary. OCRE found each of the applicable regulations to be justified and stated that these requirements are responsive to issues arising from operating experience and will greatly reduce the risk of severe accidents for plants using these standard designs. NEI believes that none of the applicable regulations are justified and stated that they are legally and technically unnecessary, could give rise to unwarranted backfits, are destabilizing and, therefore, contrary to the purpose of 10 CFR Part 52.

Response. The Commission has determined that applicable regulations are necessary, as described in section II.A.3. The justification for the specific wording of each applicable regulation is described in section II.A.4

5. Section 8(b)(5)(i) authorizes an applicant or licensee who references the design certification to depart from Tier 2 information without prior NRC approval if the applicant or licensee makes a determination that the change does not involve a change to Tier 1 or Tier 2* information, as identified in the DCD; the technical specifications; or an unreviewed safety question, as defined in Sections 8(b)(5)(ii) and (iii). Where Section 8(b)(5)(i) states that a change made pursuant to that paragraph will no longer be considered as a matter resolved in connection with the issuance or renewal of a design certification within the meaning of 10 CFR 52.63(a)(4), should this mean that the determination may be challenged as not demonstrating that the change may be made without prior NRC approval or that the change itself may be challenged as not complying with the Commission's requirements?

Comment Summary. OCRE believes that the process for making plant-specific departures from Tier 2, as well as the substantive aspect of the change itself, should be open to challenge, although OCRE believes that the second aspect is the more important. By contrast, NEI argued that neither the departure process nor the change should be subject to litigation in any licensing hearing. Rather, NEI argued that any person who wished to

challenge the change should raise the matter in a petition for an enforcement action under 10 CFR 2.206.

Response. The Commission has determined that an interested person should be provided the opportunity to challenge, in an appropriate licensing proceeding, whether the licensee properly complied with the Tier 2 departure process. Therefore, Section 8(b)(5) of this Appendix has been modified. The scope of finality for plant-specific departures is discussed in greater detail in section II.A.1 above.

6. How should the determinations made by an applicant or licensee that changes may be made under Section 8(b)(5)(i) without prior NRC approval be made available to the public in order for those determinations to be challenged or for the changes themselves to be challenged?

Comment Summary. OCRE recommends that the determinations and descriptions of the changes be set forth in the COL application and that they should be submitted to the NRC after COL issuance. Any person wishing to challenge the determinations or changes should file a petition pursuant to 10 CFR 2.206. NEI recommends submitting periodic reports that summarize departures made under Section 8(b)(5) to the NRC pursuant to Section 9(b) of the proposed design certification rules, consistent with the existing process for NRC notifications by licensees under 10 CFR 50.59. These reports will be available in the NRC's Public Document Room.

Response. The Tier 2 departure process in Section 8(b)(5) and the respective reporting requirements in Section 9(b) of the proposed design certification rule [Section 10(b) of this appendix] were based on 10 CFR 50.59. It therefore seems reasonable that the information collection and reporting requirements that should be used to control Tier 2 departures made in accordance with Section 8(b)(5) should generally follow the regulatory scheme in 10 CFR 50.59 (except that the requirements should also be applied to COL applicants), absent countervailing considerations unique to the design certification and combined license regulatory scheme in Part 52. OCRE's proposal raises policy considerations which are not unique to this design certification, but are equally applicable to the Part 50 licensing scheme. In fact, OCRE has submitted a petition (see 59 FR 30308; June 13, 1994) which raises the generic matter of public access to licensee-held information. In view of the generic nature of OCRE's concern and the pendency of

OCRE's petition, which independently raises this matter, the Commission concludes that this rulemaking should not address and resolve this matter.

7. What is the preferred regulatory process (including opportunities for public participation) for NRC review of proposed changes to Tier 2* information and the commenter's basis for recommending a particular process?

Comment Summary. OCRE recommends either an amendment to the license application or an amendment to the license, with the requisite hearing rights. NEI recommends NRC approval by letter with an opportunity for public hearing only for those Tier 2* changes that also involve either a change in Tier 1 or technical specifications, or an unreviewed safety question.

Response. The Commission has developed a change process for Tier 2* information, as described in sections II.A.2 and III.H, which essentially treats the proposed departure as a request for a license amendment with an opportunity for hearing. Since Tier 2* departures require NRC review and approval, and involve a licensee departing from the requirements of this appendix, the Commission regards such requests for departures as analogous to license amendments. Accordingly, Section 8(b)(6) specifies that such requests will be treated as requests for license amendments, and that the proposed Tier 2* departure shall not be considered to be matters resolved by this rulemaking.

8. Should determinations of whether proposed changes to severe accident issues constitute an unreviewed safety question use different criteria than for other safety issues resolved in the design certification review and, if so, what should those criteria be?

Comment Summary. OCRE supports the concept behind the criteria in the proposed rule for determining if a proposed change to severe accident issues constitutes an unreviewed safety question, but proposes changes to the criteria. NEI agrees with the criteria in the proposed rule but recommends an expansion of the scope of information that would come under the special criteria for determining an unreviewed safety question.

Response. The Commission disagrees with the recommendations of both NEI and OCRE. The Commission has decided to retain the special change process in Section 8(b)(5) of the proposed rule for severe accident information, as described in section II.A.2.

9. (a)(1) Should construction permit applicants under 10 CFR Part 50 be allowed to reference design certification rules to satisfy the relevant requirements of 10 CFR Part 50?

(2) What, if any, issue preclusion exists in a subsequent operating license stage and NRC enforcement, after the Commission authorizes a construction permit applicant to reference a design certification rule?

(3) Should construction permit applicants referencing a design certification rule be either permitted or required to reference the ITAAC? If so, what are the legal consequences, in terms of the scope of NRC review and approval and the scope of admissible contentions, at the subsequent operating license proceeding?

(4) What would distinguish the "old" 10 CFR Part 50 2-step process from the 10 CFR Part 52 combined license process if a construction permit applicant is permitted to reference a design certification rule and the final design and ITAAC are given full issue preclusion in the operating license proceeding? To the extent this circumstance approximates a combined license, without being one, is it inconsistent with Section 189(b) of the Atomic Energy Act (added by the Energy Policy Act of 1992) providing specifically for combined licenses?

(b)(1) Should operating license applicants under 10 CFR Part 50 be allowed to reference design certification rules to satisfy the relevant requirements of 10 CFR Part 50?

(2) What should be the legal consequences, from the standpoints of issue resolution in the operating license proceeding, NRC enforcement, and licensee operation if a design certification rule is referenced by an applicant for an operating license under 10 CFR Part 50?

(c) Is it necessary to resolve these issues as part of this design certification, or may resolution of these issues be deferred without adverse consequence (e.g., without foreclosing alternatives for future resolution).

Comment Summary. OCRE argued that a construction permit applicant should be allowed to reference design certifications and that the applicant be required to reference ITAAC because they are Tier 1. OCRE indicated that in a construction permit hearing, those issues representing a challenge to the design certification rule would be prohibited pursuant to 10 CFR 2.758. At the operating license stage, only an applicant whose construction permit referenced a design certification rule should be allowed to reference

the design certification. In the operating license hearing, issues would be limited to whether the ITAAC have been met. Requiring a construction permit applicant to reference the ITAAC would not be the same as a combined license under Part 52, in OCRE's view, apparently because the specific hearing provisions of 10 CFR 52.103 would not be employed. Finally, OCRE argued that resolution of these issues could be safely deferred because the circumstances with which these issues attend are not likely to be faced.

NEI also argued that a construction permit applicant should be allowed to reference design certifications. However, NEI believed that the applicant should be permitted, but not required, to reference the ITAAC. If the applicant did not reference the ITAAC, then "construction-related issues" would be subject to both NRC review and an opportunity for hearing at the operating license stage in the same manner as construction-related issues in current Part 50 operating license proceedings. NEI reiterated its view that design certification issues should be considered resolved in all subsequent NRC proceedings. With respect to deferring a Commission decision on the matter, NEI suggested that these issues be resolved now because the industry wishes to "reinforce" the permissibility of using a design certification in a Part 50 proceeding. Further, NEI argues that deletion of all mention of construction permits and operating licenses in the design certification rule could be construed as indicating the Commission's desire to preclude a construction permit or operating license applicant from referencing a design certification.

Response. Although Part 52 provides for referencing of design certification rules in Part 50 applications and licenses, the Commission wishes to reserve for future consideration whether a Part 50 applicant should be permitted to reference this design certification and, if so, should be permitted or required to reference the ITAAC. This decision is due to the manner in which ITAAC were developed for this appendix and recognition of the lack of experience with design certifications in combined licenses, in particular the implementation of ITAAC. Therefore, the Commission has decided to defer a decision on this matter. Section 4 of this Appendix contains an explicit reservation of this matter in order to avoid any uncertainty with respect to the Commission's intent.

C. Other Issues

1. NRC Verification of ITAAC Determinations.

Comment Summary. In Attachment B of its comments (pp. 58-66), NEI raised an industry concern regarding the matters to be considered by the NRC in verifying inspections, tests, analyses, and acceptance criteria (ITAAC) determinations pursuant to 10 CFR 52.99, specifically citing quality assurance and quality control (QA/QC) deficiencies. Although this issue was not specifically addressed in the proposed design certification rule, the following response is provided because of its importance relative to future considerations of the successful performance of ITAAC for a nuclear power facility.

Response. The NRC disagrees with any assertion that QA/QC deficiencies have no relevance to the NRC determination of whether ITAAC have been successfully completed. Simply confirming that an ITAAC had been performed in some manner and a result obtained apparently showing that the acceptance criteria had been met would not be sufficient to support a determination that the ITAAC had been successfully completed. The manner in which an ITAAC is performed can be relevant and material to the results of the ITAAC. For example, in conducting an ITAAC to verify a pump's flow rate, it is logical, even if not explicitly specified in the ITAAC, that the gauge used to verify the pump flow rate must be calibrated in accordance with relevant QA/QC requirements and that the test configuration is representative of the final as-built plant conditions (i.e. valve or system line-ups, gauge locations, system pressures or temperatures). Otherwise, the acceptance criteria for pump flow rate in the ITAAC could apparently be met while the actual flow rate in the system could be much less than that required by the approved design.

The NRC has determined that a QA/QC deficiency may be considered in determining whether an ITAAC has been successfully completed if: (1) the QA/QC deficiency is directly and materially related to one or more aspects of the relevant ITAAC (or supporting Tier 2 information); and (2) the deficiency (considered by itself, with other deficiencies, or with other information known to the NRC) leads the NRC to question whether there is a reasonable basis for concluding that the relevant aspect of the ITAAC has been successfully completed. This approach is consistent with the NRC's current methods for verifying initial test programs. The NRC recognizes that there may be programmatic QA/QC deficiencies that are not relevant to one or more aspects of a given ITAAC under review and, therefore, should not be relevant to or considered in the NRC's determination as to whether an ITAAC has been successfully completed. Similarly, individual QA/QC deficiencies unrelated to an aspect of the ITAAC in question would not form the basis for

an NRC determination that an ITAAC has not been met. Using the ITAAC for pump flow rate example, a specific QA deficiency in the calibration of pump gauges would not preclude an NRC determination of successful ITAAC completion if the licensee could demonstrate that the original deficiency was properly corrected (e.g., analysis, scope of effect, root cause determination, and corrective actions as appropriate), or that the deficiency could not have materially affected the test in question.

Furthermore, although the Tier 1 information was developed to focus on the performance of the structures, systems, and components of the design, the information contains implicit quality standards. For example, the design descriptions for reactor and fluid systems describe which systems are "safety-related"; important piping systems are classified as "Seismic Category I" and identify the ASME Code Class; and important electrical and instrumentation and control systems are classified as "Class 1E". The use of these terms by the evolutionary plant designers was meant to ensure that the systems would be built and maintained to the appropriate standards. Quality assurance deficiencies for these systems would be assessed for their impact on the performance of the ITAAC, based on their safety significance to the system. The QA requirements of 10 CFR Part 50, Appendix B, apply to safety-related activities. Therefore, the Commission anticipates that, because of the special significance of ITAAC related to verification of the facility, the licensee will implement similar QA processes for ITAAC activities that are not safety-related.

During the ITAAC development, the design certification applicants determined that it was impossible (or extremely burdensome) to provide all details relevant to verifying all aspects of ITAAC (e.g., QA/QC) in Tier 1 or Tier 2. Therefore, the NRC staff accepted the applicants' proposal that top-level design information be stated in the ITAAC to ensure that it was verified, with an emphasis on verification of the design and construction details in the "as-built" facility. To argue that consideration of underlying information which is relevant and material to determining whether ITAAC have been successfully completed ignores the history of ITAAC development. In summary, the Commission concludes that information such as QA/QC deficiencies which are relevant and material to ITAAC may be considered by the NRC in determining whether the ITAAC have been successfully completed. Despite this conclusion, the Commission has decided to add a provision to Section 9(b) of this appendix, which was requested by NEI. This provision requires the NRC's findings that the prescribed acceptance criteria have been met to be based solely on

the inspections, tests, and analyses. The Commission has added this provision, which is fully consistent with 10 CFR Part 52, with the understanding that it does not affect the manner in which the NRC intends to implement 10 CFR 52.99 and 52.103(g), as described above.

Licensee Documentation of ITAAC Verification

A related concern was raised by Mr. R. P. McDonald of the Advanced Reactor Corporation at the public meeting on December 4, 1995, regarding the type and quantity of information that must be submitted by a licensee to certify that an ITAAC has been successfully completed. While this issue also was not addressed in the proposed rule, this response is provided because of its importance to the industry regarding the performance of ITAAC. This response represents current NRC thinking on this subject and is not part of the Commission's binding determination in this rulemaking.

The documentation requirements for a facility that is licensed under 10 CFR Part 52 are similar to the documentation requirements under Part 50. The difference is that under Part 52 the documentation should be formatted to demonstrate the bases for completion of ITAAC. In general, sufficient information must be submitted to the NRC to adequately document the bases for the conclusion that the ITAAC have been successfully performed and the acceptance criteria have been met. However, this information is expected to be summarized because the NRC does not intend that all the details of the inspections, tests, and analyses related to a specific ITAAC must be submitted.

