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 June 20, 1997. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 20, 1997.

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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.

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 this statement of consideration.

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. Subsequently, the applicant submitted changes to the System 80+ design and the NRC staff evaluated these design changes in a supplement to the FSER (NUREG–1462, Supplement No. 1). A copy of the FSER and Supplement No. 1 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 (FDA) was issued for the System 80+ design on July 26, 1994 and revised on November 23, 1994 to provide a 15 year duration. An FDA, which incorporates the design changes, will be issued to supersede the current FDA after issuance of this final design certification rule.

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 of 1947 (APA), as amended, 10 CFR 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 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 NRC staff conducted public meetings on the development of this design certification rule on November 23, 1993, May 11 and December 4, 1995, and May 2 and July 15, 1996, in order to enhance public participation.

The Commission has considered the comments received and made appropriate modifications to this design certification rule, as discussed in Sections II and III, and revised the numbering system used in the proposed rule. With these modifications, the Commission adopts as final this design certification rule, Appendix B to 10 CFR Part 52, 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), in a letter dated August 4, 1995, which provided comments on behalf of the nuclear 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 of August 4, 1995, and some provided additional comments. The Department of Energy and the Ohio Citizens for Responsible Energy, Inc. (OCRE) also submitted comment letters.

The NRC received other letters that were entered into the docket and are part of the record of the rulemaking proceeding, including 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 Combustion Engineering, Inc., which provided proposed 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 NRC staff issued this paper because of fundamental disagreements with the nuclear 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 NRC staff both indicated agreement on the ITAAC verification issue. Subsequently, in a staff requirements memorandum (SRM) dated March 21, 1996, the Commission requested the NRC staff to meet again with industry to try to resolve the issue of applicable regulations. The NRC staff met with representatives of ABB–CE, GE Nuclear Energy, and NEI in a public meeting on March 25, 1996 and were unable to reach agreement. As a result, the NRC staff provided revised resolutions of applicable regulations and ITAAC determinations in SECY–96–077, ''Certification of Two Evolutionary Designs,'' dated April 15, 1996, that superseded the proposals in SECY–96–028. SECY–96–077 addressed the comments on the proposed design certification rules and provided final design certification rules for the Commission's consideration. Subsequently, notice of a 30 day comment period for SECY–96–077 was published in the **Federal Register** (61 FR 18099), and the comment period was extended for an additional 60 days (61 FR 27027) at the request of NEI.

In response to the supplementary comment period, ABB–CE, GE Nuclear Energy, and NEI submitted additional comments on the final design certification rules in letters dated July 23, 1996. Westinghouse also submitted comments in a letter dated July 24, 1996. NEI sent an unsolicited letter, dated September 23, 1996, to the Director of the Office of Nuclear Reactor Regulation on three design certification issues. NEI also sent a letter, dated September 16, 1996, to Chairman Jackson that provided additional information in response to questions that were asked by the Commission in its August 27, 1996 briefing on design certification rulemaking.

The following discussion is separated into three groups: (1) Resolution of the principal 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. Finality

Comment Summary. The applicant and NEI submitted extensive comments on the scope of issues that were proposed to be accorded finality under 10 CFR 52.63(a)(4), i.e. are not subject to re-review by the NRC or re-litigation in hearings. In summary, 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;
- Changes approved by the NRC should have protection under 10 CFR 52.63(a)(4);
- The rule does not provide finality in all subsequent proceedings;
- The rule should be clarified regarding finality of SAMDA evaluations;
- A *de novo* review is not required for design certification renewal;
- Finality for Technical Specifications; and
- Finality for Operational Requirements.

These comments are found in ABB–CE Comment, B.1; NEI Comments dated August 4, 1995, Attachment B, pp. 1–23; NEI Comments dated July 23, 1996, pp. 1–21; and NEI letter dated September 16, 1996.

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 dated August 4, 1995, 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 Supplement No. 1, 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 statements of consideration (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 dated August 4, 1995, 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 VI.E 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 VI of this appendix.

Changes made in accordance with the ''50.59-like'' change process. The proposed design certification rule included a change process similar to that provided in 10 CFR 50.59. Specifically, proposed 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 special backfit restrictions of 10 CFR 52.63(a). For purposes of brevity, this discussion refers to both generic changes and plant-specific departures as ''changes.''

The Commission has reconsidered and revised 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 VIII.B of this appendix, 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 (VIII.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.'' As a result, Section VI of this appendix has been amended to reflect the Commission's determination on issue resolution for Tier 2 changes made in accordance with the departure process and to provide backfit protection for changes made in accordance with the processes of Section VIII 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 departure process (VIII.B.5) 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 process (VIII.B.5) 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 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 departure process (VIII.B.5) 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 an expedited review process (VIII.B.5.f), 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.

Subsequently, in its comments dated July 23, 1996, NEI requested the Commission to modify VIII.B.5.f to clarify that a ''50.59-like'' change is not subject to a hearing under § 52.103 or § 50.90 unless the change bears directly on an asserted ITAAC noncompliance or the requested amendment, respectively. The Commission determined that NEI's proposed wording correctly stated its intention regarding the opportunity for a hearing on ''50.59-like'' departures after a license is issued and, therefore, VIII.B.5.f of this appendix has been appropriately modified.

Changes approved by the NRC should have protection under Section 52.63. NEI, in its comments dated July 23, 1996, requested the Commission to provide the special backfit protection of § 52.63 to all changes to Tier 1, Tier 2*, and changes to Tier 2 that involve an unreviewed safety question or a change in the technical specifications. The special provision in § 52.63(a)(4) states that ''* * * the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification.'' The Commission stated, in its SRM on SECY–90–377, that ''* * * the process provides issue finality on all information provided in the application that is reviewed and approved in the design certification rulemaking.'' The Commission also stated that ''* * * changes to the design reviewed and approved by the staff should be minimized * * *.'' Based on this guidance, the Commission decided that the special backfit provision should be extended to generic changes made to the DCD that are approved by rulemaking. Also, for departures that are approved by license amendment or exemption, the Commission decided that the licensee of that plant should receive the special backfit protection. However, any other licensee that references the same DCD should not have finality for that plant-specific departure, unless it was again approved by license amendment or exemption for that licensee.

Finality in all subsequent proceedings. NEI requested 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 VI of this appendix, beginning with the general subjects embodied in NEI's proposed redraft, 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 that 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, are included in Section VI of this appendix. 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 VIII of this appendix. Therefore, the Commission declines to adopt in its entirety the industry proposal that issue finality should extend to all subsequent NRC proceedings.

In its comments dated July 23, 1996, NEI requested the Commission to modify the last phrase of Section 6(b), of SECY–96–077, to reflect the NRC staff's intent regarding finality in enforcement proceedings. Section 6(b) stated that the DCD has finality in enforcement proceedings ''where these proceedings reference this appendix.'' NEI was concerned that this phrase could be construed as depriving finality to plants that reference the design certification rules in enforcement proceedings that do not explicitly reference the design certification rule. The intent of the phrase was to limit finality of the information in the design certification rule to enforcement proceedings involving a plant referencing the rule. Therefore, the Commission replaced the wording, ''where these proceedings reference this appendix,'' with ''involving plants referencing this appendix'' in Section VI.B of the final rules.

Finality regarding SAMDA evaluations. In its comments dated July 23, 1996, NEI requested the Commission to extend finality for the SAMDA evaluation when an exemption from a

site parameter specified in the evaluation has been approved. Section VI.B.7 of this appendix accords finality to severe accident mitigation design alternatives (SAMDAs) for plants referencing the design certification rules ''whose site parameters are within those specified in the Technical Support Document'' (TSD). NEI is concerned that the last phrase could open all SAMDAs to re-review and re-litigation during a subsequent proceeding where the licensee has requested an exemption from a site parameter specified in the DCD, even though the exemption has no impact on the SAMDAs. NEI also stated that a clarification to the SOC was not sufficient and believed that a modification to the rule language was needed.

