



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20585-0001

April 4, 1995

The Honorable Lauch Faircloth, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The NRC has sent to the Office of the Federal Register for publication the enclosed proposed amendments to the Commission's regulations for commercial nuclear power plants. Specifically, this proposed rule would add a new Appendix A to 10 CFR Part 52 which will when promulgated certify the standard design of the U.S. Advanced Boiling Water Reactor (ABWR) submitted to the NRC for its review by GE Nuclear Energy.

These proposed amendments are necessary to fulfill the objectives of Part 52 which were to provide early resolution of licensing issues and foster standardization while allowing sufficient flexibility to incorporate advancements in technology and equipment. Those wishing to obtain a license to build or operate a U.S. ABWR will be able to do so by referencing the standard design certified in Appendix A to Part 52.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Rathbun".

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Bob Graham

NUCLEAR REGULATORY COMMISSION

10 CFR PART 52

RIN 3150 - AF15

Standard Design Certification for the
System 80+ Design

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) proposes to approve by rulemaking a standard design certification for the System 80+ design. The applicant for certification of the System 80+ design was Asea Brown Boveri-Combustion Engineering (ABB-CE). The NRC is proposing to add a new appendix to 10 CFR Part 52 for the design certification. This action is necessary so that applicants or licensees intending to construct and operate a System 80+ design may do so by appropriately referencing the proposed appendix. The public is invited to submit comments on this proposed design certification rule (DCR) and the design control document (DCD) that is incorporated by reference into the DCR (refer to Sections IV and V). The Commission also invites the public to submit comments on the environmental assessment for the System 80+ design (refer to Section VI).

DATE: The comment period expires on [Insert date 120 days following the date of publication in the Federal Register]. Comments received after this date will be considered if it is practical to do so, but the Commission is

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only able to assure consideration for comments received on or before this date. In addition, interested parties may request an informal hearing before the Atomic Safety and Licensing Board Panel, in accordance with 10 CFR 52.51, on matters pertaining to this design certification rulemaking (refer to Section V). Requests for an informal hearing must be submitted by [Insert date 120 days following the date of publication in the Federal Register].

ADDRESSES: Mail written comments and requests for an informal hearing to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Comments may also be delivered to 11555 Rockville Pike, Rockville, MD, between 7:30 am and 4:15 pm on Federal workdays. Copies of comments received will be available for examination and copying at the NRC Public Document Room (PDR) at 2120 L Street NW. (Lower Level), Washington, DC. A copy of the environmental assessment and the design control document is also available for examination and copying at the PDR.

FOR FURTHER INFORMATION CONTACT: Harry S. Tovmassian, Office of Nuclear Regulatory Research, telephone (301) 415-6231, Jerry N. Wilson, Office of Nuclear Reactor Regulation, telephone (301) 415-3145, or Geary S. Mizuno, Office of the General Counsel, telephone (301) 415-1639. U.S. Nuclear Regulatory Commission, Washington, DC 20555.

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I. BACKGROUND

On March 30, 1989, Combustion Engineering, Inc. (ABB-CE) applied for certification of the System 80+ standard design with the NRC. The application

was made in accordance with the procedures specified in 10 CFR Part 50, Appendix O, and the Policy Statement on Nuclear Power Plant Standardization, dated September 15, 1987.

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

On August 21, 1989, ABB-CE 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 10 CFR 52.45. 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. ABB-CE's application, the Combustion Engineering Standard Safety Analysis Report - Design Certification (CESSAR-DC) up to and including amendment W and the Certified Design Material, is available for inspection and copying at the NRC Public Document Room. 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.

The NRC staff issued a final safety evaluation report (FSER) related to the certification of the System 80+ design in August 1994 (NUREG-1462). The FSER documents the results of the NRC staff's safety review of the System 80+ design against the requirements of 10 CFR Part 52, Subpart B, and delineates

the scope of the technical details considered in evaluating the proposed design. A copy of the FSER may be obtained from the Superintendent of Documents, U. S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-9328 or the National Technical Information Service, Springfield, VA 22161. The final design approval (FDA) for the System 80+ design was issued on July 26, 1994, and published in the Federal Register on August 2, 1994 (59 FR 39371).

Since the issuance of 10 CFR Part 52, the NRC staff has been working to implement Subpart B with issues such as the acceptability of using a two-tiered design certification rule and the level of design detail required for design certification. The NRC staff originally proposed a design certification rule for evolutionary standard plant designs in SECY-92-287, "Form and Content for a Design Certification Rule." On March 26, 1993, the NRC staff issued SECY-92-287A in which it responded to issues on SECY-92-287, which were put forth by the Commission, and to specific questions raised by Commissioner Curtiss in a letter dated September 9, 1992. Subsequently, the NRC staff modified the draft rule 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. On November 23, 1993, the NRC staff discussed this ANPR in a public workshop entitled "Topics Related to Certification of Evolutionary Light Water Reactor Designs." All holders of operating licenses or construction permits were informed of the issuance of the ANPR and the planned public workshop through the issuance of NRC Administrative Letter 93-05 on October 29, 1993. Separate announcements of the workshop were also sent to the Union of Concerned Scientists, the Nuclear

Information and Resource Service, the Natural Resources Defense Council, the Public Citizen Litigation Group, the Ohio Citizens for Responsible Energy (OCRE), and the State of Illinois Department of Nuclear Safety on October 18, 1993. An official transcript of the workshop proceedings is available in the PDR.

Rulemaking Procedures

10 CFR Part 52 provides for Commission approval of standard designs for nuclear power facilities (e.g., design certification) through rulemaking. In accordance with the Administrative Procedure Act (APA), Part 52 provides the opportunity for the public to submit written comments on the proposed design certification rule. However, Part 52 goes beyond the requirements of the APA by providing the public with an opportunity to request a hearing before the Atomic Safety and Licensing Board Panel in a design certification rulemaking. While Part 52 describes a general framework for conducting a design certification rulemaking, § 52.51(a) states that more detailed procedures for the conduct of each design certification will be specified by the Commission.

To assist the Commission in developing the detailed rulemaking procedures, the NRC's Office of General Counsel (OGC) prepared a paper, SECY-92-170 (May 8, 1992), which identified issues relevant to design certification rulemaking procedures, and provided OGC's preliminary analyses and recommendations with respect to those issues. SECY-92-170 was made public by the Commission, and a Commission meeting on this paper was held on June 1, 1992.

Thereafter, in SECY-92-185 (May 19, 1992), OGC proposed holding a public workshop for the purpose of facilitating public discussion on the issues raised in SECY-92-170 and obtaining public comments on those issues. The Commission approved OGC's proposal (See the May 28, 1992, Memorandum from Samuel J. Chilk to William C. Parler). Notice of the workshop was published in the Federal Register on June 9, 1992 (57 FR 24394). The notice also provided for a 30-day period following the workshop for the public to submit written comments on SECY-92-170. A transcript was kept of the workshop proceedings and placed in the PDR. Nearly 50 non-NRC individuals attended the workshop; an additional eight persons requested copies of SECY-92-170 and workshop materials but did not attend. The workshop was organized in a panel format, with representatives from OCRE (Susan Hiatt), NUMARC (Robert Bishop), GE and Westinghouse - two design certification vendors (Marcus Rowden and Barton Cowan), the State of Illinois Department of Nuclear Safety (Stephen England), the State of New York Public Service Commission (James Brew), the Administrative Conference of the United States (William Olmstead), OGC, the NRC staff, and a moderator. Eleven written comments were received after the workshop, three from OCRE (OCRE August 1992 Comments; OCRE September 1992 Letter; OCRE October 1992 Letter), NUMARC, Winston and Strawn, the State of Illinois Department of Nuclear Safety, Westinghouse Energy Systems, the U.S. Department of Energy, Asea Brown Boveri-Combustion Engineering (ABE-CE), and AECL Technologies¹. Mr. Rowden submitted an additional comment on behalf of NUMARC which addresses proprietary information.

OGC's final analyses and recommendations for design certification rulemaking procedures were set forth in SECY-92-381 (November 10, 1992). This

¹AECL is the vendor for the CANDU 3 design.

paper was prepared after consideration of the panel discussions at the public workshop and the written comments received after the workshop. On April 30, 1993, the Commission issued a Memorandum to the General Counsel which sets forth the Commission's determinations with respect to the procedural issues raised by the General Counsel's paper. Section V. below, "Comments and Hearings in the Design Certification Rulemaking," describes the procedures to be utilized in this design certification rulemaking.

II. PUBLIC COMMENT SUMMARY AND RESOLUTION

The public comment period for the ANPR for rulemakings to grant standard design certification for evolutionary light water reactor designs expired on January 3, 1994. Six comment letters were received. Five comment letters were from the nuclear industry (i.e., vendors, utilities, and industry representatives) and one from a public interest organization. Most of the commenters addressed the nine topics upon which the NRC sought the public's views. The Commission has carefully considered all the comments and wishes to express its sincere appreciation of the often considerable efforts of the commenters.

In the following public comment summary and resolution and in the section-by-section discussion (Section III below), the discussion refers to "Commission approval" of NRC staff-proposed positions or recommendations. This should be understood as meaning the Commission's tentative approval of those positions or recommendations for purposes of: (i) the NRC staff's review of the System 80+ design certification application, and (ii) preparation of this notice of proposed rulemaking. The public may submit comments and

request an informal hearing with respect to any of the "Commission approved" positions or recommendations (comments and hearings are discussed in further detail in Section V).

All of the commenters supported the basic concept of the design certification rulemaking approach including the two-tiered structure for design information. The Nuclear Management and Resources Council, which has since been subsumed within the Nuclear Energy Institute (NEI), commented for the nuclear industry. GE Nuclear Energy, Westinghouse, and ABB-CE stated that they participated in the preparation of the NEI comments and fully supported them. The following is a summary and resolution of the public comments:

Topic 1 - Acceptability of a Two-Tiered Design Certification Rule Structure

Comment Summary. On behalf of the nuclear industry, NEI stated that a two-tiered structure to a design certification rule is practical and fully consistent with the intent and requirements of 10 CFR Part 52. OCRE stated that it fully supports the concept set forth in the ANPK provided that the Tier 2 information is subject to public challenge in the standard design certification and any associated hearing.

Response. Although a two-tiered structure for design certification rules was not envisioned or subsequently deemed necessary to implement standard design certifications under 10 CFR Part 52, the Commission approved the use of a two-tiered structure for a design certification rule in its SRM of February 15, 1991, on SECY-90-377, "Requirements for Design Certification Under 10 CFR Part 52," in response to a request from NEI dated August 31,

1990. Since then, the NRC staff has worked to develop a two-tiered rule that achieves industry's goal of issue preclusion for a greater amount of information than was originally planned for design certification, while retaining flexibility for design implementation.

Tier 1 information is defined in Section 2(b) of the proposed rule and is treated as the certified information that is controlled by the change standards of 10 CFR 52.63. Tier 2 information is defined in Section 2(c) of the proposed rule and consists primarily of the information submitted in an application for design certification. The information in the two tiers is interdependent. Therefore, an applicant for a construction permit, operating license, or combined license (COL) that references this design certification must reference both tiers of information. The consolidation of both tiers of information into a Design Control Document (DCD) will provide an effective means of maintaining this information and facilitating its incorporation into the rule by reference. All matters covered in each tier, including the determination of what information should be placed in each tier, are subject to public challenge in the design certification rulemaking and any associated hearing.

Topic 2 - Acceptability of the Process and Standards for Changing Tier 2 Information

Comment Summary. NEI concurs in the process and standards to be used by COL holders and applicants for evaluating and implementing changes to Tier 2 information via the so-called "§ 50.59-like" change process. However, NEI does not agree with the statement in the ANPR (A.13(d)(3)) that "changes properly implemented through this "§ 50.59-like" process cause a loss of

finality relative to the affected portion of the design or are subject to subsequent legal challenge." NEI contends that these changes would be sanctioned through the design certification rule and that the only issue entertainable at the time of the COL licensing proceeding would be whether the licensee complied with the "§ 50.59-like" change process. Likewise, changes made subsequent to COL issuance could be challenged in the Part 52 proceeding before fuel-load authorization only on the basis that the change resulted in noncompliance with applicable acceptance criteria. However, NEI recognizes that changes from Tier 2 that require NRC approval would be subject to a hearing opportunity as specified in 10 CFR Part 52.

UCRE stated that it is important that applicant or licensee initiated changes to Tier 2 information made pursuant to the "§ 50.59-like" process will no longer be afforded the issue preclusion protection of 10 CFR 52.63. To do otherwise would turn the two-tiered system into a double standard in which utilities could deviate from the standard design but the public could not challenge these deviations. Permitting site-specific litigation of these changes would also serve to discourage changes.

Response. In order to implement the two-tiered structure for design certification rules, the Commission proposes a change process for Tier 2 information that has the same elements as the Tier 1 change process. Specifically, the Tier 2 change process has provisions for generic changes, plant-specific changes, and exemptions similar to those in 10 CFR 52.63. Although the NRC staff proposed that the backfitting standards for making generic changes to Tier 2 information should be less stringent than those for Tier 1 information, the Commission disapproved this proposal in its SRM on SECY-92-287A, dated June 13, 1993, and stated that "the backfitting standards

of 10 CFR 52.63 should be applied for such changes to Tier 2." As a result, the NRC staff adopted the backfitting standards of 10 CFR 52.63 in the Tier 2 change process proposed in the ANPR, except that the additional factor regarding "any decrease in safety that may result from the reduction in standardization" was not adopted for plant-specific changes and exemptions in order to achieve additional flexibility for Tier 2 information.

The Tier 2 change process also has a provision similar to 10 CFR 50.59 that allows changes to Tier 2 information by an applicant or licensee, without prior NRC approval, subject to certain restrictions. The Commission approved this process in its SRM on SECY-90-377, dated February 15, 1991, provided "that such changes open the possibility for challenge in a hearing." The NRC staff followed the Commission's guidance in developing the process in ANPR A.13(d)(3) that allows certain changes to Tier 2 information, without prior NRC approval. This section of the ANPR states that "Tier 2 changes will no longer be considered matters resolved in connection with the issuance or renewal of a design certification within the meaning of 10 CFR 52.63(a)(4)." The NRC staff included this provision to meet Commission guidance and to restrain Tier 2 changes in order to maintain the benefits of standardization, as discussed in SECY-92-287. Also, changes may be challenged in individual COL proceedings since the changes depart from the design information approved in the design certification rulemaking. Therefore, the NRC Commission agrees with the OCRE position on issue preclusion and specifically invites comments on this provision (See Section IV).