The licensee should certify to the NRC that an ITAAC has been successfully completed and that the acceptance criteria have been met. The certification letter should identify the specific ITAAC(s) that have been completed; it should identify, in summary form, the bases for the conclusion that the ITAAC have been met; and it should identify the location of any supporting documentation that is available for audit. The supporting documentation may include items such as test reports, engineering analyses, calculations, drawings, vendor component tests, inspections, quality assurance records, and other facility records. NEI provided a preliminary conceptual example of this type of letter in a meeting with the NRC staff on March 15, 1995, as documented in a meeting summary dated April 7, 1995. However, the specific bases for satisfaction of any particular ITAAC must be established by each licensee.

The design descriptions and functional system drawings available for review during the design certification and COL application stages were sufficient to perform licensing reviews and make final safety determinations but are not adequate for actual construction or construction inspection activities. Therefore, before construction begins on any given portion of the facility, the licensee must ensure that the certified design plus site-specific design information in the COL application, including that required by the design acceptance criteria (DAC), has been translated into detailed, plant-specific, design and construction drawings. The level of detail in the certified design and the use of DAC allow for some variation in implementing the certified design. The applicant or licensee also has some flexibility in completing the final design for Tier 2 design information, by means of the Tier 2 change process. The ITAAC will verify that the as-built facility will operate in accordance with the approved design and applicable regulations. Therefore, the licensee should ensure that the drawings and other documentation reflect the final as-built configuration of the facility so that they can be used as part of the bases, where appropriate, for completion of the ITAAC.

NRC Inspection

The licensee bears the responsibility for performing ITAAC. The NRC must verify through its inspection program that the ITAAC have been performed by the licensee in an acceptable manner, thereby ensuring there is reasonable assurance that the facility has been built and will operate in accordance with the license and applicable regulations. SECY-94-294, "Construction Inspection and ITAAC Verification," discussed the development of a construction inspection program to accommodate the requirements of future reactors licensed under Part 52 and to incorporate lessons learned from experience with the current construction inspection program. One of the objectives of this inspection program will be to inspect the licensee's process for performing ITAAC and to inspect the licensee's program for ensuring ITAAC requirements are met. This could include the results of the pre-operational test program, quality assurance program, and various facility construction programs. The NRC expects that there will be increased interaction between the licensee and the NRC throughout the facility construction stage.

Facility ITAAC Verification

The NRC must find that all acceptance criteria specified in the license are met before facility operation. Because ITAAC are the sole source of acceptance criteria, the COL for a facility must include, all those implementation issues sufficiently important to require satisfactory resolution before fuel loading. Thus, the COL ITAAC include the ITAAC in the DCD for a referenced design plus plant-specific ITAAC derived from the COL proceeding. Plant-specific ITAAC comprise ITAAC associated with site-specific design information and other significant issues submitted by the COL applicant, as approved by the NRC staff.

2. DCD Introduction.

Comment Summary. The proposed rule incorporated Tier 1 and Tier 2 information into the DCD but did not include the introduction to the DCD. The SOC for the proposed rule (60 FR 17924) indicated that this was a deliberate decision, stating:

The introduction to the DCD is neither Tier 1 nor Tier 2 information, and is not part of the information in the DCD that is incorporated by reference into this design certification rule. Rather, the DCD introduction constitutes an explanation of requirements and other provisions of this design certification rule. If there is a conflict between the explanations in the DCD introduction and the explanations of this design certification rule in these statements of consideration (SOC), then this SOC is controlling.

Both the applicant and NEI took strong exception to this statement. They both argued that the language of the DCD introduction was the subject of careful discussion and negotiation between the NRC staff, NRC's Office of the General Counsel, and representatives of the applicant and NEI. They, therefore, suggested that the definition of the DCD in Section 2(a) of the proposed rule be amended to explicitly include the DCD Introduction and that Section 4(a) of the proposed rule be amended to generally require that applicants or licensees comply with the entire DCD. However, in the event that the Commission rejected their suggestion, NEI alternatively argued that the substantive provisions of the DCD Introduction be directly incorporated into the design certification rule's language (refer to NEI Comments, Attachment B, pp. 90-108; ABB-CE Comments, Attachment A).

Response. The DCD Introduction was created to be a convenient explanation of some provisions of the design certification rule and was not intended to become rule language itself. Therefore, the Commission has adopted NEI's alternative suggestion of incorporating substantive procedural and administrative requirements into the design certification rule. It is the Commission's view that the substantive procedural and administrative provisions described in the DCD Introduction should be included in, and be an integrated part of, the design certification rule which is published in the Federal Register and codified in the Code of Federal Regulations. The portion of the rule that is published in the Federal Register contains the bulk of the rule's procedural and administrative requirements. It would be better from the standpoint of form and convenience to include the appropriate provisions into a single part of the rule. As a result, Sections 2, 4, 6, 8, and 10 have been revised and Section 9 of this Appendix was created to adopt appropriate provisions from the DCD Introduction. In some cases, the wording of these provisions has been modified to conform with the final design certification rule. Therefore, the applicant for this design certification must revise its DCD Introduction to conform with the final rule.

In section C.2 of its comments, dated August 4, 1995, ABB-CE stated that all tables within Section 19.7, "External Events Analysis," of the DCD should be deleted. ABB-CE stated that the probabilistic numerical results in these tables were included in its DCD as a result of a printing error. The Commission has determined that the deletion of these tables from Section 19.7 of the DCD is acceptable because a site-specific version of this information will be created by a COL applicant that references this design certification. Therefore, ABB-CE can delete this information when it prepares the final version of the generic DCD that conforms with the final rule.

3. Duplicate documentation in design certification rule.

Comment Summary. On page 4 of its comments, dated August 7, 1995, the Department of Energy (DOE) recommended that the process for preparing the design certification rule be simplified by eliminating the DCD, which DOE claims is essentially a repetition of the Standard Safety Analysis Report (SSAR). DOE's concern, which was further clarified during a public meeting on December 4, 1995, is that the NRC will require separate copies of the DCD and SSAR to be maintained. During the public meeting DOE, also expressed a concern that § 52.79(b) could be confusing to an applicant for a combined license because it

currently states . . . "The final safety analysis report and other required information may incorporate by reference the final safety analysis report for a certified standard design." . . .

Response. The NRC does not require duplicate documentation for this design certification rule. The DCD is the document that is incorporated by reference into this appendix in order to meet the requirements of Subpart B of Part 52. The SSAR supports the final design approval that was issued under Appendix O to 10 CFR Part 52. The DCD was developed to meet the requirements for incorporation by reference and to conform with requests from the industry such as deletion of the quantitative portions of the design-specific probabilistic risk assessment. Because the DCD terminology was not envisioned at the time that Part 52 was developed, the Commission will consider modifying § 52.79(b), as part of its future review of Part 52, in order to clarify the use of the term "final safety analysis report." In the records and reporting requirements in Section 10 of this rule, additional terms were used to distinguish between the documents to be maintained by the applicant for this design certification rule and the document to be maintained by an applicant or licensee who references this appendix. These new terms are defined in Section 2 of this appendix and further described in the section-by-section discussion on records and reporting requirements in section III.J.

III. Section-by-section discussion of the design certification rule.

A. Introduction.

The purpose of Section 1 of this appendix is to identify the standard plant design that is approved by this design certification rule and the applicant for certification of the standard design. The implementation of 10 CFR 52.63(c) depends on whether an applicant for a COL contracts with the design certification applicant to provide the generic DCD and supporting design information. If the COL applicant does not use the design certification applicant to provide this information, then the COL applicant will have to meet the requirements in 10 CFR 52.63(c). Also, Section 10(a)(1) of this appendix imposes a requirement on the design certification applicant to maintain the generic DCD throughout the time period in which this appendix may be referenced. Therefore,

identification of the design certification applicant is necessary to implement this appendix.

B. Definitions (Section 2).

The terms Tier 1, Tier 2, Tier 2*, and COL action items (license information) are defined in Section 2 of this appendix because these concepts were not envisioned when 10 CFR Part 52 was developed. The design certification applicants and the NRC staff used these terms in implementing the two-tiered rule structure that was proposed by industry after the issuance of 10 CFR Part 52. In addition, during consideration of the comments received on the proposed rule, the Commission determined that it would be useful to distinguish between the "plant-specific DCD," in order to clarify the obligations of applicants and licenses that reference this appendix, and the "generic DCD," which is incorporated by reference into this appendix and remains unaffected by plant-specific departures. Therefore, appropriate definitions for these two additional terms are included in the final rule.

The Tier 1 portion of the design-related information contained in the DCD is *certified* and required by this appendix. This information consists of an introduction to Tier 1, the design descriptions and corresponding inspections, tests, analyses, and acceptance criteria (ITAAC) for systems and structures of the design, design material applicable to multiple systems of the design, significant interface requirements, and significant site parameters for the design. The design descriptions, interface requirements, and site parameters in Tier 1 were derived entirely from Tier 2, but may be more general than the Tier 2 information. The NRC staff's evaluation of the Tier 1 information, including a description of how this information was developed is provided in Section 14.3 of the FSER. Changes to or departures from the Tier 1 information must comply with Section 8(a) of this Appendix.

The Tier 1 design descriptions serve as design commitments for the lifetime of a facility referencing the design certification. The ITAAC verify that the as-built facility conforms with the approved design and applicable regulations. In accordance with 10 CFR 52.103(g), the Commission must find that the acceptance criteria in the ITAAC are met before operation. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not constitute regulatory requirements for subsequent

modifications. However, subsequent modifications to the facility must comply with the Tier 1 design descriptions unless changes are made in accordance with the change process in Section 8 of this appendix. The Tier 1 interface requirements are the most significant of the interface requirements for systems that are wholly or partially outside the scope of the standard design, which were submitted in response to 10 CFR 52.47(a)(1)(vii) and must be met by the site-specific portions of a facility that references the design certification. The Tier 1 site parameters are the most significant site parameters, which were submitted in response to 10 CFR 52.47(a)(1)(iii), that must be addressed as part of the application for a combined license.

Tier 2 is the portion of the design-related information contained in the DCD that is *approved* and required by this appendix but is not certified. Tier 2 includes the information required by 10 CFR 52.47, with the exception of technical specifications and conceptual design information, and supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met. All of the information in Tier 2 is approved by the NRC, is required (except for the COL action items and conceptual design information) for those COL applicants and licensees whose applications reference this appendix, and is among the "matters resolved" under 10 CFR 52.63(a)(4). The definition of Tier 2 makes clear that Tier 2 information has been determined by the Commission, by virtue of its inclusion in this appendix and its designation as Tier 2 information, to be an approved ("sufficient") method for meeting Tier 1 requirements. However, there may be other acceptable ways of complying with Tier 1. The appropriate criteria for departing from Tier 2 information are set forth in Section 8 of this appendix.

Certain Tier 2 information has been designated in the generic DCD with brackets and italicized text as "Tier 2*" information. As discussed in greater detail in the section-by-section explanation for Section 8, a plant-specific departure from Tier 2* information requires prior NRC approval under Section 8(b)(6) of this appendix. However, the Tier 2* designation expires for some of this information when the facility first achieves full power after the finding required by 10 CFR 52.103(g). The process for changing Tier 2* information and the time at which its status as Tier 2* expires is set forth in Section 8(b)(6) of this appendix.

A definition of "combined license (COL) action items" (COL license information) has been added to clarify that COL applicants are required to address these matters in their

license application, but the COL action items do not include substantive criteria for judging the sufficiency of the information submitted. Thus, an applicant for a combined license may be able to address particular COL action items by justifying, in appropriate circumstances, why no further action is necessary.

In developing the proposed design certification rule, the Commission contemplated that there would be both "master" DCDs (termed generic DCDs) maintained by the NRC and the design certification applicant, as well as individual plant-specific DCDs, maintained by each applicant and licensee who references this design certification rule. The master DCDs (identical to each other) would reflect generic changes to the version of the DCD approved in this design certification rulemaking. The generic changes would occur as the result of generic rulemaking by the Commission (subject to the change criteria in Section 8 of this Appendix). In addition, the Commission understood that each applicant and licensee referencing this Appendix would be required to submit and maintain a plant-specific DCD. This plant-specific DCD would contain (not just incorporate by reference) the information in the generic or master DCD. The plant-specific DCD would be updated as necessary to reflect the generic changes to the DCD that the Commission may adopt through rulemaking, any plant-specific departures from the generic DCD that the Commission imposed on the licensee by order, and any plant-specific departures which the licensee chose to make in accordance with the relevant processes in Section 8 of this appendix. However, the proposed rule defined only the concept of the "master" DCD. The Commission continues to believe that there should be both a "master" DCD and plant-specific DCDs. To clarify this matter, the proposed rule's definition of DCD has been redesignated as the "generic DCD," a new definition of "plant-specific DCD" has been added, and conforming changes have been made to the remainder of the rule. Further information on exemptions or departures from information in the DCD is provided in section III.H below. The Final Safety Analysis Report (FSAR) that is required by § 52.79(b) will consist of the plant-specific DCD, the site-specific portion of the FSAR, and the technical specifications.

C. Scope and contents of this design certification.

The purpose of Section 3 of this appendix is to describe and define the scope and contents of the standard design certification and to set forth how documentation discrepancies or inconsistencies are to be resolved. Paragraph (a) is the required

statement of the Office of the Federal Register (OFR) for approval of the incorporation by reference of Tier 1 and Tier 2 into this appendix and paragraph (b) requires COL applicants and licensees to comply with the requirements of this appendix, including Tier 1 and Tier 2. The legal effect of incorporation by reference is that the material is treated as if it were published in the Federal Register. This material, like any other properly-issued regulation, has the force and effect of law. Tier 1 and Tier 2 information have been combined into a single document, called the design control document (DCD), in order to effectively control this information and facilitate its incorporation by reference into the rule. The DCD was prepared to meet the requirements of the OFR for incorporation by reference (1 CFR Part 51). The generic DCD for this design certification will be archived at NRC's central file with a matching copy at OFR. Copies of the up-to-date DCD will also be available at the NRC's Public Document Room. Questions concerning the accuracy of information in an application that references this Appendix will be resolved by checking the generic DCD in NRC's central file. If a generic change (rulemaking) is made to the DCD pursuant to the change process in Section 8 of this Appendix, then at the completion of the rulemaking the NRC will request approval of the Director, OFR for the changed incorporation by reference and change its copies of the generic DCD and notify the OFR and the design certification applicant to change their copies. The Commission is requiring that the design certification applicant maintain an up-to-date copy under Section 10(a)(1) of this appendix because it is likely that most applicants intending to reference the standard design will likely obtain the generic DCD from the design certification applicant. Plant-specific changes to and departures from the DCD will be maintained by the applicant or licensee that references this design certification under Section 10(a)(2) of this appendix.