The NRC staff agrees that it was not the intent to re-litigate SAMDA issues under such circumstances. The intent was that an intervenor in any subsequent proceeding could challenge a SAMDA based on an exemption to a TSD site parameter only after bringing forward evidence demonstrating that the SAMDA analysis was invalidated. However, the NRC staff does not agree that the wording should be changed. NEI's proposed modification would shift the burden of demonstrating the acceptability of the exemption from the licensee. Moreover, it would be difficult to extend the NEPA review to all available sites without any qualification. Therefore, the Commission decided not to change Section VI.B.7 of this appendix but did explain in section III.F of this SOC that requests for litigation must meet § 2.714 requirements.

A de novo review is not required for design certification renewal. In its comments dated July 23, 1996, NEI requested the Commission to extend finality to design certification renewal proceedings and to define a review procedure for renewal applications that would limit the scope of review. Subsequently, NEI stated in a letter dated September 23, 1996, that principles for renewal reviews can and should be established in the design certification rules. The extension of finality to a renewal proceeding would produce the illogical result that the NRC's conclusion in the original design certification rulemaking, that the design provided adequate protection and was in compliance with the applicable regulations, would also apply to the renewal review even though the regulations in Part 52 require another review and finding at the renewal stage 15 years later. The effect of this extension would be to extend the design certification for another 15 years (for a total of 30 years) instead of the intended 15 years.

The NRC staff agrees with NEI that the renewal review must be conducted against the Commission's regulations applicable and in effect at the time of the original certification, and that the backfit limitations in § 52.59 must be satisfied in order to require a change to the certified design. However, the NRC staff disagrees with NEI's position that the information to be considered in the renewal review is limited to ''an evaluation of experience between the time of certification and the renewal application,'' as well as NEI's implication that the scope of the design for which new information can be considered is limited to those areas which the design certification applicant concedes there is new information or proposes a modification. The effect of NEI's position would be to preclude the NRC from considering new information which could have altered the Commission's consideration and approval of the design had it been known at the time of the original certification review, and to cede control of the scope of the renewal review to the design certification applicant. Furthermore, the review procedure for a renewal application is *not* dependent on whether the applicant proposed changes to the previously certified design. The underlying philosophy was that new safety requirements and issues that arose during the duration of the design certification rule could *not* be applied to the certified design (unless the adequate protection standard was met). However, these issues could be raised for consideration at the renewal stage and applied to the application for renewal if the backfit standard in § 52.59 was met. Therefore, any portion of the certified design could be reviewed (subject to § 52.59) to ensure that the applicable regulations for the certified design are being met based on consideration of new information (e.g. operating experience, research, or analysis) resulting from the previous 15 years of experience with the design.

The Commission rejects NEI's proposal to apply the finality provision of § 52.63 to the review of renewal applications because this would suggest improperly that NRC, in its renewal review, is bound by previous safety conclusions in the initial certification review. The type of renewal review was resolved by the Commission during the development of 10 CFR Part 52. At that time, the Commission determined that the backfit standard in § 52.59(a) controls the development of new requirements during the review of applications for renewal. Therefore, the Commission disagrees with NEI's proposed revision to Section 6(b), in its letter dated September 23, 1996, and NEI's proposal for a new Section 6(e) is unnecessary because this process is already correctly covered in § 52.59.

The Commission does not plan or expect to be able to conduct a de-novo review of the entire design if a certification renewal application is filed under § 52.59. It expects that the review focus would be on changes to the design that are proposed by the applicant and insights from relevant operating experience with the certified design or other designs, or other material new information arising after the NRC staff's review of the design certification. The Commission will defer consideration of specific design certification renewal procedures until after it has issued this appendix.

Finality for Technical Specifications. In its comments dated August 4, 1995, 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. In the proposed rule, 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.

In the design certification rule that was attached to SECY–96–077, the technical specifications were removed from Tier 2 for two reasons. First, the removal from Tier 2 responded to NEI's comment regarding a single change process. NEI's proposal to include the technical specifications in Tier 2 prior to issuance of a combined license (COL), and then remove them after COL issuance is not acceptable. If the technical specifications are included in Tier 2 by the design certification rulemaking, they would remain there and be controlled by the Tier 2 change process for the life of the facility. Second, the NRC staff wanted the ability

to impose future operational requirements and standards (distinct from design matters) on the technical specifications for a plant that referenced the certified design and Section 4(c) of the rule in SECY–96–077 provided that ability. However, Section 4(c) would not be used to backfit design features (i.e., hardware changes) unless the criteria of § 52.63 were met.

In its comments dated July 23, 1996, NEI requested the Commission to extend finality to the technical specifications in Chapter 16 of the DCD. NEI stated that the technical specifications in the DCDs should remain part of the design certification and be accorded finality because they have been reviewed and approved by the NRC. NEI also proposed that, after the license is granted, the technical specifications in the DCD would no longer have any relevance to the license and there would be a single set of technical specifications that will be controlled by the 10 CFR 50.90 license amendment process and subject to the backfit provisions in 10 CFR 50.109.

The Commission does not support extension of the special backfit provisions of § 52.63 to technical specifications and other operational requirements as requested by NEI, rather the Commission supports the proposal to treat the technical specifications in Chapter 16 of the DCD as a special category of information, as described in the NRC staff's comment analyses dated August 13 and October 21, 1996. The purpose of design certification is to review and approve design information. There is no provision in Subpart B of 10 CFR Part 52 for review and approval of purely operational matters. The Commission approves a revised Section VIII.C of this appendix that would apply to the technical specifications, bases for the technical specifications, and other operational requirements in the DCD; that would provide for use of § 52.63 only to the extent the design is changed; and that would use § 2.758 and § 50.109 to the extent an NRC safety conclusion is being modified or changed but no design change is required. In applying § 2.758 and § 50.109, it will be necessary to determine from the certification rulemaking record what safety issues were considered and resolved. This is because § 2.758 will not bar review of a safety matter that was not considered and resolved in the design certification rulemaking. There would be no backfit restriction under § 50.109 because no prior position was taken on this safety matter. After the COL is issued, the set of technical specifications for the COL (the combination of plant-specific and DCD derived) would be subject to the backfit provisions in § 50.109 (assuming no Tier 1 or Tier 2 changes are involved).

Finality for operational requirements. A new provision was included in the design certification rules, set forth in Section 4(c), that were attached to SECY–96–077. The reason for this provision was that the operational requirements in the DCD had not received a complete and comprehensive review. Therefore, the new Section 4(c) was needed to reserve the right of the Commission to impose operational requirements on plants referencing this appendix, such as license conditions for portions of the plant within the scope of this design certification, e.g., start-up and power ascension testing. NEI claimed, in its comments dated July 23, 1996, that the backfit provisions in Section 4(c) contradicted 10 CFR 52.63 and were incompatible with the purpose of 10 CFR part 52.

NEI's claim that Section 4(c) contradicts 10 CFR 52.63 and enables the NRC to impose changes to the design information in the DCD without regard to the special backfit provisions of § 52.63 is wrong. Section 4(c) clearly referred to ''facility operation'' not ''facility design.'' The purpose of Section 4(c) was to ensure that any necessary operational requirements could be applied to plants that reference these certified designs because plant operational matters were not finalized in the design certification review. It was also clear that the NRC staff considered resolved design matters to be final. Refer to SECY–96–077 which states: ''Most importantly, a provision has been included in Section 4 to provide that the final rules do not resolve any issues regarding conditions needed for safe operation (as opposed to safe design).'' This is consistent with the goal of design certification, which is to preserve the resolution of design features, which are explicitly discussed or inferred from the DCD. The backfit provisions in Sections VIII.A and VIII.B of this appendix control design changes.

Subsequently, in its comments of September 23, 1996, NEI requested that all DCD requirements, including operational-related and other non-hardware requirements, be accorded finality under § 52.63. The Commission has determined that NEI's proposal to assign finality to operational requirements is unacceptable, because operational matters were not comprehensively reviewed and finalized for design certification (refer to section III.F of this SOC). Although the information in the DCD that is related to operational requirements was necessary to support the NRC's safety review of the standard designs, the review of this information was not sufficient to conclude that the operational requirements are fully resolved and ready to be assigned finality under § 52.63. Therefore, the Commission retained the former Section 4(c), but reworded this provision on operational requirements and placed it in Section VI.C of this appendix with the other provisions on finality (also refer to Section VIII.C of this appendix).