Topic 3 - The Acceptability of a Tier 2 Exemption

Comment Summary. NEI supports the inclusion of the provision that an applicant or licensee may request, and the NRC may grant, an exemption to Tier 2 information. OCRE indirectly supports the Tier 2 exemption provision but recommends that the sentence "These Tier 2 changes will no longer be considered matters resolved in connection with the issuance or renewal of a design certification within the meaning of 10 CFR 52.63(a)(4)." also be included in the Section A.13(d)(2) of the ANPR on exemptions from Tier 2 information, for clarity, and because 10 CFR 52.63(b)(1) does not mention the two-tiered system.

Response In SECY-92-287A, the NRC staff proposed the addition of an exemption provision to the Tier 2 change process so that the change process for both tiers would have the same elements and to provide additional flexibility to applicants or licensees that reference a design certification rule. The Commission deferred its decision on an exemption to the Tier 2 change process in its SRM dated June 23, 1993, and requested the NRC staff to solicit public comments on this issue.

Because no commenter objected to the addition of a Tier 2 exemption process and NEI supported the proposal, the provision was retained in the proposed rule. However, OCRE proposed that Tier 2 exemptions lose issue preclusion consistent with Tier 1 exemptions. Because that is consistent with the NRC staff's approach to Tier 2 changes and the Commission's guidance in its SRM on SECY-90-377 (see response to topic #2), OCRE's proposal has been incorporated into the proposed rule.

The additional standard in the Tier 1 exemption process, which requires that "any decrease in safety that may result from the reduction in standardization caused by the exemption" outweighs the special circumstances

in 10 CFR 50.12, was not included in the Tier 2 exemption process because the Commission views Tier 2 information as more detailed descriptions of Tier 1 information that should have a less stringent change standard than Tier 1 and the industry requested additional flexibility for Tier 2 information. Therefore, the proposed Tier 2 change process uses the same standard that is used for Part 50 exemptions, namely 10 CFR 50.12. The Commission believes that the loss of issue preclusion for Tier 2 exemptions will help minimize the consequences of the loss of standardization caused by these exemptions.

Topic 4 - Acceptability of Using a Change Process, Similar to the One in 10 CFR 50.59 Applicable to Operating Reactors, Prior to the Issuance of a Combined License that References a Certified Design

Comment Summary. NEI concurs in the NRC's proposal to have the "§ 50.59-like" change process apply to both COL applicants and licensees.

Response. In its SRM on SECY-92-287A, dated June 23, 1993, the Commission approved the NRC staff's proposal to extend the use of the "§ 50.59-like" change process for Tier 2 information to applicants that reference a certified design. Because NEI and other commenters supported this proposal, this additional flexibility has been retained for the proposed rule.

Topic 5 - The Acceptability of Identifying Selected Technical Positions from the FSER as "Unreviewed Safety Questions" that Cannot Be Changed Under a "Section 50.59-Like" Change Process

Comment Summary. NEI commented that the proposal to predesignate changes to certain design aspects as constituting "unreviewed safety

questions" is unnecessary and is tantamount to the creation of a third tier of information, which runs counter to the two-tier structure. NEI proposed that the selected Tier 2 material be designated, not broadly in the rule, but specifically in the SSAR/FSER and the DCD as requiring NRC staff notification before implementing the changes. NEI argued that at the time of notification, the NRC staff could decide whether the proposed change constitutes an "unreviewed safety question," and the applicant or COL holder would be prohibited from making the change without either NRC staff concurrence or a successful appeal of the NRC staff's determination. NEI also envisioned a time, subsequent to completion of designs and the inspections, tests, analyses, and acceptance criteria (ITACC), when the change restriction for selected Tier 2 material will no longer be necessary. NEI further stated that, whether or not the Commission adopts NEI's proposal, the NRC staff should be limited to design areas discussed with plant designers when designations of "unreviewed safety questions" are made. Also, these special designations should be as narrow and specific as practicable to avoid the inadvertent broadening of this special category of Tier 2 design information and the excessive restrictions against change that would result.

Response. The NRC's proposal to predesignate certain Tier 2 information that cannot be changed without prior NRC approval does not create a third tier of information or conflict with the two-tiered rule structure. In fact, this so-called Tier 2* information was created as a consequence of industry's implementation of the two-tiered rule structure. Specifically, industry's desire to minimize the amount of information in Tier 1 and to use design acceptance criteria in lieu of design information in certain areas resulted in the need to identify significant Tier 2 information that could not be changed

by an applicant or licensee without prior NRC approval. The previous reference to "identified unreviewed safety questions" in the ANPR was made to indicate that the process for changing the so-called Tier 2* information would be the same as for changing other Tier 2 information that an applicant or licensee determines to constitute an unreviewed safety question. Therefore, there is no third tier of information. Rather, some Tier 2 information cannot be changed without prior NRC approval and the remainder can. This is no different than the information in a Final Safety Analysis Report relative to the process in 10 CFR 50.59.

The Commission agrees with NEI that it would be clearer to future users of the certified design if the specific information that has been designated as requiring prior NRC approval (Tier 2*) is identified in the DCD rather than summarized in the design certification rule (DCR). However, the requirement for prior NRC approval does need to be specified in the DCR for the Tier 2 change process. Therefore, the NRC instructed the applicants to identify the Tier 2* information in the DCD.

In response to NEI's request, the DCR will not identify the Tier 2* information as an unreviewed safety question because that designation is not required; only prior NRC approval is required. Therefore, the Tier 2 change process has been revised to state that Tier 2* information identified in the DCD cannot be changed without prior NRC approval. Although Tier 2* changes may not result in unreviewed safety questions, the public will be afforded an opportunity to challenge the changes (see response to topic #2). The Commission also agrees that the predesignation of some of the Tier 2* information can expire when the plant first achieves 100% power while other Tier 2* information must remain in effect throughout the life of the plant

that references the DCR. This is because there is sufficient information in some of the related areas of Tier 1 to control changes after the plant is completed. The appropriate expiration point is designated in the DCD.

The NEI proposal to require notification of the NRC rather than requiring NRC approval prior to changing the Tier 2* information would create an unnecessary burden on the NRC in the Tier 2 change process. The Commission has already determined that the predesignated Tier 2* information is significant and cannot be changed before NRC approval. Therefore, the Commission has not accepted the "notification" proposal. Also, the designation of Tier 2* information is not an excessive restriction on the change process. Rather, it compensates for industry's request to minimize the amount of information in Tier 1.

Topic 6 - Need for Modifications to 10 CFR 52.63(b)(2) If the Two-Tiered Structure for the Design Certification Rule is Approved

Comment Summary. OCRE commented that modifications to § 52.63 are not necessary because the design certification rules would also become regulations. NEI commented that changes to 10 CFR Part 52 are not needed at this time but that some changes to Part 52 may be identified as appropriate for future consideration based on experience with the initial design certifications.

Response. When Part 52 was written, § 52.63(b)(2) was intended to be the change process for information that was not referenced in the design certification rule (non-certified information). Now that the Commission has decided to implement a two-tiered rule structure as described in the response to Topic #1, the two-tiered change process applies to all information

referenced by the design certification rule. Therefore, there does not appear to be a need for § 52.63(b)(2) in a two-tiered rule structure.

In the absence of any perceived need for changes to 10 CFR 52.63(b)(2) to accommodate the two-tiered concept in design certification, the Commission does not intend to modify 10 CFR Part 52 at this time. However, as NEI suggests, the Commission is evaluating the need for changes to Part 52 as it gains experience with the initial design certification reviews.

Topic 7 - Whether the Commission Should Either Incorporate or Identify the Information in Tier 1 or Tier 2 or Both in the Combined License

Comment Summary. On the question of whether Tier 1 or Tier 2 information should be incorporated in the combined license (COL) or identified in the COL, NEI stated that this question need not be resolved for design certification purposes but provides two alternatives for future NRC consideration. Alternative one would be to incorporate Tier 1 information and identify Tier 2 information in the COL. The second alternative would be to incorporate both tiers of information in the rule, provided that the Tier 2 change provisions are incorporated in the rule as well.

OCRE stated that both Tier 1 and Tier 2 information should be incorporated in the COL because both tiers contain important design information.

Response. The NRC is deferring the decision on this issue because resolution of this issue is not needed to develop a design certification rule. However, because the commenters all supported incorporation of both tiers of information, the NRC staff will evaluate that option for a combined license under Subpart C of 10 CFR Part 52.

Topic 8 - Acceptability of Using Design Specific Rulemakings Rather Than Generic Rulemaking for the Technical Issues Whose Resolution Exceeds Current Requirements

Comment Summary. NEI, GE Nuclear Energy, and Westinghouse Electric Corporation took exception with the NRC position on the issue of designating severe accident and technical requirements, beyond those in current regulations, as "applicable regulations" in the design certification rule. NEI stated that "Commission approved NRC staff positions will be reflected in a design certification rule by means of design provisions contained in Tier 1 and Tier 2 of the DCD incorporated in the rule." NEI argued that the NRC staff's proposed approach would result in needless duplication, complexity, and delay because matters that have been agreed to in detail would then be formulated in broadly stated positions requiring another round of extensive discussions to reach agreement in a process equivalent to a series of complex, discrete rulemakings. In addition, NEI stated that these "broadly stated, free standing applicable regulations carry the potential for new and diverse interpretations by the NRC staff during the life of the design certification." These interpretations may be at odds with the understandings that translated into specific Tier 1 and Tier 2 requirements in the DCD. GE Nuclear Energy reiterated these comments but added that "The course proposed by the NRC staff would enormously complicate pre-rulemaking preparation, the conduct of the rulemakings themselves and COL licensing and pos.-licensing facility construction and operation. It would, moreover, impose schedule delays and generate needless duplication, if not outright conflicts." Also, NEI saw little difference between the proposal to incorporate applicable regulations

in design certification rules and the similar effect of proceeding with generic severe accident rulemaking.

OCRE stated that the resolution of technical issues whose resolution exceeds current requirements will likely be design-specific and therefore, it may make little difference whether the rulemakings are design-specific or generic. OCRE further stated that, if the NRC wants all plants constructed as of a certain date to incorporate certain design features or otherwise address certain technical issues, then a generic rulemaking may be the safest and most cost-effective way to accomplish this goal. OCRE also noted that a generic rule would cover an applicant that might decide not to use a standard certified design.

Response. The Commission has used design-specific rulemaking rather than generic rulemaking for the selected technical and severe accident issues that go beyond current requirements for light-water reactors (LWRs). The Commission adopted this approach, early in the review process, because it believed that the new requirements would be design-specific, as OCRE stated. Also, the NRC was concerned that generic rulemakings would cause significant delay in the design certification reviews. The Commission approved this approach in its SRM on SECY-91-262, dated January 28, 1992, and has continued to support this approach for evolutionary LWRs, as stated in its SRM on SECY-93-226, dated September 14, 1993. The Commission has deferred its decision on the need for generic rulemaking for advanced LWRs.

Both the industry and OCRE concluded that there would be little difference in the requirements for the certified designs, regardless if the approach was generic or design-specific. The Commission agrees that at the conclusion of the design certification rulemaking the effect of the new

regulations is basically the same but that the specific wording of the regulations may have been different if generic rulemaking was used.

In implementing the rules of 10 CFR Part 52 and the Commission's Severe Accident Policy Statement (50 FR 32138; August 8, 1985), the NRC staff set out to achieve a higher level of safety performance for both evolutionary and passive LWR designs in the area of severe accidents and in other selected areas. The NRC staff proposed new requirements to implement these goals in various Commission papers, such as SECY-90-016 and SECY-93-087. The NRC staff then selected the applicable requirements for each evolutionary design and evaluated the design information that describes how those requirements were met in the FSERs for the U.S. ABWR and System 80+ designs. In the proposed rule for each design, the NRC has identified these requirements as applicable regulations in order to specify the requirements that were applicable and in effect at the time the certification was issued for the purposes of §§ 52.48, 52.54, 52.59, and 52.63.

These applicable regulations, which were identified in each FSER, are set forth in the design certification rule, with minor editing, to achieve codification through the design certification rulemaking. These codified regulations, which supplement the list of regulations in § 52.48, become part of the Commission's regulations that are "applicable and in effect at the time the certification was issued." Without this complete list of applicable regulations, the NRC staff could not perform reviews in accordance with §§ 52.59 and 52.63. By codifying these requirements, the NRC intends to make it clear that for the purpose of renewal of a certified design under § 52.59, these requirements are part of the applicable regulations in effect at the time that the design certification was first issued. The NRC also intends to

make it clear that the Commission may, pursuant to § 52.63(a)(1) and (3), impose modification of Tier 1 information or to issue a plant-specific order, respectively, to ensure that the certified design or the plant complies with the applicable regulations of the design certification rule. The rationale is that the Commission could not, without re-reviewing the merits of each position, impose a change to Tier 1 information or issue a plant-specific order merely because the modification was necessary for compliance with a matter involving these proposed requirements. Also, the Commission would not have a complete baseline of regulations for evaluating proposed changes from the public, applicants, or licensees, thereby degrading the predictability of the licensing process.

The codification of these proposed requirements, in reference to § 52.48, is also necessary for two other reasons. First, it serves as a basis for obtaining public comment on the proposed adoption of the requirements as applicable regulations. Second, it provides confirmation that the requirements are being adopted by the Commission as applicable regulations under § 52.54 for the design certification being approved. In the absence of this codification, a design certification applicant could argue that the Commission cannot lawfully condition approval of the design certification on compliance with the proposed requirements used during its review of the design. This is because the requirements are not "applicable standards and requirements of the ... Commission's regulations" without further Commission action under § 52.54.

By identifying the regulations that are applicable to each design, the Commission has improved the stability and predictability of the licensing process. By approving the design information that describes how these

regulations were met, the Commission has minimized the potential for a differing interpretation of the regulations. Finally, the NRC staff told NEI in a meeting on April 25, 1994, and in a letter dated July 25, 1994, that the industry-proposed alternative to applicable regulations was unacceptable. The NRC staff stated that design information cannot function as a surrogate for 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 design information. Therefore, consideration of the comments on Topic #8 has not altered the Commission's decision to proceed with design-specific rulemaking for the proposed requirements and to publish the appropriate applicable regulations in each design certification rule.