In order to meet the requirements of OFR for incorporation by reference, the design certification applicant must make the DCD available upon request after the final design certification rule is issued. Therefore, this Section states that copies of the DCD can be obtained from [the applicant or an organization designated by the applicant. If the applicant selects an organization, such as the National Technical Information Service, to distribute the generic DCD, then the applicant must provide that organization with an up-to-date copy.]

Paragraphs (c) and (d) set forth the manner in which potential conflicts are to be resolved. Paragraph (c) establishes the Tier 1 description in the DCD as controlling in

the event of an inconsistency between the Tier 1 and Tier 2 information in the DCD.

Paragraph (d) establishes the generic DCD as the controlling document in the event of an inconsistency between the DCD and either the application for certification of the standard design, or the final safety evaluation report (FSER) for the standard design.

Paragraph (e) clarifies that the conceptual design information and the technical specifications in the generic DCD are not considered to be part of this appendix. The conceptual design information is for those portions of the plant that are outside the scope of the standard design and are intermingled throughout Tier 2. As provided by 10 CFR 52.47(a)(1)(ix), these conceptual designs are not part of this appendix and, therefore, are not applicable to an application for a combined license that references this appendix. The technical specifications, which are provided in Chapter 16 of the generic DCD, are not part of this appendix but may be used to develop the technical specifications for a nuclear facility that references this appendix.

D. Applications and licenses referencing this design certification: additional requirements and restrictions.

Section 4 of this appendix is a new section which sets forth additional requirements and restrictions imposed upon the applicant or licensee who references this Appendix. Section 4(a) sets forth the additional information required of combined license applicants who reference this Appendix. This Appendix distinguishes between information and/or documents which must actually be *included* in the application or the DCD, versus those which may be *incorporated by reference* (i.e., referenced in the application as if the information or documents were actually included in the application), thereby reducing the bulk of the application. Any incorporation by reference in the application should be clear and should specify the title, date, edition, or version of a document, and the page number(s) and table(s) containing the relevant information to be incorporated by reference.

Paragraph (a)(1) requires an applicant to incorporate by reference this appendix. This appendix is legally-binding on any applicant or licensee who references this appendix. Paragraph (a)(2)(i) is intended to make clear that the initial application must include a plant-specific DCD. This assures, among other things, that the applicant commits to complying with both Tier 1 and Tier 2 of the DCD. This paragraph also requires

the plant-specific DCD to use the same format as the generic DCD and to reflect the applicant's proposed departures and exemptions from the generic DCD as of the time of submission of the application. The Commission expects that the plant-specific DCD will become the basis for the plant's final safety analysis report (FSAR), by including within its pages, at the appropriate points, information such as site-specific information for the portions of the plant outside the scope of the referenced design, including related ITAAC, and other matters required to be included in an FSAR by 10 CFR 50.34. Integration of the plant-specific DCD and remaining information, as the plant's FSAR, will be easier to use and should minimize "duplicate documentation" and the attendant possibility for confusion. Paragraph (a)(2)(i) is also intended to make clear that the initial application must include the reports on departures and exemptions as of the time of submission of the application. Paragraph (a)(2)(ii) requires that the application include the reports required by Section 10(b) of this design certification rule for exemptions and departures proposed by the applicant as of the date of submission of its application. Paragraph (a)(2)(iii) requires submission of technical specifications for the plant in accordance with the requirements in effect at the time of the COL review. Paragraph (a)(2)(iv) makes clear that the applicant must provide information demonstrating that the proposed site falls within this rule's site parameters and that the plant-specific design complies with the interface requirements, as required by 10 CFR 52.79(b). Paragraph (a)(2)(v) requires submission of information addressing COL Action Items, which are identified in the generic DCD as COL License Information, in the COL application. The COL Action Items (COL License Information) identify matters that need to be addressed by an applicant or licensee that references this appendix, as required by 10 CFR 52.77 and 52.79. The COL applicant does not need to conform with the conceptual design information in the generic DCD that was provided by the design certification applicant in response to 10 CFR 52.47(a)(1)(ix). The conceptual design information, which are examples of site-specific design features, was required to facilitate the design certification review. Conceptual design information is neither Tier 1 nor 2. The introduction to the DCD identifies the location of the conceptual design information and explains that this information is not applicable to a COL application. Paragraph (a)(2)(vi) requires that the application include the information required by 10 CFR 52.47(a) that is not within the scope of this rule, such as generic issues that must be addressed by an applicant that references this rule. The detailed methodology and quantitative portions of the design-

specific probabilistic risk assessment (PRA), as required by 10 CFR 52.47(a)(1)(v), was not included in the DCD. The NRC agreed with the design certification applicant's request to delete this information because conformance with the deleted portions of the PRA is not required. The NRC's position is also predicated in part upon NEI's acceptance, in conceptual form, of a future generic rulemaking that will require a COL applicant or licensee to have a plant-specific PRA that updates and supersedes the design-specific PRA and maintain it throughout the operational life of the plant.

Paragraph (a)(2)(vii) requires a COL applicant to include descriptions of in-service testing (IST) and in-service inspection (ISI) programs that include the features described in sub-paragraphs (A), and (B) in their application. This requirement was moved from Section 5(c) of this appendix in response to NEI comments that, since the programs are the responsibility of the applicant and licensee, it was not appropriate as a new applicable regulation. The Commission's views on ISI and IST have been evolving. The purpose of this requirement is to ensure that a licensee will use the best available methods and incorporate the techniques specified in this requirement.

Paragraph (a)(2)(viii) requires a COL applicant to include a description of their outage planning and control program that includes consideration of shutdown risk concerns. This requirement was moved from Section 5(c) of this appendix in response to NEI comments that, since the program is the responsibility of the applicant and licensee, it was not appropriate as a new applicable regulation. The purpose of the requirement is to ensure that, in light of the Commission's findings in NUREG-1449, the applicant's program for outage planning and control adequately addresses shutdown risk concerns.

Paragraph (a)(2)(ix) requires a COL applicant to include a description of a design reliability assurance program (DRAP) in their application. As background information, in SECY-89-013, "Design Requirements Related to the Evolutionary Advanced Light Water Reactors," dated January 19, 1989, the staff identified several issues for next-generation light water reactors that may go beyond present acceptance criteria defined in the SRP. The reliability assurance program (RAP), as one of these issues, was defined as a program to ensure that the design reliability of safety significant structures, systems, and components (SSCs) is maintained over the life of a plant. In SECY-93-087, the staff gave the Commission its interim position that a high-level commitment to a RAP should be required as a generic Tier 1 requirement with no associated inspections, tests, analyses, and acceptance criteria. DRAP involves a top-level program at the design stage that

defines the scope, conceptual framework, and essential elements of an effective RAP. DRAP also implements those aspects of the program that are applicable to the design process. In addition, DRAP identifies the relevant aspects of plant operation, maintenance, and performance monitoring for the risk-significant SSCs for the operator's consideration.

The conceptual framework, program structure, and essential elements of the D-RAP are discussed in section 17.3 of the DCD. The DRAP should (1) identify and prioritize a list of risk-significant SSCs based on the design certification PRA and other sources, (2) ensure that the vendor's design organization determines that significant design assumptions, such as equipment that satisfies the design reliability and unavailability, are realistic and achievable, (3) provide input to the procurement process for obtaining equipment that satisfies the design reliability assumptions, and (4) provide these design assumptions as input to the COL applicant for consideration. A COL applicant would augment the design certification DRAP with site-specific design information and would implement the balance of the D-RAP, including input to the procurement process.

The staff's final position on RAP was presented in the Commission Paper on the Regulatory Treatment of Non-Safety Systems (RTNSS), SECY-94-084, dated March 28, 1994. The Commission approved this position in an SRM dated June 30, 1994. Note that in paragraph (a)(4)(iii)(B), the staff expects that the "other analytical methods" would include sound engineering judgement.

Paragraph (a)(3) requires the applicant to physically include, not simply reference, the proprietary information referenced in the System 80+ DCD, to assure that the applicant has actual notice of these requirements.

Paragraph (a)(4) requires an applicant to establish and implement a design reliability assurance program that includes the features specified in Section 4(a)(2)(ix) because additional design work will be performed by the COL applicant and DRAP must be implemented during this period before the COL application is approved by the Commission.

Paragraphs (b)(1), (b)(2) and (b)(3) require a holder of a COL to implement the programs described above. The NRC intends that the requirement of paragraph (b)(2) to implement the D-RAP program will apply from the date of COL issuance until the date of fuel load. The ISI, IST and outage planning and control programs are required to be implemented throughout the service life of the plant.

Section 4(c) reserves the right of the Commission to impose limited plant-specific requirements for post-fuel load operational safety, including verification activities, as

license conditions for portions of the plant within the scope of this design certification, e.g. start-up and power ascension testing. The requirement to perform these testing programs is contained in Tier 1 information. However, ITAAC cannot be specified for these subjects because the matters to be addressed in these license conditions cannot be verified prior to fuel load and operation, when the combined license ITAAC are satisfied. As provided in Section 9(b)(3), ITAAC do not constitute regulatory requirements after the finding required by 10 CFR 52.103(g). Therefore, another regulatory vehicle is necessary to assure that holders of combined licenses comply with the matters contained in the license conditions. License conditions for these areas cannot be developed now because this requires the type of detailed design information that will be developed after design certification. In the absence of detailed design information to evaluate the need for and develop specific post-fuel load verifications for these matters, the Commission, by rule, is reserving the right to impose these limited license conditions for post-fuel load verification activities for portions of the plant within the scope of the design certification.

Section 4(d) reserves to the Commission the right to determine whether and in what manner this design certification may be referenced by an applicant for a construction permit or operating license under 10 CFR Part 50. This determination may occur in the context of a subsequent rulemaking modifying Part 52 or this design certification rule, or on a case-by-case basis in the context of a specific application for a Part 50 construction permit or operating license.

E. Applicable regulations.

The purpose of Section 5 of this appendix is to identify the regulations that are applicable and in effect at the time that this design certification was issued. These regulations consist of the technically relevant regulations identified in paragraph (a), except for the regulations in paragraph (b) that are not applicable, and the new regulations in paragraph (c) that are applicable to this standard design.

Paragraph (a) identifies the regulations in 10 CFR Parts 20, 50, 73, and 100 that are applicable to the System 80+ design. Since the NRC staff completed its review with the issuance of the FSER for the System 80+ design (August 1994), the Commission has amended several existing regulations and adopted several new regulations in those Parts of Title

10 of the Code of Federal Regulations. The Commission has reviewed these regulations to determine if they are applicable to this design and, if so, to confirm that the design meets these regulations. The Commission finds that the System 80+ design either meets the requirements of these regulations or that these regulations are not applicable to the design, as discussed below.

10 CFR Part 73, Protection Against Malevolent Use of Vehicles at Nuclear Power Plants (59 FR 38889; August 1, 1994).

The objective of this regulation is to modify the design basis threat for radiological sabotage to include use of a land vehicle by adversaries for transporting personnel and their hand-carried equipment to the proximity of vital areas and to include a land vehicle bomb. This regulation also requires reactor licensees to install vehicle control measures, including vehicle barrier systems, to protect against the malevolent use of a land vehicle. The Commission has determined that this regulation will be addressed in the COL applicant's site-specific security plan. Therefore, no additional actions are required for this design.

10 CFR 19 and 20, Radiation Protection Requirements: Amended Definitions and Criteria (60 FR 36038; July 13, 1995).

The objective of this regulation is to revise the radiation protection training requirement so that it applies to workers who are likely to receive, in a year, occupational dose in excess of 100 mrem (1 mSv); revise the definition of the "Member of the public" to include anyone who is not a worker receiving an occupational dose; revise the definition of "Occupational Dose" to delete reference to location so that the occupational dose limit applies only to workers whose assigned duties involve exposure to radiation and not to members of the public; revise the definition of the "Public Dose" to apply to dose received by members of the public from material released by a licensee or from any other source of radiation under control of the licensee; assure that prior dose is determined for anyone subject to the monitoring requirements in 10 CFR Part 20, or in other words, anyone likely to receive, in a year, 10 percent of the annual occupational dose limit; and retain a requirement that known overexposed individuals receive copies of

any reports of the exposure that are required to be submitted to the NRC. The Commission has determined that these requirements will be addressed in the COL applicant's operational radiation protection program. Therefore, no additional actions are required for this design.

10 CFR 50, Technical Specifications (60 FR 36953; July 19, 1995).

The objective of this revised regulation is to codify criteria for determining the content of technical specification (TS). The four criteria were first adopted and discussed in detail in the Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors (58 FR 39132; July 22, 1993). The Commission has determined that these requirements will be addressed in the COL applicant's technical specifications. Therefore, no additional actions are required for this design.

10 CFR 73, Changes to Nuclear Power Plant Security Requirements Associated with Containment Access Control (60 FR 46497; September 7, 1995).

The objective of this revised regulation is to delete certain security requirements for controlling the access of personnel and materials into reactor containment during periods of high traffic such as refueling and major maintenance. This action relieves nuclear power plant licensees of requirement to separately control access to reactor containments during these periods. The Commission has determined that this regulation will be addressed in the COL applicant's site-specific security plan. Therefore, no additional actions are required for this design.