2. Tier 2 Change Process

Comment Summary. NEI submitted many comments on the following aspects of the Tier 2 change process:

- Scope of the change process in VIII.B.5;
- Post-design certification rulemaking changes to Tier 2 information;
- Restrictions on Tier 2* information; and
- Additional aspects of the change process.

Response. The proposed design certification rule provided a change process for Tier 2 information that had 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) of the proposed rule provided 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 had 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 change process in VIII.B.5. In its comments dated August 4, 1995, 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 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 ''substantial increase'' criteria in VIII.B.5.c of this appendix for Tier 2 information that is associated with the resolution of severe accident issues. The (§ 50.59-like) criteria in VIII.B.5.b of this appendix, 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 be based on the criteria in VIII.B.5.b of this appendix.

However, NEI 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 Section 19.15 of the generic DCD.

Subsequently, in its comments dated July 23, 1996, NEI requested the Commission to expand the scope of design information that is controlled by the special change process for severe accident issues to all of the information in Chapter 19 of the DCD. The NRC staff intended that this special change process be limited to severe accident design features, where the intended function of the design feature is relied upon to resolve postulated accidents when the reactor core has melted and exited the reactor vessel and the containment is being challenged (severe accidents). These design features are identified in Section 19.11 of the System 80+ DCD and Section 19E of the ABWR DCD. This special change process was not intended for design features that are discussed in Chapter 19 for other reasons, such as resolution of generic safety issues. However, the NRC staff recognizes that the severe accident design features identified in Section 19.11 are described in other areas of the DCD. Therefore, the location of design information is not important to the application of the special change process for severe accident issues and it is not specified in Section VIII.B.5. The importance of this provision is that it be limited to the severe accident design features. In addition, the Commission is cognizant of certain design features that have intended functions to meet ''design basis'' requirements and to resolve ''severe accidents.'' These design features will be reviewed under either VIII.B.5.b or VIII.B.5.c depending upon the design function being changed. Finally, the Commission rejects NEI's request to expand the scope of design information that is controlled by the special change process for severe accident issues.

Post-design certification rulemaking changes to Tier 2 information. In its comments dated August 4, 1995, 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 are not applicable to applicant-initiated changes. The NEI proposal conflicts 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 appendix. The applicant (as any member of the public) may submit a petition for rulemaking pursuant to Subpart H of 10 CFR Part 2, 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 VIII.B.2 of this appendix. Also, the applicant could develop acceptable documentation to support a Tier 2 departure in accordance with VIII.B of this appendix. This documentation could be submitted for NRC staff review and approval, similar to the manner in which the NRC staff reviews topical reports.[1] 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. 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.

Subsequently, in its comments dated July 23, 1996, NEI requested the Commission to modify this SOC to reflect NRC openness to discuss a post-design certification change process and related issues after the design certification rules are completed. The Commission has determined that vendors who submit a design, which is subsequently certified by rulemaking, may not make changes under a ''50.59-like'' process and that NEI's request is outside the scope of this rulemaking. The Commission believes that vendors should be limited in making changes to rulemaking to amend the certification and that this appendix provides an appropriate process for making generic

[1] Topical 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.

changes to the DCD (refer to the SRM on SECY–90–377 and the SOC for 10 CFR Part 52, Section II.1.h). This process is available to everyone and the standard for changes is the same for NRC, the applicant, and the public. This restrictive change process is consistent with the NRC's goal of achieving and preserving resolutions of safety issues to provide a stable and predictable licensing process.

Restrictions on Tier 2 information.* In its comments dated August 4, 1995, Attachment B, pp. 119–123, and in subsequent comments dated July 23, 1996, pp. 50–54, 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. The Commission stated in the proposed design certification rule that 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 Commission does not want this significant information to be changed without prior NRC approval. This Tier 2* information is identified in the generic DCD with italicized text and brackets.

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 comments, the NRC again reevaluated the duration 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. The NRC decided that the Tier 2* restrictions for equipment seismic qualification methods and piping design acceptance criteria could expire at first full power, because the approved versions of the ASME code provide sufficient control of Tier 2* changes for these two areas. However, for fuel and control rod design, the licensing criteria had not been developed sufficiently when the System 80+ DCD was prepared and, therefore, the Tier 2* designation was not applied to the licensing acceptance criteria for 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 for review following the first fuel cycle. Also, the NRC decided that the Tier 2* change restriction for control room human factors engineering cannot expire for the System 80+ design at first full power because there is insufficient control over the implementation process in Tier 1.

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 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.

NEI also stated in its comments dated July 23, 1996, that to the extent the Commission does not adopt its recommendation that all Tier 2* restrictions expire at first full power, the SOC should be modified to reflect the NRC staff's intent that Tier 2* material in the DCD may be superseded by information submitted with a license application or amendment. The Commission decided that, if certain Tier 2* information is changed in a generic rulemaking, the category of the new information (Tier 1, 2*, or 2) would also be determined in the rulemaking and the appropriate process for future changes would apply. If certain Tier 2* information is changed on a plant-specific basis, then the appropriate modification to the change process would apply only to that plant.

Additional aspects of the change process. In its comments dated August 4, 1995, 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 SOC for 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. The Commission does not believe there is a need for a change to the language of this appendix. The statement above was not included in section III.H of this SOC.

NEI also requested that Section 8(b) of the proposed rule 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 VIII.B of this appendix should not also require an exemption, unless otherwise required by, or implied by 10 CFR part 52, Subpart B and, accordingly, has revised paragraph VIII.B.6 of this appendix. As discussed above, the technical specifications in Chapter 16 of the generic DCD are not in Tier 2 and, in its comments dated September 23, 1996, NEI proposed that requested departures from Chapter 16 by an applicant for a COL require an exemption. The Commission agrees with NEI's new position and included this provision in Section VIII.C of this appendix. 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 of this SOC.

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 VIII.B.5 of this appendix. 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.

Subsequently, in its comments dated July 23, 1996, NEI requested the Commission to modify Section VIII.B.4 of this appendix so that exemption requests are only subject to an opportunity for a hearing. The Commission decided that NEI's proposal was consistent with the intent of this appendix and modified Section VIII.B.4, accordingly. Also, NEI requested the Commission to modify Section VIII.B.6.b of this appendix to restrict the need for a license amendment and an opportunity for a hearing to those Tier 2* changes involving unreviewed safety questions. NEI claimed that a hearing opportunity for Tier 2* changes was unnecessary and should be provided only if the change involves an unreviewed safety question. The Commission disagrees with NEI because of the safety significance of the Tier 2* information. The safety significance of the Tier 2* information was determined at the time that the Tier 1 information was selected. Any changes to Tier 2* information will require a license amendment with the appropriate hearing opportunity.

3. Need for Additional 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 Comments dated August 4, 1995, Attachment B, pp. 24–57; NEI Comments dated July 23, 1996, pp. 27–34; and NEI letter dated September 16, 1996).

Response. NEI raised many issues in its comments. These comments have been consolidated into the following groups to facilitate documentation of the NRC staff's responses.

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. NEI also stated that the adoption of new applicable regulations is contrary to the purpose of design certification and Commission policy. The NRC staff developed the new applicable regulations in accordance with the goals of 10 CFR part 52, Commission guidance, 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, and the History of Applicable Regulations in Attachment 9 to SECY–96–077, dated April 15, 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 (refer to SRMs on SECY–91–262 and SECY–93–226). Furthermore, the SOC discussion for Part 52, Section II.1.e, ''Applicability of Existing Standards,'' states that new standards may be required and that these new standards may be developed in a design-specific rulemaking.

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 NRC 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. In response, the NRC staff stated that 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. Furthermore, 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.

NEI was also 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, thereby eroding licensing stability. 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. Also, NEI claimed that the additional applicable regulations were vague and, in some cases, inconsistent with previous Commission directions. In response to NEI's comments, the NRC staff proposed revised wording and a special provision for compliance backfits to the additional applicable regulations (refer to SECY–96–077). However, in subsequent comments, NEI stated that the proposed wording changes and backfit provision did not mitigate its concerns.