Topic 9 - The Appropriate Form and Content of a Design Control Document.

Comment Summary. Concerning the form and content of the DCD, NEI envisioned a document that consisted of three parts including an introductory section, Tier 1 information, and Tier 2 information. NEI also proposed an algorithm that described the industry's view of the contents of a DCD.

NEI stated that, based on its interactions with the NRC staff on the guidance for preparing a DCD, two main issues have emerged. The first issue is the nature and treatment for rulemaking purposes of secondary references contained in the DCD. At issue is the extent to which references to codes, standards, Regulatory Guides, etc. need to be explicitly "incorporated by reference" in specific design certification rules (DCRs). It is industry's position that the burden of incorporating these secondary references into the rule would outweigh the increase in regulatory certainty and predictability

that such an effort would provide. The second issue relates to the regulatory significance of information contained in the DCD and, in particular, design Probabilistic Risk Assessment (PRA) information. Specifically, NEI is concerned with the inclusion of the design PRA in the DCD and a perceived requirement to use the PRA to support the "50.59-like" change process.

Response. As defined in SECY-92-287, the DCD is the master document that contains the Tier 1 and 2 information referenced by the design certification rule. The NRC staff has had several meetings with the design certification applicants on the preparation of a DCD and provided guidance to the applicants in letters dated August 26, 1993; August 3 and 5, 1994; and October 4, 1994. Although the Commission agrees with NEI on the basic form of the DCD, it does not agree with NEI's proposed algorithm on the contents of a DCD.

Because the DCD is the master reference document, it should, to the extent possible, retain as much of the applicant's standard safety analysis report (SSAR), as required in 10 CFR 52.47. Due to the requirement that all information incorporated in the rule be publicly available, proprietary and safeguards information cannot be included in the DCD. Also, the NRC concluded that the detailed methodology and quantitative portions of the design PRA do not need to be included in the DCD but the assumptions, insights, and discussions of PRA analyses must be retained in the DCD. The NRC also decided that COL applicants and licensees will be encouraged, but not required, to use the PRA to support the change process. This position was predicated in part upon NEI's acceptance, in conceptual form, of a future generic rulemaking that requires a COL applicant or holder to have a plant-specific PRA that updates and supersedes the design PRA to account for site-specific and detailed as-

built aspects of the plant. The Commission approved the requirement for a plant-specific PRA in its SRM on SECY-94-182, "Probabilistic Risk Assessment (PRA) Beyond Design Certification," in approving the development of a generic "Operational Rule" that would apply to all COL applicants and holders. The remainder of the applicant's SSAR, including all of the assumptions, issue resolutions, and safety analyses, should be retained in the DCD.

With regard to NEI's concern with secondary references, the NRC staff met with NEI on January 6, 1994, and issued a letter to NEI on May 3, 1994, that documented an agreement with the industry on the resolution of this issue. The agreement states that combined license (COL) applicants and licensees who reference a DCR will treat these secondary references as requirements, in the context that they are described in the documents referenced in the DCD. However, these secondary references will not be incorporated by reference in the DCR, and thus there is no issue preclusion for secondary references. With the above stated guidance, the NRC believes that the appropriate form and content of a DCD has been defined.

III. SECTION-BY-SECTION DISCUSSION OF DESIGN CERTIFICATION RULE

Pursuant to 10 CFR Part 52, Subpart B, the NRC has been working for some time to develop a rule that will achieve the Commission's goals for standard design certifications. Therefore, this proposed rule seeks to achieve the early resolution of safety issues and to enhance the safety and reliability of nuclear power plants. The Commission also expects to achieve a more predictable and stable licensing process through the certification of standard designs by rulemaking. An applicant for a combined license (COL) that

references a design certification rule (DCR) must meet the requirements in the DCR and in the design control document that is incorporated by reference in the DCR.

The NRC staff's first proposal of a standard design certification rule was provided in Enclosure 1 to SECY-92-287, dated August 18, 1992. This proposal was modified based on Commission guidance, and an updated version was published in Appendix 2 to the ANPR. The proposed rule in this Federal Register notice has the same basic form and content as the ANPR version, but there has been some reorganization of the contents. The following discusses the purpose and key aspects of each section of the rule and also discusses issues raised on those sections that are not covered in the public comment summary. Changes made to the ANPR version of the proposed rule for the sake of clarity, brevity, consistency, or organization are not discussed below. All references to the proposed rule are to the provisions in proposed Appendix B to 10 CFR Part 52.

A. Scope

The purpose of Section 1 of the proposed rule entitled, "Scope," is to identify the standard plant design that is to be approved by this design certification rule. The applicant for certification of the design is also identified in this section. While the design certification applicant does not have special rights pursuant to this rule, the implementation of 10 CFR 52.63(c) depends on whether an applicant for a COL contracts with the design certification applicant to provide the certified design. If the COL applicant necessary to implement this rule.

Because the requirements of 10 CFR 52.63(c) apply to an applicant for a COL, the NRC proposes that this requirement be added to 10 CFR Part 52, Subpart C, specifically to a new Section 10 CFR 52.79(e). The NRC requests comments on the desirability of making this change to 10 CFR Part 52 (refer to Section IV).

B. Definitions

The terms Tier 1, Tier 2, and Tier 2* are defined in Section 2 of the proposed rule entitled, "Definitions," because these concepts were not envisioned at the time that 10 CFR Part 52 was developed. The design certification applicants and the NRC used these terms in implementing the two-tiered rule structure that was proposed by industry after the issuance of Part 52 (refer to discussion on Topic #1). The design control document (DCD) contains both the Tier 1 and 2 information, along with an introduction. After the issuance of the ANPR, the phrase Tier 2* was added to the list of definitions. Some of the information in Tier 2 that requires special treatment in the change process and was commonly referred to as Tier 2* during the design review. Therefore, the Commission believes that it would be useful to define and use this phrase in the proposed rule. Further information on changes to or departures from information in the DCD is provided below in the discussion on Section 8, "Change Process." The NRC requests suggestions on other words or phrases that may need to be defined in this rule (refer to Section IV).

C. [Reserved]

The purpose of Section 3, "Information collection requirements," in the proposed rule was originally intended to provide the citation for the control number which has been assigned by the Office of Management and Budget when it approved the information collection requirements in this rulemaking. Because this citation has been placed in § 52.8, Section 3 to the rule is no longer necessary.

D. Contents of the design certification

Section 4 of the proposed rule entitled, "Contents of the design certification," identifies the design-related information that is incorporated by reference into this rule (4(a)) and includes some related provisions of the proposed rule (4(b) and (c)). Both tiers of design-related information have been combined into a single document, called the design control document (DCD), in order to effectively control this information and facilitate its incorporation into the rule by reference (refer to Topic #9 for discussion on the DCD). The DCD was prepared to meet the requirements of the Office of the Federal Register (OFR) for incorporation by reference (1 CFR Part 51). Section 4(a) of this proposed rule would incorporate the DCD by reference upon approval of the Director, OFR. 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.

An applicant for a construction permit or COL that references this design certification rule must conform with the requirements in the proposed rule and the DCD. The master DCD for this design certification will be archived at NRC's central file with a matching copy at OFR. Copies of the up-to-date DCD will also be maintained at the NRC's Public Document Room and Library. Questions concerning the accuracy of information in an application that references this design certification will be resolved by checking the master DCD in NRC's central file. If a generic change (rulemaking) is made to the DCD pursuant to the change process in Section 3 of the proposed rule, then at the completion of the rulemaking the NRC will change its copies of the DCD and notify the OFR and design certification applicant to change their copies.

The applicant for this design certification rule is responsible for preparing the DCD in accordance with NRC and OFR requirements and maintaining an up-to-date copy pursuant to Section 9(a)(1) of the proposed rule. Plant-specific changes to and departures from the DCD will be maintained by the applicant or licensee that references this design certification pursuant to Section 9(a)(2) of the proposed rule. In order to meet the requirements of OFR for incorporation by reference, the originator of the DCD (design certification applicant) must make the document available upon request after the final design certification rule is issued. Therefore, the proposed rule states that copies of the DCD can be obtained from the applicant or an organization designated by the applicant. The applicant for this design certification has stated that it may request distribution of its DCD by the National Technical Information Service (NTIS). If the applicant selects an organization, such as NTIS, to distribute the DCD, then the applicant must

provide that organization with an up-to-date copy. A copy of the DCD must also be made available at the NRC and OFR.

The DCD contains an introduction that explains the purpose and uses of the DCD and two tiers of design-related information. The significance of designating design information as Tier 1 or Tier 2 is that different change processes and criteria apply to each tier, as explained below in Section H, "Change Process." 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.

The Tier 1 portion of the design-related information contained in the DCD is certified by this rule. This information consists of an introduction to Tier 1, the certified design descriptions and corresponding inspections, tests, analyses, and acceptance criteria (ITAAC) for systems and structures of the design, design material applicable to multiple systems of the design, significant interface requirements, and significant site parameters for the design. The 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.

The information in the Tier 1 portion of the DCD was extracted from the detailed information contained in the application for design certification. The Tier 1 information addresses the most safety-significant aspects of the

design, and was organized primarily according to the structures and systems of the design. Additional design material and related ITAAC is also provided in Tier 1 for selected design and construction activities that are applicable to multiple systems of the design. The Tier 1 design descriptions serve as design commitments for the lifetime of a facility referencing the design certification, and the ITAAC verify that the as-built facility conforms with the approved design and applicable regulations. In accordance with 10 CFR 52.103(g), the Commission must find that the acceptance criteria in the ITAAC are met before operation. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not constitute regulatory requirements for subsequent modifications. However, subsequent modifications to the facility must comply with the Tier 1 design descriptions, unless changes are made in accordance with the change process in Section 8 of this proposed rule.

The Tier 1 interface requirements are the most significant of the interface requirements for the standard design, which were submitted in response to 10 CFR 52.47(a)(1)(vii), that must be met by the site-specific portions of a facility that references the design certification. The Tier 1 site parameters are the most significant site parameters, which were submitted in response to 10 CFR 52.47(a)(1)(iii), that must be addressed as part of the application for a construction permit or COL.

Tier 2 is the portion of the design-related information contained in the DCD that is approved by this rule but is not certified. The change process defines the procedural differences between Tier 1 and 2. Changes to or departures from the certified design material (Tier 1) must comply with Section 8(a) of this proposed rule. Changes to or departures from the approved information (Tier 2) must comply with Section 8(b) of this proposed

rule. Tier 2 includes the information required by 10 CFR 52.47 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. Compliance with the more detailed Tier 2 information provides a sufficient method, but not the only acceptable method, for complying with the more general design requirements included in Tier 1. A supplementary description of Tier 2 information is provided in the DCD introduction. If an applicant or licensee used methods other than those described in Tier 2, then the alternative method would be open to staff review and a possible subject for a hearing.

When completing the design information for a plant, an applicant for a COL must conform with all of the requirements in the DCD, unless the information in the DCD is changed pursuant to the process in Section 8 of this proposed rule. Accordingly, an applicant for a construction permit or COL, or licensee that references this certified design must conform with all of the requirements from the DCD, including the codes, standards, and other guidance documents that are referenced from the DCD (so-called secondary references). The industry agreed to treat these secondary references as requirements even though they are not incorporated by reference, in the context as described in the DCD, as set forth in a letter from Dennis Crutchfield of the NRC to Joe Colvin of the Nuclear Energy Institute, dated May 3, 1994.

An applicant for a construction permit or COL that references this proposed rule must also describe those portions of the plant design which are site-specific, and demonstrate compliance with the interface requirements, as required by 10 CFR 52.79(b). The COL applicant does not need to conform with the conceptual design information in the DCD that was provided by the design

certification applicant in response to 10 CFR 52.47(a)(1)(ix). The conceptual design information, which are examples of site-specific design features, was required to facilitate the design certification review, and it is neither 1 nor 2. The introduction to the DCD identifies the location of the conceptual design information and explains that this information is not applicable to a COL application.

An applicant must address COL Action Items, which are identified in the DCD as COL License Information, in its COL application. The COL Action Items (COL License Information) identify matters that need to be addressed by an applicant or licensee that references the design certification, as required by 10 CFR 52.77 and 52.79. A further explanation of the status of the COL License Information is provided in the DCD introduction. Also, the detailed methodology and quantitative portions of the design-specific probabilistic risk assessment (PRA), as required by 10 CFR 52.47(a)(1)(v), was not included in the DCD. The NRC agreed with the design certification applicant's request to delete this information because conformance with the deleted portions of the PRA is not required. The Commission's position is also predicated in part upon NEI's acceptance, in conceptual form, of a future generic rulemaking that requires a COL applicant or licensee to have a plant-specific PRA that updates and supersedes the design-specific PRA and maintain it throughout the operational life of the plant.

The application for design certification contained proprietary and safeguards information. This information was part of the NRC staff's bases for its safety findings in the FSER. The proprietary information, or its equivalent, that was provided in the design certification application by reference but not included in the DCD, must be included as part of a COL

application. The Commission considers this information to be requirements for plants that reference this rule. Since the proprietary information was not included in the DCD, or otherwise approved by OFR for incorporation by reference, it would not have issue preclusion in a construction permit or COL proceeding.

There is other information that is within the scope of the certified design (i.e., as-built, as-procured, and evolving technology design information) that must be developed by a COL applicant or holder. This detailed design information must be completed in accordance with the requirements in the DCD and the acceptance criteria in ITAAC, including design acceptance criteria (DAC). Since the Tier 1 and 2 information is solely contained within the DCD, the remainder of the design-related information that is developed by a COL applicant or holder that references this proposed rule will not be either Tier 1 or 2 information, whether it is within the scope of the design certification or not. Therefore, the change process in Section 8 of this proposed rule will not control this COL information. Although the change process for this COL information does not need to be developed until a COL application is submitted, the Commission is interested in the public's view on how this information should be controlled (refer to Section IV).