10 CFR Part 50, Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors (60 FR 49495; September 26, 1995).

The objective of this revised regulation is to provide a performance-based option for leakage-rate testing of containments of light-water-cooled nuclear power plants. This performance-based option, option B to Appendix J, is available for voluntary adoption by licensees in lieu of compliance with the prescriptive requirements contained in the current regulation. As a result, Appendix J now includes two options, A & B, either of

which can be chosen for meeting the requirements of this appendix to 10 CFR Part 52. The Commission has determined that option B to Appendix J has no impact on the System 80+ design because ABB-CE has chosen option A to Appendix J. However, the System 80+ design addresses primary reactor containment leakage testing in a manner different from that provided in option A, as described in the discussion on exemptions to Appendix J below. Therefore, no additional actions are required by this design.

10 CFR Parts 50, 70, and 72, Physical Security Plan Format (60 FR 53507; October 16, 1995).

The objective of this revised regulation is to eliminate the requirement for applicants for power reactor, Category I fuel cycle, and spent fuel storage licenses to submit physical security plans in two parts. This action is necessary to allow for a quicker and more efficient review of the physical security plans. The Commission has determined that this revised regulation will be addressed in the COL applicant's site-specific security plan. Therefore, no additional action is required for this design.

10 CFR Part 50, Fracture Toughness Requirements for Light Water Reactor Pressure Vessels (60 FR 65456; December 19, 1995).

The objective of this revised regulation is to clarify several items related to fracture toughness requirements for reactor pressure vessels (RPV). This regulation clarifies the pressurized thermal shock (PTS) requirements, makes changes to the fracture toughness requirements and the reactor vessel material surveillance program requirements, and provides new requirements for thermal annealing of a reactor pressure vessel. The Commission has determined that 10 CFR 50.61 only applies to pressurized water reactors for which an operating license has been issued. Likewise, 10 CFR 50.66 applies only to those light-water reactors where neutron radiation has reduced the fracture toughness of the reactor vessel materials. Therefore, no additional actions are required by this design.

In paragraph (b), the Commission identified the regulations that do not apply to the System 80+ design. The Commission has determined that the System 80+ design should be exempt from portions of 10 CFR 50.34(f), Appendix J to Part 50, and Part 100, as described in the final safety evaluation report (NUREG-1462) and summarized below:

(1) Paragraph (f)(2)(iv) of 10 CFR 50.34 - Separate Plant Safety Parameter Display Console.

10 CFR 50.34(f)(2)(iv) requires that an application provide a plant safety parameter display console that will display to operators a minimum set of parameters defining the safety status of the plant, be capable of displaying a full range of important plant parameters and data trends on demand, and be capable of indicating when process limits are being approached or exceeded.

The purpose of the requirement for a safety parameter display system (SPDS), as stated in NUREG-0737, "Clarification of TMI Action Plan Requirements," Supplement 1, is to ". . . provide a concise display of critical plant variables to the control room operators to aid them in rapidly and reliably determining the safety status of the plant. . . . and in assessing whether abnormal conditions warrant corrective action by operators to avoid a degraded core."

ABB-CE committed to meet the intent of this requirement. However, the functions of the SPDS will be integrated into the control room design rather than on a separate "console." ABB-CE has made the following commitments in the generic DCD:

! Section 18.7.1.8.1, Safety-Related Data, states that the Nuplex 80+ Advanced Control Complex provides a concise display of critical function and success path performance indications to control room operators via the Data Processing System (DPS),

! Section 18.7.1.8.1 states that the integrated process status overview (IPSO) big board display is a dedicated display which continuously shows all critical function alarms and key critical function and success path parameters,

! Section 18.7.1.8.1 describes the SPDS for the System 80+ and states that all five of the safety function elements are included in the DPS critical function hierarchy which forms the basis of the Nuplex 80+ SPDS function:

- (a) Reactivity control
- (b) Reactor core cooling and heat removal from the primary system
- (c) Reactor coolant system integrity

(d) Radioactivity control

(e) Containment conditions, and

! Section 18.7.1.8.2 states that the critical function and success path monitoring application in conjunction with the continuous IPSO display and the DPS CRTs meet SPDS requirements for Nuplex 80+ without using stand-alone monitoring and display systems.

In view of the above, the Commission has determined that an exemption from the requirement for an SPDS "console" is justified based upon (1) the description in the generic DCD of the intent of the System 80+ design to incorporate the SPDS function as part of the plant status summary information which is continuously displayed on the fixed-position displays on the large display panel; and (2) a separate "console" is not necessary to achieve the underlying purpose of the SPDS rule which is to display to operators a minimum set of parameters defining the safety status of the plant. Therefore, the Commission concludes that an exemption from 10 CFR 50.34(f)(2)(iv) is justified by the special circumstances set forth in 10 CFR 50.12(a)(2)(ii).

(2) Paragraphs (f)(2)(vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34- Accident Source Terms

10 CFR 50.34(f)(2)(xxviii) requires the evaluation of pathways that may lead to control room habitability problems "under accident conditions resulting in a TID 14844 source term release." Similar wording appears in subparagraphs (vii), (viii), and (xxvi). ABB-CE has implemented the new source term technology summarized in Draft NUREG-1465, "Accident Source Terms for Light-Water Nuclear Power Plants," dated June 1992, not the old TID 14844 source term cited in 10 CFR Part 50.

The NRC staff has encouraged the development and implementation of the new source term technology. The use of the revised source term technology is an important departure from previous practice. The new approach generally yields lower estimates of fission product releases to the environment and will employ a physically-based source term based on substantial research and experience gained over two decades. The TID-14844 non-mechanistic methodology intentionally employed conservative assumptions that were intended to ensure that future plants would provide sufficient safety margins even with the

recognized uncertainties associated with accident sequences and equipment reliability. Although the new source term technology may lead to relaxation in some aspects of the design, it also provides safety benefits by removing unrealistically stringent testing requirements.

Based on the NRC staff's review and ABB-CE's commitments in Chapter 15 of the generic DCD, the Commission has determined that the special circumstances described in 10 CFR 50.12(a)(ii) exist in that the regulation need not be applied in this particular circumstance to achieve the underlying purpose because ABB-CE has proposed acceptable alternatives that accomplish the intent of the regulation. On this basis, the Commission concludes that an exemption from the requirements of paragraphs (f)(2)(vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34 is justified.

(3) Paragraph (f)(2)(viii) of 10 CFR 50.34 - Post-Accident Sampling for Hydrogen, Boron, Chloride, and Dissolved Gases.

In SECY-93-087, the NRC staff recommended that the Commission approve its position for evolutionary and passive ALWRs of the pressurized water reactor (PWR) type that they be required to have the capability to analyze for dissolved gases in the reactor coolant and for hydrogen in the containment atmosphere in accordance with the requirements of 10 CFR 50.34(f)(2)(viii) and Item III.B.3 of NUREG-0737. The NRC staff acknowledged that determination of chloride concentrations, although helpful in ensuring that plant personnel take appropriate actions to minimize the likelihood of accelerated primary system corrosion following the accident, is a secondary consideration because long-term samples could likely be taken at a low pressure. Therefore, it does not constitute a mandatory requirement of the post-accident sampling system (PASS). The time for taking these samples can be extended to 24 hours following the accident. The NRC staff also recommended that the Commission approve the deviation from the requirements of Item II.B.3 of NUREG-0737 with regard to requirements for sampling reactor coolant for boron concentration and activity measurements using the PASS in evolutionary and passive ALWRs.

The rationale is that both of these measurements are used only to confirm the accident mitigation measures and conditions of the core obtained by other methods and do not need to be performed in an early phase of an accident. Neutron flux monitoring instrumentation that complies with Category I criteria of RG 1.97, will have fully qualified, redundant

channels that monitor neutron flux over the required power range. Therefore, sampling for boron concentration will not be needed for the first eight hours after an accident. Samples for activity measurements provide the information used in evaluating the condition of the core. However, this information will be made available during the accident management phase by monitoring other pertinent variables. Accordingly, sampling for activity measurement could be postponed until 24 hours following an accident.

In its July 21, 1993, Staff Requirements Memorandum (SRM), the Commission approved the recommendation to exempt the PASS for ALWRs of PWR design from determining the concentration of hydrogen in the containment atmosphere in accordance with the requirements of 10 CFR 50.34(f)(2)(viii) and Item III.B.3 of NUREG-0737. It also approved extending the time limit for analysis of the coolant for boron and activity to eight hours and 24 hours, respectively. The Commission modified the recommendations regarding evolutionary and passive ALWRs of the PWR type to have the capability to determine the gross amount of dissolved gases (not necessarily pressurized) as a means to meet the intent of 10 CFR 50.34(f)(2)(viii) and Item III.B.3 of NUREG-0737.

Accordingly, the Commission has determined that the special circumstances described in 10 CFR 50.12(a)(2)(ii) exist in that the regulation need not be applied in this particular circumstance to achieve the underlying purpose because ABB-CE has proposed acceptable alternatives that accomplish the intent of the regulation. On this basis, the Commission concludes an exemption from the requirements of Paragraph (f)(2)(viii) of 10 CFR 50.34 is justified.

(4) Paragraph (f)(3)(iv) of 10 CFR 50.34 - Dedicated Containment Penetration.

Paragraph (3)(iv) of 10 CFR 50.34(f) requires one or more dedicated containment penetrations, equivalent in size to a single 0.91 m (3 ft) diameter opening, in order not to preclude future installation of systems to prevent containment failure such as a filtered containment vent system. This requirement is intended to ensure provision of a containment vent design feature with sufficient safety margin well ahead of a need that may be perceived in the future to mitigate the consequences of a severe accident situation.

In the generic DCD, ABB-CE shows that the containment is sufficiently robust to not require venting before 24 hours. However, to further improve containment performance, the

System 80+ containment is equipped with two 7.6-cm (3.0-in.) diameter hydrogen purge vents that can be used to relieve containment pressure before containment pressure reaches ASME Code Service Level C. With respect to core concrete interaction (CCI), the vent could be used to prevent catastrophic overpressurization failure of the containment for severe-accident sequences involving prolonged periods of CCI. The hydrogen purge vents are capable of opening when exposed to an internal pressure corresponding to ASME Code Service Level C, of 972 kPa (141 psia) at a temperature of 177 °C (350 °F), and can be powered by the alternate AC source.

ABB-CE has provided this venting capability; however, they have demonstrated that venting is not needed for most of the severe-accident events. For those sequences in which venting would aid in limiting the containment pressure below ASME Code Service Level C limits, venting would not be needed before 24 hours after the onset of core damage.

Based on the NRC staff's review and ABB-CE's commitments in Chapter 19 of the generic DCD, the Commission determined that the special circumstances described in 10 CFR 50.12(a)(ii) exist in that the regulation need not be applied in this particular circumstance to achieve the underlying purpose because ABB-CE has proposed acceptable alternatives that accomplish the intent of the regulation. On this basis, the Commission concludes that an exemption from the requirement of 10 CFR 50.34(f)(iv) is justified.

(5) Paragraphs III.A.1(a) and III.C.3(b) of Appendix J to 10 CFR 50 -Containment Leakage Testing

(a) Paragraph III.A.1(a)

ABB-CE committed to containment leakage testing for the System 80+ design, in accordance with option A to the new Appendix J to 10 CFR Part 50, with the following exceptions:

- ! The COL applicant may use the mass point leak rate test method in ANSI/ANS 56.8-1987 as an alternative to Type A testing method specified in ANSI 45.4-1972, and
- ! Leaks occurring during the Type A test that could affect the test results will not prevent completion of this test if: (a) the leaks are isolated for the balance of the test; (b) the leaking component had a "pre-maintenance" local leak rate test whose

results, when added to those from the Type A test, are in conformance with the acceptance criteria of Appendix J; or (c) a "post-maintenance" local leak rate test of the leaking component(s) is performed and the results, when added to those from the Type A test, conform to the acceptance criteria of Appendix J.

The first exception is acceptable because the current version of Section III.A.3 of Appendix J to 10 CFR Part 50 includes the ANSI/ANS 56.8-1987 method (mass point method) as an acceptable alternative. The second exception does not conform to the requirements of Appendix J to 10 CFR Part 50. Section III.A.1.(a) of Appendix J requires that a Type A test, defined as a test to measure the primary containment overall integrated leakage rate be terminated if, during this test, potentially excessive leakage paths are identified which would either interface with satisfactory completion of the test or which would result in the Type A tests not meeting the applicable acceptance criteria of Section III.A.4(b) or III.A.5(b). Section III.A.1(a) further requires that, after terminating a Type A test due to potentially excessive leakage, the leakage through the potentially excessive leakage paths be measured using local leakage testing methods and repairs and/or adjustments to the affected equipment be made. The Type A test shall then be conducted. ABB-CE proposed that the test not be terminated when leakage is found during a Type A test. Instead, ABB-CE proposed that leaks be isolated and the Type A test continued. After completion of the modified Type A test (i.e., a Type A test with the leakage paths isolated), local leakage rates of those paths isolated during the modified Type A test will be measured before or after the maintenance to those paths.

ABB-CE proposed that the adjusted "as-found" leakage rate for the Type A test be determined by adding the local leakage rates measured before maintenance to those previously isolated leakage paths, to the containment integrated leakage rate determined in the modified Type A test. This adjusted "as-found" leakage rate is to be used in determining the scheduling of the periodic Type A tests in accordance with Section III.A.6 of Appendix J.

Finally, ABB-CE proposed that the acceptability of the modified Type A test be determined by calculating the adjusted "as-left" containment overall integrated leakage rate and comparing this to the acceptance criteria of Appendix J. The adjusted "as-left" Type A leakage rate is determined by adding the local leakage rates measured after any

maintenance to those previously isolated leakage paths, to the leakage rate determined in the modified Type A test.

The differences between the proposed leak testing and the requirements in Section III.A.1(a) of Appendix J are that: (1) the potentially excessive leakage paths will be repaired and/or adjusted after completion of the Type A test rather than before the test; and (2) the Type A test leakage rate is partially determined by calculation rather than by direct measurement. With respect to the first issue, the NRC staff does not identify any significant difference in the end result (i.e., the "as-left" local leakage rates will be maintained within an acceptable range). With respect to the second issue, the measured "as-left" local leakage rates will represent a relatively small correction to the containment overall integrated leakage rate measured in the modified Type A test. Accordingly, there will be insignificant differences between the calculated "as-left" containment leakage rate (i.e., a modified Type A test) and one that would be directly measured in compliance with the requirements of Section III.A.1. (a).