NEI commented in 1995 that some of the additional applicable regulations are requirements on an applicant or licensee who references this appendix, and requested in 1996 that these requirements be deleted from the final rule. The NRC staff moved these requirements from Section 5 of the proposed rules to Section 4 of the rules set forth in SECY–96–077, in response to NEI's 1995 comment (refer to pp. 46–47 of Attachment 1 to SECY–96–077). The Commission has removed those requirements from Section IV and has reserved the right to impose these operational requirements on applicants and licensees who reference this appendix (refer to VI.C of this appendix). The additional applicable regulations that are applicable to applicants or licensees who reference this appendix are specified in the generic DCD as COL license information.

NEI stated that the proposed additional applicable regulations were viewed as penalizing advanced plants for incorporating design features that enhance safety and could impact the regulatory threshold for currently operating plants. NEI also stated that applicable regulations are not needed to permit the NRC to deny an exemption request for a design feature that is subject to an applicable regulation. The Commission decided not to codify the additional applicable regulations that were identified in section 5(c) of the proposed rule. Instead, the Commission adopted the following position relative to the proposed additional applicable regulations.

Although it is the Commission's intent in 10 CFR part 52 to promote standardization and design stability of power reactor designs, standardization and design stability are not exclusive goals. The Commission recognized that there may be special circumstances when it would be appropriate for applicants or licensees to depart from the referenced certified designs. However, there is a desire of the Commission to maintain standardization across a group of reactors of a given design. Nevertheless, Part 52 provides for changes to a certified design in carefully defined circumstances, and one of these circumstances is the option provided to applicants and licensees referencing certified designs to request an exemption from one or more elements of the certified design, e.g., 10 CFR 52.63(b)(1). The final design certification rule references this provision for Tier 1 and includes a similar provision for Tier 2. The criteria for NRC review of requests for an exemption from Tier 1 and Tier 2 in the final rule are the same as those for NRC review of rule exemption requests under 10 CFR part 50 directed at non-certified designs, except that the final rule requires consideration of an additional factor for Tier 1 exemptions—whether special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. It has been the practice of the Commission to require that there be no significant decrease in the level of safety provided by the regulations when exemptions from the regulations in Part 50 are requested. The Commission believes that a similar practice should be followed when exemptions from one or more elements of a certified design are requested, that is, the granting of an exemption under 10 CFR 50.12 or 52.63(b)(1) should not result in any significant decrease in the level of safety provided by the design (Tier 1 and Tier 2). The exemption standards in sections VIII.A.4 and VIII.B.4 of the final rule have been modified from the proposed rule to codify this practice.

In adopting this policy the Commission recognizes that the System 80+ design not only meets the Commission's safety goals for internal events, but also offers a substantial overall enhancement in safety as compared, generally, with the current generation of operating power reactors. *See*, e.g., NUREG–1462 at Section 19.1. The Commission recognizes that the safety enhancement is the result of many elements of the design, and that much but not all of it is reflected in the results of the probabilistic risk assessment (PRA) performed and documented for them. In adopting a rule that the safety enhancement should not be eroded significantly by exemption requests, the Commission recognizes and expects that this will require both careful analysis and sound judgment, especially considering uncertainties in the PRA and the lack of a precise, quantified definition of the enhancement which would be used as the standard. Also, in some cases scientific proof that a safety margin has or has not been eroded may be difficult or even impossible. For this reason, it is appropriate to express the Commission's policy preference regarding the grant of exemptions in the form of a qualitative, risk informed standard, in section VIII of the final rule, and inappropriate to express the policy in a quantitative legal standard as part of the additional applicable regulations.

There are three other circumstances where the enhanced safety associated with the System 80+ design could be eroded: By design changes introduced by ABB–CE at the certification renewal stage; by operational experience or other new information suggesting that safety margins believed to be achieved are not in fact present; and by applicant or licensee design changes under section VIII.B.5 of the final rule (for changes to Tier 2 only). In the first two cases Part 52 limits NRC's ability to require that the safety enhancement be restored, unless a question of adequate protection or compliance would be presented or, in the case of renewals, unless the restoration offers cost-justified, substantive additional protection. Thus, unlike the case of exemptions where a policy of maintaining enhanced safety can be enforced consistent with the basic structure of Part 52, in the case of renewals and new information, implementation of such a policy over industry objections would require changes to the basic structure of Part 52. The Commission has been and still is unwilling to make fundamental changes to Part 52 because this would introduce great uncertainty and defeat industry's reasonable expectation of a stable regulatory framework. Nevertheless, the Commission on its part also has a reasonable expectation that vendors and utilities will cooperate with the Commission in assuring that the level of enhanced safety believed to be achieved with this design will be reasonably maintained for the period of the certification (including renewal).

This expectation that industry will cooperate with NRC in maintaining the safety level of the certified designs applies to design changes suggested by new information, to renewals, and to changes under section VIII.B.5 of the final rule. If this reasonable expectation is not realized, the Commission would carefully review the underlying reasons and, if the circumstances were sufficiently persuasive, consider the need to reexamine the backfitting and renewal standards in Part 52 and the criteria for Tier 2 changes under section VIII.B.5. At this time there is no reason

to believe that cooperation will not be forthcoming and, therefore, no reason to change the regulations. With this belief and stated Commission policy (and the exemption standard discussed above), there is no need for the proposed additional applicable regulations to be embedded in the final rule because the objective of the additional applicable regulations—maintaining the enhanced level of safety—should be achieved without them.

B. Responses to Specific Requests for Comment From Proposed Rule

Only two commenters addressed the specific requests for comments that were set forth in section IV of the SOC for 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.

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 II of this appendix as a result of comments from NEI and DOE. A discussion of these changes is provided in sections II.C.2 and II.C.3 of this SOC.

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. Subsequently, in its comments dated July 23, 1996, NEI requested the Commission to modify the response to this question that was set forth in SECY–96–077. Specifically, NEI stated that plant-specific changes should be implemented under § 50.59 or § 50.90, as appropriate. The Commission did not significantly modify its former response because the change process must consider the effect on information in the DCD, as NEI previously acknowledged.

Response. The Commission will develop a change process for the plant-specific information submitted in a COL application that references this appendix 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 VIII.B.5 of this appendix. 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 licensing hearing. A discussion of the information that will have issue preclusion is provided in sections II.A.1 and III.F of this SOC.

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 it is not necessary to codify the new applicable regulations, as explained in section II.A.3 of this SOC.

5. Section 8(b)(5)(i) of the Proposed Rule 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 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 applicant or licensee properly complied with the Tier 2 departure process. Therefore, VIII.B.5 of this appendix has been modified to include a provision for challenging Tier 2 departures. The scope of finality for plant-specific departures is discussed in greater detail in section II.A.1 of this SOC.

6. How Should the Determinations Made by an Applicant or Licensee That Changes May Be Made Under Section 8(b)(5)(i) of the Proposed Rule, 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 (VIII.B.5 and X.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 VIII.B.5 of this appendix 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 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 of this SOC, 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, VIII.B.6 of this appendix specifies that such requests will be treated as requests for license amendments after the license is issued, and that the Tier 2* departure shall not be considered to be matters resolved by this rulemaking prior to a license being issued.

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 for severe accident information, as described in sections II.A.2 and III.H of this SOC.

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 proposed 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 applicant under 10 CFR 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 10 CFR Part 52 provides for referencing of design certification rules in Part 50 applications and licenses, the Commission wishes to reserve for future consideration the manner in which a Part 50 applicant could be permitted to reference this design certification and whether it 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 that it is appropriate for the final rule to have some uncertainty regarding the manner in which this appendix could be referenced in a Part 50 proceeding, as set forth in Section IV.B of this appendix.

C. Other Issues

1. NRC Verification of ITAAC Determinations

Comment Summary. In Attachment B of its comments dated August 4, 1995 (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 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. Subsequently, in its comments dated July 23, 1996, NEI requested the Commission to delete significant portions of the NRC's response, which was originally set forth in SECY–96–077 (refer to pages 33–36 of Attachment 1).