The purpose of Section 4(b) of this proposed rule is to ensure that an applicant that references this design certification references both tiers of information in the DCD. The two tiers of information were developed together and both tiers of information are needed to complete the design of a plant that references the rule. For example, the ITAAC in Tier 1 contains not only the acceptance criteria for verifying that the as-built plant conforms with the approved design, but it also contains various design processes with

acceptance criteria (DAC), for completing selected areas of the plant design. The DAC are described in Section 14.3 of the SSAR and FSER. The NRC staff relied on DAC for its evaluation of selected design areas where the applicant for design certification did not provide complete design information. Also, the Tier 2 information contains explanations and procedures on how to implement ITAAC. Therefore, the Commission proposes that an applicant could not reference this design certification rule without meeting ITAAC, even though it is not a requirement in 10 CFR Part 50. (see Section J for further discussion)

The applicant for design certification initially prepared the DCD to be consistent with the SSAR and the NRC staff's FSER. The applicant for design certification made some corrections and clarifications to the DCD since the completion of the SSAR and issuance of the FSER. If there is an inconsistency between the SSAR and the FSER, or between either of these documents and the DCD, then the DCD is the controlling document. That is the purpose of Section 4(c) of this proposed rule.

E. Exemptions and applicable regulations

The purpose of Section 5 of the proposed rule entitled, "Exemptions and applicable regulations," is to identify the complete set of regulations that were applicable and in effect at the time the design certification was issued for the purposes of 10 CFR 52.48, 52.54, 52.59, and 52.63. In accordance with 10 CFR 52.48, the NRC staff used the technically relevant regulations (safety standards) in 10 CFR Parts 20, 50, 73, and 100 in performing its review of the application for design certification. The effective date of these applicable

regulations is the date of the FSER, as set forth in Section 5(b) of the proposed rule. During its review of the application for design certification, the NRC staff identified certain regulations for which application of the regulation to the standard design would not serve or was not necessary to achieve the underlying purpose of the regulation. These proposed exemptions to the NRC's current regulations are identified in Section 5(a) of this proposed rule. The basis for these exemptions is provided in the FSER.

In implementing the goals of 10 CFR Part 52 and the Commission's Severe Accident Policy Statement, the NRC staff set out to achieve a higher level of safety performance for both evolutionary and passive LWR standard designs in the area of severe accidents and in other selected areas. As a result, the NRC staff proposed new requirements in various Commission papers, such as SECY-90-016 and SECY-93-087, to be used in the design certification review and treated as applicable regulations in the design certification rulemaking (refer to discussion on Topic #8). The bases for these requirements are set forth in SECY-90-016 and SECY-93-087. The Commission approved the use of these proposed regulations for purposes of the design certification review in the respective SRMs. These proposed regulations deviated from or were not embodied in current regulations applicable to the standard design. The NRC staff then selected proposed regulations that were applicable to the design under review and reviewed the design pursuant to these applicable regulations. The FSER identifies the applicable regulations that were used and describes how these regulations were met by the design-related information in the SSAR. The Commission approved the evaluation of the design pursuant to the applicable regulations in its approval to publish the FSER.

These proposed applicable regulations are identified in Section 5(c) of this proposed rule to achieve codification through the design certification rulemaking. The proposed applicable regulations in Section 5(c) are substantively the same as those in the FSER but have been edited for clarity. These codified requirements, which supplement the regulations in Section 5(b), will become part of the Commission's regulations that were "applicable and in effect at the time the certification was issued," if the Commission adopts them in the final design certification rule. The Commission requests comments on whether each specific applicable regulation is justified (refer to Section IV).

The codification of these additional requirements, in reference to 10 CFR §2.48, is necessary for two reasons. First, it serves as a basis for obtaining public comment on the adoption of the proposed requirements as applicable regulations. Second, it provides confirmation that the requirements are being adopted by the Commission as applicable regulations under § 52.54 for the design certification being approved. In the absence of this codification, a design certification applicant could argue that the Commission cannot lawfully condition approval of the design certification on compliance with the requirements used during its review of the design. This is because the proposed requirements, without further Commission action, could be argued as not being "applicable standards and requirements of the ... Commission's regulations" under § 52.54. Also, without codification of the applicable regulations, the NRC could not perform its reviews in accordance with §§ 52.59 and 52.63. By codifying these requirements, the NRC intends that for renewal of a certified design under § 52.59, these requirements are

part of the applicable regulations in effect at the time that the design certification was first issued.

The Commission may, pursuant to § 53.63(a)(1) and (3), impose a modification of Tier 1 information or issue a plant-specific order, respectively, to ensure that the certified design or the plant complies with the applicable regulations of the design certification rule. The rationale is that the Commission could not, without re-reviewing the merits of each position, impose a change to Tier 1 information or issue a plant-specific order merely because the modification was necessary for compliance with a matter involving these requirements. Also, the Commission would not have a complete list of regulations for use in evaluating requested changes from the public, applicants, or licensees, thereby degrading the predictability of the licensing process.

By identifying the regulations that are applicable to each design, the Commission has improved the stability and predictability of the licensing process. By approving the design information that describes how these regulations were met, the Commission has minimized the potential for a differing interpretation of the regulations. Finally, the NRC rejected NEI's proposed alternative to applicable regulations in a meeting on April 25, 1994, and in a letter dated July 25, 1994. NEI's proposal to use design information as a surrogate for design-specific (applicable) regulations is not workable for proposed changes because the design information only represents one way of implementing a regulation. The NRC would need the regulation for the design feature in order to evaluate a proposed change to the design information.

F. Issue resolution for the design certification

The purpose of Section 6 of the proposed rule entitled, "Issue resolution for the design certification," is to identify the issues that are considered resolved, if the Commission adopts a final design certification rule and therefore, these issues receive issue preclusion within the scope and intent of 10 CFR 52.63(a)(4). Specifically, all nuclear safety issues arising from the Atomic Energy Act that are associated with the information in the NRC staff's FSEER or the applicant's DCD are resolved within the meaning of § 52.63(a)(4). All issues arising under the National Environmental Policy Act of 1969 associated with the information in the NRC staff's environmental assessment or the severe accident design alternatives in the applicant's Technical Support Document are also resolved within the scope and intent of § 52.63(a)(4). The issues that are associated with information that is not included in the DCD, such as proprietary information, do not have issue preclusion within the meaning of 10 CFR 52.63(a)(4).

G. Duration of the design certification

The purpose of Section 7 of the proposed rule entitled, "Duration of the design certification," is in part to specify the time period during which the standard design certification may be referenced by an applicant for a construction permit or COL, pursuant to 10 CFR 52.55. This section of the rule also states that the design certification remains valid for an applicant or licensee that references the design certification until their application is withdrawn or their license expires. Therefore, if an application

references this design certification during the 15-year period, then the design certification rule 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 the proposed rule 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 rulemaking changes to or plant-specific departures from information in the DCD must be made pursuant to the change process in Section 8 of this proposed rule for the life of the plant.

H. Change Process

The purpose of Section 8 of this proposed rule entitled, "Change process," is to set forth the process for requesting rulemaking changes to or plant specific departures from information in the DCD. The Commission has developed a more restrictive change process than for plants that were licensed pursuant to 10 CFR Part 50, in order to achieve a more stable licensing process for applicants and licensees that reference a design certification rule. The change process in Section 8 is substantively the same as the process proposed in the ANPR.² As a result, Section 8(a) provides the process for changing Tier 1 information and Section 8(b) provides the process

²This change process has been reorganized for clarity and conformance to the two-tiered rule structure, and to distinguish between generic changes to Tier 1 and 2 information, which are accomplished via rulemaking, and plant-specific departures from Tier 1 and 2 information which may be accomplished by the process defined in Section 8 of this proposed rule. For brevity, this SOC refers to both aspects as constituting the "change process" for this design certification rule.

for changing Tier 2 information. The change process for Tier 1 information uses the change process developed by the Commission in the Part 52 rulemaking for certified design-related information. Therefore, the provisions in Section 8(a) of the proposed rule simply refer to the appropriate sections in 10 CFR 52.63. A description of the Tier 1 information that is controlled by Section 8(a) is provided in the above discussion on contents of the design certification (III.D).

As discussed in Topic #2, the NRC developed a change process for Tier 2 that has the same elements as the Tier 1 change process. Specifically, the Tier 2 change process in Section 8(b) has provisions for generic changes, plant-specific orders, and exemptions similar to those in 10 CFR 52.63, but some of the standards for plant-specific orders and exemptions are different. The standards that must be met in order to justify a generic change to either Tier 1 or 2 information are the same. When NEI proposed a two-tiered structure for design certification rules in its letter of August 31, 1990, it also stated that "NRC backfits involving matters described in the first tier would be governed by the provisions of § 52.63, whereas § 50.109 would govern backfitting as respects the second tier." As a result, the NRC staff used the backfit standards in § 50.109 for generic changes to Tier 2 in its proposed design certification rule in SECY-92-287. Subsequently, in a letter dated October 5, 1992, NEI changed its position and agreed with the Commission that the standard for generic changes to Tier 2 should be the same as the Tier 1 standard. This issue is discussed further in SECY-92-287A, dated March 26, 1993. Therefore, Section 8 of this proposed rule uses the same standards for generic changes to both Tier 1 and 2 information.

Although the process in Section 8 for plant-specific orders and exemptions is the same for Tier 1 and 2 information, the standards are different. In order to preserve the benefits of standardization, which is one of the important goals of design certification, the Commission proposes in Section 8(a)(3) that plant-specific orders or exemptions from Tier 1 information must consider whether the special circumstances which § 50.12(a)(2) required to be present outweigh any decrease in safety that may result from the reduction in standardization, as required in 10 CFR 52.63(a)(3). The Commission is not proposing to adopt this additional consideration for plant-specific orders or exemptions from Tier 2 information, in order to achieve additional flexibility. The Commission believes this is acceptable because the Tier 2 information is not as safety significant as the Tier 1 information. Therefore, Sections 8(b)(3) and (4) of the proposed rule do not require the additional consideration of the reduction in standardization caused by proposed departures from Tier 2 information.

A generic change to either Tier 1 or 2 information in the DCD is accomplished by rulemaking. Any person seeking to make a generic change to the DCD, including the applicant for this design certification, must submit a petition pursuant to 10 CFR 2.802. This petition must describe how the proposed change meets the standards in 10 CFR 52.63(a)(1) for justifying a generic change to the DCD. Any generic changes to the DCD resulting from the rulemaking will be noticed in the Federal Register. The NRC will update the master DCD in its central files and the copies in the NRC Library and public document room (refer to the discussion in Section III.D). Under Sections 8(a)(2) and (b)(2), generic changes to Tier 1 and Tier 2, respectively, will be applicable to all plants referencing the design certification. However, if

the Commission determines that a generic change is not technically relevant to a particular plant, based on plant-specific changes made pursuant to Section 8, then the generic rulemaking will indicate that the change will not be applicable to that plant. If the proposed change to the DCD also results in a violation of an underlying regulation that is applicable to this design certification, then an exemption to that regulation is also required.

A plant-specific departure from either Tier 1 or 2 information in the DCD does not require rulemaking. Any person requesting a Commission order directing a plant-specific change, including the applicant for this design certification, must submit a petition pursuant to 10 CFR 2.206. This petition must describe how the proposed change meets the standards in 10 CFR 52.63(a)(3) or Section 8(b)(3) for departures from Tier 1 or 2 information, respectively. By contrast, an applicant or licensee that references this design certification rule may request exemptions from Tier 1 or 2 information pursuant to 10 CFR 52.63(b)(1) or Section 8(b)(4) of this rule, respectively. The NRC recognized that there may be special circumstances pertaining to a particular applicant or licensee that would justify an exemption from the DCD. The request must describe how the exemption from Tier 1 or 2 meets the standards in 10 CFR 52.63(b)(1) or Section 8(b)(4) of this proposed rule, respectively. The exemption may be contested in a hearing, if the exemption is granted in connection with issuance of a construction permit, operating license, or combined license; it may also be contested in a hearing, if the exemption also requires the issuance of a license amendment. If a plant-specific change or exemption from the DCD also results in a violation of the underlying regulation that is applicable to this design certification, then an exemption to that regulation is also required.

In addition to the plant-specific changes described above, an applicant or licensee that references this design certification rule may depart from Tier 2 information, without prior NRC approval pursuant to Section 8(b)(5) of this proposed rule. However, the Commission believes that these changes should open the possibility for challenge in a hearing (refer to discussion on Topic #2). The Commission approved the use of this "§ 50.59-like" change process in its SRMs on SECY-90-377 and SECY-92-287A. The NRC is interested in the public's view on how these changes could be challenged in a hearing (refer to Section IV).

As in 10 CFR 50.59, an applicant or licensee cannot make changes that involve an unreviewed safety question (USQ) or technical specifications, without prior NRC approval. Also, for changes pursuant to Section 8(b)(5), an applicant or licensee cannot make changes to Tier 1 or Tier 2* information without prior NRC approval. If the proposed change does not involve these factors, then the NRC will allow changes to previously approved information in Tier 2 without prior NRC approval. However, if the change involves an issue that the Commission has not previously approved, then NRC approval is required. The process for evaluating proposed tests or experiments not described in Tier 2 will be developed for an operating or combined license that references this design certification (refer to Section IV).

The restriction on changing Tier 1 information is included in the process in Section 8(b)(5) because this information can only be changed pursuant to Section 8(a) of the proposed rule. Whereas, the restriction on changing Tier 2* information resulted from the development of the Tier 1 information in the DCD. A description of the Tier 1 information is provided in the discussion in Section III.D on contents of the design certification.

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 the applicant or licensee that 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 relatively significant information only exists in Tier 2 and the Commission does not want this significant information changed without prior NRC approval. The NRC specified this information in its FSER and the design certification applicant has identified this information in its DCD. This information has come to be known as Tier 2* information and it has compensated for industry's desire to minimize the amount of information in Tier 1.

In the ANPR, the NRC referred to the Tier 2* information as pre-identified unreviewed safety questions (USQs) because there was already an established procedure in 10 CFR 50.59 for FSAR changes that constitute USQs, which require NRC approval. NEI stated in its comments on the ANPR that it was not necessary to create an artificial set of USQs in order to accomplish the NRC's objective of requiring prior approval. Therefore, the proposed rule was changed from the ANPR to simply state that the Tier 2* information cannot be changed without prior NRC approval. Also, NEI requested in its comments that the Tier 2* information not be identified in the design certification rule, as was proposed in the ANPR, and that an expiration date be considered for the restriction in the change process for Tier 2* information. NRC agrees that Tier 2* information can be identified in the DCD and Section 8(b)(5) of the proposed rule was changed accordingly. The NRC also reevaluated the duration of the change restriction for Tier 2* information and determined that

some of the Tier 2* information can expire when the plant first achieves 100% power while other Tier 2* information must remain in effect throughout the life of the plant that references the DCR. The DCD sets forth an expiration date for some of the Tier 2* information.