In view of the above, the Commission has determined that the special circumstances described in 10 CFR 50.12(a)(2)(ii) exist in that the regulation need not be applied in this particular circumstance to achieve the underlying purpose because ABB-CE has proposed acceptable alternatives that accomplish the intent of the regulation. On this basis, the Commission concludes that a partial exemption from the requirements of Paragraph III.A.1. (a) of Appendix J to 10 CFR Part 50 is justified.

(b) Paragraph III.C.3(b)

In Section 6.2.6 and Table 6.2.4-1 of the generic DCD, ABB-CE presented information on the System 80+ containment leakage testing program, including the planned leak test data for specific containment isolation valves (CIVs). In Table 6.2.4-1, ABB-CE lists those CIVs which are vented and drained for the Type A test and those CIVs which are subject to the Type C test, and justifies those CIVs not included in the Type C test program. ABB-CE presented the following justifications for not performing CIV Type C tests:

1. CIVs on piping connected to the secondary side of the steam generator would leak into the containment because, during a design-basis LOCA, the secondary side pressure is higher than the primary-side pressure.

2. The water always present in the in-containment refueling water storage tank (IRWST) seals CIVs on piping connected directly to the IRWST.

3. The discharge pressure from the safety injection pump effectively seals against leakage for CIVs on pump discharge (or injection) lines.

4. The shutdown cooling system (SCS) with these CIVs must maintain safe shutdown conditions. These CIVs cannot be tested without compromising safety and therefore will be separately water tested as part of the RCS pressure boundary.

The NRC staff did not find justifications 3 and 4 acceptable because multiple systems would allow the CIVs on one loop to be tested while the others are available. The two 100-percent redundant SCS would ensure safe shutdown with one system operating while the CIVs in the other are being leak tested. If the safety injection pump fails and the system switches from cold-leg to hot-leg injection, any leakage from the system safety injection pump CIVs would pass to the environment. Therefore, the NRC staff concluded that both the SCS and safety injection pump system CIVs should be tested for leaks in accordance with 10 CFR Part 50, Appendix J.

ABB-CE rearranged valve elevations so that safety injection system (SIS) valves SI-602, 603, 616, 626, 636, and 646 are approximately 1.2 m (4 ft) below the minimum IRWST water level and SCS valves SI-600 and 601 are approximately 0.44 m (1.5 ft) below the minimum water level. The minimum IRWST water level is at elevation 24.5 m (80.5 ft) which is determined by the calculated minimum IRWST water level following a large LOCA. By using this valve re-arrangement, the IRWST will provide a manometer effect to establish a water seal at the valves because the containment pressure is exerted on the surface of the IRWST liquid and the SIS forms a closed loop with containment following a pipe break. ABB-CE states that it complies with the intent of the regulation in 10 CFR Part 50, Appendix J, in maintaining water-sealed valves.

The NRC staff has reviewed the proposed alternative. Appendix J to 10 CFR Part 50, Section III.C.3(b) states that the installed isolation valve seal water system fluid inventory is sufficient to assure the sealing function for at least 30 days at a pressure of 1.1 Pa. The proposed design of water-sealed isolation valves conforms to the requirement of 30-day water inventory but not on the sealing pressure of 1.1 Pa. However,

the NRC staff finds that the closed loop and the manometer effect provide sufficient water sealing as long as the integrity of the closed loop and the elevation differential between the valves and the water level are maintained. As a result of the review, ABB-CE has committed to provide: (1) periodic pressure testing as described in DCD Sections 3.9.6 and 6.6 to ensure the integrity of the closed loop SIS outside containment is being maintained; and (2) a pre-operational test as described in DCD Section 14.2 to ensure the existence of the water seal.

Based on the NRC staff review and ABB-CE's commitment to the above periodic and pre-operational tests, the Commission has determined that the special circumstances described in 10 CFR 50.12(a)(2)(ii) exist in that the regulation need not be applied in this particular circumstance to achieve the underlying purpose because ABB-CE has proposed acceptable alternatives that accomplish the intent of the regulation. On this basis, the Commission concludes that a partial exemption from the requirements of Section III.C.3(b) is justified because the alternative water-sealed-valve design accomplishes the objectives of the regulatory requirement of sealing pressure of 1.1 Pa.

(6) Paragraph VI(a)(2) of Appendix A to 10 CFR Part 100 - Operating Basis Earthquake Design Consideration.

Appendix A to 10 CFR Part 100 requires, in part, that all structures, systems, and components (SSCs) of the nuclear power plant necessary for continued operation without undue risk to the health and safety of the public shall be designed to remain functional and within applicable stress and deformation limits when subject to an operating basis earthquake (OBE). In addition 10 CFR Part 100, Appendix A requires that the maximum vibratory ground acceleration of the OBE be at least one-half the maximum vibratory ground acceleration of the safe-shutdown earthquake (SSE).

In SECY-90-016, "Evolutionary Light Water Reactor Certification Issues and Their Relationship to Current Regulatory Requirements," dated January 12, 1990, the NRC staff requested the Commission's approval to decouple the level of the OBE ground motion from that of the SSE. The Commission approved this position in its staff requirements memorandum (SRM) of June 26, 1990. In SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," dated April 2, 1993, the NRC staff further requested that the Commission approve eliminating the

OBE from the design of SSCs in both evolutionary and passive advanced reactors designs.

The Commission approved this recommendation in its SRM of July 21, 1993.

The purpose of designing SSCs necessary for continued operation without undue risk to the health and safety of the public to withstand an OBE is to ensure that these SSCs remain functional and within applicable stress and deformation limits when subjected to the effects of the OBE vibratory ground motion. However, Appendix A to Part 100 also requires that these SSCs be designed to withstand the SSE and remain functional. Thus, when these SSCs are designed to remain functional for the SSE, they will also remain functional at a lesser earthquake level (one-third the SSE) provided all design functions at the OBE are accounted for. The basis for selecting one-third of the SSE as the earthquake level at which the plant will be required to shutdown and be inspected for damage was that, at this level, the likelihood of damage and the frequency of earthquakes occurring was judged to be low based on actual earthquake experience. It should be noted that certain design functions had been verified only for the OBE loads in the past. These design functions were the evaluations of fatigue damage caused by earthquake cycles and relative seismic anchor motions in piping systems. With the elimination of the OBE from design, these design functions would not have been explicitly verified. Consequently, for System 80+, these design functions will be verified in conjunction with the SSE using applicable stress and deformation limits as described in Section 3.1.1 of NUREG-1462, "Final Safety Evaluation Report Related to the Certification of the System 80+ Design," dated August 1994.

Accordingly, the special circumstances described by 10 CFR 50.12(a)(2)(ii) exist in that the regulation need not be applied in this particular circumstance to achieve the underlying purpose of the rule because ABB-CE has proposed acceptable alternative analysis methods that accomplish the intent of the regulation. On this basis, the Commission has determined that the exemption is justified because the alternative analyses performed for the SSE and the need to perform an inspection of the plant following an earthquake at or above one-third of the SSE accomplish the design objectives of the OBE design analyses.

Paragraph (b)(3) of 10 CFR 50.49 - Environmental Qualification of Post-Accident Monitoring Equipment

In the generic DCD, ABB-CE stated that the design of the information systems important to safety will be in conformance with the guidelines of Regulatory Guide (RG) 1.97, "Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environmental Conditions During and Following an Accident," Revision 3. However, the footnote for § 50.49(b)(3) references Revision 2 of RG 1.97 for selection of the types of post-accident monitoring equipment. As a result, the proposed design certification rule provided an exemption to this requirement.

In section C.1 of its comments, dated August 4, 1995, ABB-CE stated that it did not believe that an exemption from paragraph (b)(3) of 10 CFR 50.49 is needed or required. ABB-CE stated that:

The specific issue in question is a footnote to that regulation which identifies Revision 2 of RG 1.97 for guidance as to the types of variables to be monitored. RG 1.97 is clearly identified as a guidance document only and, therefore, the use of RG 1.97, Revision 3 for System 80+ -- at the request of the Staff and with the agreement of ABB-CE -- is not counter to any regulation, and does not require an exemption from any regulation.

The Commission agrees with ABB-CE's assertion that Revision 2 of RG 1.97 is identified in footnote 4 of 10 CFR 50.49 and should not be viewed as binding in this instance. Therefore, the Commission has determined that there is no need for an exemption from paragraph (b)(3) of 10 CFR 50.49 and has removed it from Section 5(b) of this appendix.

In paragraph (c), the Commission identified the new regulations that are applicable to the System 80+ design for the purposes of 10 CFR 52.48, 52.54, 52.59, and 52.63. The new regulations cover the following subjects:

1. Intersystem LOCA
2. Inservice Testing of Pumps and Valves
3. Digital Instrumentation and Control Systems
4. Alternate Offsite Power Source to Non-Safety Equipment
5. Offsite Power Source to Safety Divisions
6. Post-Fire Safe Shutdown
7. Analysis of External Events
8. Alternate AC Power Source

9. Core Debris Cooling
10. High Pressure Core Melt Ejection
11. Equipment Survivability
12. Containment Performance
13. Shutdown Risk
14. Steam Generator Tube Rupture

A detailed discussion and comment analysis for each new regulation is contained in Section II.A.4. The new regulations have the same effect as any other regulation, except for the additional compliance-backfit standard described in Section 8(c) of this appendix.

F. Issue resolution for this design certification.

The purpose of Section 6 of this appendix is to identify the scope of issues that are resolved by the Commission in this rulemaking and; therefore, are "matters resolved" within the meaning and intent of 10 CFR 52.63(a)(4). The section is divided into four parts: (a) the Commission's safety findings in adopting this appendix, (b) the scope and nature of issues which are resolved by this rulemaking, (c) the backfit restrictions applicable to the Commission with respect to this appendix, and (d) availability of secondary references.

Paragraph (a) describes in general terms the nature of the Commission's findings, and makes the finding required by 10 CFR 52.54 for the Commission's approval of this final design certification rule. Furthermore, paragraph (a) explicitly states the Commission's determination that this design provides adequate protection to the public health and safety.

Paragraph (b) sets forth the scope of issues which may not be challenged as a matter of right in subsequent proceedings. The introductory phrase of paragraph (b) clarifies that issue resolution as described in the remainder of the paragraph extends to the delineated NRC proceedings referencing this appendix. The remaining portion of paragraph (b) describes the general categories of information for which there is issue resolution.

Specifically, paragraph (b)(1) provides that all nuclear safety issues arising from the Atomic Energy Act of 1954, as amended, that are associated with the information in the NRC staff's FSER, the applicant's DCD, and the rulemaking record for this appendix are resolved within the meaning of § 52.63(a)(4). These issues include the information

referenced in the DCD that are requirements (i.e., "secondary references"), as well as all issues arising from proprietary information which are intended to be requirements. Paragraph (b)(2) provides for issue preclusion of proprietary information. As discussed in section II.A.1 of this SOC, the inclusion of proprietary information within the scope of issues resolved within the meaning of § 52.63(a)(4) represents a change from the Commission's intent during the proposed rule. Paragraph (b)(3) clarifies that departures from the DCD which are accomplished in compliance with the relevant procedures and criteria in Section 8 of this Appendix continue to be matters resolved in connection with this rulemaking. Paragraph (b)(4) provides that, for those plants located on sites whose site parameters do not exceed those assumed in the Technical Support Document (January 1995), all issues with respect to severe accident design alternatives arising under the National Environmental Policy Act of 1969 associated with the information in the Environmental Assessment for this design and the information regarding severe accident design alternatives in the applicant's Technical Support Document (January 1995) are also resolved within the meaning and intent of § 52.63(a)(4).

Paragraph (c) simply reiterates the restrictions (contained in 10 CFR 52.63 and Section 8 of this appendix) placed upon the Commission in ordering generic or plant-specific modifications, changes or additions to structures, systems or components, design features, design criteria, and ITAAC within the scope of the standard design. While the Commission does not believe that this rule language is necessary, the Commission has included such language in Section 6 to provide a concise statement of the scope and finality of this design certification rule.

Paragraph (d) provides the procedure for an interested member of the public to obtain access to proprietary information for the System 80+ design, in order to request and participate in proceedings identified in Section 6(b)(1) of this appendix, viz., proceedings involving licenses and applications which reference this appendix. As set forth in paragraph (d), access must first be sought from the design certification applicant. If ABB-CE refuses to provide the information, the person seeking access must request access from the Commission or the presiding officer, as applicable. Access to the proprietary information may be ordered by the Commission, but shall be subject to an appropriate non-disclosure agreement.

G. Duration of this design certification.

The purpose of Section 7 of this appendix is in part to specify the time period during which this design certification may be referenced by an applicant for a combined license, pursuant to 10 CFR 52.55. This section also states that the design certification remains valid for an applicant or licensee that references the design certification until the application is withdrawn or the license expires. Therefore, if an application references this design certification during the 15-year period, then the design certification continues in effect until the application is withdrawn or the license issued on that application expires. Also, the design certification continues in effect for the referencing license if the license is renewed. The Commission intends for this appendix to remain valid for the life of the plant that references the design certification to achieve the benefits of standardization and licensing stability. This means that changes to or plant-specific departures from information in the plant-specific DCD must be made pursuant to the change processes in Section 8 of this appendix for the life of the plant.

H. Processes for changes and departures.

The purpose of Section 8 of this appendix is to set forth the processes for generic changes to or plant-specific departures (including exemptions) from this appendix. The Commission adopted this restrictive change process in order to achieve a more stable licensing process for applicants and licensees that reference a design certification rule. Section 8 is divided into three paragraphs, which correspond to Tier 1, Tier 2, and backfitting for compliance with any of the additional applicable regulations identified in Section 5(c) of this appendix. The language of Section 8 distinguishes between generic *changes to* the DCD versus plant-specific *departures from* the DCD. Generic *changes* must be accomplished by rulemaking because the intended subject of the change is the design certification rule itself, as is contemplated by 10 CFR 52.63(a)(1). Consistent with 10 CFR 52.63(a)(2), any generic rulemaking changes are applicable to all plants, absent circumstances which render the change ("modification" in the language of § 52.63(a)(2)) "technically irrelevant." By contrast, plant-specific *departures* could be either a Commission-issued order to one or more applicants or licensees; or an applicant or licensee-initiated departure applicable only to that applicant's or licensee's plant(s),

i.e., a § 50.59-like departure or an exemption. Because these plant-specific departures will result in a DCD that is unique for that plant, Section 10 of this appendix requires an applicant or licensee to maintain a plant-specific DCD. For purposes of brevity, this discussion refers to both generic changes and plant-specific departures as "change processes."