Response. The Commission decided to delete the responses in SECY–96–077 on licensee documentation of ITAAC verification; NRC inspection; and facility ITAAC verification; because they do not directly relate to the design certification rulemakings. However, the NRC disagrees with NEI's 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 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 this appendix (IX.B.1), 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.

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 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 dated August 4, 1995, Attachment B, pp. 90–108, and July 23, 1996, pp. 43–49; 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 declines the suggestion to incorporate the DCD introduction, but 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 procedural and administrative provisions described in the DCD Introduction should be included in, and be an integrated part of, the design certification rule. As a result, Sections II, III, IV, VI, VIII, and X of this appendix have been revised and Section IX was created to adopt appropriate provisions from the DCD Introduction. In some cases, the wording of these provisions has been modified, as appropriate, to achieve clarity or to conform with the final design certification rule language.

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 System 80+ 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 decided 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 an applicant that references this appendix.

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 only 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 (FDA) 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 X of this appendix, 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 II of this appendix and further described in the section-by-section discussion on records and reporting in section III.J of this SOC. The applicant chose to continue to reference the SSAR as the supporting document for its FDA. As a result, the applicant must maintain the SSAR for the duration of the FDA.

III. Section-by-Section Discussion

A. Introduction

The purpose of Section I of Appendix B to 10 CFR Part 52 (''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. Identification of the design certification applicant is necessary to implement this appendix, for two reasons. First, the implementation of 10 CFR 52.63(c) depends on whether an applicant for a combined license (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 must meet the requirements in 10 CFR 52.63(c). Also, X.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.

B. Definitions

The terms Tier 1, Tier 2, Tier 2*, and COL action items (license information) are defined in 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. ABB–CE used the terms ''certified design material'' and ''approved design material'' for Tier 1 and Tier 2

information, respectively, in the System 80+ DCD. 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'' and the ''generic DCD,'' the latter of which is incorporated by reference into this appendix and remains unaffected by plant-specific departures. This distinction is necessary in order to clarify the obligations of applicants and licensees that reference this appendix. Also, the technical specifications that are located in Chapter 16 of the generic DCD were designated as ''generic technical specifications'' to facilitate the special treatment of this information in the final rule (refer to section II.A.1 of this SOC). Therefore, appropriate definitions for these additional terms are included in the final rule.

The Tier 1 portion of the design-related information contained in the DCD is certified by this appendix and, therefore, subject to the special backfit provisions in VIII.A of this appendix. An applicant who references this appendix is required to incorporate by reference and comply with Tier 1, under III.B and IV.A.1 of this appendix. This information consists of an introduction to Tier 1, the design descriptions and corresponding 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 VIII.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 licensees or for renewal of the COL. However, subsequent modifications to the facility must comply with the design descriptions in the plant-specific DCD unless changes are made in accordance with the change process in Section VIII 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 design features 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). An application that references this appendix must demonstrate that the site parameters (both Tier 1 and Tier 2) are met at the proposed site (refer to discussion in III.D of this SOC).

Tier 2 is the portion of the design-related information contained in the DCD that is approved by this appendix but is not certified. Tier 2 information is subject to the backfit provisions in VIII.B of this appendix. Tier 2 includes the information required by 10 CFR 52.47, with the exception of generic 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. As with Tier 1, III.B and IV.A.1 of this appendix require an applicant who references this appendix to incorporate Tier 2 by reference and to comply with Tier 2 (except for the COL action items and conceptual design information). 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 VIII of this appendix. Departures from Tier 2 do not negate the requirement in Section III.B to reference Tier 2. NEI requested the Commission, in its comments dated July 23, 1996, to include several statements on compliance with Tier 2 in the definitions of Tier 1 and Tier 2. The Commission determined that inclusion of those statements in the Tier 2 definition was appropriate, but to also include them in the Tier 1 definition would be unnecessarily redundant.

Certain Tier 2 information has been designated in the generic DCD with brackets and italicized text as ''Tier 2*'' information and, as discussed in greater detail in the section-by-section explanation for Section VIII, a plant-specific departure from Tier 2* information requires prior NRC approval. 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 VIII.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 are not the only acceptable set of information. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in its FSAR.

In developing the proposed design certification rule, the Commission contemplated that there would be both generic (master) 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 generic 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 VIII 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 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 that the licensee chose to make in accordance with the relevant processes in Section VIII of this appendix. Thus, the plant-specific DCD would function akin to an updated Final Safety Analysis Report, in the since that it would provide the most complete and accurate information on a plant's licensing basis for that part of the plant within the scope 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 generic 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 plant-specific technical specifications.

During the resolution of comments on the final rules in SECY–96–077, the Commission decided to treat the technical specifications in Chapter 16 of the DCD as a special category of information and to designate them as generic technical specifications (refer to II.A.1 of SOC). A COL applicant must submit plant-specific technical specifications that consist of the generic technical specifications, which may be modified under Section VIII.C of this appendix, and the remaining plant-specific information needed to complete the technical specifications, including bracketed values.

C. Scope and Contents

The purpose of Section III of this appendix is to describe and define the scope and contents of this 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, Tier 2, and the generic technical specifications into this appendix and paragraph B requires COL applicants and licensees to comply with the requirements of this appendix. 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, as well as the generic technical specifications have been combined into a single document, called the generic design control document (DCD), in order to effectively control this information and facilitate its incorporation by reference into the rule. The generic DCD was prepared to meet the requirements of the OFR for incorporation by reference (1 CFR Part 51). One of the requirements of OFR for incorporation by reference is that the design certification applicant must make the DCD available upon request after the final rule becomes effective. The applicant requested the National Technical Information Service (NTIS) to distribute the generic DCD for them. Therefore, paragraph A states that copies of the DCD can be obtained from NTIS, 5285 Port Royal Road, Springfield, VA 22161. The NTIS order numbers for paper or CD–ROM copies of the System 80+ DCD are PB97–147854 or PB97–502108, respectively.

The generic DCD (master copy) 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 VIII 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 X.A.1 of this appendix because it is likely that most applicants intending to reference the standard design will obtain the generic DCD from the design certification applicant. Plant-specific changes to and departures from the generic DCD will be maintained by the applicant or licensee that references this appendix in a plant-specific DCD, under X.A.2 of this appendix.

In addition to requiring compliance with this appendix, paragraph B clarifies that the conceptual design information and the ''Technical Support Document'' 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 that references this appendix. Therefore, the applicant does not need to conform with the conceptual design information that was provided by the design certification applicant. The conceptual design information, which consists of site-specific design features, was required to facilitate the design certification review. Conceptual design information is neither Tier 1 nor Tier 2. The introduction to Tier 2 identifies the location of the conceptual design information. The Technical Support Document provides ABB–CE's evaluation of various design alternatives to prevent and mitigate severe accidents, and does not constitute design requirements. The Commission's assessment of this information is discussed in section IV of this SOC on environmental impacts. The detailed methodology and quantitative portions of the design-specific probabilistic risk assessment (PRA), as required by 10 CFR 52.47(a)(1)(v), were not included in the DCD, as requested by NEI and the applicant for design certification. The NRC agreed with the request to delete this information because conformance with the deleted portions of the PRA is not necessary. Also, the NRC's position is 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 supporting this rulemaking and maintain it throughout the operational life of the facility.

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, referred to as the Standard Safety Analysis Report, or the final safety evaluation report for the certified design and its supplement.

Paragraph E makes it clear that design activities that are wholly outside the scope of this design certification may be performed using site-specific design parameters, provided the design activities do not affect Tier 1 or Tier 2, or conflict with the interface requirements in the DCD. This provision applies to site-specific portions of the plant, such as the service water intake structure. NEI requested insertion of this clarification into the final rule (refer to its comments on the Tier 1 definition dated July 23, 1996). Because this statement is not a definition, the Commission decided that the appropriate location is in Section III of the final rule.