As part of this rulemaking, the NRC is seeking public comments on the appropriate regulatory process to use for review of proposed changes to Tier 2* information. Currently, pursuant to 10 CFR 50.59, the NRC approves changes to FSAR information that constitute a USQ or involve technical specifications through the issuance of license amendments. However, if an applicant or licensee requests NRC approval for a proposed change to Tier 2* information, should the NRC review process be similar to that for a USQ? While it is clear that these proposed changes would all involve significant design-related information and that prior review of proposed departures from Tier 2 information is necessary, the NRC has not determined if it is always appropriate to process the approved changes as either an amendment to the license application or an amendment to the license, with the requisite hearing rights. Therefore, the NRC requests the public's view on the preferred regulatory process for these changes (refer to Section IV).

An applicant or licensee that plans to depart from Tier 2 information, pursuant to Section 8(b)(5), must prepare a safety evaluation which provides the bases for the determination that the proposed change does not involve an unreviewed safety question, a change to Tier 1 or Tier 2* information, or a change to the technical specifications. In order to achieve the Commission's goals for design certification, the evaluation needs to consider all of the matters that were resolved in the DCD, including the generic issues discussed in Chapter 20 of the FSER. The benefits of the early resolution of safety

issues would be lost if changes were made to the DCD that violated these resolutions without NRC approval. The evaluation of the resolved issues needs to consider the proposed change over the full range of power operation from startup to shutdown, including issues resolved under the heading of shutdown risk, as it relates to anticipated operational occurrences, transients, and design basis accidents. The evaluation should consider the tables in Sections 14.3 and 19.15 of the DCD to ensure that the proposed change does not impact Tier 1. These tables contain various cross-references from the plant safety analyses in Tier 2 to the important parameters that were included in Tier 1. Although many issues and analyses could have been cross-referenced, the listings in these tables were developed only for key plant safety analyses for the design. GE provided more detailed cross-references to Tier 1 for these analyses in a letter dated March 31, 1994, and ABB-CE provided more detailed cross-references in a letter dated June 10, 1994. The NRC does not endorse NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," for performing the safety evaluations required by Section 8(b)(5) of the proposed rule. However, the NRC will work with industry, if it is desired, to develop an appropriate guidance document for implementing Section 8 after the final rule is issued.

During the review of its DCD, GE requested that the determination of whether a proposed departure from Tier 2 information that involves severe accident issues constitutes a USQ use criteria that are different from the criteria for USQ determinations proposed in the ANPR [10 CFR 50.59(a)(2)]. GE argued that not all increases in the probability or consequences of severe accidents are significant from a safety standpoint. Minor increases in the probability of some accident scenarios will not affect the overall core damage frequency or the conclusions of the severe accident evaluations. Therefore,

GE proposed that changes to Tier 2 information that result in insignificant increases in the probability or consequences of severe accidents not constitute a USQ.

The NRC 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 NRC has proposed, in Section 8(b)(5), separate criteria for determining whether a departure from information associated with severe accident issues constitutes a USQ. The new criteria in Section 8(b)(5)(iii) will only apply to Tier 2 information that is associated with the severe accident issues discussed in the section of the DCD identified in the rule. The criteria for USQ determinations in Section 8(b)(5)(ii), which are the same as those proposed in the ANPR, will apply to other 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 should be based upon the criteria in Section 8(b)(5)(ii). The NRC is interested in the public's view on whether the Tier 2 information involving resolutions of severe accident issues should be treated differently for USQ determinations than all other safety issues? If so, are the proposed criteria in Section 8(b)(5)(iii) sufficient to determine if a proposed departure from information associated with severe accident issues constitutes a USQ? (Refer to Section IV)

The NRC is also proposing two additional provisions to the change process that were not in the ANPR. The first is Section 8(b)(5)(iv), which provides that changes made pursuant to Section 8(b)(5) do not also require an

exemption from the design certification rule. Because the Tier 2 information is incorporated by reference into the design certification, a departure from Tier 2 pursuant to Section 8(b)(5) would also require an exemption from the design certification rule absent this proposed provision. The second provision is Section 8(c), which makes it clear that proposed changes to requirements in this design certification rule that are neither Tier 1 nor Tier 2 must be done by exemption pursuant to 10 CFR 50.12. Such requirements include the recordkeeping and reporting requirements in Section 9 of this proposed rule.

I. Records and Reports

The purpose of Section 9 of this proposed rule entitled, "Records and Reports," is to set forth the requirements for maintaining records of DCD changes and submitting reports to the NRC. This section is similar to the requirements for records and reports in 10 CFR Part 50 and § 52.63(b)(2), with the following differences. Section 9(a)(1) requires an applicant for design certification to maintain an up-to-date copy of the DCD that includes all generic changes to Tier 1 and 2 information that are made by rulemaking. This will ensure that the design certification applicant provides up-to-date versions of the DCD to prospective applicants that want to reference this design certification or to other interested parties who want copies of the DCD. Section 9(a)(2) requires an applicant or licensee that references this design certification to maintain an up-to-date plant-specific version of the DCD that includes both generic changes to the DCD, as well as plant-specific departures from the DCD. This ensures that the plant records which include an

accurate DCD reflecting information specific to the plant as well as changes to the DCD.

The proposed rule also establishes reporting requirements in Section 9(b) for applicants or licensees that reference this design certification rule. The requirements in Section 9(b) are similar to the reporting requirements in 10 CFR Part 50, except that they include reporting of changes to or departures from the plant-specific DCD. In addition, the reporting requirements in Section 9(b) vary according to whether the changes are made as part of an application, during plant construction, or during operation. Also, the reporting frequency of summary reports of departures from and periodic updates to the DCD increases during plant construction. If an applicant that references this design certification rule decides to adopt departures from the DCD that were developed, but not approved pursuant to Section 8 of this proposed rule, before its application (i.e., first of a kind engineering), then the proposed departures from the DCD must be submitted with the initial application for a construction permit or combined license.

For currently operating plants, a licensee is required to maintain records of the basis for any design change made to the plant pursuant to 10 CFR 50.59. Further, a licensee is required to provide a summary of these changes to the NRC annually or along with updates to the final safety analysis report pursuant to 10 CFR 50.71. The proposed rule allows departures from the DCD during the periods of application, construction, and operation of the plant. Therefore, the proposed rule requires timely submittal of summary reports of departures from, as well as updates to, the DCD during each of these intervals, consistent with the Commission's guidance on reporting frequency in its SRM on SECY-90-377.

NEI proposed reporting of design changes at a 6-month interval, in its comments on the ANPR, to "avoid unnecessarily diverting owner/operator resources to meet excessive reporting requirements." The NRC modified the provisions in the proposed rule to relax the reporting requirements before issuance of a construction permit or combined license. During this interval, summary reports of changes and updates to the DCD should be submitted to the NRC as part of the amendments to the construction permit or combined license application. However, the NRC does not agree with the NEI proposal for semi-annual reporting of design changes during plant construction because it does not provide for sufficiently timely notification of design changes. Therefore, the Commission retained the requirement for quarterly reporting of changes in the proposed rule during this interval. Also, the NRC relaxed the provisions in Section 9(b) so that during operation of a plant, the reporting requirements are the same as for currently operating plants.

The Commission believes that quarterly reporting of design changes during the period of construction are necessary to closely monitor the status and progress of the construction of the plant. As required by 10 CFR 52.99, the NRC must find that the ITAAC have been successfully met. The ITAAC verify that the as-built facility conforms with the approved design and emphasize design reconciliation and design verification of the as-built plant. To make its finding, the NRC must tailor its inspection program to monitor plant construction and adjust its program to accommodate changes. Quarterly reporting of design changes will facilitate these adjustments in a timely manner and aids in a common understanding of the plant as the changes are being made. This 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.

Section 9(c) of the proposed rule requires that records are kept for the lifetime of a facility, as in 10 CFR Part 50 and § 52.63(b)(2).

J. Applicability of a DCR in 10 CFR Part 50 licensing proceedings.

Several provisions in 10 CFR Part 52, Subpart B suggest that design certification rules (DCRs) may be referenced not only in combined license proceedings under 10 CFR Part 52, Subpart C but also in licensing proceedings under 10 CFR Part 50. Section 52.63(c) states:

The Commission will require, prior to granting a construction permit, combined license, or operating license which references a standard design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if such information is necessary for the Commission to make its safety determination, including the determination that the application is consistent with the certified design. (Emphasis supplied.)

See also §§ 52.41, 52.55(b), 52.55(c), 52.63(a)(4), 52.63(b)(1). However, these provisions of 10 CFR Part 52, Subpart B are inconsistent in identifying the *type* of Part 50 proceeding in which design certification rules may be referenced. For example, although § 52.63(c) (quoted above) and

§ 52.55(c) explicitly provide for referencing of design certification rules in 10 CFR Part 50 *construction permit* proceedings, §§ 52.55(b), 52.63(a)(4) and 52.63(b)(1) refer only to *operating license* proceedings. Section 52.63(a)(4) is illustrative:

Except as provided for in 10 CFR 2.758, in making the findings required for issuance of a combined license or **operating license**, or for any hearing under § 52.103, the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification. (Emphasis supplied.)

Therefore, some might question whether the Commission intended construction permits applicants under 10 CFR Part 50 to have the option of referencing design certification rules. However, the Commission has not identified any regulatory or policy reasons for precluding a construction permit applicant from referencing a design certification rule while allowing an operating license applicant to do so. Thus, the Commission believes that 10 CFR Part 52 provides the discretion to authorize a construction permit applicant under 10 CFR Part 50 to reference a design certification rule.

Assuming that the Commission has such discretion, there are a number of issues that present themselves. Should the Commission exercise its discretion to allow construction permit applicants to reference this design certification rule? Should the Commission require that if a design certification rule is to be relied upon in 10 CFR Part 50 licensing proceedings, it must be referenced in both the construction permit and operating license applications? Would it make

sense to allow an operating license applicant to reference a design certification if the underlying construction permit did not reference the design certification? The Commission recognizes that consideration of these issues depends in part upon the legal significance of a design certification in the 10 CFR Part 50 licensing proceeding, as well as its significance for the permittee or licensee once the construction permit or operating license is granted. In particular, 10 CFR Part 52, Subpart B does not say what the legal effect is (if any) of ITAAC in a Part 50 operating license proceeding in which the underlying construction permit references a design certification.

In view of the status of ITAAC as Tier 1 information, how would a construction permit applicant referencing a design certification rule avoid referencing the ITAAC? What would be the consequences for the construction permit applicant of referencing ITAAC? If the underlying construction permit referenced ITAAC, then what (if any) would be the scope and nature of "issue preclusion" at the operating license stage, in terms of staff/Commission review and approval of the operating license application, as well as issues which are precluded from consideration under 10 CFR 2.758? The Commission seeks the public's views on the referencing of design certification rules in 10 CFR Part 50 applications (refer to Section IV).

IV. SPECIFIC REQUESTS FOR COMMENTS

In addition to the general invitation to submit comments on the proposed rule, the DCD, and the environmental assessment, the NRC also invites specific comments on the following questions:

1. Should the requirements of 10 CFR 52.63(c) be added to a new 10 CFR 52.79(e)? (Refer to discussion in III.A.)
2. Are there other words or phrases that should be defined in Section 2 of the proposed rule? (Refer to discussion in III.B.)
3. What change process should apply to design-related information developed by a COL applicant or holder that references this design certification rule? (Refer to discussion in III.D.)
4. Are each of the applicable regulations set forth in Section 5(c) of the proposed rule justified? (Refer to discussion in III.E.)
5. Section 8(b)(5)(i) authorizes an applicant or licensee who references the design certification to depart from Tier 2 information without prior NRC approval if the applicant or licensee makes a determination that the change does not involve a change to Tier 1 or Tier 2* information, as identified in the DCD, the technical specifications, or an unreviewed safety question as defined in Sections 8(b)(5)(ii) and (iii). Where Section 8(b)(5)(i) states that a change made pursuant to that paragraph will no longer be considered as a matter resolved in connection with the issuance or renewal of a design certification within the meaning of 10 CFR 52.63(a)(4), should this mean that the determination may be challenged as not demonstrating that the change may be made without prior NRC approval or that the change itself may be challenged as not complying with the Commission's requirements? (Refer to discussion in III.H.)
6. How should the determinations made by an applicant or licensee that changes may be made under Section 8(b)(5)(i) without prior NRC approval be made available to the public in order for those determinations to be challenged or for the changes themselves to be challenged? (Refer to discussion in III.H.)

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? (Refer to discussion in III.H.)

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? (Refer to discussion in III.H.)

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? (Refer to discussion in III.J.)

(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?

9(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? (Refer to discussion in III.J.)

(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).

V. COMMENTS AND HEARINGS IN THE DESIGN CERTIFICATION RULEMAKING

A. Opportunity to Submit Written and Electronic Comments

Any person may submit written comments on the proposed design certification rule to the Commission for its consideration.³ Commenters have 120 days from the publication of this notice to file written comments on the proposed design certification rule. Commenters needing access to proprietary information in order to provide written comments must follow the procedures and filing deadlines (including the date for filing written comments) which are set forth in Section V.E. below.

Commenters are encouraged to submit, in addition to the original paper copy, a copy of the comment letter in electronic format on a DOS-formatted (IBM compatible) 3.5 or 5.25 inch computer diskette. Text files should be provided

³An opportunity for public comment is required by Section 553 of the Administrative Procedures Act and 10 CFR 52.51(b).

in WordPerfect format or unformatted ASCII code. The format and version should be identified on the diskette's external label. Comments may also be submitted electronically, in either ASCII text or Wordperfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet.