Both Section 8 and this SOC refer to an "exemption" from one or more aspects of this appendix and the criteria for granting an exemption. The Commission cautions that where the exemption involves an underlying substantive requirement ("applicable regulation"), then the applicant or licensee requesting the exemption must also show that an exemption from the underlying applicable requirement meets the criteria of 10 CFR 50.12.

Tier 1.

The change processes for Tier 1 information are covered in paragraph 8(a). Generic changes to Tier 1 are accomplished by rulemaking that amends the generic DCD and are governed by the standards in 10 CFR 52.63(a)(1). This provision provides that the Commission may not modify, change, rescind, or impose new requirements by rulemaking except where necessary either to bring the certification into compliance with the Commission's regulations applicable and in effect at the time of issuance of the design certification or to assure adequate protection of the public health and safety or common defense and security. The rulemakings must include an opportunity for hearing with respect to the proposed change, as required by 10 CFR 52.63(a)(1), and the hearings will be conducted in accordance with 10 CFR Part 2, Subpart H. Departures from Tier 1 may occur in two ways: (1) the Commission may *order* a licensee to depart from Tier 1, as provided in paragraph (a)(3); and (2) an applicant or licensee may request an *exemption* from Tier 1, as provided in paragraph (a)(4). If the Commission seeks to order a licensee to depart from Tier 1, paragraph (a)(3) requires that the Commission find both that the departure is necessary for adequate protection or for compliance, and that special circumstances as defined in 10 CFR 50.12(a) are present. Paragraph (a)(4) provides that exemptions from Tier 1 requested by an applicant or licensee are governed by the requirements of 10 CFR 52.63(b)(1) and 52.97(b), which provide an opportunity for a hearing.

Tier 2.

The change processes for the three different categories of Tier 2 information, viz., Tier 2, Tier 2*, and Tier 2* with a time of expiration are set forth in paragraph 8(b). The change process for Tier 2 has the same elements as the Tier 1 change process, but some of the standards for plant-specific orders and exemptions are different. The Commission also adopted a "§ 50.59-like" change process in accordance with its SRMs on SECY-90-377 and SECY-92-287A.

The process for generic Tier 2 changes (including changes to Tier 2* and Tier 2* with a time of expiration) tracks the process for generic Tier 1 changes. As set forth in paragraph (b)(1), generic Tier 2 changes are accomplished by rulemaking amending the generic DCD, and are governed by the standards in 10 CFR 52.63(a)(1). This provision provides that the Commission may not modify, change, rescind or impose new requirements by rulemaking except where necessary either to bring the certification into compliance with the Commission's regulations applicable and in effect at the time of issuance of the design certification or to assure adequate protection of the public health and safety or common defense and security.

Departures from Tier 2 may occur in five ways: (1) the Commission may order a plant-specific departure, as set forth in paragraph (b)(3); (2) an applicant or licensee may request an exemption from a Tier 2 requirement as set forth in paragraph (b)(4); (3) a licensee may make a departure without prior NRC approval in accordance with paragraph (b)(5) [the "§ 50.59-like" process]; (4) the licensee may request NRC approval for proposed departures which do not meet the requirements in paragraph (b)(5) as provided in paragraph (b)(5)(iv); and (5) the licensee may request NRC approval for a departure from Tier 2* information, in accordance with paragraph (b)(6).

Similar to Commission-ordered Tier 1 departures and generic Tier 2 changes, Commission-ordered Tier 2 departures cannot be imposed except where necessary either to bring the certification into compliance with the Commission's regulations applicable and in effect at the time of issuance of the design certification or to assure adequate protection of the public health and safety or common defense and security, as set forth in paragraph 8(b)(3).

An applicant or licensee may request an exemption from Tier 2 information as set forth in paragraph (b)(4) of this Appendix. The applicant or licensee must establish that the

exemption complies with 10 CFR 50.12. If the exemption is requested by an applicant for a combined license, the exemption is subject to litigation in the same manner as other issues in the combined license hearing, consistent with 10 CFR 52.63(b)(1).

Paragraph (b)(5) allows an applicant or licensee to depart from Tier 2 information without prior NRC approval if the proposed departure does not involve a change to or departure from Tier 1 or Tier 2* information, technical specifications, or involves an unreviewed safety question (USQ) as defined in paragraphs (b)(5)(ii) and (iii). The technical specifications identified in this paragraph are the technical specifications that will be developed during the COL review. Prior to issuance of the COL, an applicant is not controlled by the technical specifications under development but should be cognizant of the technical specifications in Chapter 16 of the generic DCD. The definition of a USQ in paragraph (b)(5)(ii) is similar to the definition in 10 CFR 50.59 and it applies to all information in Tier 2 except for the information, identified in paragraph (b)(5)(ii), that resolves the severe accident issues. The process for evaluating proposed tests or experiments not described in Tier 2 will be incorporated into the change process for the portion of the design that is outside the scope of this design certification. Although paragraph (b)(5) does not specifically state, the Commission notes that departures must also comply with all applicable regulations unless an exemption or other relief is obtained.

The Commission believes that it is important to preserve and maintain the resolution of severe accident issues just like all other safety issues that were resolved during the design certification review (refer to SRM on SECY-90-377). However, because of the increased uncertainty in severe accident issue resolutions, the Commission has adopted separate criteria for determining whether a departure from information that resolves severe accident issues constitutes a USQ. The new criteria in paragraph (b)(5)(iii) will only apply to Tier 2 information in the sections of the generic DCD identified in paragraph (b)(5)(iii). If the proposed departure from Tier 2 information involves the resolution of other safety issues in addition to the severe accident issues, then the USQ determination for those issues should be based upon the criteria in Section 8(b)(5)(ii) of this appendix. An applicant or licensee that plans to depart from Tier 2 information, under Section 8(b)(5), must prepare a safety evaluation which provides the bases for the determination that the proposed change does not involve an unreviewed safety question, a change to Tier 1 or Tier 2* information, or a change to the technical specifications. In

order to achieve the Commission's goals for design certification, the evaluation needs to consider all of the matters that were resolved in the DCD, such as generic issue resolutions that are relevant to the proposed departure. The benefits of the early resolution of safety issues would be lost if departures from the DCD were made that violated these resolutions without appropriate review. The evaluation of the relevant resolved issues needs to consider the proposed departure over the full range of power operation from startup to shutdown, including issues resolved under the heading of shutdown risk, as it relates to anticipated operational occurrences, transients, design basis accidents, and severe accidents. The evaluation should consider the tables in Sections 14.3 and 19.8 of the DCD to ensure that the proposed change does not impact Tier 1. These tables contain various cross-references from the plant safety analyses in Tier 2 to the important parameters that were included in Tier 1. Although many issues and analyses could have been cross-referenced, the listings in these tables were developed only for key plant safety analyses for the design. GE provided more detailed cross-references to Tier 1 for these analyses in a letter dated March 31, 1994, and ABB-CE provided more detailed cross-references in a letter dated June 10, 1994. If a proposed departure from Tier 2 involves a change to or departure from Tier 1 or Tier 2* information, technical specifications, or otherwise constitutes a USQ, then the applicant or licensee must obtain NRC approval through the appropriate process set forth in this appendix before implementing the proposed departure. The NRC does not endorse NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," for performing safety evaluations required by Section 8(b)(5) of this appendix. However, the NRC will work with industry, if it is desired, to develop an appropriate guidance document for processing proposed changes under Section 8(b).

A party to an adjudicatory proceeding (*e.g.*, for issuance of a combined license) who believes that an applicant or licensee has not complied with Section 8(b)(5) when departing from Tier 2 information, may petition to admit such a contention into the proceeding. As set forth in paragraph (b)(5)(vi), the petition must comply with the requirements of § 2.714(b)(2) and show that the departure does not comply with paragraph (b)(5). Any other party may file a response to the petition. If on the basis of the petition and any responses, the presiding officer in the proceeding determines that the required showing has been made, the matter shall be certified to the Commission for its final determination. In the absence of a proceeding, petitions alleging non-conformance

with paragraph (b)(5) requirements applicable to Tier 2 departures will be treated as petitions for enforcement action under 10 CFR 2.206.

Certain Tier 2* information listed in paragraph (b)(6)(iii) is no longer designated as Tier 2* information after full power operation is first achieved following the Commission finding in 10 CFR 52.103(g). Thereafter, that information is deemed to be Tier 2 information that is subject to the departure requirements in paragraph (b)(5). By contrast, the Tier 2* information identified in paragraph (b)(6)(ii) retains its Tier 2* designation throughout the term of the combined license, including any period of renewal. Any requests for departures from Tier 2* information that affect Tier 1 must also comply with the requirements in Section 8(a) of this appendix.

Regardless of the way in which a departure is achieved, the Commission has determined that it is not necessary to impose an additional limitation, similar to that imposed on Tier 1 departures by 10 CFR 52.63(a) and paragraph 8(a)(3) and (4) of this appendix, whether the special circumstances in § 50.12(a) outweigh any decrease in safety that may result from the reduction in standardization. This type of additional limitation would unnecessarily restrict the flexibility of applicants and licensees with respect to Tier 2, which by its nature is not as safety significant as Tier 1.

Backfitting for Compliance with Additional Applicable Regulations

Paragraph (c) sets forth the criteria which must be met if the Commission is to require a backfit to either this appendix or, for a plant referencing this appendix, that portion of the plant subject to the appendix, where the backfit is for compliance with an "additional applicable regulation" in Section 5(c) of this appendix. Such backfitting can occur either by rulemaking amending this appendix (and may be initiated by the Commission either at its own instance or upon petition); or by Commission issuing an order to one or more plants referencing this appendix. Any backfit intended to achieve compliance with an "additional applicable regulation" must meet stringent criteria. First, the Commission must find that the asserted non-compliance constitutes a "substantial reduction in protection" to the public health and safety or common defense and security. If such is the case, the Commission must tailor the backfit to return to approximately the level of protection originally embodied at the time the new applicable regulation was first adopted; the Commission does not intend to impose such "compliance backfits" to achieve a

level of protection greater than that intended when it adopted the "additional applicable regulation". Finally, the Commission must determine that the costs, both direct and indirect, of the implementation of the backfit are "justified in view of [the] compensating increase in protection." The Commission regards these criteria as stringent enough to ensure that marginal compliance backfits are not imposed, thereby addressing the industry concerns about unfettered compliance backfits with new applicable regulations. The Commission would nonetheless be able to correct those significant non-compliances which result in the appendix (and any plant referencing this appendix) not achieving the level of protection to the public that was originally intended when the Commission adopted the additional applicable regulation.

I. Inspections, tests, analyses, and acceptance criteria (ITAAC).

The purpose of Section 9 of this Appendix is to set forth how the ITAAC in Tier 1 of this design certification rule are to be treated in a combined license proceeding. Paragraph (a) restates the responsibilities of the combined license applicant and holder in performing and successfully completing ITAAC, and notifying the NRC of such completion. Paragraph (a)(1) makes it clear that an applicant for a COL may proceed at its own risk with design and procurement activities subject to ITAAC, and that a COL holder may proceed at its own risk with design, procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC has been successfully completed. Paragraph (a)(2) requires the licensee to notify the NRC that the required inspections, tests, and analyses in the ITAAC have been completed and that the acceptance criteria have been met. Paragraphs (b)(1) and (2) essentially reiterate the NRC's responsibilities with respect to ITAAC as set forth in 10 CFR 52.99 and 52.103, as explained in II.C.1. Finally, paragraph (b)(3) states that ITAAC do not constitute regulatory requirements either for subsequent plant modifications within the scope of this design certification rule, or for renewal of the combined license. However, subsequent modifications must comply with the Tier 1 design descriptions unless the applicable requirements in 10 CFR 52.97 and Section 8 of this appendix have been complied with. As discussed in II.B.9, the Commission will defer a determination of the applicability of ITAAC and their effect in terms of issue resolution in 10 CFR Part 50

licensing proceedings to such time, if any, that a Part 50 applicant decides to reference this appendix.

J. Records and Reporting.

The purpose of Section 10 of this appendix is to set forth the requirements for maintaining records of changes to and departures from the generic DCD, which are to be reflected in the plant-specific DCD. Section 10 also sets forth the requirements for submitting reports (including updates to the plant-specific DCD) to the NRC. This section of the appendix is similar to the requirements for records and reports in 10 CFR Part 50, except for minor differences in information collection and reporting requirements, as discussed in section V below. Section 10(a)(1) of this appendix requires that a generic DCD and the proprietary information referenced in the generic DCD be maintained by the applicant for this rule. The generic DCD was developed, in part, to meet the requirements for incorporation by reference, including availability requirements. Therefore, the proprietary information could not be included in the generic DCD because it is not publicly available. However, the proprietary information was reviewed by the NRC and, as stated in Section 6(b)(2) of this appendix, the Commission considers the information to be resolved within the meaning of 10 CFR 52.63(a)(4). Because this information is not in the generic DCD, the proprietary information, or its equivalent, is required to be provided by an applicant for a combined license. Therefore, to ensure that this information will be available, a requirement to maintain the proprietary information was added to Section 10(a)(1) of this appendix. The acceptable version of the proprietary information is identified in the version of the DCD that is incorporated into this rule. The generic DCD and the acceptable version of the proprietary information must be maintained for the period of time that this rule may be referenced.

Sections 10(a)(2) and (a)(3) of this appendix place record-keeping requirements on the applicant or licensee that references this design certification to maintain its plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made pursuant to Section 8 of this appendix. The term "plant-specific" was added to Section 10(a)(2) and other Sections of this appendix to distinguish between the generic DCD that is incorporated by reference into this appendix, and the plant-specific DCD that the applicant is required to submit under Section 4(a)(2)(i) of

this appendix. The requirement to maintain the generic changes to the generic DCD is explicitly stated to ensure that these changes are not only reflected in the generic DCD, which will be maintained by the applicant for design certification, but that the changes are also reflected in the plant-specific DCD. Therefore, records of generic changes to the DCD will be required to be maintained by both entities to ensure that both entities have up-to-date DCDs.