D. Additional Requirements and Restrictions.

Section IV of this appendix sets forth additional requirements and restrictions imposed upon an applicant who references this appendix. Paragraph IV.A sets forth the information requirements for these applicants. 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 physical 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 who references this appendix to incorporate by reference this appendix in its application. The legal effect of such incorporation by reference is that this appendix is legally binding on the applicant or licensee. Paragraph A.2.a 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 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 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 site-specific information into the plant's FSAR, will result in an application that is easier to use and should minimize ''duplicate documentation'' and the attendant possibility for confusion (refer to sections II.C.3 and III.J of this SOC). Paragraph A.2.a 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.b requires that the application include the reports required by paragraph X.B of this appendix for exemptions and departures proposed by the applicant as of the date of submission of its application. Paragraph A.2.c requires submission of plant-specific technical specifications for the plant that consists of the generic technical specifications from Chapter 16 of the DCD, with any changes made under Section VIII.C of this appendix, and the technical specifications for the site-specific portions of the plant that are either partially or wholly outside the scope of this design certification, such as the ultimate heat sink. The applicant must also provide the plant-specific information designated in the generic technical specifications, such as bracketed values. Paragraph A.2.d makes it clear that the applicant must provide information demonstrating that the proposed site falls within the site parameters for this appendix and that the plant-specific design complies with the interface requirements, as required by 10 CFR 52.79(b).

If the proposed site has a characteristic that exceeds one or more of the site parameters in the DCD, then the proposed site is unacceptable for this design unless the applicant seeks an exemption under Section VIII of this appendix and justifies why the certified design should be found acceptable on the proposed site. Paragraph A.2.e requires submission of information addressing COL Action Items, which are identified in the generic DCD as COL License Information, in the application. The COL Action Items (COL License Information) identify matters that need to be addressed by an applicant that references this appendix, as required by Subpart C of 10 CFR Part 52. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in its application (FSAR). Paragraph A.2.f 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. Paragraph A.3 requires the applicant to physically include, not simply reference, the proprietary information referenced in the System 80+ DCD, or its equivalent, to assure that the applicant has actual notice of these requirements.

Paragraph IV.B reserves to the Commission the right to determine 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 10 CFR 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. This provision was necessary because the evolutionary design certifications were not implemented in the manner that was originally envisioned at the time that Part 52 was created. The Commission's concern is with the manner in which ITAAC were developed and the lack of experience with design certifications in license proceedings (refer to section II.B.9 of this SOC). Therefore, it is appropriate for the final rule to have some uncertainty regarding the manner in which this appendix could be referenced in a Part 50 licensing proceeding.

E. Applicable Regulations

The purpose of Section V of this appendix is to specify the regulations that were applicable and in effect at the time that this design certification was approved. These regulations consist of the technically relevant regulations identified in paragraph A, except for the regulations in paragraph B that are not applicable to this certified design.

Paragraph A identifies the regulations in 10 CFR Parts 20, 50, 73, and 100 that are applicable to the System 80+ design. After the NRC staff completed its FSER for the System 80+ design (August 1994), the Commission 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 determine if 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. The Commission's determination of the applicable regulations was made as of the date specified in paragraph V.A of this appendix. The specified date is the date that this appendix was approved by the Commission and signed by the Secretary of the Commission.

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, an 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 doses 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. Appendix J includes two options, A and B, either of which can be chosen for meeting the requirements of this appendix. The Commission has determined that option B to Appendix J has no impact on the System 80+ design because ABB–CE elected to comply with option A. 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 fractures 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.

10 CFR Parts 21, 50, 52, 54, and 100, Reactor Site Criteria Including Seismic and Earthquake Engineering Criteria for Nuclear Power Plants (61 FR 65157; December 11, 1996)

The objective of this regulation is to update the criteria used in decisions regarding power reactor siting, including geologic, seismic, and earthquake engineering considerations for future nuclear power plants. Two sections of this regulation apply to applications for design certification. With regard to the revised design basis accident radiation dose acceptance criteria in 10 CFR 50.34, the Commission has determined that the System 80+ design meets the new dose criteria, based on the NRC staff's radiological consequence analyses, provided that the site parameters are not revised. With regard to the revised earthquake engineering criteria for nuclear power plants in Appendix S to 10 CFR Part 50, the Commission has determined that the System 80+ design meets the new single earthquake design requirements based on the NRC staff's evaluation in NUREG–1462. Therefore, the Commission has determined that this design meets the applicable requirements of this new regulation.

10 CFR Parts 20 and 35, Criteria for the Release of Individuals Administered Radioactive Material (62 FR 4120; January 29, 1997)

The objective of this revised regulation is to specifically state that the limitation on dose to individual members of the public in 10 CFR Part

20 does not include doses received by individuals exposed to patients who were administered radioactive materials and released under the new criteria in 10 CFR Part 35. This revision to Part 20 is not applicable to the design or operation of nuclear power plants and, therefore, does not affect the safety findings for this design.

In paragraph V.B of this appendix, 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) and Appendix J to Part 50, as described in the FSER (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 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 the 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 II.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.

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 Environs Conditions During and Following an Accident,'' Revision 3. 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. 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 V.B of this appendix.

F. Issue Resolution

The purpose of Section VI 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 five 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) issues which are not resolved by this rulemaking, (D) the backfit restrictions applicable to the Commission with respect to this appendix, and (E) 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 (NUREG–1503) and Supplement No. 1, the Tier 1 and Tier 2 information, 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. Paragraphs B.3, B.4, B.5, and B.6 clarify that approved changes to and departures from the DCD which are accomplished in compliance with the relevant procedures and criteria in Section VIII of this appendix continue to be matters resolved in connection with this rulemaking (refer to the discussion in section II.A.1 of this SOC). Paragraph B.7 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 mitigation design alternatives (SAMDAs) arising under the National Environmental Policy Act of 1969 associated with the information in the Environmental Assessment for this design and the information regarding SAMDAs in the applicant's Technical Support Document (January 1995) are also resolved within the meaning and intent of § 52.63(a)(4). Refer to the discussion in section II.A.1 of this SOC regarding finality of SAMDAs in the event an exemption from a site parameter is granted. The exemption applicant has the initial burden of demonstrating that the original SAMDA analysis still applies to the actual site parameters but, if the exemption is approved, requests for litigation at the COL stage must meet the requirements of § 2.714 and present sufficient information to create a genuine controversy in order to obtain a hearing on the site parameter exemption.

Paragraph C reserves the right of the Commission to impose operational requirements on applicants that reference this appendix. This provision reflects the fact that operational requirements, including technical specifications, were not completely or comprehensively reviewed at the design certification stage. Therefore, the special backfit provisions of § 52.63 do not apply to operational requirements. However, all design changes would be restricted by the appropriate provision in Section VIII of this appendix (refer to section III.H of this SOC). Although the information in the DCD that is related to operational requirements was necessary to support the NRC staff's safety review of this design, the review of this information was not sufficient to conclude that the operational requirements are fully resolved and ready to be assigned finality under § 52.63. As a result, if the NRC wanted to change a temperature limit and that operational change required a consequential change to a design feature, then the temperature limit backfit would be restricted by § 52.63. However, changes to other operational issues, such as in-service testing and in-service inspection programs, post-fuel load verification activities, and shutdown risk that do not require a design change would not be restricted by § 52.63.

Paragraph C allows the NRC to impose future operational requirements (distinct from design matters) on applicants who reference this design certification. Also, license conditions for portions of the plant within the scope of this design certification, e.g. start-up and power ascension testing, are not restricted by § 52.63. 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 ITAAC are satisfied. Therefore, another regulatory vehicle is necessary to ensure that licensees 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 is reserving the right to impose license conditions by rule for post-fuel load verification activities for portions of the plant within the scope of this design certification.

Paragraph D reiterates the restrictions (contained in 10 CFR 52.63 and Section VIII of this appendix) placed upon the Commission when ordering generic or plant-specific modifications, changes or additions to structures, systems or components, design features, design criteria, and ITAAC (VI.D.3 addresses ITAAC) within the scope of the certified design. Although the Commission does not believe that this language is necessary, the Commission has included this language to provide a concise statement of the scope and finality of this rule in response to comments from NEI.

Paragraph E 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 VI.B of this appendix, viz., proceedings involving licenses and applications which reference this appendix. As set forth in paragraph E, access must first be sought from the design certification applicant. If ABB–CE refuses to provide the information, the person seeking access shall request access from the Commission or the presiding officer, as applicable. Access to the proprietary information may be ordered by the Commission, but must be subject to an appropriate non-disclosure agreement.