If using a personal computer and modem, the NRC subsystem on FedWorld can be accessed directly by dialing the toll free number (1-800-303-9672). Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI terminal emulation, the NRC rules subsystem can then be accessed by selecting the "Rules" option from the "NRC Main Menu." For further information about options available for NRC at FedWorld consult the "Help/Information Center" from the "NRC Main Menu." Users will find the "FedWorld Online User's Guides" particularly helpful. Many NRC subsystems and databases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld can also be accessed by a direct dial phone number for the main FedWorld BBS: 703-321-3339; Telnet via Internet: fedworld.gov (192.239.92.3); File Transfer Protocol (FTP) via Internet: ftp.fedworld.gov (192.239.92.205); and World Wide Web using: <http://www.fedworld.gov> (this is the Uniform Resource Locator (URL)).

If using a method other than the toll free number to contact FedWorld, then the NRC subsystem will be accessed from the main FedWorld menu by selecting the "U.S. Nuclear Regulatory Commission" option from FedWorld's "Subsystems/Databases" menu or by entering the command `/go nrc` at a FedWorld command line. If NRC access is obtained through FedWorld's

"Subsystems/Databases" menu, then return to FedWorld is accomplished by selecting the "Return to FedWorld" option from the "NRC Main Menu." However, if NRC access at FedWorld is accomplished by using NRC's toll-free number, access to all NRC systems is available, but there will be no access to the main FedWorld system. For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-5780; e-mail AXD3@nrc.gov.

Public Meeting

The NRC staff plans to conduct a public meeting on this proposed rule on May 11, 1995, at the NRC Auditorium in Two White Flint North. Further details on the meeting are provided in a document published in this issue of the Federal Register. The purpose of the public meeting will be to discuss this proposed rule and respond to questions on the meaning and intent of any provisions of this proposed rule. It is hoped that this meeting will be helpful to persons who intend to submit written comments on the proposed rule. An official transcript of the proceedings of the public meeting will be prepared.

B. Opportunity to Request Hearing

Any person may request an *informal* hearing on one or more specific matters with respect to the proposed design certification rule.⁴ An informal hearing provides the admitted party with an opportunity to provide written and oral presentations on those matters to an Atomic Safety and Licensing Board, and to request that the licensing board question the applicant on those matters. The

⁴An opportunity for a hearing is provided by 10 CFR 52.51(b).

conduct of an informal hearing is discussed in more detail in Section C. below. Under certain circumstances, a party in an informal hearing may request that the Commission hold a formal hearing on specific and substantial factual disputes necessary to resolution of the matters for which the party was granted an informal hearing (see Section C.11 below).

A person may request an informal hearing even though that person has not submitted separate written comments on the design certification rule (i.e., is not a commenter). Requests for an informal hearing must be received by the Commission no later than 120 days from the publication of this notice, and a copy of the request must be sent via overnight mail to the design certification applicant at the following address: Mr. Charles B. Brinkman, Director, Nuclear Systems Licensing, ABB-Combustion Engineering, Inc., P.O. Box 500, 1000 Prospect Hill Road, Windsor, CT 06095-0500. The information which a person requesting a hearing must provide in the hearing request, as well as the procedures and standards to be used by the Commission in its determination of the request, are discussed in Sections C.1 through C.4 below.

A person who needs to review proprietary information submitted by the design certification applicant in order to prepare a request for an informal hearing must follow the procedures and filing schedule set forth in Section V.E. below.

The Commission is also providing an opportunity for interested State, county, and city/municipal and other local Governments, as well as Native American tribal governments to participate as "interested governments" in any informal hearings which the Commission authorizes, similar to their participation as "interested governments" in Subpart G hearings under 10 CFR 2.715. State, county, city/municipal, local, and tribal Governments

wishing to participate as an "interested government" in any design certification rulemaking hearings which may be held must file their request to participate no later than 120 days from the publication of this notice.

C. Hearing Process

1. Filings and Computation of Times

All notices, papers, or other filings discussed in this section must be filed by express mail.⁵ The time periods specified in this section have been established based upon such a filing. The express mail filing requirement shall be considered in establishing other filing deadlines.

In computing any period of time, the day of the act, event, or default after which the designated period of time begins to run is not included. The last day of the period so computed is included, unless it is a Saturday, Sunday, or legal holiday at the place where the action or event is to occur, in which case the period runs until the next day which is neither a Saturday, Sunday, nor holiday.

2. Content of Hearing Request

The Commission will grant a request for an informal hearing only if the hearing request satisfies each of the following two requirements. First, the hearing request must include the written presentations which the requestor

⁵Filings discussed in this section may also be served upon the Commission in electronic form in lieu of express mail. However, parties must serve copies of their filings on other parties by express mail, unless the receiving party agrees to filing in electronic form. These filings must be transmitted no later than the last day of the time period specified for filing and must be in accordance with the requirements specified in the Summary.

wishes to be included in the record of the hearing. The written presentations must:

- (i) Identify the specific portion of the proposed design certification rule or supporting bases which are challenged,
- (ii) Describe the reasons why the proposed rule or supporting bases are incorrect or insufficient, and
- (iii) Identify the references or sources upon which the person requesting the hearing relies.

If the requestor has submitted written comments in the public comment period addressing these three factors for the specific issue for which the requestor seeks a hearing, it will be sufficient for the requestor to identify the portions of the written comments which the requestor intends to submit as a written presentation. Also, the hearing request must demonstrate that the requestor (or other persons identified in the hearing request who will represent, assist, or speak on behalf of the requestor at the hearing) has appropriate knowledge and qualifications to enable the requestor to contribute significantly to the development of the hearing record on the specific matters at issue. The Commission does not intend that the requestor meet a judicial "expert witness" standard in order to meet the second criterion. Nonetheless, given the substantial commitment of time and resources associated with any hearing, the Commission believes it to be a reasonable prerequisite that the hearing requestor demonstrate that he/she (or his/her assistant) has:

- (i) Substantial familiarity with the publicly available docketed information relevant to the issue for which a hearing is requested;
- (ii) The requisite technical capability to understand the factual matters and develop a record on the issue for which a hearing is requested, and

(iii) An understanding of the NRC's hearing procedures in 10 CFR Part 2.⁶

3. Request to Hold Hearing Outside of Washington, DC

Any hearing(s) which the Commission may authorize ordinarily will be conducted in the Washington, DC. metropolitan area. However, the Commission at its discretion may schedule hearings outside the Washington, DC. metropolitan area in response to requests submitted by a person requesting a hearing that all or part of the hearing be held elsewhere. These requests must be submitted in conjunction with the request for hearing, and must specifically explain the special circumstances for holding a hearing outside the Washington, DC. metropolitan area.

4. Responses to Hearing Request

The applicant may file a response to any hearing request within 15 days of the date of the hearing request. The NRC staff will not provide a response to the hearing request unless requested to do so by the Commission but may assist the Commission in its ruling on the request.

5. Commission Determination of Hearing Request

The Commission intends to rule on a hearing request within 20 days of the close of the period for requesting a hearing. The Commission's determination will be based upon the materials accompanying the hearing request and the applicant's response (and the NRC staff's response, if requested by the Commission). The hearing request shall be granted if:

⁶Requestors will satisfy this requirement by stating that they possess and have read a copy of 10 CFR Part 2, Subparts A, G, and L.

(i) The request is accompanied by a written presentation containing the information required by Section C.2. above; and

(ii) the requestor has the appropriate knowledge and qualifications to enable the requestor to contribute significantly to the development of the hearing record on the matters sought to be controverted.

The Commission may consult with the NRC staff before its determination of a hearing request. A written decision either granting or denying the hearing request will be published by the Commission.

If a hearing request is granted in whole or in part, the Commission's decision will delineate the controverted matter that will be the subject of the hearing and whether any issues and/or parties are to be consolidated (see Section C.7. below). The Commission's decision granting the hearing will direct the establishment of a licensing board to preside over the informal hearing. Finally, the Commission's decision will specify:

(i) The date by which any requests for discovery must be filed with the licensing board (normally 20 days after the date of the Commission's decision), and

(ii) The date by which any objections to discovery must be filed (see Section C.9. below).

The Commission's decision will be sent to each admitted party by overnight mail. Separate hearings may be granted for each controverted matter or set of consolidated matters. Thus, if there are three different controverted matters, the Commission may establish three separate hearings. In this fashion, closing of the hearing record on a controverted matter and its referral to the Commission for resolution need not await completion of the hearing on the other controverted matters. Finally, the Commission's decision will rule on any

requests for hearings outside of the Washington, DC. metropolitan area (see Section C.3 above).

6. Authority of the Licensing Board

If the Commission authorizes an informal hearing on a controverted matter, the licensing board will function as a "limited magistrate" in that hearing with the authority and responsibility for assuring that a sufficient record is developed on those controverted matters which the Commission has determined are appropriate for consideration in that hearing. The licensing board shall have the following specific responsibilities and authority:

(i) Schedule and expeditiously conduct the informal hearing for each admitted controverted matter, consistent with the rights of all the parties,

(ii) Review all discovery requests against the criteria established by the Commission, and refer all appropriate requests to the Commission with a decision explaining the licensing board's action,

(iii) Preside over and resolve any issues regarding the scheduling and conduct of any discovery authorized by the Commission,

(iv) Order such further consolidation of parties and issues as the licensing board determines is necessary or desirable,

(v) Orally examine persons making oral presentations in the informal hearing, based in part upon the licensing board's review of the parties' proposed oral questions to be asked of persons making oral presentations,

(vi) Request that the NRC staff:

(A) Answer licensing board questions about the SER or the proposed rule,

(B) Provide additional information or documentation with respect to the design certification, and

(C) Provide other assistance as the licensing board may request.

Licensing board requests for NRC staff assistance should be framed such that the NRC staff does not assume a role as an adversary party in the informal hearing (see Section C.8 below),

(vii) Review all requests for additional hearing procedures and refer all appropriate requests to the Commission with a decision explaining the licensing board's action,

(viii) Certify the hearing record to the Commission, based upon the licensing board's determination that the hearing record contains sufficient information for the Commission to make a reasoned determination on the controverted matter; and

(ix) Include with its certification any concerns identified by the licensing board in the course of the hearing which, although neither raised by the parties nor necessary to resolution of the controverted hearing matters, are significant enough in the licensing board's view to warrant attention by the Commission.

Licensing board determinations with respect to referral of requests to the Commission, as well as licensing board determinations of parties' motions, are not appealable to the Commission as an interlocutory matter. Instead, any disagreements with the licensing board's determinations and a specific discussion of how the hearing record is deficient with respect to the contested issue must be set forth in the parties' proposed findings of fact which are submitted directly to the Commission (see Section C.13 below).

As suggested by Item (10) above, the licensing board shall not have any "sua sponte" authority analogous to 10 CFR 2.760a. The Commission believes that in the absence of a request for an informal hearing on a matter, the Commission

should resolve issues with respect to the design certification rule in the same manner as other agency-identified rulemaking issues, viz., through NRC staff consideration of the issue followed by the Commission's review and its final resolution of the matter. However, when it certifies the completed hearing record to the Commission (see Section C.12. below), the licensing board should identify to the Commission any concerns identified during the hearing that are significant enough to warrant Commission consideration but that are unnecessary or irrelevant to the resolution of the controverted hearing matter.

The licensing board shall close the hearing and certify the record to the Commission only after it determines that the record on the controverted matter is sufficiently complete for the Commission to make a reasoned determination with respect to that matter. However, the licensing board shall not have any responsibility or authority to resolve and decide controverted matters in either an informal or a formal hearing. Rather, the Commission retains its traditional authority in rulemaking proceedings to evaluate and resolve all rulemaking issues identified in public comments on a proposed rule. Therefore, the Commission will resolve any controverted matters that are the subject of a hearing in this design certification rulemaking.

7. Consolidation of Parties and Issues; Joint Hearings on Related Issues.

If two or more persons seek an informal hearing on the same or similar matters, the Commission may, in its discretion, grant an informal hearing and consolidate the matters into a single issue (as defined by the Commission). The Commission may also, in its discretion, require that the parties be consolidated analogous to the consolidation permitted under 10 CFR 2.715a. If the Commission

consolidates two or more issues into a single consolidated issue but does not consolidate parties, each admitted person will be deemed a separate party with an individual right to:

- (i) Submit separate written presentations,
- (ii) Submit separate sets of proposed oral questions to be asked by the licensing board (see Section C.10 below),
- (iii) Make separate oral presentation, and
- (iv) Submit and separately respond to motions.

If the Commission also requires that parties be consolidated, the consolidated parties must participate jointly, including deciding upon written and oral presentations, submitting a single set of written questions, submitting motions supported by each of the consolidated parties, and responding to motions filed by other parties.

During the 'nformal hearing, the licensing board may decide that further consolidation of issues or parties would simplify the overall conduct of informal hearings or materially reduce the time or resources devoted to the hearings. In these instances, the licensing board may direct such consolidation. The licensing board shall set forth the issues and/or parties to be consolidated and the reasons for such consolidation in a written order.

8. Status of the Design Certification Applicant, the NRC staff, and Requesting Party

The design certification applicant shall be a party in the informal hearing, with the right to submit written and oral presentations, propose questions to be asked by the licensing board of oral presenters, and file and submit appropriate motions.

The NRC staff shall *not* be a party in the informal hearing but shall be available in the informal hearing to answer licensing board questions about the FSER or the proposed rule, provide additional information or documentation with respect to the design certification, and provide other assistance that the licensing board may request without the NRC staff assuming the role of a party in the informal hearing.

A party whose hearing requests have been granted with respect to a particular controverted matter shall not participate with respect to any controverted matter on which the party was not granted a hearing. For example, if Person 1 has been authorized as a party on Issue A and Person 2 has been authorized as a party on Issue B, then Person 1 may participate only in the informal hearing on Issue A, and may *not* participate in the informal hearing on Issue B. Conversely, Person 2 may participate only in the informal hearing on Issue B, and may *not* participate in the informal hearing on Issue A.

9. Requests for Discovery

Any party may request the opportunity to conduct discovery against another party before the oral phase of the informal hearing. The request for discovery must:

- (i) Identify the type of discovery permitted under 10 CFR §§ 2.740, 2.740a, 2.740a(b), 2.741, and 2.742 which the party seeks to use;
- (ii) Identify the subject matter or nature of the information sought to be obtained by discovery; and
- (iii) Explain *with particularity* the relevance of the information sought to the controverted matter which is the subject of the hearing and why this

information is indispensable to the presentation of the party's position on the controverted matter.