Section 10(a) of this appendix does not place record-keeping requirements on site-specific information that is outside the scope of this rule. As discussed in section III.D, the final safety analysis report (§ 52.79) will contain the plant-specific DCD and the site-specific information for a facility that references this rule. The phrase "site-specific portion of the final safety analysis report" in section 10(b)(3)(iv) of this appendix refers to the information that is contained in the final safety analysis report for a facility but is not part of the plant-specific DCD, i.e. required by Subpart C of Part 52 and Section 4 of this appendix. Therefore, this rule does not require that duplicate documentation be maintained by an applicant or licensee that references this rule, because the plant-specific DCD is part of the final safety analysis report for the facility (refer to the discussion on DOE's comment in section II.C.3).

Section 10(b)(1) and (b)(2) of this appendix establishes reporting requirements for applicants or licensees that reference this rule that are similar to the reporting requirements in 10 CFR Part 50. For currently operating plants, a licensee is required to maintain records of the basis for any design changes to the facility made under 10 CFR 50.59. Section 50.59(b)(2) requires a licensee to provide a summary report of these changes to the NRC annually, or along with updates to the facility final safety analysis report under 10 CFR 50.71(e). Section 50.71(e)(4) requires that these updates be submitted annually, or 6 months after each refueling outage if interval between successive updates does not exceed 24 months.

The reporting requirements vary according to four different time periods during facilities' lifetime as specified in Section 10(b)(3) of this appendix. Section 10(b)(3)(i) requires that if an applicant that references this rule decides to make departures from the generic DCD, then the departures and any updates to the plant-specific DCD must be submitted with the initial application for a combined license. Under Section 10(b)(3)(ii), the applicant may submit any subsequent reports and updates along with its amendments to the application provided that the submittals are made at least once per

year. Because amendments to an application are typically made more frequently than once a year, this should not be an unnecessary burden on the applicant.

Section 10(b)(3)(iii) requires that the reports be submitted quarterly during the period of facility construction. This increase in frequency of summary reports of departures from the plant-specific DCD is in response to the Commission's guidance on reporting frequency in its SRM on SECY-90-377, dated February 15, 1991. NEI stated in its comments (Attachment B, p. 116) that ... "the requirement for quarterly reporting imposes unnecessary additional burdens on licensees and the NRC." NEI recommended that the Commission adopt a "less onerous" requirement (e.g., semi-annual reports). The NRC does not agree with the NEI request because it does not provide for sufficiently timely notification of design changes during the critical period of facility construction. The NRC disagrees that the reports are an onerous burden because they are only summary reports, which describe the design changes, rather than detailed evaluations of the changes and determinations. The detailed evaluations remain available for audit on site, consistent with the requirements of 10 CFR Part 50. Quarterly reporting of design changes during the period of construction is necessary to closely monitor the status and progress of the construction of the plant. To make its finding under 10 CFR 52.99, the NRC must monitor the design changes made in accordance with Section 8 of this appendix. The ITAAC verify that the as-built facility conforms with the approved design and emphasizes design reconciliation and design verification. Quarterly reporting of design changes is particularly important in times where the number of design changes could be significant, such as during the procurement of components and equipment, detailed design of the plant at the start of construction, and during pre-operational testing. The frequency of updates to the plant-specific DCD is not increased during facility construction. After the facility begins operation, the frequency of reporting reverts to the requirement in Section 10(b)(3)(iv), which is consistent with the requirement for plants licensed under 10 CFR Part 50.

IV. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended (NEPA), and the Commission's regulations in 10 CFR Part 51, Subpart A, that this design certification rule is not a major Federal action significantly affecting the

quality of the human environment and, therefore, an environmental impact statement (EIS) is not required. The basis for this determination, as documented in the final environmental assessment, is that this amendment to 10 CFR Part 52 does not authorize the siting, construction, or operation of a facility using the System 80+ design; it only codifies the System 80+ design in a rule. The NRC will evaluate the environmental impacts and issue an EIS as appropriate in accordance with NEPA as part of the application(s) for the construction and operation of a facility.

In addition, as part of the final environmental assessment for the System 80+ design, the NRC reviewed ABB-CE's evaluation of various design alternatives to prevent and mitigate severe accidents that was submitted in its Technical Support Document. The Commission finds that ABB-CE's evaluation provides a sufficient basis to conclude that there are no additional severe accident design alternatives beyond that currently incorporated into the System 80+ design which are cost-beneficial, whether considered at the time of the approval of the System 80+ design certification or in connection with the licensing of a future facility referencing the System 80+ design certification, where the plant referencing this appendix is located on a site whose site parameters do not exceed those assumed in the Technical Support Document. These issues are considered resolved for the System 80+ design.

The final environmental assessment, upon which the Commission's finding of no significant impact is based, and the Technical Support Document for the System 80+ design are available for examination and copying at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Single copies are also available from Mr. Dino C. Scaletti, Mailstop O-11 H3, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 415-1104.

V. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0151. Should an application be received, the additional public reporting burden for this collection of information, above those contained in Part 52, is estimated to average 8 hours per response, including the time for reviewing instructions, searching existing data sources,

gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments on any aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0151), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Regulatory Analysis

The NRC has not prepared a regulatory analysis for this final rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications are not generic rulemakings in the sense that design certifications do not establish standards or requirements for which all licensees must comply. Rather, design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certification rulemakings are initiated by an applicant for a design certification, rather than the NRC. Preparation of a regulatory analysis in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC. For these reasons, the Commission concludes that preparation of a regulatory analysis is neither required nor appropriate.

VII. Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rulemaking will not have a significant economic impact upon a substantial number of small entities. The rule provides certification for a nuclear power plant design. Neither the design certification applicant nor prospective nuclear

power plant licensees who reference this design certification rule fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act, 15 U.S.C. 632, or the Small Business Size Standards set out in regulations issued by the Small Business Administration in 13 CFR Part 121. Thus, this rule does not fall within the purview of the act.

VIII. Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule because these amendments do not impose requirements on existing 10 CFR Part 50 licensees. Therefore, a backfit analysis was not prepared for this rule.

List of Subjects in 10 CFR Part 52

Part 52 - Administrative practice and procedure, Anti trust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Incorporation by reference, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and record keeping requirements, Standard design, Standard design certification.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR Part 52.

1. The authority citation for 10 CFR Part 52 continues to read as follows:

AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1243, 1244, 1246, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

2. In § 52.8, paragraph (b) is revised to read as follows:

§ 52.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 52.15, 52.17, 52.29, 52.45, 52.47, 52.57, 52.75, 52.77, 52.78, 52.79, Appendix A, and Appendix B.

3. A new Appendix B to 10 CFR Part 52 is added to read as follows:

Appendix B To Part 52--Design Certification Rule for the System 80+ design

1. Introduction.

Appendix B constitutes design certification for the System 80+¹ standard plant design, in accordance with 10 CFR Part 52, Subpart B. The applicant for certification of the System 80+ design was Combustion Engineering, Inc. (ABB-CE).

2. Definitions.

As used in this part:

(a) *Generic design control document* (generic DCD) means the document that contains the generic Tier 1 and Tier 2 information that is incorporated by reference into this appendix.

(b) *Plant-specific DCD* means the document, maintained by an applicant or licensee who references this design certification rule, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section 8 of this appendix.

(c) *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this design certification rule (hereinafter

¹"System 80+" is a trademark of Combustion Engineering, Inc.

Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

- (1) Definitions and general provisions;
- (2) Design descriptions;
- (3) Inspections, tests, analyses, and acceptance criteria (ITAAC);
- (4) Significant site parameters; and
- (5) Significant interface requirements.

(d) *Tier 2* means the portion of the design-related information contained in the generic DCD that is approved but not certified by this design certification rule (hereinafter Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section 8 of this appendix. Tier 2 information includes:

- (1) Information required by 10 CFR 52.47, with the exception of technical specifications and conceptual design information;
- (2) Information required for a final safety analysis report under 10 CFR 50.34;
- (3) Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
- (4) Combined License (COL) action items (COL license information), which identify certain matters that shall be addressed in the site-specific portion of the final safety analysis report by an applicant who references this appendix. These items constitute information requirements but do not otherwise constitute substantive requirements for judging the adequacy of the information submitted.

(e) *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section 8(b)(6) of this appendix. This designation expires for some Tier 2* information pursuant to Section 8(b)(6).

(f) All other terms in this appendix have the meaning set out in 10 CFR 50.2, 10 CFR 52.3, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

3. Scope and contents of this design certification.

(a) Tier 1 and Tier 2 in the System 80+ Design Control Document, ABB-CE, dated ___ are approved for incorporation by reference by the Director of the Office of the Federal Register on [Insert date of approval] in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the generic DCD may be obtained from [Insert name and address of applicant

or organization designated by the applicant]. Copies are also available for examination and copying at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555, and for examination at the NRC Library, 11545 Rockville Pike, Rockville, Maryland 20582-2738.

(b) An applicant or licensee referencing this appendix, in accordance with Section 4 of this appendix, shall comply with the requirements of this appendix, including Tier 1 and Tier 2, except as otherwise provided in this appendix.

(c) If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

(d) If there is a conflict between the generic DCD and either the application for design certification for the System 80+ design or NUREG-1462, "Final Safety Evaluation Report related to the Certification of the System 80+ Design," dated August 1994 (FSER) and any supplements thereto, then the generic DCD controls.

(e) Conceptual design information and generic technical specifications, as set forth in the generic DCD, are not part of this appendix.

4. Applications and licenses referencing this design certification: additional requirements and restrictions.

(a) An applicant for a combined license that wishes to reference this Appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.78, and 52.79, comply with the following requirements:

(1) Incorporate by reference, as part of its application, this appendix;

(2) Include, as part of its application:

(i) A plant-specific DCD containing the same information and utilizing the same organization and numbering as the generic DCD for the System 80+ design, as modified and supplemented by the applicant's exemptions and departures;

(ii) The reports on departures from and updates to the plant-specific DCD required by Section 10(b) of this Appendix;

(iii) Technical specifications for the plant that are required by § 50.36 and § 50.36a;

(iv) Information demonstrating compliance with the site parameters and interface requirements;

(v) Information that addresses the COL action items; and

(vi) The information required by 10 CFR 52.47(a) that is not within the scope of this rule.

(vii) Descriptions of the initial 120-month in-service testing (IST) and in-service inspection (ISI) programs for pumps and valves subject to the test requirements set forth in 10 CFR 50.55a(f), which utilize:

(A) Non-intrusive techniques available twelve months prior to the date of the COL application to detect degradation and monitor performance characteristics of check valves; and

(B) A method to determine the frequency necessary for disassembly and inspection of each pump and valve to detect degradation that would prevent the component from performing its safety function and which cannot be detected through the use of non-intrusive techniques;

(viii) A description of a program for outage planning and control that ensures:

(A) The availability and functional capability during shutdown and low power operations of features important to safety during such operations; and

(B) The consideration of fire, flood, and other hazards during shutdown and low power operations; and

(ix) A description of a design reliability assurance program that:

(A) Includes the program's scope, purpose, and objectives;

(B) Evaluates the structures, systems, and components in the design to determine their degree of risk-significance;

(C) Generates a list of structures, systems, and components designated as risk-significant;

(D) For those structures, systems, and components designated as risk-significant, considers both:

(AA) Industry-wide experience, analytical models, and applicable requirements to determine dominant failure modes; and

(BB) Industry-wide operational, maintenance, and monitoring experience to identify key assumptions and risk insights from probabilistic, deterministic, and other analytical methods; and

(E) Considers the dominant failure modes, incorporates the risk insights, and preserves the key assumptions identified in paragraph (a)(2)(ix)(BB) of this Section in the design.

(3) Physically include, in the plant-specific DCD, the proprietary information referenced in the System 80+ DCD; and

(4) Implement the design reliability assurance program required by paragraph (a)(2)(ix) of this Section.

(b) A holder of a combined license that references this appendix shall, in addition to complying with the requirements in 10 CFR 52.83, and 52.99 comply with the following requirements:

(1) Implement the portions of the IST and ISI programs required by paragraph (a)(2)(vii) of this section, as approved by the Commission and include in each successive 120-month IST testing program non-intrusive techniques available twelve months prior to the date of the start of each 120-month interval to detect degradation and monitor performance characteristics of check valves.

(2) Implement the program for outage planning and control required by paragraph (a)(2)(viii) of this Section; and

(3) Implement the design reliability assurance program required by paragraph (a)(2)(ix) of this Section

(c) Facility operation is not within the scope of this appendix, and the Commission reserves the right to impose requirements for facility operation on holders of licenses referencing this appendix by rule, regulation, order, or license condition.

(d) The Commission reserves the right to determine whether, and in what manner, this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR Part 50.

5. Applicable regulations.

(a) Except as indicated in paragraphs (b) and (c) of this section, the regulations that apply to the System 80+ design are in 10 CFR Parts 20, 50, 73, and 100 codified as of [insert the date 30 days after the publication date] that are applicable and technically relevant, as described in the FSER and any associated supplements.

(b) The System 80+ design is exempt from portions of the following regulations, as described in the FSER (index provided in Section 1.6 of the FSER):

(1) Paragraph (f)(2)(iv) of 10 CFR 50.34 - Separate Plant Safety Parameter Display Console;

(2) Paragraphs (f)(2)(vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34 - Accident Source Terms;

(3) Paragraph (f)(2)(viii) of 10 CFR 50.34 - Post-Accident Sampling for Hydrogen, Boron, Chloride, and Dissolved Gases;

(4) Paragraph (f)(3)(iv) of 10 CFR 50.34 - Dedicated Containment Penetration;

(5) Paragraphs III.A.1(a) and III.C.3(b) of Appendix J to 10 CFR 50 - Containment Leakage Testing; and

(6) Paragraph VI(a)(2) of 10 CFR Part 100, Appendix A - Operating Basis Earthquake Design Consideration.