G. Duration of This Appendix

The purpose of Section VII 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 VIII of this appendix for the life of the plant.

H. Processes for Changes and Departures

The purpose of Section VIII of this appendix is to set forth the processes for generic changes to or plant-specific departures (including exemptions) from the DCD. The Commission adopted this restrictive change process in order to achieve a more stable licensing process for applicants and licensees that reference this design certification rule. Section VIII is divided into three paragraphs, which correspond to Tier 1, Tier 2, and Operational requirements. The language of Section VIII 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 X 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 VIII of this appendix and this SOC refer to an ''exemption'' from one or more requirements 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 VIII.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 approval of the design certification or to ensure 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 Commission expects such hearings to 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; or (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 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. In addition, the Commission will not grant requests for exemptions that may result in a significant decrease in the level of safety otherwise provided by the design (refer to discussion in II.A.3 of this SOC).

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 VIII.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 approval of the design certification or to assure adequate protection of the public health and safety or common defense and security. If a generic change is made to Tier 2* information, then the category and expiration, if necessary, of the new information would also be determined in the rulemaking and the appropriate change process for that new information would apply (refer to II.A.2 of this SOC).

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.d; 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 approval of the design certification or to ensure adequate protection of the public health and safety or common defense and security, as set forth in paragraph B.3. However, the special circumstances for the Commission-ordered Tier 2 departures do not have to outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order, as required

by 10 CFR 52.63(a)(3). The Commission determined that it was not necessary to impose an additional limitation similar to that imposed on Tier 1 departures by 10 CFR 52.63 (a)(3) and (b)(1). This type of additional limitation for standardization would unnecessarily restrict the flexibility of applicants and licensees with respect to Tier 2, which by its nature is not as safety significant as Tier 1.

An applicant or licensee may request an exemption from Tier 2 information as set forth in paragraph B.4. The applicant or licensee must demonstrate that the exemption complies with one of the special circumstances in 10 CFR 50.12(a). In addition, the Commission will not grant requests for exemptions that may result in a significant decrease in the level of safety otherwise provided by the design (refer to discussion in II.A.3 of this SOC). However, the special circumstances for the exemption do not have to outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. If the exemption is requested by an applicant for a license, the exemption is subject to litigation in the same manner as other issues in the license hearing, consistent with 10 CFR 52.63(b)(1). If the exemption is requested by a licensee, then the exemption is subject to litigation in the same manner as a license amendment.

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 B.5.b and B.5.c of this paragraph. The technical specifications referred to in B.5.a and B.5.b of this paragraph are the technical specifications in Chapter 16 of the generic DCD, including bases, for departures made prior to issuance of the COL. After issuance of the COL, the plant-specific technical specifications are controlling under paragraph B.5 (refer to discussion in II.A.1 of this SOC on Finality for Technical Specifications). The bases for the plant-specific technical specifications will be controlled by the bases control procedures for the plant-specific technical specifications (analogous to the bases control provision in the Improved Standard Technical Specifications). The definition of a USQ in paragraph B.5.b is similar to the definition in 10 CFR 50.59 and it applies to all information in Tier 2 except for the information 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 has determined 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 in B.5.c for determining whether a departure from information that resolves severe accident issues constitutes a USQ. For purposes of applying the special criteria in B.5.c, severe accident resolutions are limited to design features when the intended function of the design feature is relied upon to resolve postulated accidents where the reactor core has melted and exited the reactor vessel and the containment is being challenged (refer to discussion in II.A.2 of this SOC). These design features are identified in Section 19.11 of the System 80+ DCD and Section 19E of the ABWR DCD, but may be described in other sections of the DCD. Therefore, the location of design information in the DCD is not important to the application of this special procedure for severe accident issues. However, the special procedure in B.5.c does not apply to design features that resolve so-called beyond design basis accidents or other low probability events. The important aspect of this special procedure is that it is limited solely to severe accident design features, as defined above. Some design features of the evolutionary designs have intended functions to meet both ''design basis'' requirements and to resolve ''severe accidents.'' If these design features are reviewed under paragraph VIII.B.5, then the appropriate criteria from either B.5.b or B.5.c are selected depending upon the design function being changed.

An applicant or licensee that plans to depart from Tier 2 information, under VIII.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, as explained above. 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 matters needs to consider the proposed departure over the full range of power operation from startup to shutdown, as it relates to anticipated operational occurrences, transients, design basis accidents, and severe accidents. The evaluation must also include a review of all relevant secondary references from the DCD because Tier 2 information intended to be treated as requirements is contained in the secondary references. 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. ABB–CE provided more detailed cross-references to Tier 1 for these analyses 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 VIII.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 VIII.B of this appendix.

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 VIII.B.5 when departing from Tier 2 information, may petition to admit such a contention into the proceeding. As set forth in B.5.f, 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.

Paragraph B.6 provides a process for departing from Tier 2* information. This provision is bifurcated because of the expiration of some Tier 2* information. The Commission determined that the Tier 2* designation should expire for some Tier 2* information in response to comments from NEI (refer to section II.A.2 of this SOC). Therefore, certain Tier 2* information listed in B.6.c 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 B.6.b retains its Tier 2* designation throughout the duration of the 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 VIII.A of this appendix.

If Tier 2* information is changed in a generic rulemaking, the designation of the new information (Tier 1, 2*, or 2) would also be determined in the rulemaking and the appropriate process for future changes would apply. If a plant-specific departure is made from Tier 2* information, then the new designation would apply only to that plant. If an applicant who references this design certification makes a departure from Tier 2* information, the new information is subject to litigation in the same manner as other plant-specific issues in the licensing hearing (refer to B.6.a). If a licensee makes a departure, it will be treated as a license amendment under 10 CFR 50.90 and the finality is in accordance with paragraph VI.B.5 of this appendix.

Operational Requirements

The change process for technical specifications and other operational requirements is set forth in paragraph VIII.C. This change process has elements similar to the Tier 1 and Tier 2 change process in paragraphs VIII.A and VIII.B, but with significantly different change standards (refer to the explanation in II.A.1 of this SOC). The Commission did not support NEI's request to extend the special backfit provisions of 10 CFR 52.63 to technical specifications and other operational requirements (refer to explanation in III.F of this SOC). Rather, the Commission decided to designate a special category of information, consisting of the technical specifications and other operational requirements, with its own change process in paragraph VIII.C. The key to using the change processes in Section VIII is to determine if the proposed change or departure requires a change to a design feature described in the generic DCD. If a design change is required, then the appropriate change process in paragraph VIII.A or VIII.B applies. However, if a proposed change to the technical specifications or other operational requirements does not require a change to a design feature in the generic DCD, then paragraph VIII.C applies. The language in paragraph VIII.C also distinguishes between generic and plant-specific technical specifications to account for the different treatment and finality accorded technical specifications before and after a license is issued.

The process in C.1 for making generic changes to the generic technical specifications in Chapter 16 of the DCD or other operational requirements in the generic DCD is accomplished by rulemaking and governed by the backfit standards in 10 CFR 50.109. The determination of whether the generic technical specifications and other operational requirements were completely reviewed and approved in the design certification rulemaking is based upon the extent to which an NRC safety conclusion in the FSER or its supplement is being modified or changed. If it cannot be determined that the technical specification or operational requirement was comprehensively reviewed and finalized in the design certification rulemaking, then there is no backfit restriction under 10 CFR 50.109 because no prior position was taken on this safety matter. Some generic technical specifications contain bracketed values, which clearly indicate that the NRC staff's review was not complete. Generic changes made under VIII.C.1 are applicable to all applicants or licensees, unless the change is irrelevant because of a plant-specific departure (refer to VIII.C.2).

Plant-specific departures may occur by either a Commission order under VIII.C.3 or an applicant's exemption request under VIII.C.4. The basis for determining if the technical specification or operational requirement was completely reviewed and approved is the same as for VIII.C.1 above. If the technical specification or operational requirement was comprehensively reviewed and finalized in the design certification rulemaking, then the Commission must demonstrate that special circumstances are present before ordering a plant-specific departure. If not, there is no restriction on plant-specific changes to the technical specifications or operational requirements, prior to issuance of a license, provided a design change is not required. Although the generic technical specifications were reviewed by the NRC staff to facilitate the design certification review, the Commission intends to consider the lessons learned from subsequent operating experience during its licensing review of the plant-specific technical specifications. The process for petitioning to intervene on a technical specification or operational requirement is similar to other issues in a licensing hearing, except that the petitioner must also demonstrate why special circumstances are present (refer to VIII.C.5).

Finally, the generic technical specifications will have no further effect on the plant-specific technical specifications after the issuance of a license that references this appendix (refer to sections II.A.1 and II.B.3 of this SOC). The bases for the generic technical specifications will be controlled by the change process in Section VIII.C of this appendix. After a license is issued, the bases will be controlled by the bases change provision set forth in the administrative controls section of the plant-specific technical specifications.

I. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

The purpose of Section IX of this appendix is to set forth how the ITAAC in Tier 1 of this design certification rule are to be treated in a license proceeding. Paragraph A restates the responsibilities of an applicant or licensee for performing and successfully completing ITAAC, and notifying the NRC of such completion. Paragraph A.1 makes it clear that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee 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 B.2 essentially reiterate the NRC's responsibilities with respect to ITAAC as set forth in 10 CFR 52.99 and 52.103(g) [refer to explanation in section II.C.1 of this SOC]. Finally, paragraph B.3 states that ITAAC do not, by virtue of their inclusion in the DCD, constitute regulatory requirements after the licensee has received authorization to load fuel or for renewal of the license. However, subsequent modifications must comply with the design descriptions in the DCD unless the applicable requirements in 10 CFR 52.97 and Section VIII of this appendix have been complied with. As discussed in sections II.B.9 and III.D of this SOC, 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 that a Part 50 applicant decides to reference this appendix.

J. Records and Reporting

The purpose of Section X 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 X 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 of this SOC. Paragraph X.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 paragraph VI.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 license. Therefore, to ensure that this information will be available, a requirement for the design certification applicant to maintain the proprietary information was added to paragraph X.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 appendix may be referenced.

Paragraphs A.2 and A.3 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 VIII of this appendix. The term ''plant-specific'' was added to paragraph 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 IV.A 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 X.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 of this SOC, the final safety analysis report required by 10 CFR 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 paragraph X.B.3.d of this appendix refers to the information that is contained in the final safety analysis report for a facility (required by 10 CFR 52.79) but is not part of the plant-specific DCD (required by IV.A 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 section II.C.3 of this SOC).

Paragraphs B.1 and B.2 establish 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 the interval between successive updates does not exceed 24 months.

The reporting requirements vary according to four different time periods during a facilities' lifetime as specified in paragraph B.3. Paragraph B.3.a 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 license. Under B.3.b, 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 excessive burden on the applicant.

Paragraph B.3.c 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 dated August 4, 1995 (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 Commission disagrees with the NEI request because it does not provide for sufficiently timely notification of design changes during the critical period of facility construction. Also, the Commission 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 VIII 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 paragraph X.B.3.d, 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,'' dated January 1995. The Commission finds that ABB–CE's evaluation provides a sufficient basis to conclude that there are no additional severe accident design alternatives beyond those currently incorporated into the System 80+ design which are cost-beneficial, whether considered at the time of the approval of the 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 are within those specified 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 with 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

Administrative practice and procedure, Antitrust, 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 recordkeeping 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, 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

I. 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).

II. Definitions

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

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter 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.

E. Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (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 VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.47, with the exception of generic 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 (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

F. 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 VIII.B.6 of this appendix. This designation expires for some Tier 2* information under VIII.B.6.

G. 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.

III. Scope and Contents

A. Tier 1, Tier 2, and the generic technical specifications in the System 80+ Design Control Document, ABB–CE, with revisions dated January 1997, are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the generic DCD may be obtained from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for examination and copying at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555. Copies are also available for examination at the NRC Library, 11545 Rockville Pike, Rockville, Maryland 20582 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2, and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information, as set forth in the generic DCD, and the Technical Support Document for the System 80+ design are not part of 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 of the System 80+ design or NUREG–1462, ''Final Safety Evaluation Report related to the Certification of the System 80+ Design,'' (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site-specific design parameters, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a 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:

a. 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;

b. The reports on departures from and updates to the plant-specific DCD required by X.B of this appendix;

c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;

d. Information demonstrating compliance with the site parameters and interface requirements;

e. Information that addresses the COL action items; and

f. Information required by 10 CFR 52.47(a) that is not within the scope of this appendix.

3. Physically include, in the plant-specific DCD, the proprietary information referenced in the System 80+ DCD.

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

V. Applicable Regulations

A. Except as indicated in paragraph B 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 May 9, 1997, that are applicable and technically relevant, as described in the FSER (NUREG–1462) and Supplement No. 1.

B. The System 80+ design is exempt from portions of the following regulations:

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

VI. Issue Resolution

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 V of this appendix; and therefore, provide

[1] ''System 80+'' is a trademark of Combustion Engineering, Inc.

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 involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (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, are intended as requirements in the generic DCD for the System 80+ design;

3. All generic changes to the DCD pursuant to and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD pursuant to and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that proceeding;

5. All departures from the DCD that are approved by license amendment, but only for that proceeding;

6. Except as provided in VIII.B.5.f of this appendix, all departures from Tier 2 pursuant to and in compliance with the change processes in VIII.B.5 of this appendix that do not require prior NRC approval;

7. All environmental issues concerning severe accident mitigation design alternatives associated with the information in the NRC's final environmental assessment for the System 80+ design and 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. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(4). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII 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.

E.1. 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 this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from ABB–CE. The request must state with particularity:

a. The nature of the proprietary or other information sought;

b. The reason why the information currently available to the public in the NRC's public document room is insufficient;

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

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. 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 nondisclosure agreement.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from June 20, 1997, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix 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.

VIII. 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 applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required 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). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

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

4. An applicant or licensee who references this appendix 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 Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix 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.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, involves an unreviewed safety question if—

(1) 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;

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

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

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, involves an unreviewed safety question if—

(1) 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

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

d. 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.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with VIII.B.5 of this appendix 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 VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. 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 VIII.B.5 of this appendix.

6.a. An applicant who references this appendix 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 VI of this appendix and 10 CFR 52.63(a)(4).

b. A licensee who references this appendix 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.

(1) Maximum fuel rod average burnup.

(2) Control room human factors engineering.

c. A licensee who references this appendix 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.b 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.

(1) ASME Boiler & Pressure Vessel Code, Section III.

(2) ACI 349 and ANSI/AISC N–690.

(3) Motor-operated valves.

(4) Equipment seismic qualification methods.

(5) Piping design acceptance criteria.

(6) Fuel and control rod design, except burnup limit.

(7) Instrumentation & controls setpoint methodology.

(8) Instrumentation & controls hardware and software changes.

(9) Instrumentation & controls environmental qualification.

(10) Seismic design criteria for non-seismic category I structures.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic technical specifications and other operational requirements are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.758(b) are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. 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 grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such petition must comply with the general requirements of 10 CFR 2.714(b)(2) and must demonstrate why special circumstances as defined in 10 CFR 2.758(b) are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. 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. All other issues with respect to the plant-specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license 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 who references this appendix 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 who references this appendix 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 VIII 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 paragraph VIII.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 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, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a Section 103(a) hearing, their expiration will occur upon final Commission action in such proceeding. 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 VIII of this appendix.

X. Records and Reporting

A. Records

1. The applicant for this appendix 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 and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made pursuant to Section VIII 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 appendix shall prepare and maintain written safety evaluations which provide the bases for the determinations required by Section VIII 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 appendix 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 who references this appendix 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 VIII 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 paragraphs B.1 and B.2 of this section must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application shall include the report and any updates to the plant-specific DCD.

b. During the interval from the date of application to the date of issuance of a 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.

c. During the interval from the date of issuance of a 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.

d. 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 license.

Dated at Rockville, Maryland, this 9th day of May, 1997.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

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