The request shall be filed with the licensing board, with copies of the request to be filed with the party against which discovery is sought, and the NRC staff. The requests must be received no later than the deadline specified by the Commission in its decision granting a party's hearing request (see Section C.5. above). A party against whom discovery is sought may file a response objecting to part or all of the request. Such a response must explain *with particularity* why the discovery request should not be granted.

The licensing board shall review all discovery requests and refer to the Commission those requests that it believes should be granted within 7 days after the date for receiving a party's objections to a discovery request. The licensing board shall issue a written decision explaining its basis for either referring the request to the Commission or declining to refer it. The written decision shall accompany the discovery requests which are referred by the licensing board to the Commission.

The Commission will determine whether to grant any discovery requests forwarded to it based upon the licensing board's decision, together with the request and the design certification applicant's response (and any NRC staff response requested by the licensing board). Discovery will be at the discretion of the Commission. In this regard, the Commission notes that there are several docket files in which the NRC staff has placed information and documents received from the design certification applicant for the System 80+ design certification review. 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 No. STN 50-470 and Project No. 675. This

information includes the Design Control Document and the Technical Support Document for Amendments to 10 CFR Part 51 Considering Severe Accidents Under NEPA for Plants of the System 80+ Design, Revision 2. Furthermore, the docket files contain NRC staff communications and documents, such as written questions and comments provided to the design certification applicant, and summaries of meetings held between the NRC staff and the design certification applicant. The NRC staff's bases for approving the System 80+ design are set forth in the FSER (NUREG-1462), dated August 1994. The Commission also notes that each admitted party has already disclosed a substantial amount of information in its hearing request, relating both to bases for the party's position with respect to the controverted matter as well as information on the qualifications of the party (or its representatives and witnesses in the hearing).

As discussed above, much of the information documenting the NRC staff's review and approval of the design certification application has been routinely placed in the docket file. Furthermore as discussed above in Section C.8., the NRC staff is not a party in an informal hearing. Therefore, the Commission has decided that in an informal hearing, the parties should *not* be afforded discovery against the NRC staff.

10. Conduct of Informal Hearing

If the Commission authorizes discovery, the licensing board shall establish a schedule for the conduct and completion of discovery. Normally, the licensing board should not permit more than one round of discovery. The Commission will not entertain any interlocutory appeals from licensing board orders resolving any discovery disputes or otherwise complaining of the scheduling of discovery.

Following the completion of discovery, the licensing board should issue an order setting forth the date of commencement of the oral phase of each informal hearing, and the date (no less than 30 days before the commencement of the oral phase of the hearing) by which parties must submit:

(i) The identities and curriculum vitae of those persons providing oral presentations;

(ii) The outlines of the oral presentations; and

(iii) Any questions which a party would like the licensing board to ask.

The licensing board may schedule the oral phases of two or more informal hearings to be held during the same session. The licensing board shall publish a notice in the Federal Register announcing the commencement of the oral phase of the informal hearing(s). The notice shall set forth the place and time of the oral hearing session, the subject matter of the informal hearing(s), a brief description of the informal hearing procedures, and a statement indicating that the public may observe the informal hearing.

Based upon the parties' outlines of the oral presentations and proposed questions, the licensing board should determine whether it has specific questions of the NRC staff with respect to the staff's review of the design certification application. These questions should be submitted in writing to the NRC staff no less than 20 days before the commencement of the oral phase of the hearing and must specify the date by which the NRC staff shall provide its written answers to the licensing board. The licensing board shall send copies of the request by overnight mail to all parties. The NRC staff shall file its written answers with the licensing board and the parties.

During the oral phase of the hearing, the licensing board shall receive into evidence the written presentations of the parties and permit each party (or

the representatives identified in their hearing request) to make oral presentations addressing the controverted matter. Normally, the party raising the controverted matter should make their presentations, followed by the presentations of the design certification applicant. The licensing board may question the persons making oral presentations, using its own questions as well as those submitted to the licensing board by the other parties. Based upon the parties' oral presentations and/or responses to licensing board questions, the licensing board may also orally question the NRC staff.

11. Additional Hearing Procedures and Formal Hearings

After the parties have made their oral presentations and the licensing board has concluded its questioning of the presenters (and, as applicable, the NRC staff), the licensing board should declare that the oral phase of an informal hearing on a controverted matter (or consolidated set of controverted matters) is complete.

No later than 10 days after the licensing board has declared that the oral phase of the informal hearing has been completed, parties may file with the licensing board (with copies to the applicant and the NRC staff) a request that some or all of the procedures described in 10 CFR Part 2, Subpart G (e.g., direct and cross-examination by the parties) be utilized. The request shall:

(i) Identify the specific hearing procedures which the party seeks, or state that a formal hearing is requested;

(ii) Identify the specific *factual* issues for which the additional procedures would be utilized;

(iii) Explain why resolution of these factual disputes are necessary to the Commission's decision on the controverted issue;

(iv) Explain, with specific citations to the hearing record, why the record is insufficient on the controverted matter; and

(v) Identify the nature of the evidence that would be developed utilizing the additional procedures requested.

The design certification applicant may file a response to these requests no later than 7 days after the applicant's receipt of a request for additional procedures. The NRC staff will not provide a response unless specifically requested to do so by the licensing board.

The licensing board will review all requests for additional hearing procedures or a formal hearing and refer those that it believes should be granted to the Commission for its determination. The licensing board shall issue a written decision explaining its determination whether to forward the request to the Commission no later than 7 days after receipt of any applicant response to the request. The decision will provide the basis for either forwarding the request to the Commission or declining to forward it. In the absence of any requests for hearing procedures or if the licensing board concludes that none of the requests should be referred to the Commission, the licensing board should declare that the hearing record is closed (see Section C.12 below).

The Commission will determine whether to grant any requests for additional procedures or a formal hearing that are forwarded by the licensing board. The Commission's determination shall be based upon the licensing board's decision along with the request and the design certification applicant's response. If the Commission directs that a formal hearing be held on a controverted factual matter, the NRC staff shall be a party in the formal hearing. After either the additional hearing procedures authorized by the Commission are completed or the

formal hearing is concluded on the factual dispute, the licensing board should declare the hearing record closed (see Section C.12 below).

12. Licensing Board's Certification of Hearing Record to the Commission.

After the oral phase of a hearing is completed and either:

(i) There are no requests for additional hearing procedures or a formal hearing; or

(ii) The licensing board concludes that none of the requests should be referred to the Commission, then the licensing board should declare that the hearing record is closed.

If the Commission directs that additional hearing procedures should be utilized or a formal hearing be held on specific factual disputes, the licensing board should declare the hearing record closed after completion of the additional hearing procedures or the formal hearing. Within 30 days of the closing of the hearing record the licensing board should certify the hearing record to the Commission on each controverted matter (or consolidated set of controverted matters).⁷

The licensing board's certification for each controverted matter (or consolidated set of controverted matters) shall contain:

(i) The hearing record, including a transcript of the oral phase of the hearing (and any pre-hearing conferences) and copies of all filings by the parties and the licensing board,

⁷An informal hearing is deemed to be completed when the period for requesting additional procedures or a formal hearing expires and no request is received.

(ii) A list of all documentary evidence admitted by the licensing board, including the written presentations of the parties,

(iii) Copies of the documentary evidence admitted by the licensing board,

(iv) A list of all witnesses who provided oral testimony,

(v) The NRC staff's written answers to licensing board requests, and

(vi) A licensing board statement that the hearing record contains sufficient information for the Commission to make a reasoned determination on the controverted matter.

Finally, as discussed in Section C.6 above, the licensing board should identify any issues not raised by the parties or otherwise are not relevant to the controverted matters in the hearing, that the licensing board believes are significant enough to warrant attention by the Commission.

13. Parties' Proposed Findings of Fact and Conclusions

The applicant must file directly with the Commission proposed findings of fact and conclusions for each controverted hearing matter (or consolidated set of controverted matters) within 30 days following the close of the hearing record on that matter in the form of a proposed final rule and statement of considerations with respect to the controverted hearing issues.

Other parties are encouraged, but not required, to file with the Commission proposed findings of fact and conclusions limited to those issues which a party was afforded a hearing by the Commission (*i.e.*, a party may *not* file proposed findings of fact and conclusions on issues which it was *not* admitted). Any findings that a party wishes the Commission to consider must be received by the Commission no later than 30 days after the licensing board closes the hearing record on that issue. Although parties are not required to

file proposed findings and conclusions, a party who does not file a finding may not, upon appeal, claim or otherwise argue that the Commission either misunderstood the party's position, or failed to address a specific piece of evidence or issue.

D. Resolution of Issues for the Final Rulemaking

1. Absence of Qualifying Hearing Request.

If the Commission does not receive any request for hearing within the 120-day period for submitting a request, or does not grant any of the requests (see Section B. above), the Commission will determine whether the proposed design certification rule meets the applicable standards and requirements of the Atomic Energy Act of 1954, as amended (AEA), the National Environmental Policy Act of 1969, as amended (NEPA), and the Commission's rules and regulations. The Commission's determination will be based upon the rulemaking record, which includes: the application for design certification, including the SSAR and DCD; the applicant's responses to the NRC staff's requests for additional information; the NRC staff's FSER and any supplements thereto; the report on the application by the ACRS; the applicant's Technical Support Document addressing consideration of severe accident mitigation design alternatives (SAMDA) for purposes of NEPA; the NRC staff's EA and draft FONSI; the proposed rule, and the public comments received on the proposed rule. If the Commission makes an affirmative finding, it will issue a standard design certification in the form of a rule by adding a new appendix to 10 CFR Part 52, and publish the design certification rule and a statement of considerations in the Federal Register.

2. Commission Resolution of Issues Where a Hearing is Granted.

All matters related to the proposed design certification rule, including those matters for which the Commission authorizes a hearing (see Sections B. and C. above), will be resolved by the Commission after the licensing board has closed the hearing record and certified it to the Commission. The Commission will determine whether the proposed design certification rule meets the applicable standards and requirements of the AEA, NEPA, and the Commission's rules and regulations. The Commission's determination will be based upon the rulemaking record as described in Section D.1 above, with the addition of the hearing record for controverted matters. If the Commission makes an affirmative finding, the Commission will issue a final design certification rule as described in Section D.1.

E. Access to Proprietary Information in Rulemaking

1. Access to Proprietary Information for the Preparation of Written Comments or Informal Hearing Requests

Persons who determine that they need to review proprietary information submitted by the design certification applicant to the NRC in order to submit written comments on the proposed certification or to prepare an informal hearing request, may request access to such information from the applicant.

The request shall state with *particularity*:

- (i) The nature of the proprietary information sought,
- (ii) The reason why the nonproprietary information currently available to the public in the NRC's Public Document Room is insufficient either to develop public comments or to prepare for the hearing,
- (iii) The relevance of the requested information either to the issue which the commenter wishes to comment on, and

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

Requests must be filed with the applicant such that they are received by the applicant no later than 45 days after the date that this notice of proposed rulemaking is published in the Federal Register.

Within ten (10) days of receiving the request, the applicant must send a written response to the person seeking access. The response must either provide the documents requested (or state that the document will be provided no later than ten days after the date of the response), or state that access has been denied. If access is denied, the response shall state with particularity the reasons for its refusal. The applicant's response must be provided via express mail.

The person seeking access may then request a Commission hearing for the purpose of obtaining a Commission order directing the design certification applicant to disclose the requested information. The person must include copies of the original request (and any subsequent clarifying information provided by the person requesting access to the applicant) and the applicant's response. The Commission will base its decision solely on the person's original request (including any clarifying information provided to the applicant by the person requesting access), and the applicant's response. Accordingly, a person seeking access to proprietary information should ensure that the request sets forth in sufficient detail and particularity the information required to be included in the request. Similarly, the applicant should ensure that its response to any request states with sufficient detail and particularity the reasons for its refusal to provide the requested information.

If the Commission orders access in whole or part, the Commission will specify the date by which the requesting party must file with the Commission written comments and any request for an informal hearing before a licensing board as discussed in Section V.C. above. A request for an informal hearing must meet the requirements set forth above in Section V.C., in particular the requirements governing the content of the hearing request, and shall be governed by the procedures and standards governing such requests set forth in Section V.C.

2. Access to Proprietary Information in a Hearing

Parties who are granted a hearing may request access to proprietary information. Parties must first request access to proprietary information regarding the proposed design certification from the applicant. The request shall state *with particularity*:

(i) The nature of the proprietary information sought,

(ii) The reason why the nonproprietary information currently available to the public in the NRC's Public Document Room is insufficient to prepare for the hearing,

(iii) The relevance of the requested information to the hearing issue(s) for which the party has been admitted, and

(iv) A showing that the requesting party has the capability to understand and utilize the requested information.

The request must be filed with the applicant no later than the date established by the Commission for filing discovery requests with the licensing board.

If the applicant declines to provide the information sought, within 10 days of receiving the request the applicant must send a written response to

the requesting party setting forth *with particularity* the reasons for its refusal. The party may then request the licensing board to order disclosure. The party must 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 licensing board shall base its decision *solely* on the party's original request (including any clarifying information provided by the requesting party to the applicant), and the applicant's response.

Accordingly, a party requesting proprietary information from the applicant should ensure that its request sets forth in sufficient detail and particularity the information required to be included in the request. Similarly, the applicant should ensure that its response to any request states with sufficient detail and particularity the reasons for its refusal to provide the requested information. The licensing board may order the Applicant to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

F. *Ex Parte* and Separation of Functions Restrictions

Unless the formal procedures of 10 CFR Part 2, Subpart G are approved for a formal hearing in the design certification rulemaking proceeding, the NRC staff will not be a party in the hearing and separation of functions limitations will not apply. The NRC staff may assist in the hearing by answering questions about the FSER put to it by the licensing board, or to provide additional information, documentation, or other assistance as the licensing board may request. Furthermore, other than in a formal hearing, the NRC staff shall not be subject to discovery by any party, whether by way of interrogatory, deposition, or request for production of documents.

Second, the Commission has determined that once a request for an informal or formal hearing is received, certain elements of the *ex parte* restrictions in 10 CFR 2.780(a) will be applicable with respect to the subject matter of that hearing request. Under these restrictions, the Commission will communicate with interested persons/parties, the NRC staff, and the licensing board with respect to the issues covered by the hearing request only through docketed, publicly-available written communications and public meetings. Individual Commissioners may communicate privately with interested persons and the NRC staff; however, the substance of the communication shall be memorialized in a document which will be placed in the PDR and distributed to the licensing board and relevant parties.

VI. FINDING OF NO SIGNIFICANT ENVIRONMENTAL IMPACT: AVAILABILITY

The Commission has determined under NEPA and the Commission's regulations in 10 CFR Part 51, Subpart A, that this proposed design certification rule, if adopted, would not be 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 environmental assessment, is that the amendment to 10 CFR Part 52 would not authorize the siting, construction, or operation of a facility using the System 80+ design; it would only codify 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 environmental assessment for the System 80+ design, the NRC reviewed pursuant to NEPA, ABB-CE's evaluation of various design alternatives to prevent and mitigate severe accidents that was submitted in ABB-CE's "Technical Support Document for the System 80+." The Commission finds that ABB-CE's evaluation provides a sufficient basis to conclude that there is reasonable assurance that an amendment to 10 CFR Part 52 certifying the System 80+ design will not exclude a severe accident design alternative for a facility referencing the certified design that would have been cost beneficial had it been considered as part of the original design certification application. These issues are considered resolved for the System 80+ design.

The environmental assessment, upon which the Commission's finding of no significant impact is based, and the Technical Support Document for the System 80+ 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. Harry Tovmassian, Mailstop T-9 F33, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 415-6231.

VII. PAPERWORK REDUCTION ACT STATEMENT

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements. The public reporting burden for this collection of information is zero hours. Send comments regarding this burden estimate or any other aspect of this collection of information, including

suggestions for reducing this burden, to the Information and Records Management Branch (T 6-F33), U.S. Nuclear Regulatory Commission, Washington, DC. 20555-0001; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0151), Office of Management and Budget, Washington, DC 20503.

VIII. REGULATORY ANALYSIS

The NRC has not prepared a regulatory analysis for this proposed rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements. Design certifications are not generic rulemakings. 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.

IX. REGULATORY FLEXIBILITY ACT CERTIFICATION

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

X. BACKFIT ANALYSIS

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

List of Subjects in 10 CFR Part 52

Part 52 - Administrative practice and procedure, 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. 553; the NRC proposes to adopt the following amendment to 10 CFR Part 52.

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

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

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

§ 52.8 Information collection requirements: OMB approval.

* * * * *

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

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

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

1. Scope.

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

2. Definitions.

As used in this part:

(a) *Design control document (DCD)* means the master document that contains the Tier 1 and Tier 2 information that is incorporated by reference into this design certification rule.

(b) *Tier 1* means the portion of the design-related information contained in the DCD that is certified by this design certification rule (hereinafter Tier 1 information). Tier 1 information consists of:

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

The certified design descriptions, interface requirements, and site parameters are derived from Tier 2 information.

(c) *Tier 2* means the portion of the design-related information contained in the DCD that is approved by this design certification rule (hereinafter Tier 2 information). Tier 2 information includes:

- (1) The information required by 10 CFR 52.47,

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

(2) The information required for a final safety analysis report under 10 CFR 50.34(b), and

(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.

(d) *Tier 2** means the portion of the Tier 2 information which cannot be changed without prior NRC approval. This information is identified in the DCD.

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

3. [Reserved].

4. Contents of the design certification.

(a) Both Tier 1 and Tier 2 of the System 80+ Design Control Document, ABB-CE, Revision 1, February 1995 are incorporated by reference. This incorporation by reference was approved by the Director of the Office of the Federal Register on [Insert date of approval] in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the System 80+ DCD may be obtained from [Insert name and address of applicant or organization designated by the applicant]. Copies are also available for examination and copying at the NRC Public Document Room, 2120 L Street NW, Washington, DC 20555, and for examination at the NRC Library, 11545 Rockville Pike, Rockville, Maryland 20582-2738.

(b) An applicant for a construction permit, operating license, or combined license that references this design certification must reference both Tier 1 and Tier 2 of the System 80+ DCD.

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

5. Exemptions and applicable regulations.

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

(1) Section VI(a)(2) of Appendix A to 10 CFR Part 100 - Operating Basis Earthquake Design Consideration;

(2) Section (b)(3) of 10 CFR 50.49 - Environmental Qualification of Post-Accident Monitoring Equipment;

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

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

(5) Section (f)(3)(iv) of 10 CFR 50.34 - Dedicated Containment Penetration;

(6) Section III.A.1.(a) of Appendix J to 10 CFR 50 - Containment Leakage Testing; and

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

(b) Except as indicated in paragraph (c) of this Section, the regulations that apply to the System 80+ design are those regulations in 10 CFR Parts 20, 50, 73, and 100 [August 1994], that are applicable and technically relevant, as described in the FSER.

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

(1) In the standard design, the effects of intersystem loss-of-coolant accidents must be minimized by designing low-pressure piping systems that interface with the reactor coolant pressure boundary to withstand full reactor coolant system pressure to the extent practical.

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

(A) Full flow testing of pumps and check valves at maximum design flow, and

(B) Testing of motor operated valves under maximum achievable differential pressure, up to design basis differential pressure, to demonstrate the capability of the valves to operate under design basis conditions.

(ii) For pumps and valves subject to the test requirements set forth in 10 CFR 50.55a(f), an applicant for a combined license which references this standard design certification rule shall submit, as part of the application:

(A) a program for testing check valves that incorporates the use of advanced non-intrusive techniques to detect degradation and monitor performance characteristics, and

(B) a program to determine the frequency necessary for disassembly and inspection of each pump and valve to detect degradation that would prevent the component from performing its safety function and which cannot be detected through the use of advanced non-intrusive techniques. The licensee shall implement these programs throughout the service life of the plant.

(3) For digital instrumentation and control systems, the design must include:

(i) An assessment of the defense-in-depth and diversity of instrumentation and control systems;

(ii) A demonstration of adequate defense against common-mode failures; and

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

(4) The electric power system of the standard design must include an alternate power source that has sufficient capacity and capability to power the necessary complement of non-safety equipment that would most facilitate the ability of the operator to bring the plant to safe shutdown, following a loss of the normal power supply and reactor trip.

(5) The electric power system of the standard design must include at least one offsite circuit supplied directly from one of the offsite power sources to each redundant safety division with no intervening non-safety buses in such a manner that the offsite source can power the safety buses upon a failure of any non-safety bus.

(6)(i) The requirements of 10 CFR 50.48(a)² and 10 CFR Part 50, Appendix R, Section III G.1.a, apply to all structures, systems, and components important to safety.

(ii) Notwithstanding any provision in paragraph (i) of this section, all structures, systems, and components important to safety in the standard design must be designed to ensure that:

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

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

(C) In the reactor containment, redundant shutdown systems are provided with fire protection capabilities and means to limit fire damage such that, to the extent practicable, one shutdown division remains free of fire damage.

(7) The standard design must include and an applicant for a combined license which references this standard design certification rule shall submit as part of the application:

(i) The description of the reliability assurance program used during the design that includes scope, purpose, and objectives;

²For the standard design, the footnote reference in 10 CFR 50.48(a) to Branch Technical Position Auxiliary Power Conversion System Branch BTP APCS9.5-1, "Guidelines for Fire Protection for Nuclear Power Plants," will be to the July, 1981 version.

(ii) The process used to evaluate and prioritize the structures, systems, and components in the design, based on their degree of risk-significance;

(iii) A list of structures, systems, and components designated as risk-significant; and

(iv) For those structures, systems, and components designated as risk-significant:

(A) A process to determine dominant failure modes that considered industry experience, analytical models, and applicable requirements; and

(B) Key assumptions and risk insights from probabilistic, deterministic, and other methods that considered operation, maintenance, and monitoring activities.

(8) The probabilistic risk assessment required by 10 CFR 52.47(a)(1)(v) must include an assessment of internal and external events. For external events, simplified probabilistic methods and margins methods may be used to assess the capacity of the standard design to withstand the effects of events such as fires and earthquakes. Traditional probabilistic techniques should be used to evaluate internal floods. For earthquakes, a seismic margin analysis must consider the effects of earthquakes with accelerations approximately one and two-thirds the acceleration of the safe-shutdown earthquake.

(9) The standard design must include an on-site alternate ac power source of diverse design capable of powering at least one complete set of equipment necessary to achieve and maintain safe-shutdown for the purposes of dealing with station blackout.

(10)(i) The standard design must include the features in paragraphs (A) - (C) below that reduce the potential for and effect of interactions of molten core debris with containment structures:

- (A) Reactor cavity floor space to enhance debris spreading;
- (B) A means to flood the reactor cavity to assist in the cooling process; and
- (C) Concrete to protect portions of the containment liner and other structural members.

(ii) The features required by paragraph (i) of this section, in combination with other features, must ensure for the most significant severe accident sequences that the best-estimate environmental conditions (pressure and temperature) resulting from core-concrete interaction do not exceed ASME Code Service Level 2 for steel containments or Factored Load Category for concrete containments for approximately 24 hours.

(11) The standard design must include: (i) a reliable means to depressurize the reactor coolant system and (ii) cavity design features to reduce the amount of ejected core debris that may reach the upper containment.

(12) The standard design must include analyses based on best-available methods to demonstrate that:

(i) Equipment, both electrical and mechanical, needed to prevent and mitigate the consequences of severe accidents is capable of performing its function for the time period needed in the best-estimate environmental conditions of the severe accident (e.g., pressure, temperature, radiation) in which the equipment is relied upon to function; and

(ii) Instrumentation needed to monitor plant conditions during a severe accident is capable of performing its function for the time period needed in the best-estimate environmental conditions of the severe accident (e.g., pressure, temperature, radiation) in which the instrumentation is relied upon to function.

(13) The standard design must include features to limit the conditional containment failure probability for the more likely severe accident challenges.

(14)(i) The standard design must include a systematic examination of features in relation to shutdown risk assessing:

(A) Specific design features that minimize shutdown risk;

(B) The reliability of decay heat removal systems;

(C) Vulnerabilities introduced by new design features; and

(D) Fires and floods occurring with the plant in modes other than full power.

(ii) An applicant for a combined license which references this design certification rule shall submit as part of the application a description of the program for outage planning and control that ensures:

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

(B) The consideration of fire, flood, and other hazards during shutdown and low power operations. The licensee shall implement this program throughout the service life of the plant.

(15) The standard design must include a best-estimate, systematic evaluation of the plant response to a steam generator tube rupture (SGTR) to:

(i) Identify potential design vulnerabilities, and

(ii) Assess potential design improvements to mitigate the amount of containment bypass leakage that could result from a SGTR.

6. Issue resolution for the design certification.

(a) All nuclear safety issues associated with the information in the FSER or DCD are resolved within the meaning of 10 CFR 52.63(a)(4).

(b) All environmental issues associated with the information in the NRC's Environmental Assessment for the System 80+ design or the severe accident design alternatives in Revision 2 of the Technical Support Document for the System 80+ dated January 1995 are resolved within the meaning of 10 CFR 52.63(a)(4).

7. Duration of the design certification.

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

8. Change process.

(a) Tier 1 information.

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

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

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

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

(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 plants referencing the design certification as set forth in 10 CFR 52.63(a)(2).

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

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

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

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

(5)(i) An applicant or licensee who references the design certification may depart from Tier 2 information, without prior NRC approval, unless the proposed change involves 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 paragraphs (b)(5)(ii) or (b)(5)(iii) of this section. When evaluating the proposed change, an applicant or licensee shall consider all matters described in the DCD, including generic issues and shutdown risk for all postulated accidents including severe accidents. These changes will no longer be considered "matters resolved in connection with the issuance or renewal of a design certification" within the meaning of 10 CFR 52.63(a)(4).

(ii) A proposed departure from Tier 2 information, other than severe accident issues identified in Section 19.11 of the DCD, including appendices 19.11A through 19.11L, must be deemed to involve an unreviewed safety question if:

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

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

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

(iii) A proposed departure from information associated with severe accident issues identified in Section 19.11 of the DCD, including appendices 19.11A through 19.11L, must be deemed to involve an unreviewed safety question if:

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

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

(iv) Departures from Tier 2 information made in accordance with Section 8(b)(5) above do not require an exemption from this design certification rule.

(c) Other requirements of this design certification rule.

An applicant or licensee who references the design certification may not depart from this rule's requirements, other than Tier 1 or 2 information, other than by an exemption in accordance with 10 CFR 50.12.

9. Records and Reports.

(a) *Records.*

(1) The applicant for this design certification shall maintain a copy of the DCD that includes all generic changes to Tier 1 and Tier 2 information.

(2) An applicant or licensee that references this design certification shall maintain records of all changes to and departures from the DCD pursuant to Section 8 of this Appendix. Records of changes made pursuant to Section 8(b)(5) must include a written 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.

(b) *Reports.* An applicant or licensee that references this design certification shall submit a report to the NRC, as specified in 10 CFR 50.4, containing a brief description of any departures from the DCD, including a summary of the safety evaluation of each. An applicant or licensee shall also submit updates to the DCD to ensure that the DCD contains the latest material developed for both Tier 1 and 2 information. The requirements of 10 CFR 50.71 for safety analysis reports must apply to these updates. These reports and updates must be submitted at the frequency specified below:

(1) During the interval from the date of application to the date of issuance of either a construction permit under 10 CFR Part 50 or a combined license under 10 CFR Part 52, the report and any updates to the DCD may be submitted along with amendments to the application.

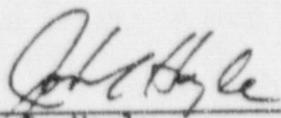
(2) During the interval from the date of issuance of either a construction permit under 10 CFR Part 50 or a combined license under 10 CFR Part 52 until the applicant or licensee receives either an operating license under 10 CFR Part 50 or the Commission makes its findings under 10 CFR 52.103, the report must be submitted quarterly. Updates to the DCD must be submitted annually.

(3) Thereafter, reports and updates to the DCD may be submitted annually or along with updates to the safety analysis report for the facility as required by 10 CFR 50.71, or at such shorter intervals as may be specified in the license.

(c) *Retention Period.* The DCD and the records of changes to and departures from the DCD must be maintained until the date of termination of the construction permit or license.

Dated at Rockville, Maryland, this 31st day of March, 1995.

For the Nuclear Regulatory Commission.



John C. Hoyle,
Secretary of the Commission