(c) In addition to the regulations specified in paragraph (a) of this section, the following new regulations are applicable for the purposes of 10 CFR 52.48, 52.54, 52.59 and 52.63:

(1) The low-pressure piping systems and subsystems of this design that interface with the reactor coolant pressure boundary must be designed for a normal operating pressure of at least 40 percent of the normal reactor operating pressure, to the extent practical as determined on **[insert date of Commission approval]**.

(2) Piping systems of this design associated with pumps and valves subject to the test requirements set forth in 10 CFR 50.55a(f) must be designed to allow for:

(i) Full flow testing of pumps at maximum design flow,

(ii) Flow testing of check valves at flows sufficient to fully-open the valve, provided the valve's full-open position can be positively confirmed, or with the maximum design basis accident flowrate, and

(iii) Testing of motor operated valves under conditions as specified in section 3.9 of the DCD, up to design basis differential pressure, to demonstrate the capability of the valves to operate under design basis conditions.

(3) The digital instrumentation and control systems of this design must provide for:

(i) defense-in-depth and diversity,

(ii) adequate defense against common-mode failures, and

(iii) independent backup manual controls and displays for critical safety functions in the control room.

(4) The electric power system of this design must include an alternate offsite power source that has sufficient capacity and capability to provide power to non-safety

equipment sufficient to provide the operator with the capability to bring the plant to a safe shutdown, following a loss of the normal power supply and reactor trip.

(5) The electric power system of this design must include at least one offsite circuit for supplying power to each redundant safety division. This circuit shall be designed such that non-safety loads do not have any significant adverse effect on the capability of the offsite circuit to provide power to each safety division.

(6) All structures, systems, and components of this design important to safe shutdown, except for the containment annulus, must be designed to ensure that:

(i) Safe shutdown can be achieved assuming that all equipment in any one fire area will be rendered inoperable by fire and that re-entry into the fire area for repairs and operator actions is not possible, except that this provision does not apply to (1) the main control room, provided that an alternative shutdown capability exists and is physically and electrically independent of the main control room, and (2) the reactor containment;

(ii) Smoke, hot gases, or fire suppressant will not migrate from one fire area into another to the extent they could adversely affect safe-shutdown capabilities, including operator actions; and

(iii) In the reactor containment, redundant shutdown systems must be provided with fire protection capabilities and means to limit fire damage such that, to the extent practical as of **[insert date of Commission approval]**, one shutdown division be free of fire damage.

(7) The probabilistic risk assessment (PRA) required by 10 CFR 52.47(a)(1)(v) must include an assessment of internal and external events. For external events, simplified (bounding) probabilistic methods and margins methods may be used instead of detailed PRA analyses to identify potential vulnerabilities and important safety insights for the design in order to incorporate the insights in the design. Simplified bounding risk analyses for fires and floods may be performed when detailed design information, such as pipe and cable routing, is not available. For earthquakes, the seismic margins analysis must be based on a review earthquake level of one and two-thirds the acceleration of the safe-shutdown earthquake (i.e., review earthquake level of 0.5g.)

(8) The electric power system of this design must include an on-site alternate AC power source of diverse design capable of providing power to at least one complete set of

equipment sufficient to achieve and maintain safe-shutdown in the event of a station blackout.

(9) For the severe accident sequences identified in Section 19.11 of the DCD, this design must include the following design features that, in combination with other design features, ensure that environmental conditions (pressure and temperature) described in Section 19.11 of the DCD resulting from interactions of molten core debris with containment structures do not exceed ASME Code Service Level C for steel containments or Factored Load Category for concrete containments for a time from the initiation of the accident sequence sufficient to mitigate them in view of their probability of occurrence and the uncertainties in severe accident progression and phenomenology:

(i) A minimum of 79 m² of unobstructed reactor cavity floor space for molten core debris spreading;

(ii) A system capable of directly or indirectly flooding the reactor cavity for cooling molten core debris; and

(iii) Concrete to protect portions of the containment liner and the reactor pedestal.

(10) This design must include:

(i) a safety-related or other highly reliable means to depressurize the reactor coolant system and

(ii) cavity design features to reduce the amount of ejected core debris that may reach the upper containment.

(11) This design must include analyses based on analytical techniques in use as of **[insert date of Commission approval]**, to demonstrate that:

(i) Electrical and mechanical equipment that prevents or mitigates the consequences of a severe accident must be capable of performing their functions for a time period sufficient to prevent or mitigate the consequences of that severe accident under the environmental conditions (e.g., pressure, temperature, radiation) described in Section 19.11.4.4.1 of the DCD for that severe accident; and

(ii) Instrumentation that monitors plant conditions during a severe accident must be capable of performing its function for a time period sufficient to prevent or mitigate the consequences of that severe accident under the environmental conditions (e.g., pressure, temperature, radiation) described in Section 19.11.4.4.1 of the DCD for that severe accident.

(12) This design must include design features intended to limit the conditional containment failure probability to less than 0.1 for the severe accident sequences identified in Section 19.11 of the DCD.

(13) This design must include assessments of:

- (i) Features that minimize shutdown risk;
- (ii) The reliability of decay heat removal systems;
- (iii) Features that mitigate vulnerabilities resulting from other design features; and
- (iv) Features that assure the operator's ability to shut down the plant safely and maintain it in a safe condition in the event of fires and floods occurring with the plant in modes other than full power.

(14) This design must include a systematic evaluation of plant response to a steam generator tube rupture (SGTR) to:

- (i) Identify potential design vulnerabilities;
- (ii) Assess potential design improvements that reduce the amount of containment bypass leakage that could result from a SGTR; and
- (iii) Incorporate in the design those design improvements that are significant and practical and do not impact excessively on the plant.

6. Issue resolution for this design certification.

(a) The Commission has determined that the structures, systems, components, and design features of the System 80+ design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section 5 of this appendix, and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the System 80+ design.

(b) The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(4) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held pursuant to 10 CFR 52.103, and enforcement proceedings where these proceedings reference this appendix:

(1) All nuclear safety issues associated with the information in the FSER and any associated supplements, the generic DCD (including referenced information which the

context indicates is intended as requirements), and the rulemaking record for certification of the System 80+ design;

(2) All nuclear safety issues associated with the information in proprietary documents referenced and in context is intended as requirements in the generic DCD for the System 80+ design;

(3) Except as provided in Section 8(b)(5)(vi) of this appendix, all departures from Tier 2 pursuant to and in compliance with the change processes in Section 8(b)(5) of this appendix that do not require prior NRC approval;

(4) All environmental issues concerning severe accident design alternatives associated with the information in the NRC's final environmental assessment for the System 80+ design and Revision 2 of the Technical Support Document for the System 80+ design, dated January 1995, for plants referencing this appendix whose site parameters are within those specified in the Technical Support Document.

(c) Except in accordance with the change processes in Section 8 of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

(1) Modify structures, systems, components, or design features as described in the generic DCD;

(2) Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or

(3) Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

(d) Persons who wish to review proprietary information or other secondary references in the DCD for the System 80+ design, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or participate in any other hearing relating to the certified design in which interested persons have adjudicatory hearing rights, shall first request access to such information from ABB-CE. The request must state *with particularity*:

(i) the nature of the proprietary or other information sought;

(ii) the reason why the information currently available to the public in the NRC's public document room is insufficient;

(iii) the relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

(iv) a showing the requesting person has the capability to understand and utilize the requested information.

(3) If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the Federal Register of the notice required either by 10 CFR 52.85 or 10 CFR 52.103. If ABB-CE declines to provide the information sought, ABB-CE shall send a written response within ten (10) days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions *solely* on the person's original request (including any clarifying information provided by the requesting person to ABB-CE), and ABB-CE's response. The Commission and presiding officer may order ABB-CE to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

7. Duration of this design certification.

This design certification may be referenced for a period of 15 years from [insert the date 30 days after the publication date], except as provided for in 10 CFR 52.55(b) and 52.57(b). This design certification remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

8. Processes for changes and departures.

(a) Tier 1 information.

(1) Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

(2) Generic changes to Tier 1 information are applicable to all plants referencing the design certification as set forth in 10 CFR 52.63(a)(2).

(3) Departures from Tier 1 information that are imposed by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(3).

(4) Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and § 52.97(b).

(b) Tier 2 information.

(1) Generic changes to Tier 2 information shall be governed by the same requirements in 10 CFR 52.63(a)(1) that govern generic changes to Tier 1.

(2) Generic changes to Tier 2 information are applicable to all plants referencing the design certification as set forth in 10 CFR 52.63(a)(2).

(3) The Commission may not impose new requirements on Tier 2 by plant-specific order while the design certification is in effect under §§ 52.55 or 52.61, unless:

(i) A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, as set forth in Section 5 of this Appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

(ii) Special circumstances as defined in 10 CFR 50.12(a) are present.

(4) An applicant or licensee who references the design certification may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The granting of such an exemption must be subject to litigation in the same manner as other issues in the combined license hearing.

(5)(i) An applicant or licensee who references the design certification may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or involves an unreviewed safety question as defined in paragraphs (b)(5)(ii) and (b)(5)(iii) of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

(ii) A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in Section 19.11 of the plant-specific DCD including appendices 19.11A through 19.11L, involves an unreviewed safety question if:

(A) The probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the plant-specific DCD may be increased;

(B) A possibility for an accident or malfunction of a different type than any evaluated previously in the plant-specific DCD may be created; or

(C) The margin of safety as defined in the basis for any technical specification is reduced.

(iii) A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in Section 19.11 of the plant-specific DCD, including appendices 19.11A through 19.11L, involves an unreviewed safety question if:

(A) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(B) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

(iv) If a departure involves an unreviewed safety question as defined in paragraph (b)(5) of this section, it is governed by 10 CFR 50.90 and 92.

(v) A departure from Tier 2 information that is made under paragraph (b)(5) of this section does not require an exemption from this Appendix.

(vi) A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a combined license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee has not complied with paragraph (b)(5) of this Section when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.714(b)(2), the petition must demonstrate that the departure does not comply with paragraph (b)(5) of this Section. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of fact regarding compliance with paragraph (b)(5) of this Section.

(6)(i) An applicant for a combined license may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section 6 of this appendix and 10 CFR 52.63(a)(4).

(ii) A holder of a combined license may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR §§ 50.90 and 50.92.

- (A) Equipment seismic qualification methods.
- (B) Piping design acceptance criteria.
- (C) Fuel burnup limit.
- (D) Control room human factors engineering.

(iii) A holder of a combined license may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except in accordance with paragraph (b)(6)(ii) of this Section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph (b)(5) of this Section.

- (A) ASME Boiler & Pressure Vessel Code, Section III.
- (B) AISC N-690 and ACI 349 Industrial Codes.
- (C) Motor-operated valves.
- (D) First cycle fuel and control rod design, except burnup limit.
- (E) Instrumentation and controls setpoint methodology.
- (F) Instrumentation and controls hardware and software changes.
- (G) Instrumentation and controls environmental qualification.

(iv) Departures from Tier 2* information that are made under paragraph (b)(6) of this section do not require an exemption from this appendix.

- (c) Additional applicable regulations.

The Commission may not modify or rescind existing requirements or impose new requirements on either this appendix or a plant referencing this appendix, whether on the Commission's own motion or in response to a petition from any person, on the basis that either the DCD or the referencing plant fails to comply with an additional applicable regulation in Section 5(c) of this appendix, unless the Commission determines that:

- (1) the failure to comply results in a substantial reduction in the protection of public health and safety or common defense and security;
- (2) the new requirements provide a compensating increase in protection not exceeding the level of protection originally embodied in the additional applicable regulation; and
- (3) the direct and indirect costs of implementation are justified in view of this compensating increase in protection.

9. Inspections, tests, analyses, and acceptance criteria (ITAAC).

(a)(1) An applicant or licensee who references the design certification shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a COL may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been satisfied.

(2) The licensee shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

(3) In the event that an activity is subject to an ITAAC, and the applicant or licensee has not demonstrated that the ITAAC has been satisfied, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section 8 of this appendix and 10 CFR 52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of Section 8(a)(1) of this appendix.

(b)(1) The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

(2) In accordance with 10 CFR 52.99 and 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the combined license are met before fuel load.

(3) After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not constitute regulatory requirements either for subsequent plant modifications during operation, or for renewal of the combined license. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.97 and Section 8 of this appendix.

10. Records and Reporting.

(a) Records.

(1) The applicant for this design certification rule shall maintain a copy of the generic DCD that includes all generic changes to Tier 1 and Tier 2. The applicant shall maintain the proprietary information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section 7 of this appendix.

(2) An applicant or licensee who references this design certification shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made pursuant to Section 8 of this appendix throughout the period of application and for the term of the license (including any period of renewal).

(3) An applicant or licensee who references this design certification shall prepare and maintain written safety evaluations which provide the bases for the determinations required by Section 8(b) of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

(b) Reporting.

(1) An applicant or licensee who references this design certification rule shall submit a report to the NRC containing a brief description of any departures from the plant-specific DCD, including a summary of the safety evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 50.4.

(2) An applicant or licensee shall submit updates to its plant-specific DCD, which reflect the generic changes to the generic DCD and the plant-specific departures made pursuant to Section 8 of this appendix. These updates shall be filed in accordance with the filing requirements applicable to final safety analysis report updates in 10 CFR 50.4 and 50.71(e).

(3) The reports and updates required by Section 10(b)(1) and (2) above must be submitted as follows:

(i) On the date that an application for a combined license referencing this design certification rule is submitted, the application shall include the report and any updates to the plant-specific DCD.

(ii) During the interval from the date of application to the date of issuance of a combined license, the report and any updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

(iii) During the interval from the date of issuance of a combined license to the date the Commission makes its findings under 10 CFR 52.103(g), the report must be submitted quarterly. Updates to the plant-specific DCD must be submitted annually.

(iv) After the Commission has made its finding under 10 CFR 52.103(g), reports and updates to the plant-specific DCD may be submitted annually or along with updates to the site-specific portion of the final safety analysis report for the facility at the intervals required by 10 CFR 50.71(e), or at shorter intervals as specified in the combined license.

Dated at Rockville, Maryland, this ___ day of _____, 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission